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Rehabilitation interventions to improve patient reported outcomes and physical fitness in survivors of muscle invasive bladder cancer: a systematic review protocol

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Complete List of Authors:	Rammant, Elke; Universitair Ziekenhuis Gent, Department of Radiation Oncology and Experimental Cancer Research Bultijnck, Renée; Universitair Ziekenhuis Gent, Department of Radiation Oncology and Experimental Cancer Research Sundahl, Nora; Universitair Ziekenhuis Gent, Department of Radiation Oncology and Experimental Cancer Research Ost, Piet; Universitair Ziekenhuis Gent, Department of Radiation Oncology and Experimental Cancer Research Pauwels, Nele; Universitair Ziekenhuis Gent, Knowledge Center Ghent Deforche, Benedicte; Universiteit Gent, Department of Public Health Pieters, Ronny; Universitair Ziekenhuis Gent, Department of Urology Decaestecker, Karel; Universitair Ziekenhuis Gent, Department of Urology Fonteyne, Valérie; Universitair Ziekenhuis Gent, Department of Radiation Oncology and Experimental Cancer Research
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3 **Rehabilitation interventions to improve patient reported outcomes and**
4 **physical fitness in survivors of muscle invasive bladder cancer: a systematic**
5 **review protocol**
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8 Elke Rammant¹, Renée Bultijnck¹, Nora Sundahl¹, Piet Ost¹, Nele S. Pauwels², Benedicte
9 Deforche³, Ronny Pieters⁴, Karel Decaestecker⁴, Valérie Fonteyne¹
10
11

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13
14 **Affiliations:**

- 15
16 1. Department of Radiation Oncology and Experimental Cancer Research, Ghent
17 University Hospital, Ghent, Belgium
18 2. Knowledge Center Ghent, Ghent University Hospital, Ghent, Belgium
19 3. Department of Public Health, Ghent University, Ghent, Belgium
20 4. Department of Urology, Ghent University Hospital, Ghent, Belgium
21
22
23
24

25 **Corresponding Author:**

26
27
28 Elke Rammant, MSc.
29 Department of Radiation Oncology and Experimental Cancer Research,
30 Ghent University Hospital
31 De Pintelaan 185, B-9000 Ghent, Belgium
32 Tel: +32 9 33 21552
33 E-mail: elke.rammant@ugent.be
34
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36

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ABSTRACT

Introduction

Survivors of muscle invasive bladder cancer (MIBC) experience physical and psychosocial side effects of cancer diagnosis and treatment. These negative side effects have a crucial impact on the quality of life (QoL). To date, there is evidence that rehabilitation interventions such as physical activity and psychosocial support have a positive effect on the QoL of cancer survivors. Unfortunately, there are no specific guidelines for rehabilitation or survivorship programs for MIBC survivors. Therefore, this systematic review aims to assess the effects of exercise-based and psychosocial rehabilitation interventions for MIBC survivors.

Methods and analysis

The approach of this review is consistent with the Cochrane methodology. Randomized controlled trials and non-randomized studies will be included. The population of interest is patients (≥ 18 years of age) with diagnosis of MIBC and there will be two eligible intervention types for inclusion: exercise-based and psychosocial rehabilitation interventions. The primary outcome measures are patient reported outcomes (e.g. QoL, fatigue, pain) and physical fitness. Studies will be identified independently by two review authors by searching the Cochrane Central Register of Controlled Trials, MEDLINE, Embase, Web of Science and the Physiotherapy Evidence Database. A third reviewer will be asked by disagreements. Risk of bias will be assessed using the Cochrane Collaboration's tools. Data will be summarized descriptively. If homogeneity of the studies is sufficient, meta-analysis will be undertaken.

Discussion

This systematic review is expected to provide guidance to development of evidence-based rehabilitation or survivorship programs for MIBC survivors. The broad scope of this review (i.e. different interventions and study designs) is needed to have a comprehensive view on effective rehabilitation interventions.

Ethics and dissemination

Ethics approval is not required, as no primary data will be collected. Results will be disseminated through a peer-reviewed publication.

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Keywords

Bladder neoplasm— exercise – psychosocial intervention – rehabilitation

Strengths and limitations of this study

Strengths

- The overall approach of this review is consistent with the methodology described in the Cochrane Handbook for Systematic reviews of Interventions
- It's an innovative topic in the field of bladder cancer.
- Actual problem because the incidence of bladder cancer is rising.

Limitations

- Possible paucity of studies meeting the inclusion criteria.

BACKGROUND

Description of the condition

Bladder cancer (BC) is the 11th most common cancer worldwide. When both genders are considered separately, BC in men is rising to the 7th place whilst BC in women is dropping to the 17th place of most common cancer worldwide^{1,2}. Worldwide, the age-standardized incidence rate (per 100,000 person/years) is 9.0 for men and 2.2 for women. In 2012, the age-standardized mortality rate (per 100,000 person/years) was 3.2 for men and 0.9 for women³. Besides the fact that BC is more common in men than in women, BC is also known as a disease of the elderly. Due to the growth of an aging population, it is expected that BC will become an enormous challenge in the near future^{4,5}.

Thirty percent of the patients diagnosed with BC present with muscle invasive BC (MIBC, stages T2, T3, and T4)⁶. Also, depending on risk stratification, up to 45% of patients with non MIBC will progress to MIBC⁷. The standard treatment in patients with MIBC is neo-adjuvant chemotherapy followed by radical cystectomy (bladder removal), extended pelvic lymph node dissection and urinary diversion (continent or incontinent bladder replacement)¹. These are major interventions associated with a variety of negative side effects, especially on the urinary and sexual function⁸. This can lead to a loss of quality of life (QoL), which refers to overall wellbeing and happiness, and encompasses physical, functional, psychological and social aspects⁹. Combined radiochemotherapy is an alternative for radical cystectomy in order to preserve the bladder. Both radiotherapy and chemotherapy can also be used in the adjuvant or palliative setting and can also cause a variety of treatment related side effects. Therefore, follow-up care beyond the acute diagnosis and treatment phase is necessary¹⁰.

Description of the intervention

“Cancer rehabilitation is a concept that is defined by the patient and involves helping a person with cancer to obtain maximum physical, social, psychological, and vocational functioning within the limit by the disease and its treatment”¹¹. Therefore, a rehabilitation or survivorship program for cancer patients needs to comprise different intervention approaches^{12,13}.

Physical activity (PA) is seen as one of the rehabilitation interventions to improve patients QoL and survival outcomes. PA is defined as “any movement created by the skeletal muscles that causes a substantial increase in energy expenditure”⁹. It is important that the terms ‘physical activity’ and ‘exercise’ are not mixed with each other. PA can be seen as an overarching term that includes exercise as well as other activities which involve bodily movement and are done as part of playing, working, active transportation, house chores and recreational activities. Exercise on the other hand, is a subcategory of PA. It is planned, structured, repetitive, and purposeful to improve or maintain one or more components of

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3 physical fitness (cardiorespiratory fitness, muscular strength, muscular endurance, flexibility
4 and body composition)¹⁴. These components represent important outcomes in cancer
5 survivors that may mediate the influence of exercise on other outcomes⁹.

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7 Psychosocial interventions are another important focus in rehabilitation. These sort of
8 interventions aim to help patients cope with negative side effects of cancer diagnosis and
9 treatment¹⁵. Based on a framework proposed by Cunningham, there are five categories of
10 interventions: patient education, social support, coping skills training, psychotherapy and
11 spiritual/existential therapy¹⁶.

12 13 14 15 **How the intervention might work**

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17 Rehabilitation in BC patients can be complicated due to the synergistic interaction of two
18 factors. Firstly, cancer treatments can lead to harmful consequences and side effects.
19 Secondly, the older age of BC patients can lead to an aging process associated with
20 functional and psychosocial declines. Thus, the first factor may stimulate the aging process
21 resulting in amplified physical and psychosocial constraints and subsequent disability, if not
22 remedied through intervention. Therefore, interventions to improve physiologic and
23 psychosocial limitations are of significance to the longevity of cancer survivors¹⁷.

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26 Rehabilitation interventions have been investigated in other cancer diseases and have been
27 proven to be effective. Exercise can lead to better managing of patients physiologic
28 symptoms, improve a variety of mental health outcomes including fatigue, anxiety, QoL and
29 mood and possibly even better survival outcomes^{17 18}. Research into effectiveness of
30 psychosocial interventions in cancer patients is scarce. Nonetheless, there is evidence that
31 psychosocial interventions can improve patients' QoL¹⁹.

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35 Rehabilitation interventions can be categorized as a tertiary prevention approach. Tertiary
36 prevention aims to prevent and manage cancer-related and treatment-induced side effects.
37 Additionally, tertiary prevention provide a knowledge basis for optimal follow-up care and
38 cancer surveillance, and optimize health after cancer treatment¹⁰.

39 40 41 **Why it is important to do this review**

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43 With an increasing number of cancer survivors, tertiary prevention will become imperative in
44 cancer survivorship. In order to develop evidence-based rehabilitation programs for patients
45 with MIBC, it is essential to have a global picture of effective rehabilitation interventions.
46 Therefore, a systematic review assessing the effects of exercise-based and psychosocial
47 rehabilitation interventions for BC patients is needed. A previous systematic review assessed
48 the effects of lifestyle factors (diet, smoking and physical activity) on health-related quality
49 of life in bladder cancer survivors. Findings of this review concluded that there was limited
50 evidence to support a positive association between health-related quality of life and physical
51 activity in bladder cancer survivors²⁰. Our review differs with previous review in several
52 aspects. First we want to identify well defined supervised interventions that are effective. In
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3 previous review, they evaluated the physical activity pattern of the patient, which is not the
4 same as a supervised exercise intervention. Furthermore, this review will not only focus on
5 health-related quality of life, we will also assess the effects of rehabilitation interventions on
6 other outcomes (explained below). Additionally, to our knowledge, there is no systematic
7 review that has summarized the evidence of psychosocial rehabilitation interventions for
8 MIBC survivors in a systematic manner.
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11 No specific guidelines exist for exercise-based and/or psychosocial rehabilitation
12 interventions for MIBC survivors. This review could give guidance to the development of
13 specific evidence-based guidelines. Although this review focuses only on the exercise and
14 psychosocial part of rehabilitation, it is important to note that rehabilitation of cancer
15 patients requires also other interventions such as diet counseling, smoking cessation, etc.¹².
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19 AIMS AND OBJECTIVES

21 Primary objective

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23 To assess the effects of rehabilitation interventions (exercise-based and psychosocial
24 interventions) on patient reported outcomes (e.g. QoL, fatigue, pain) and physical fitness of
25 MIBC survivors.
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28 Secondary objectives

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30 To identify significant demographic, clinical, personal, or intervention related moderators of
31 intervention effects.
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34 METHODS

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36 The overall approach of this review is consistent with the methodology described in the
37 Cochrane Handbook for Systematic reviews of Interventions²¹ and is described below.
38 Reports of current systematic review protocol adhere to the preferred items for systematic
39 reviews and meta-analysis protocol (PRISMA-P) checklist²². The systematic review itself will
40 adhere to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses
41 (PRISMA)²³.
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45 Criteria for considering studies for this review

47 Types of studies

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49 Because of the anticipated low amount of randomized controlled trials (RCTs), RCTs and non-
50 randomized studies (NRS) (i.e., cohort studies, case-control studies, cross-sectional studies
51 and quasi-randomized controlled clinical trials (CCTs)) will be considered as appropriate
52 study designs. Results from RCTs and NRS will be presented separately.
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Types of participants

The population of interest will be adults (≥ 18 years of age) with medically confirmed diagnosis of localized MIBC or high risk non-muscle invasive bladder cancer (NMIBC) for whom a radical cystectomy is indicated. Patients with metastasized BC will be excluded. Demographic factors are no exclusion criteria except for age (< 18 years of age). Studies involving participants with a range of cancers or other diagnoses that report results specifically for patients with MIBC will be included. Studies involving participants with urologic cancers where data is not provided separately for MIBC patients will be excluded.

Types of interventions

Exercise-based rehabilitation interventions considered for this review will be aerobic or endurance activities, strength or resistance training, balance exercises, flexibility exercises (with inclusion of yoga and Pilates), exercises specific to address sexual functioning and pelvic floor exercises in case of bladder preserving strategies or bladder reconstruction after radical cystectomy. Generalized advice to engage in regular PA activity will not be considered as an exercise-based rehabilitation intervention. In this review, the focus will be placed on exercise in a planned, structured, repetitive and purposeful rehabilitation intervention. PA as part of playing, working, active transportation, house chores or recreational activities will not be included.

Psychosocial rehabilitation interventions eligible for inclusion will be based on the framework proposed by Cunningham: patient education (e.g. stoma management, generalized advice to engage in PA activity), social support, coping skills training, psychotherapy and spiritual/existential therapy¹⁶. Alternative medicine and therapies will not be included in this review.

Both intervention types have to be supervised by a professional, can either be individual or in group, hospital-based or home-based (with follow up by a professional), and can be given before, during and/or after treatment. No limits will be placed on the timing, frequency, intensity and duration of rehabilitation interventions. The interventions will be compared with an inactive control intervention (e.g. no treatment, standard care or a waiting list control).

Types of outcome measures

For both primary and secondary outcome measures, there will be no exclusion based on length of follow up.

Primary outcomes

1. Patient reported outcomes (PROs) including overall quality of life, specific quality of life domains including symptoms such as fatigue, pain, urinary incontinence, sexual dysfunction, gastro-intestinal dysfunction and psychological factors such as anxiety, depression, stress

and self-esteem. Due to the wide range of questionnaires used for PROs and the non-consensus of using one standardized questionnaire, only studies using the standardized and validated measurement instruments for PRO, found in Table 1^{24 36} will be included. All studies using other measurement instruments will be excluded, unless proof of their validation can be found in literature.

2. Physical fitness assessed by VO₂ peak, VO₂ max, 6- or 12-minute walk test, 400-m walk test, handgrip strength tests, sit and reach tests or other proven to be validated instruments.

Secondary outcomes

1. Cancer recurrence, cancer-specific survival, progression-free survival, overall survival, mortality, years of life lost or 5-year survival.

2. Body composition assessed by height, weight, body mass index, fat mass, lean body mass, thickness of skin folds, body fat, arm circumference, waist circumference, hip circumference or waist-hip ratio.

3. Bone mineral density or fracture risk assessed by fracture risk assessment tool (FRAX)³⁷.

4. Karnofsky performance score (KPS)³⁸.

Table 1 – standardized and validated measurement instruments for the included PROs

Patient reported outcome	Validated measurement instrument
HRQOL	EQ-5D visual analogue scale, MID: 7 points, SF-36, Ferrans and Powers Quality of Life Index, World Health Organization Quality of Life, SF-12, Padilla QLI, 20-item short form health survey and Satisfaction With Life Scale
Cancer specific QOL	FACT-G, EORTC QLQ-C30, Functional Living Index-Cancer, Selby's QLI, Cleary's QLI and Cancer Rehabilitation Evaluation System –SF
Bladder cancer specific QOL	QLQ-BLM30, BCI and FACT-BI
Sexual function	IIEF-5 and FSFI
Gastro-intestinal function	GIQLI
Urinary incontinence	BCI supplement, ICIQ-UI SF, IPSS
Psychological factors	
Depression	BSI-18, BDI,ISR-depression scale
Anxiety	STAI anxiety scales, numeric rating scales or visual analogue scale
Stress	Perceived Stress Scale
Self-esteem	Rosenberg self-esteem scale

Search methods for identification of studies

Electronic searches

The following electronic databases will be searched from inception until the search date: the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (using the PubMed interface), Embase (using the embase.com interface), Web of Science and the Physiotherapy Evidence Database (PEDro). The search strategies will be evaluated using the PRESS checklist³⁹ and will be monitored and peer reviewed by an information specialist (NSP). The search strategies are presented in 'Supplementary File 1'.

Searching other resources

The cited and citing references of the included studies will be checked via Web of Science.

Data collection and analysis

Selection of studies

All references found through the search process will be downloaded in a database created by reference management software (Endnote). After removing duplicates in Endnote, all references will be imported into Covidence for screening purposes. Obviously irrelevant studies, based on title and abstract, will independently be excluded by two review authors (ER and VF). After screening titles and abstracts, two review authors (ER and VF) will independently assess full-text reports for eligibility. Discrepancies will be discussed with a third review author (NS). Reasons for exclusion of full-texts will be documented. Studies will be excluded if no full-text is available. Abstracts in any other language than English will be excluded. There will be no language restriction for full texts and translations will be carried out if necessary. If studies have multiple publications with the same outcome(s) reported, manuscripts with the longest follow-up will be selected for inclusion. Older publications referred to in included articles will be accessed to clarify methods if required.

Data extraction

A modified EPOC data collection form of the Cochrane collaboration will be used and pilot tested with at least three studies in the review⁴⁰. After pilot testing the form, adjustments can be made. Data extraction will be performed independently by two review authors (ER and VF). Following data will be extracted for each study:

- **General information:** date form completed, name of person extracting data, report title, report ID, authors' names, source, country, contact address, language of publication, year of publication.
- **Population and setting:** population description (from which study participants are drawn), setting (e.g. inpatient, outpatient, hospital setting, home setting,

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3 combination), inclusion and exclusion criteria and sampling method (e.g.,
4 convenience, random).

- 5 • **Methods:** aim of study, design, unit of allocation, start and end date, duration of
6 participation.
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8 • **Participants:** number of participants in intervention and control groups, details of
9 clusters if applicable, baseline imbalances, participant demographics such as sex, age
10 and ethnicity, disease related characteristics such as stage of disease, received
11 treatment(s), time after diagnosis and comorbidities.
- 12
13 • **Intervention:** type of intervention (exercise-based, psychosocial or combination),
14 details of intervention type (e.g. aerobic, pelvic floor exercises, counseling, patient
15 education), co-intervention(s), type of control intervention, frequency, duration,
16 intensity and providers of the intervention.
- 17
18 • **Outcomes:** outcome name, time points measured and reported, outcome definition,
19 person measuring/reporting, upper and lower limits of scales, unit measurement if
20 relevant, if outcome/tool is validated, imputation of missing data and assumed risk
21 estimate.
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23 • **Results:** outcome, measurement effects (please see data analyses below) for
24 intervention and comparison group, baseline data, number of missing participants
25 and reasons, statistical methods used.
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29 Assessment of risk of bias in included studies

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31 The Cochrane Collaboration's tool for assessing risk of bias will be used for RCTs. Assessment
32 of risk of bias in NRS will be done using the Newcastle-Ottawa Scale for observational
33 studies. Assessment of risk of bias of individual studies as well as the overall quality of the
34 body of evidence will be evaluated with these two tools (which correspond to the GRADE
35 approach). A summary assessment of risk of bias will be done for each outcome 'within' a
36 study and for each outcome 'across' studies of the same study design. This will be
37 summarized in the 'Summary of findings table'. Given the nature of exercise and
38 psychosocial interventions, it is impossible to blind participants and personnel for this
39 interventions. Therefore, 'blinding of participants and personnel' will not be taken into
40 account in the risk of bias assessment, but this will be taken into consideration in the
41 discussion section.
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46 Dealing with missing data

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48 If the data required are not available in the publication, we will first attempt to contact the
49 study authors. If this is not possible, we will try to back-calculate from the data presented. If
50 data will be obtained from other study authors, this will be reported in the review in a
51 transparent manner. This way, we can keep in mind that this missing data obtained from
52 study authors was not peer reviewed. Studies assessing lifestyle interventions may have
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3 issues with compliance. Therefore, reasons for missing data (e.g. dropouts, losses to follow-
4 up and withdrawals) will be carefully reported.
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6 Assessment of heterogeneity 7

8 Heterogeneity will be assessed for each different study design type. Statistical heterogeneity
9 will be quantified using the I^2 statistic. We will consider the statistical heterogeneity to be
10 high if $I^2 > 50\%$. Depending on the heterogeneity of the studies and their results, we will
11 decide if a meta-analysis can be conducted. We will attempt to explain any observed
12 heterogeneity in the review.
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15 Assessment of reporting bias 16

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18 Funnel plots will be used to assess publication bias when ten or more studies are included in
19 a meta-analysis.
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21 Data synthesis 22

23 The findings from the included studies will be summarized descriptively. For dichotomous
24 outcomes, measurement of treatment effect will be reported as risk ratios (RRs) and 95 %
25 confidence intervals (CIs). For continuous outcomes, we will calculate mean differences and
26 95 % CIs when results are reported on the same scale (or can be converted to the same
27 scale) or standardized mean differences and 95 % CIs if results are reported on different
28 scales.
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32 There will be a moderator analysis to identify the most effective timing, frequency and
33 duration of the rehabilitation interventions. There will also be an attempt to identify
34 significant demographical or clinical moderators. To prevent co-intervention bias, there will
35 be a subgroup analysis based on the type of intervention (only exercised-based
36 interventions, only psychosocial interventions or a combination).
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40 When homogeneity of the studies is sufficient, random-effects meta-analysis will be
41 undertaken separately for each type of study design. Only studies with low risk of bias will be
42 included in meta-analyses. Therefore, we will perform sensitivity analyses to investigate how
43 conclusions might be affected if studies at high or unclear risk of bias were included.
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46 Ethics and dissemination 47

48 Ethics approval is not required, as no primary data will be collected. Results will be
49 disseminated through a peer-reviewed publication.
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51 Discussion 52

53 To date, there are no specific guidelines for exercise-based or psychosocial rehabilitation
54 interventions for MIBC survivors. This systematic review is expected to provide guidance to
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3 the development of specific guidelines and evidence-based rehabilitation or survivorship
4 programs for MIBC survivors.
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6 The scope of this review is broad (i.e., different rehabilitation interventions and study
7 designs). Although this means that heterogeneity might be present between the studies,
8 evaluation of different intervention approaches is needed to develop optimal rehabilitation
9 or survivorship programs. Caution will be present in the interpretation of the results because
10 of the fact that evidence from RCTs is higher than evidence from NRS. Therefore, the results
11 derived from RCTs will be seen as the primary evidence. Results from NRS will be seen as
12 additional evidence to support the results from RCTs.
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16 **Authors' contribution**

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18 ER drafted the manuscript and developed the methods and analyses strategy. VF coordinated the process. NSP
19 and NS aided in developing the search strategy. VF, PO and KD provided uro-oncology specific expertise. RB and
20 BD gave valuable input concerning rehabilitation.
21

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26

27 **Competing interests statement**

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29 None declared.
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For peer review only

Search Strategy		
Database	Data last searched	Search Syntax
The Cochrane Central Register of Controlled Trials (CENTRAL)	13/12/2016	<ol style="list-style-type: none"> [mh "Urinary Bladder Neoplasms"] OR [mh "Carcinoma, Transitional Cell"] OR ("bladder cancer"):ti,ab,kw OR ("bladder carcinoma"):ti,ab,kw OR ("bladder malignancy"):ti,ab,kw OR ("bladder neoplasm"):ti,ab,kw OR ("bladder tumor"):ti,ab,kw OR ("transitional cell carcinoma"):ti,ab,kw OR ("transitional cell cancer"):ti,ab,kw OR ("transitional cell malignancies"):ti,ab,kw OR ("transitional cell tumor"):ti,ab,kw OR ("urothelial cancer"):ti,ab,kw OR ("urothelial carcinoma"):ti,ab,kw OR ("urothelial malignancy"):ti,ab,kw OR ("urothelial tumor"):ti,ab,kw OR ("urinary tract carcinoma"):ti,ab,kw OR ("urinary tract cancer"):ti,ab,kw OR ("urinary tract malignancy"):ti,ab,kw OR ("urinary tract tumor"):ti,ab,kw [mh "exercise"] OR [mh "Exercise Movement Techniques"] OR [mh "Sports"] OR [mh "Physical Fitness"] OR [mh "Physical Exertion"] OR [mh "Exercise Therapy"] OR [mh "Dance Therapy"] OR [mh "Recreation Therapy"] OR [mh "Rehabilitation, Vocational"] OR [mh "Telerehabilitation"] OR [mh "Occupational Therapy"] OR [mh "Self Care"] OR [mh "Urinary Incontinence/rehabilitation"] OR [mh "Pelvic Floor/therapy"] OR ("self care"):ti,ab,kw OR (exercise):ti,ab,kw OR (sport):ti,ab,kw OR ("physical activity"):ti,ab,kw OR (physiotherapy):ti,ab,kw OR (kinesiotherapy):ti,ab,kw OR ("physical conditioning"):ti,ab,kw OR ("physical education"):ti,ab,kw OR ("physical fitness"):ti,ab,kw OR (running):ti,ab,kw OR (swimming):ti,ab,kw OR (walking):ti,ab,kw OR (jogging):ti,ab,kw OR ("weight lifting"):ti,ab,kw OR (dance):ti,ab,kw OR ("tai chi"):ti,ab,kw OR (yoga):ti,ab,kw OR (pilates):ti,ab,kw OR (gymnastic):ti,ab,kw OR ("resistance training"):ti,ab,kw OR ("aerobic training"):ti,ab,kw OR ("anaerobic training"):ti,ab,kw OR ("muscle training"):ti,ab,kw OR (stretching):ti,ab,kw OR (aerobic):ti,ab,kw OR (rehabilitation):ti,ab,kw OR ("prehabilitation"):ti,ab,kw OR (prehabilitation):ti,ab,kw OR (aquagym):ti,ab,kw OR (football):ti,ab,kw OR (soccer):ti,ab,kw OR ("circuit training"):ti,ab,kw OR (fitness):ti,ab,kw OR ("bladder training"):ti,ab,kw OR ("incontinence management"):ti,ab,kw OR ("urinary management"):ti,ab,kw [mh "Tertiary Prevention"] OR [mh "Social Support"] OR [mh "Psychiatric Rehabilitation"] OR [mh "Health Promotion"] OR [mh "Psychotherapy"] OR [mh "Counseling"] OR [mh "Patient Education as Topic"] OR [mh "Sex Education"] OR [mh "Sexuality/rehabilitation"] OR [mh "Health Literacy"] OR [mh "psychology/education"] OR [mh "psychology/therapy"] OR [mh "Problem Solving"] OR [mh "Mind-body therapies"] OR [mh "patient participation"] OR [mh "Existentialism"] OR [mh "spiritual therapies"] OR [mh "problem-based learning"] OR [mh "Sedentary Lifestyle"] OR ("psychosocial intervention"):ti,ab,kw OR ("psychologic intervention"):ti,ab,kw OR ("psychological intervention"):ti,ab,kw OR ("psychology intervention"):ti,ab,kw OR ("social intervention"):ti,ab,kw OR ("psychosocial therapy"):ti,ab,kw OR ("psychologic therapy"):ti,ab,kw OR ("psychological therapy"):ti,ab,kw OR ("psychology therapies"):ti,ab,kw OR (psychotherapy):ti,ab,kw OR ("tertiary health care"):ti,ab,kw OR ("tertiary prevention"):ti,ab,kw OR ("social support"):ti,ab,kw OR ("social behavior"):ti,ab,kw OR ("support care"):ti,ab,kw OR ("supportive care"):ti,ab,kw OR ("behavior treatment"):ti,ab,kw OR ("behavior therapy"):ti,ab,kw OR ("cognitive treatment"):ti,ab,kw OR ("cognitive

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MEDLINE (via PubMed interface)	13/12/2016	<p>1. "Urinary Bladder Neoplasms"[MESH] OR "Urinary Bladder/abnormalities"[MESH] OR "Urinary bladder/surgery"[MESH] OR "Carcinoma, Transitional Cell"[Mesh] OR "bladder cancer"[TIAB] OR "bladder cancers"[TIAB] OR "bladder carcinoma"[TIAB] OR "bladder carcinomas"[TIAB] OR "bladder malignancy"[TIAB] OR "bladder malignancies"[TIAB] OR "bladder neoplasm"[TIAB] OR "bladder neoplasms"[TIAB] OR "bladder tumor"[TIAB] OR "bladder tumors"[TIAB] OR "bladder tumour"[TIAB] OR "bladder tumours"[TIAB] OR "transitional cell carcinoma"[TIAB] OR "transitional cell carcinomas"[TIAB] OR "transitional cell cancer"[TIAB] OR "transitional cell cancers"[TIAB] OR "transitional cell malignancies"[TIAB] OR "transitional cell tumor"[TIAB] OR "transitional cell tumors"[TIAB] OR "transitional cell tumour"[TIAB] OR "transitional cell tumours"[TIAB] OR "urothelial cancer"[TIAB] OR "urothelial cancers"[TIAB] OR "urothelial carcinoma"[TIAB] OR "urothelial carcinomas"[TIAB] OR "urothelial malignancy"[TIAB] OR "urothelial malignancies"[TIAB] OR "urothelial tumor"[TIAB] OR "urothelial tumors"[TIAB] OR "urothelial tumour"[TIAB] OR "urothelial tumours"[TIAB] OR "urinary tract carcinoma"[TIAB] OR "urinary tract carcinomas"[TIAB] OR "urinary tract cancer"[TIAB] OR "urinary tract cancers"[TIAB] OR "urinary tract malignancy"[TIAB] OR "urinary tract malignancies"[TIAB] OR "urinary tract tumor"[TIAB] OR "urinary tract tumors"[TIAB] OR "urinary tract tumour"[TIAB] OR "urinary tract tumours"[TIAB]</p> <p>2. "exercise"[MESH] OR "Exercise Movement Techniques"[Mesh] OR "Sports"[Mesh] OR "Physical Fitness"[Mesh] OR "Physical Exertion"[Mesh] OR "Exercise Therapy"[Mesh] OR "Dance Therapy"[Mesh] OR "Recreation Therapy"[Mesh] OR "Rehabilitation, Vocational"[Mesh] OR "Telerehabilitation"[Mesh] OR "Occupational Therapy"[Mesh] OR "Self Care"[Mesh] OR "Urinary Incontinence/rehabilitation"[Mesh] OR "Pelvic Floor/therapy"[Mesh] OR "self care"[TIAB] OR</p>

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3. "Tertiary Prevention"[Mesh] OR "Social Support"[Mesh] OR "Psychiatric Rehabilitation"[Mesh] OR "Health Promotion"[Mesh] OR "Psychotherapy"[Mesh] OR "Counseling"[Mesh] OR "Patient Education as Topic"[Mesh] OR "Sex Education"[Mesh] OR "Sexuality/rehabilitation"[Mesh] OR "Health Literacy"[Mesh] OR "psychology/education"[MESH] OR "psychology/therapy"[MESH] OR "Problem Solving"[MESH] OR "Mind-body therapies"[Mesh] OR "patient participation"[MESH] OR "Existentialism"[MESH] OR "spiritual therapies"[MESH] OR "problem-based learning"[MESH] OR "Sedentary Lifestyle"[Mesh] OR psychosocial intervention*[TIAB] OR psychologic intervention*[TIAB] OR psychological intervention*[TIAB] OR psychology intervention*[TIAB] OR social intervention*[TIAB] OR psychosocial therap*[TIAB] OR psychologic therap*[TIAB] OR “psychological therapy”[TIAB] OR “psychological therapies”[TIAB] OR “psychology therapies”[TIAB] OR “psychotherapy”[TIAB] OR “tertiary health care”[TIAB] OR “tertiary prevention”[TIAB] OR “social support”[TIAB] OR social behav*[TIAB] OR “support care”[TIAB] OR “supportive care”[TIAB] OR behavior treatment*[TIAB] OR behavioral treatment*[TIAB] OR behavior therap*[TIAB] OR behavioral therap*[TIAB] OR cognitive treatment*[TIAB] OR cognitive therap*[TIAB] OR “counseling”[TIAB] OR patient education*[TIAB] OR “patient participation”[TIAB] OR health education*[TIAB] OR sex education*[TIAB] OR sexual education*[TIAB] OR psychoeducation*[TIAB] OR sex therap*[TIAB] OR sexual therap*[TIAB] OR stoma education*[TIAB] OR stoma therap*[TIAB] OR health literac*[TIAB] OR health promotion*[TIAB] OR health behavio*[TIAB] OR “cognitive behavior”[TIAB] OR “behavior training”[TIAB] OR “behavioral training”[TIAB] OR “behavioural training”[TIAB] OR CBT[TIAB] OR complementary therap*[TIAB] OR mind body therap*[TIAB] OR spiritual therap*[TIAB] OR relaxation therap*[TIAB] OR “relaxation training”[TIAB] OR client centered therap*[TIAB] OR conditioning[TIAB] OR stoma management[TIAB] OR bowel management[TIAB] OR coping [TIAB] OR mindfulness[TIAB] OR empowerment[TIAB] OR empowering[TIAB] OR self-monitoring*[TIAB] OR motivation therap*[TIAB] OR motivational therap*[TIAB] OR motivation interview[TIAB] OR motivation interviewing[TIAB] OR motivational interview[TIAB] OR motivational interviewing[TIAB] OR motivation treatment*[TIAB] OR motivational treatment*[TIAB] OR psychology[TIAB] OR problem solv*[TIAB] OR “psychosocial care”[TIAB] OR “psychological care”[TIAB] OR “psychologic care”[TIAB] OR caregiver support*[TIAB] OR sociotherap*[TIAB] OR occupational therap*[TIAB] OR care deliver*[TIAB] OR functional therap*[TIAB] OR “functional training”[TIAB] OR existentialism[TIAB] OR “spiritual healing”[TIAB] OR spiritual therap*[TIAB] OR “transcultural care”[TIAB] OR “life style”[TIAB]
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5. 1 AND 4

EMBASE (via Embase.com interface)	13/12/2016	<ol style="list-style-type: none"> <li data-bbox="699 279 1999 646">1. 'bladder tumor'/exp OR 'urinary tract carcinoma'/exp OR 'bladder surgery'/exp OR 'transitional cell carcinoma'/exp OR 'bladder cancer':ab,ti OR 'bladder cancers':ab,ti OR 'bladder carcinoma':ab,ti OR 'bladder carcinomas':ab,ti OR 'bladder malignancy':ab,ti OR 'bladder malignancies':ab,ti OR 'bladder neoplasm':ab,ti OR 'bladder neoplasms':ab,ti OR 'bladder tumor':ab,ti OR 'bladder tumors':ab,ti OR 'bladder tumour':ab,ti OR 'bladder tumours':ab,ti OR 'transitional cell carcinoma':ab,ti OR 'transitional cell carcinomas':ab,ti OR 'transitional cell cancer':ab,ti OR 'transitional cell cancers':ab,ti OR 'transitional cell malignancies':ab,ti OR 'transitional cell tumor':ab,ti OR 'transitional cell tumors':ab,ti OR 'transitional cell tumour':ab,ti OR 'transitional cell tumours':ab,ti OR 'urothelial cancer':ab,ti OR 'urothelial cancers':ab,ti OR 'urothelial carcinoma':ab,ti OR 'urothelial carcinomas':ab,ti OR 'urothelial malignancy':ab,ti OR 'urothelial malignancies':ab,ti OR 'urothelial tumor':ab,ti OR 'urothelial tumors':ab,ti OR 'urothelial tumour':ab,ti OR 'urothelial tumours':ab,ti OR 'urinary tract carcinoma':ti,ab OR 'urinary tract carcinomas':ti,ab OR 'urinary tract cancer':ti,ab OR 'urinary tract cancers':ti,ab OR 'urinary tract malignance':ti,ab OR 'urinary tract malignancy':ti,ab OR 'urinary tract malignancies':ti,ab OR 'urinary tract tumor':ti,ab OR 'urinary tract tumors':ti,ab OR 'urinary tract tumour':ti,ab OR 'urinary tract tumours':ti,ab <li data-bbox="699 646 1999 1013">2. 'physical activity'/exp OR 'exercise'/exp OR 'physiotherapy'/exp OR 'kinesiotherapy'/exp OR 'fitness'/exp OR 'sport'/exp OR 'bladder training'/exp OR 'cancer rehabilitation'/exp OR 'cognitive rehabilitation'/exp OR 'functional training'/exp OR 'geriatric rehabilitation'/exp OR 'muscle training'/exp OR 'home rehabilitation'/exp OR 'occupational therapy'/exp OR 'pelvic floor muscle training'/exp OR 'self care':ab,ti OR 'exercise':ab,ti OR 'exercising':ab,ti OR 'exercises':ab,ti OR 'sport':ab,ti OR 'sports':ab,ti OR 'physical activity':ab,ti OR 'physical activities':ab,ti OR 'physiotherapy':ab,ti OR 'kinesiotherapy':ab,ti OR 'physical conditioning':ab,ti OR 'physical education*':ab,ti OR 'physical fitness':ab,ti OR 'running':ab,ti OR 'swimming':ab,ti OR 'walking':ab,ti OR 'jogging':ab,ti OR 'weight lifting':ab,ti OR 'dancing':ab,ti OR 'dance':ab,ti OR 'tai chi':ab,ti OR 'tai ji':ab,ti OR 'yoga':ab,ti OR 'pilates':ab,ti OR 'gymnastic':ab,ti OR 'gymnastics':ab,ti OR 'resistance training':ab,ti OR 'aerobic training':ab,ti OR 'anaerobic training':ab,ti OR 'muscle training':ab,ti OR 'stretching':ab,ti OR 'aerobic':ab,ti OR 'aerobics':ab,ti OR 'rehabilitation':ab,ti OR 'pre-habilitation':ab,ti OR 'prehabilitation':ab,ti OR 'aquagym':ab,ti OR 'football':ab,ti OR 'soccer':ab,ti OR 'circuit training':ab,ti OR 'fitness':ab,ti OR 'bladder training':ab,ti OR 'incontinence management':ab,ti OR 'urinary management':ab,ti <li data-bbox="699 1013 1999 1343">3. 'psychosocial rehabilitation'/exp OR 'recreational therapy'/exp OR 'sociotherapy'/exp OR 'telerehabilitation'/exp OR 'vocational rehabilitation'/exp OR 'caregiver support'/exp OR 'psychosocial care'/exp OR 'social support'/exp OR 'spiritual care'/exp OR 'psychotherapy'/exp OR 'preoperative education'/exp OR 'psychoeducation'/exp OR 'patient education'/exp OR 'health promotion'/exp OR 'reinforcement'/exp OR 'patient participation'/exp OR 'counseling'/exp OR 'problem solving'/exp OR 'home physiotherapy'/exp OR 'cancer prevention'/exp OR 'learning'/exp OR 'rehabilitation care'/exp OR 'bladder and bowel management'/exp OR 'empowerment'/exp OR 'coping behavior'/exp OR 'social interaction'/exp OR 'social participation'/exp OR 'behavior change'/exp OR 'lifestyle'/exp OR 'psychosocial intervention*':ab,ti OR 'psychologic intervention*':ab,ti OR 'psychological intervention*':ab,ti OR 'psychology intervention*':ab,ti OR 'social intervention*':ab,ti OR 'psychosocial therap*':ab,ti OR 'psychologic therap*':ab,ti OR 'psychological therapy':ab,ti OR 'psychological therapies':ab,ti OR 'psychology therapies':ab,ti OR 'psychotherapy':ab,ti OR 'tertiary health care':ab,ti OR 'tertiary prevention':ab,ti OR 'social support':ab,ti OR 'social behav*':ab,ti OR 'support care':ab,ti OR 'supportive
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<p>Web of Science</p>	<p>13/12/2016</p>	<p>1. TS=("bladder cancer") OR TS=("bladder cancers") OR TS=("bladder carcinoma") OR TS=("bladder carcinomas") OR TS=("bladder malignancy") OR TS=("bladder malignancies") OR TS=("bladder neoplasm") OR TS=("bladder neoplasms") OR TS=("bladder tumor") OR TS=("bladder tumors")OR TS=("bladder tumour") OR TS=("bladder tumours") OR TS=("transitional cell carcinoma") OR TS=("transitional cell carcinomas") OR TS=("transitional cell cancer") OR TS=("transitional cell cancers") OR TS=("transitional cell malignancies") OR TS=("transitional cell tumor") OR TS=("transitional cell tumors") OR TS=("transitional cell tumour") OR TS=("transitional cell tumours") OR TS=("urothelial cancer") OR TS=("urothelial cancers") OR TS=("urothelial carcinoma") OR TS=("urothelial carcinomas")OR TS=("urothelial malignancy") OR TS=("urothelial malignancies") OR TS=("urothelial tumor") OR TS=("urothelial tumors")OR TS=("urothelial tumour") OR TS=("urothelial tumours") OR TS=("urinary tract carcinoma") OR TS=("urinary tract carcinomas") OR TS=("urinary tract cancer") OR TS=("urinary tract cancers") OR TS=("urinary tract malignancy") OR TS=("urinary tract malignancies") OR TS=("urinary tract tumor") OR TS=("urinary tract tumors") OR TS=("urinary tract tumour") OR TS=("urinary tract tumours")</p> <p>2. TS=("self care") OR TS=(exercise) OR TS=(exercising) OR TS=(exercises) OR TS=(sport) OR TS=(sports) OR TS=("physical activity") OR TS=("physical activities") OR TS=(physiotherapy) OR TS=(kinesiotherapy) OR TS=("physical conditioning") OR TS=("physical education*") OR TS=("physical fitness") OR TS=(running) OR TS=(swimming) OR TS=(walking) OR TS=(jogging) OR TS=("weight lifting") OR TS=(dancing) OR TS=(dance) OR TS=("tai chi") OR TS=("tai ji") OR TS=(yoga) OR TS=(pilates) OR TS=(gymnastic) OR TS=(gymnastics) OR TS=("resistance training") OR TS=("aerobic training") OR TS=("anaerobic training") OR TS=("muscle training") OR TS=(stretching) OR TS=(aerobic) OR TS=(aerobics) OR TS=(rehabilitation) OR TS=("pre-habilitation") OR TS=(prehabilitation) OR TS=(aquagym) OR TS=(football) OR TS=(soccer)</p>

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OR TS=(“circuit training”) OR TS=(fitness) OR TS=(“bladder training”) OR TS=(“incontinence management”) OR TS=(“urinary management”)

3. TS=(“psychosocial intervention*”)OR TS=(“psychologic intervention*”) OR TS=(“psychological intervention*”)OR TS=(“psychology intervention*”)OR TS=(“social intervention*”) OR TS=(“psychosocial therap*”)OR TS=(“psychologic therap*”)OR TS=(“psychological therapy”)OR TS=(“psychological therapies”) OR TS=(“psychology therapies”) OR TS=(psychotherapy) OR TS=(“tertiary health care”) OR TS=(“tertiary prevention”) OR TS=(“social support”) OR TS=(“social behav*”) OR TS=(“support care”) OR TS=(“supportive care”) OR TS=(“behavior treatment*”) OR TS=(“behavioral treatment*”)OR TS=(“behavior therap*”)OR TS=(“behavioral therap*”) OR TS=(“cognitive treatment*”) OR TS=(“cognitive therap*”) OR TS=(counseling) OR TS=(“patient education*”)OR TS=(“patient participation”)OR TS=(“health education*”)OR TS=(“sex education*”) OR TS=(“sexual education*”)OR TS=(psychoeducation*)OR TS=(“sex therap*”)OR TS=(“sexual therap*”) OR TS=(“stoma education*”)OR TS=(“stoma therap*”)OR TS=(“health literac*”) OR TS=(“health promotion*”)OR TS=(“health behavio*”) OR TS=(“cognitive behavior”) OR TS=(“behavior training”) OR TS=(“behavioral training”) OR TS=(“behavioural training”) OR TS=(CBT) OR TS=(“complementary therap*”)OR TS=(“mind body therap*”)OR TS=(“spiritual therap*”)OR TS=(“relaxation therap*”)OR TS=(“relaxation training”) OR TS=(“client centered therap*”)OR TS=(conditioning)OR TS=(“stoma management”)OR TS=(“bowel management”) OR TS=(coping) OR TS=(mindfulness)OR TS=(empowerment) OR TS=(empowering) OR TS=(“self-monitoring*”)OR TS=(“motivation therap*”)OR TS=(“motivational therap*”)OR TS=(“motivation interview”) OR TS=(“motivation interviewing”) OR TS=(“motivational interview”) OR TS=(“motivational interviewing”) OR TS=(“motivation treatment*”)OR TS=(“motivational treatment*”)OR TS=(psychology)OR TS=(“problem solv*”)OR TS=(“psychosocial care”)OR TS=(“psychological care”)OR TS=(“psychologic care”)OR TS=(“caregiver support*”)OR TS=(sociotherap*) OR TS=(“occupational therap*”) OR TS=(“care deliver*”)OR TS=(“functional therap*”)OR TS=(“functional training”) OR TS=(existentialism)OR TS=(“spiritual healing”) OR TS=(“spiritual therap*”)OR TS=(“transcultural care”) OR TS=(“life style”)

4. 2 OR 3

5. 1 AND 4

PEDro	13/12/2016	Title/abstract: bladder cancer
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The **cited and citing** articles of the included studies, retrieved with the above searches, will be screened through **Web of Science** to potentially identify other studies.

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	line number
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	2-3
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	61
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	4-22
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	365-368
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	
Support:			
Sources	5a	Indicate sources of financial or other support for the review	369-371
Sponsor	5b	Provide name for the review funder and/or sponsor	369-371
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	370-371
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	92-176
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	177-184
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	192-251
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	253-260
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	Supplementary file 1
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	263-265

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Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis) 263-274
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators 275-279
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications 280-303
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale 231-249
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis 304-315
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised 328-329
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I ² , Kendall's τ) 326-327 335-349
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) 344, 348
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned 335
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies) 331-333
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE) 307-309

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

BMJ Open

Rehabilitation interventions to improve patient reported outcomes and physical fitness in survivors of muscle invasive bladder cancer: a systematic review protocol

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Manuscript ID	bmjopen-2017-016054.R1
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Complete List of Authors:	Rammant, Elke; Universitair Ziekenhuis Gent, Department of Radiation Oncology and Experimental Cancer Research Bultijnck, Renée; Universitair Ziekenhuis Gent, Department of Radiation Oncology and Experimental Cancer Research Sundahl, Nora; Universitair Ziekenhuis Gent, Department of Radiation Oncology and Experimental Cancer Research Ost, Piet; Universitair Ziekenhuis Gent, Department of Radiation Oncology and Experimental Cancer Research Pauwels, Nele; Universitair Ziekenhuis Gent, Knowledge Center Ghent Deforche, Benedicte; Universiteit Gent, Department of Public Health Pieters, Ronny; Universitair Ziekenhuis Gent, Department of Urology Decaestecker, Karel; Universitair Ziekenhuis Gent, Department of Urology Fonteyne, Valérie; Universitair Ziekenhuis Gent, Department of Radiation Oncology and Experimental Cancer Research
Primary Subject Heading:	Urology
Secondary Subject Heading:	Evidence based practice, Oncology, Rehabilitation medicine
Keywords:	Muscle invasive bladder cancer, Exercise, Psychosocial intervention, systematic review, Rehabilitation

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3 **Rehabilitation interventions to improve patient reported outcomes and**
4 **physical fitness in survivors of muscle invasive bladder cancer: a systematic**
5 **review protocol**
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7

8 Elke Rammant¹, Renée Bultijnck¹, Nora Sundahl¹, Piet Ost¹, Nele S. Pauwels², Benedicte
9 Deforche³, Ronny Pieters⁴, Karel Decaestecker⁴, Valérie Fonteyne¹
10
11

12
13
14 **Affiliations:**

- 15
16 1. Department of Radiation Oncology and Experimental Cancer Research, Ghent
17 University Hospital, Ghent, Belgium
18 2. Knowledge Center Ghent, Ghent University Hospital, Ghent, Belgium
19 3. Department of Public Health, Ghent University, Ghent, Belgium
20 4. Department of Urology, Ghent University Hospital, Ghent, Belgium
21
22
23
24

25 **Corresponding Author:**

26
27
28 Elke Rammant, MSc.
29 Department of Radiation Oncology and Experimental Cancer Research,
30 Ghent University Hospital
31 De Pintelaan 185, B-9000 Ghent, Belgium
32 Tel: +32 9 33 21552
33 E-mail: elke.rammant@ugent.be
34
35
36

37 **Word count excluding title page, abstract, references, figures and tables: 3576**
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ABSTRACT

Introduction

Survivors of muscle invasive bladder cancer (MIBC) experience physical and psychosocial side effects of cancer diagnosis and treatment. These negative side effects have a crucial impact on the quality of life (QoL). To date, there is evidence that rehabilitation interventions such as physical activity and psychosocial support have a positive effect on the QoL of cancer survivors. Unfortunately, there are no specific guidelines for rehabilitation or survivorship programs for MIBC survivors. Therefore, this systematic review aims to assess the effects of exercise-based and psychosocial rehabilitation interventions for MIBC survivors.

Methods and analysis

The approach of this review is consistent with the Cochrane methodology. Randomized controlled trials and non-randomized studies will be included. The population of interest is patients (≥ 18 years of age) with diagnosis of MIBC and there will be two eligible intervention types for inclusion: exercise-based and psychosocial rehabilitation interventions. The primary outcome measures are patient reported outcomes (e.g. QoL, fatigue, pain) and physical fitness. Studies will be identified independently by two review authors by searching the Cochrane Central Register of Controlled Trials, MEDLINE, Embase, Web of Science and the Physiotherapy Evidence Database. A third reviewer will be asked by disagreements. Risk of bias will be assessed using the Cochrane Collaboration tool and the Newcastle-Ottawa Scale. Data will be summarized descriptively. If homogeneity of the studies is sufficient, meta-analysis will be undertaken.

Discussion

This systematic review is expected to provide guidance to development of evidence-based rehabilitation or survivorship programs for MIBC survivors. The broad scope of this review (i.e. different interventions and study designs) is needed to have a comprehensive view on effective rehabilitation interventions.

Ethics and dissemination

Ethics approval is not required, as no primary data will be collected. Results will be disseminated through a peer-reviewed publication.

PROSPERO registration number: CRD42017055306

Keywords

Bladder neoplasm— exercise – psychosocial intervention – rehabilitation

Strengths and limitations of this study

Strengths

- The overall approach of this review is consistent with the methodology described in the Cochrane Handbook for Systematic reviews of Interventions
- It's an innovative topic in the field of bladder cancer.
- Actual problem because the incidence of bladder cancer is rising.

Limitations

- Possible paucity of studies meeting the inclusion criteria.

BACKGROUND

Description of the condition

Bladder cancer (BC) is the 11th most common cancer worldwide. When both genders are considered separately, BC in men is rising to the 7th place whilst BC in women is dropping to the 17th place of most common cancer worldwide^{1,2}. Besides the fact that BC is more common in men than in women, BC is also known as a disease of the elderly. Due to the growth of an aging population, it can be expected that the incidence of BC will rise in the near future^{3,4}. Thirty percent of the patients diagnosed with BC present with muscle invasive BC (MIBC, stages T2-T4)⁵. Also, depending on risk stratification, up to 45% of patients with non-muscle invasive bladder cancer (NMIBC) will progress to MIBC⁶. The standard treatment in MIBC is neo-adjuvant chemotherapy followed by radical cystectomy (bladder removal), extended pelvic lymph node dissection and urinary diversion (continent or incontinent bladder replacement). Also patients with high-risk NMIBC are offered a radical cystectomy.¹ These are major interventions associated with a variety of negative side effects, especially on the urinary, gastro-intestinal and sexual function. This can lead to a loss of health-related quality of life (HRQoL), which refers to the patients' own perceptions of their health and ability to function⁷ encompassing physical, psychological, social, and spiritual dimensions⁸. Combined radiochemotherapy is an alternative for radical cystectomy in order to preserve the bladder. Both radiotherapy and chemotherapy can also be used in the adjuvant or palliative setting and can also cause a variety of treatment related side effects. Therefore, follow-up care beyond the acute diagnosis and treatment phase is necessary⁹.

Description of the intervention

The World Health Organisation (WHO) has defined rehabilitation as "the use of all means aimed at reducing the impact of disabling and handicapping conditions at enabling people with disabilities to achieve optimal social integration"¹⁰. A more specific definition of rehabilitation in the setting of cancer is the following: "cancer rehabilitation is a concept that is defined by the patient and involves helping a person with cancer to obtain maximum physical, social, psychological, and vocational functioning within the limit by the disease and its treatment"¹¹. Therefore, cancer rehabilitation needs to comprise different intervention approaches^{12,13}.

Physical activity (PA) is seen as one of the rehabilitation interventions to improve patients quality of life (QoL) and survival outcomes. PA is defined as "any movement created by the skeletal muscles that causes a substantial increase in energy expenditure"¹⁴. It is important that the terms 'physical activity' and 'exercise' are not mixed with each other. PA can be seen as an overarching term that includes exercise as well as other activities which involve bodily movement and are done as part of playing, working, active transportation, house chores and recreational activities. Exercise on the other hand, is a subcategory of PA. It is planned, structured, repetitive and purposeful to improve or maintain one or more

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3 components of physical fitness (cardiorespiratory fitness, muscular strength, muscular
4 endurance, flexibility and body composition)¹⁵. These components represent important
5 outcomes in cancer survivors that may mediate the influence of exercise on other
6 outcomes¹⁴.
7

8
9 Psychosocial interventions are another important focus in rehabilitation. These sort of
10 interventions aim to help patients cope with negative side effects of cancer diagnosis and
11 treatment¹⁶. Based on a framework proposed by Buffart et al., there are five categories of
12 interventions: patient education, social support, coping skills training, psychotherapy and
13 spiritual/existential therapy¹⁷.
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16 **How the intervention might work**

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18 In order to explain how cancer rehabilitation interventions might work, the revised Wilson
19 and Cleary Model for HRQoL will be used as a conceptual framework¹⁸. This is useful to
20 explain the pathways between different patient outcomes¹⁹. The model proposes five types
21 of patient outcome measurements (biological function, symptoms, functional status, health
22 perception and overall QOL), which have a causal relationship^{18 20}. These five patient
23 outcome measurements can be influenced by individual and environment characteristics.
24
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26
27 In the context of bladder cancer, morbidity associated with the disease and its treatment
28 can lead to complications related to urinary diversion, fatigue, urinary incontinence or
29 constipation, sexual dysfunction²¹ and psychological distress²². This can potentially lead to a
30 loss of physical, social, psychological and role function, which affects activities in daily life. As
31 a consequence, the general health perceptions of the patient can be damaged which can
32 finally lead to an overall impaired QOL. All of these outcomes can be influenced by
33 environment and individual characteristics.
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35

36
37 The provision of cancer rehabilitation can be seen as a physical environment
38 characteristic. Since it has been proven in other cancer populations that cancer
39 rehabilitation interventions have a positive influence on for example physical fitness²³,
40 muscle capacity²⁴, fatigue and emotional distress²⁵, we can conclude, according to the
41 revised Wilson and Cleary Model for HRQoL, that cancer rehabilitation interventions can
42 have a positive influence on other patient outcomes such as HRQoL¹⁸.
43
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46 Individual characteristics, such as age and the associated increased risk of co morbidities, are
47 important factors to take into account in bladder cancer patients. These characteristics are
48 associated with poorer health²⁶ such as functional and psychosocial declines²⁷. Although this
49 supports the need for cancer rehabilitation, the older age of bladder cancer patients creates
50 challenges in recommending rehabilitation interventions. Potential difficulties are the lack of
51 social support in older patients and the need for extra time and resources to enroll these
52 patients²⁸. Additionally, the high prevalence of urinary complications and problems with
53 body image in bladder cancer patients can act as potential barriers to participate in exercise
54 interventions²⁶. According to Karvinen et al., exercise interventions aimed at bladder cancer
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3 survivors should focus on offering enjoyable activities, education on the benefits of regular
4 exercise, enhancing activity levels in important others and targeting perceived barriers. They
5 also note that adjuvant therapy, age and invasiveness of the tumor may affect exercise
6 participation²⁶. Furthermore, bladder cancer survivors seem to be most interested in walking
7 and home-based, individual exercises that are not supervised²⁹.
8
9

10 **Why it is important to do this review**

11
12 With an increasing number of cancer survivors, cancer rehabilitation will become imperative
13 in cancer survivorship. In order to develop evidence-based rehabilitation programs for
14 patients with MIBC, it is essential to have a global picture of effective rehabilitation
15 interventions. Therefore, a systematic review assessing the effects of exercise-based and
16 psychosocial rehabilitation interventions for BC patients is needed. A previous systematic
17 review assessed the effects of lifestyle factors (diet, smoking and physical activity) on HRQoL
18 in bladder cancer survivors. Findings of this review concluded that there was limited
19 evidence to support a positive association between HRQoL and physical activity in bladder
20 cancer survivors³⁰. Our review differs with previous review in several aspects. First we want
21 to identify well defined interventions that are effective. In previous review, they evaluated
22 the physical activity pattern of the patient, which is not the same as an exercise intervention.
23 Furthermore, this review will not only focus on HRQoL, we will also assess the effects of
24 rehabilitation interventions on other outcomes (explained below). Additionally, to our
25 knowledge, there is no systematic review that has summarized the evidence of psychosocial
26 rehabilitation interventions for MIBC survivors in a systematic manner.
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33 So far, no specific guidelines exist for exercise-based and/or psychosocial rehabilitation
34 interventions for MIBC survivors. This review could give guidance to the development of
35 specific evidence-based guidelines. Although this review focuses only on the exercise and
36 psychosocial part of rehabilitation, it is important to note that rehabilitation of cancer
37 patients requires also other interventions such as diet counseling, smoking cessation, etc.¹².
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40 It should also be noticed that the provision of cancer rehabilitation is an often-neglected
41 facet of cancer care in terms of health policy and infrastructure³¹. Frequently reported
42 barriers to rehabilitation interventions are the lack of expertise, inappropriate referrals by
43 physicians, funding issues^{24 31} and availability of rehabilitation resources³². The results of this
44 review may increase the awareness of physicians and funders of the importance of cancer
45 rehabilitation.
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49 **AIMS AND OBJECTIVES**

50 **Primary objective**

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53 1. Assessing the effects of rehabilitation interventions (exercise-based and psychosocial
54 interventions) on patient reported outcomes (PROs) (e.g. QoL, fatigue, pain) and physical
55 fitness of MIBC survivors.
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Secondary objective

1. Identifying significant moderators of intervention effects.

METHODS

The overall approach of this review is consistent with the methodology described in the Cochrane Handbook for Systematic reviews of Interventions³³ and is described below. Reports of current systematic review protocol adhere to the preferred items for systematic reviews and meta-analysis protocol (PRISMA-P) checklist³⁴. The systematic review itself will adhere to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)³⁵.

Criteria for considering studies for this review

Types of studies

Because of the anticipated low amount of randomized controlled trials (RCTs), RCTs and non-randomized studies (NRS) (i.e., cohort studies, case-control studies, cross-sectional studies and quasi-randomized controlled clinical trials (CCTs)) will be considered as appropriate study designs. Results from RCTs and NRS will be presented separately.

Types of participants

The population of interest will be adults (≥ 18 years of age) with medically confirmed diagnosis of localized MIBC or high risk non-muscle invasive bladder cancer (NMIBC) for whom a radical cystectomy is indicated. Studies with a majority of patients with metastasized BC will be excluded. Demographic factors are no exclusion criteria except for age (< 18 years of age). Studies involving participants with a range of cancers or other diagnoses that report results specifically for patients with MIBC will be included. Studies involving participants with urologic cancers where data is not provided separately for MIBC patients will be excluded.

Types of interventions

Exercise-based rehabilitation interventions considered for this review will be aerobic or endurance activities, strength or resistance training, balance exercises, flexibility exercises (with inclusion of yoga and Pilates), exercises specific to address sexual functioning and pelvic floor exercises in case of bladder preserving strategies or bladder reconstruction after radical cystectomy. Generalized advice to engage in regular PA activity will not be considered as an exercise-based rehabilitation intervention. In this review, the focus will be placed on exercise in a planned, structured, repetitive and purposeful rehabilitation intervention. PA as part of playing, working, active transportation, house chores or recreational activities will not be included.

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3 Psychosocial rehabilitation interventions eligible for inclusion will be based on the
4 framework proposed by Buffart et al.: patient education (e.g. stoma management,
5 generalized advice to engage in PA activity), social support, coping skills training,
6 psychotherapy and spiritual/existential therapy¹⁷. Alternative medicine and therapies will
7 not be included in this review.
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10 Both intervention types can either be individual or in group, hospital-based or home-based
11 (with follow up by a professional), supervised by a physiotherapist or not and can be given
12 before, during and/or after treatment. No limits will be placed on the timing, frequency,
13 intensity and duration of rehabilitation interventions. The interventions will be compared
14 with an inactive control intervention (e.g. no treatment, standard care or a waiting list
15 control).
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18 Types of outcome measures

19 For both primary and secondary outcome measures, there will be no exclusion based on
20 length of follow up.
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23 *Primary outcomes*

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26 1. PROs including overall HRQoL, specific HRQoL domains including symptoms such as
27 fatigue, pain, urinary incontinence, sexual dysfunction, gastro-intestinal dysfunction and
28 psychological factors such as anxiety, depression, stress and self-esteem. Due to the wide
29 range of questionnaires used for PROs and the non-consensus of using one standardized
30 questionnaire, only studies using the standardized and validated measurement instruments
31 for PRO, found in Table 1^{36 48} will be included. All studies using other measurement
32 instruments will be excluded, unless proof of their validation can be found in literature.
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36 2. Physical fitness assessed by VO₂ peak, VO₂ max, 6- or 12-minute walk test, 400-m walk
37 test, handgrip strength tests, sit and reach tests or other proven to be validated instruments.
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40 *Secondary outcomes*

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42 1. Cancer recurrence, cancer-specific survival, progression-free survival, overall survival,
43 mortality, years of life lost or 5-year survival.
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45 2. Body composition assessed by height, weight, body mass index, muscle capacity, fat mass,
46 lean body mass, thickness of skin folds, body fat, arm circumference, waist circumference,
47 hip circumference or waist-hip ratio.
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49 3. Bone mineral density or fracture risk assessed by fracture risk assessment tool (FRAX)⁴⁹.
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51 4. Karnofsky performance score (KPS)⁵⁰.
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Table 1 – standardized and validated measurement instruments for the included PROs

Patient reported outcome	Validated measurement instrument
HRQOL	EQ-5D visual analogue scale, MID: 7 points, SF-36, Ferrans and Powers Quality of Life Index, World Health Organization Quality of Life, SF-12, Padilla QLI, 20-item short form health survey and Satisfaction With Life Scale
Cancer specific QOL	FACT-G, EORTC QLQ-C30, Functional Living Index-Cancer, Selby's QLI, Cleary's QLI and Cancer Rehabilitation Evaluation System –SF
Bladder cancer specific QOL	QLQ-BLM30, BCI and FACT-BI
Sexual function	IIEF-5 and FSFI
Gastro-intestinal function	GIQLI
Urinary incontinence	BCI supplement, ICIQ-UI SF, IPSS
Psychological factors	
Depression	BSI-18, BDI,ISR-depression scale
Anxiety	STAI anxiety scales, numeric rating scales or visual analogue scale
Stress	Perceived Stress Scale
Self-esteem	Rosenberg self-esteem scale

Search methods for identification of studies

Electronic searches

The following electronic databases will be searched from inception until the search date: the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (using the PubMed interface), Embase (using the embase.com interface), Web of Science and the Physiotherapy Evidence Database (PEDro). The search strategies will be evaluated using the PRESS checklist⁵¹ and will be monitored and peer reviewed by an information specialist (NSP). The search strategies are presented in 'Supplementary File 1'.

Searching other resources

The cited and citing references of the included studies will be checked via Web of Science.

Data collection and analysis

Selection of studies

All references found through the search process will be downloaded in a database created by reference management software (Endnote). After removing duplicates in Endnote, all references will be imported into Covidence for screening purposes. Obviously irrelevant

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3 studies, based on title and abstract, will independently be excluded by two review authors
4 (ER and VF). After screening titles and abstracts, two review authors (ER and VF) will
5 independently assess full-text reports for eligibility. Discrepancies will be discussed with a
6 third review author (NS). Reasons for exclusion of full-texts will be documented. Studies will
7 be excluded if no full-text is available. Abstracts in any other language than English will be
8 excluded. There will be no language restriction for full texts and translations will be carried
9 out if necessary. If studies have multiple publications with the same outcome(s) reported,
10 manuscripts with the longest follow-up will be selected for inclusion. Older publications
11 referred to in included articles will be accessed to clarify methods if required.
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15 Data extraction

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17 A modified EPOC data collection form of the Cochrane collaboration will be used and pilot
18 tested with at least three studies in the review⁵². After pilot testing the form, adjustments
19 can be made. Data extraction will be performed independently by two review authors (ER
20 and VF). At least following data will be extracted for each study:
21
22

- 23 • **General information:** date form completed, name of person extracting data, report
24 title, report ID, authors' names, source, country, contact address, language of
25 publication, year of publication.
- 26 • **Population and setting:** population description (from which study participants are
27 drawn), setting (e.g. inpatient, outpatient, hospital setting, home setting,
28 combination), inclusion and exclusion criteria.
- 29 • **Methods:** aim of study, design, unit of allocation, start and end date, duration of
30 participation.
- 31 • **Participants:** number of participants in intervention and control groups, details of
32 clusters if applicable, baseline imbalances, participant demographics such as sex and
33 age, disease related characteristics such as stage of disease, received treatment(s)
34 and comorbidities.
- 35 • **Intervention:** type of intervention (exercise-based, psychosocial or combination),
36 details of intervention type (e.g. aerobic, pelvic floor exercises, counseling, patient
37 education), co-intervention(s), type of control intervention, frequency, duration and
38 providers of the intervention.
- 39 • **Outcomes:** outcome name, time points measured and reported, outcome definition,
40 person measuring/reporting, upper and lower limits of scales, unit measurement if
41 relevant, if outcome/tool is validated, imputation of missing data and assumed risk
42 estimate if reported.
- 43 • **Results:** outcome, measurement effects (please see data analyses below) for
44 intervention and comparison group, baseline data, number of missing participants
45 and reasons, and statistical methods used.
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Assessment of risk of bias in included studies

The Cochrane Collaboration's tool for assessing risk of bias will be used for RCTs. Assessment of risk of bias in NRS will be done using the Newcastle-Ottawa Scale for observational studies. The assessment of risk of bias will be done independently by two reviewers (ER and NSP). Differences will be discussed and a third reviewer (NS) will be consulted when needed. Results will be summarized both in a graph and a narrative summary. In order to evaluate selective reporting, the reviewers will check clinical trial registries or search any protocols of the studies for a priori reported primary and secondary outcome measures. The strength of the body of evidence will be assessed according to the GRADE approach.

Dealing with missing data

If essential data is not available in the publication, we will first attempt to contact the study authors. If this is not possible, we will try to back-calculate from the data presented. If data will be obtained from other study authors, this will be reported in the review in a transparent manner. This way, we can keep in mind that this missing data obtained from study authors was not peer reviewed. Studies assessing lifestyle interventions may have issues with compliance. Therefore, reasons for missing data (e.g. dropouts, losses to follow-up and withdrawals) will be carefully reported.

Assessment of heterogeneity

First, there will be a critical consideration of the heterogeneity between the different interventions and outcomes to evaluate whether there is clinical diversity or not. Based on this evaluation, there will be a decision if a meta-analysis can be conducted. When there's no clinical heterogeneity, statistical heterogeneity will be quantified using the I^2 statistic. We will consider the statistical heterogeneity to be high if $I^2 > 50\%$. Depending on the heterogeneity of the studies and their results, we will further decide if a meta-analysis can be conducted. We will attempt to explain any observed heterogeneity in the review.

Assessment of reporting bias

Funnel plots will be used to assess publication bias when ten or more studies are included in a meta-analysis.

Data synthesis

The findings from the included studies will be summarized descriptively. For dichotomous outcomes, measurement of treatment effect will be reported as risk ratios (RRs) and 95% confidence intervals (CIs). For continuous outcomes, we will calculate mean differences and 95% CIs when results are reported on the same scale (or can be converted to the same scale) or standardized mean differences and 95% CIs if results are reported on different scales.

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3 There will be an attempt to identify significant moderators, based on the most important
4 demographical and clinical characteristics in this population. In order to do this, there will be
5 a subgroup analysis for age and urinary diversion type. To prevent co-intervention bias,
6 there will also be a subgroup analysis based on the type of intervention (only exercised-
7 based interventions, only psychosocial interventions or a combination).
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10 When homogeneity of the studies is sufficient, random-effects meta-analysis will be
11 undertaken separately for each type of study design. Only studies with low risk of bias will be
12 included in meta-analyses. Therefore, we will perform sensitivity analyses to investigate how
13 conclusions might be affected if studies at high or unclear risk of bias were included.
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16 **Ethics and dissemination**

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18 Ethics approval is not required, as no primary data will be collected. Results will be
19 disseminated through a peer-reviewed publication.
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22 **Discussion**

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24 The scope of this review is broad (i.e., different rehabilitation interventions and study
25 designs). Although this means that heterogeneity might be present between the studies,
26 evaluation of different intervention approaches is needed to develop optimal rehabilitation
27 or survivorship programs. Caution will be present in the interpretation of the results because
28 of the fact that evidence from RCTs is higher than evidence from NRS. Therefore, the results
29 derived from RCTs will be seen as the primary evidence. Results from NRS will be seen as
30 additional evidence to support the results from RCTs.
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34 This systematic review has several strengths. First, the overall approach of this review is
35 consistent with the methodology described in the Cochrane Handbook for Systematic
36 reviews of Interventions. Secondly, rehabilitation interventions are an innovative topic in the
37 field of bladder cancer so this review ensures an absolute value. A third strength is the fact
38 that MIBC is an actual problem because of the potentially rising incidence of MIBC due to the
39 aging population.
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43 The results of this systematic review could also have potential limitations in terms of biased
44 results due to the nature of exercise and psychosocial interventions. It is impossible for such
45 interventions to blind participants and personnel. Therefore, 'blinding of participants and
46 personnel' will not be taken into account in the risk of bias assessment because of the
47 thought that this will not necessarily affect the study quality. On the other hand, attrition
48 and adherence biases and selective reporting biases are other common concerns around
49 high risk of bias that would affect the study quality⁵³. Therefore, it's important that the risk
50 of bias assessment will be carried out very carefully. Another limitation of this review could
51 be the possible paucity of studies meeting the inclusion criteria.
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3 In spite of these anticipated limitations, it's important to conduct this review because of the
4 expected implications for health care, research and survivorship. To date, there are no
5 specific guidelines for exercise-based or psychosocial rehabilitation interventions for MIBC
6 survivors. This systematic review is expected to provide guidance to the development of
7 specific guidelines and evidence-based rehabilitation or survivorship programs for MIBC
8 survivors. Development of such programs could have further implications for health care if
9 they will be translated into daily clinical practice.
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13 By identifying those interventions that have a positive effect on patient outcomes and which
14 underlying factors ensure the success of such rehabilitation interventions, new interventions
15 can be developed that can contribute to further research. The positive influence of physical
16 activity on survivorship is already suggested in different tumor types⁵⁴. The results of this
17 systematic review can contribute to patient survivorship from the hypothesis that this
18 positive association is also applicable in MIBC.
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21 **Authors' contribution**

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23 ER drafted the manuscript and developed the methods and analyses strategy. VF coordinated the process. NSP
24 and NS aided in developing the search strategy. VF, PO and KD provided uro-oncology specific expertise. RB and
25 BD gave valuable input concerning rehabilitation.
26

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28
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30 or analysis.
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32 **Competing interests statement**

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34 None declared.
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Search Strategy		
Database	Data last searched	Search Syntax
The Cochrane Central Register of Controlled Trials (CENTRAL)	13/12/2016	<ol style="list-style-type: none"> [mh "Urinary Bladder Neoplasms"] OR [mh "Carcinoma, Transitional Cell"] OR ("bladder cancer"):ti,ab,kw OR ("bladder carcinoma"):ti,ab,kw OR ("bladder malignancy"):ti,ab,kw OR ("bladder neoplasm"):ti,ab,kw OR ("bladder tumor"):ti,ab,kw OR ("transitional cell carcinoma"):ti,ab,kw OR ("transitional cell cancer"):ti,ab,kw OR ("transitional cell malignancies"):ti,ab,kw OR ("transitional cell tumor"):ti,ab,kw OR ("urothelial cancer"):ti,ab,kw OR ("urothelial carcinoma"):ti,ab,kw OR ("urothelial malignancy"):ti,ab,kw OR ("urothelial tumor"):ti,ab,kw OR ("urinary tract carcinoma"):ti,ab,kw OR ("urinary tract cancer"):ti,ab,kw OR ("urinary tract malignancy"):ti,ab,kw OR ("urinary tract tumor"):ti,ab,kw [mh "exercise"] OR [mh "Exercise Movement Techniques"] OR [mh "Sports"] OR [mh "Physical Fitness"] OR [mh "Physical Exertion"] OR [mh "Exercise Therapy"] OR [mh "Dance Therapy"] OR [mh "Recreation Therapy"] OR [mh "Rehabilitation, Vocational"] OR [mh "Telerehabilitation"] OR [mh "Occupational Therapy"] OR [mh "Self Care"] OR [mh "Urinary Incontinence/rehabilitation"] OR [mh "Pelvic Floor/therapy"] OR ("self care"):ti,ab,kw OR (exercise):ti,ab,kw OR (sport):ti,ab,kw OR ("physical activity"):ti,ab,kw OR (physiotherapy):ti,ab,kw OR (kinesiotherapy):ti,ab,kw OR ("physical conditioning"):ti,ab,kw OR ("physical education"):ti,ab,kw OR ("physical fitness"):ti,ab,kw OR (running):ti,ab,kw OR (swimming):ti,ab,kw OR (walking):ti,ab,kw OR (jogging):ti,ab,kw OR ("weight lifting"):ti,ab,kw OR (dance):ti,ab,kw OR ("tai chi"):ti,ab,kw OR (yoga):ti,ab,kw OR (pilates):ti,ab,kw OR (gymnastic):ti,ab,kw OR ("resistance training"):ti,ab,kw OR ("aerobic training"):ti,ab,kw OR ("anaerobic training"):ti,ab,kw OR ("muscle training"):ti,ab,kw OR (stretching):ti,ab,kw OR (aerobic):ti,ab,kw OR (rehabilitation):ti,ab,kw OR ("prehabilitation"):ti,ab,kw OR (prehabilitation):ti,ab,kw OR (aquagym):ti,ab,kw OR (football):ti,ab,kw OR (soccer):ti,ab,kw OR ("circuit training"):ti,ab,kw OR (fitness):ti,ab,kw OR ("bladder training"):ti,ab,kw OR ("incontinence management"):ti,ab,kw OR ("urinary management"):ti,ab,kw [mh "Tertiary Prevention"] OR [mh "Social Support"] OR [mh "Psychiatric Rehabilitation"] OR [mh "Health Promotion"] OR [mh "Psychotherapy"] OR [mh "Counseling"] OR [mh "Patient Education as Topic"] OR [mh "Sex Education"] OR [mh "Sexuality/rehabilitation"] OR [mh "Health Literacy"] OR [mh "psychology/education"] OR [mh "psychology/therapy"] OR [mh "Problem Solving"] OR [mh "Mind-body therapies"] OR [mh "patient participation"] OR [mh "Existentialism"] OR [mh "spiritual therapies"] OR [mh "problem-based learning"] OR [mh "Sedentary Lifestyle"] OR ("psychosocial intervention"):ti,ab,kw OR ("psychologic intervention"):ti,ab,kw OR ("psychological intervention"):ti,ab,kw OR ("psychology intervention"):ti,ab,kw OR ("social intervention"):ti,ab,kw OR ("psychosocial therapy"):ti,ab,kw OR ("psychologic therapy"):ti,ab,kw OR ("psychological therapy"):ti,ab,kw OR ("psychology therapies"):ti,ab,kw OR (psychotherapy):ti,ab,kw OR ("tertiary health care"):ti,ab,kw OR ("tertiary prevention"):ti,ab,kw OR ("social support"):ti,ab,kw OR ("social behavior"):ti,ab,kw OR ("support care"):ti,ab,kw OR ("supportive care"):ti,ab,kw OR ("behavior treatment"):ti,ab,kw OR ("behavior therapy"):ti,ab,kw OR ("cognitive treatment"):ti,ab,kw OR ("cognitive

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<p>MEDLINE (via PubMed interface)</p>	<p>13/12/2016</p>	<p>1. "Urinary Bladder Neoplasms"[MESH] OR "Urinary Bladder/abnormalities"[MESH] OR "Urinary bladder/surgery"[MESH] OR "Carcinoma, Transitional Cell"[Mesh] OR "bladder cancer"[TIAB] OR "bladder cancers"[TIAB] OR "bladder carcinoma"[TIAB] OR "bladder carcinomas"[TIAB] OR "bladder malignancy"[TIAB] OR "bladder malignancies"[TIAB] OR "bladder neoplasm"[TIAB] OR "bladder neoplasms"[TIAB] OR "bladder tumor"[TIAB] OR "bladder tumors"[TIAB] OR "bladder tumour"[TIAB] OR "bladder tumours"[TIAB] OR "transitional cell carcinoma"[TIAB] OR "transitional cell carcinomas"[TIAB] OR "transitional cell cancer"[TIAB] OR "transitional cell cancers"[TIAB] OR "transitional cell malignancies"[TIAB] OR "transitional cell tumor"[TIAB] OR "transitional cell tumors"[TIAB] OR "transitional cell tumour"[TIAB] OR "transitional cell tumours"[TIAB] OR "urothelial cancer"[TIAB] OR "urothelial cancers"[TIAB] OR "urothelial carcinoma"[TIAB] OR "urothelial carcinomas"[TIAB] OR "urothelial malignancy"[TIAB] OR "urothelial malignancies"[TIAB] OR "urothelial tumor"[TIAB] OR "urothelial tumors"[TIAB] OR "urothelial tumour"[TIAB] OR "urothelial tumours"[TIAB] OR "urinary tract carcinoma"[TIAB] OR "urinary tract carcinomas"[TIAB] OR "urinary tract cancer"[TIAB] OR "urinary tract cancers"[TIAB] OR "urinary tract malignancy"[TIAB] OR "urinary tract malignancies"[TIAB] OR "urinary tract tumor"[TIAB] OR "urinary tract tumors"[TIAB] OR "urinary tract tumour"[TIAB] OR "urinary tract tumours"[TIAB]</p> <p>2. "exercise"[MESH] OR "Exercise Movement Techniques"[Mesh] OR "Sports"[Mesh] OR "Physical Fitness"[Mesh] OR "Physical Exertion"[Mesh] OR "Exercise Therapy"[Mesh] OR "Dance Therapy"[Mesh] OR "Recreation Therapy"[Mesh] OR "Rehabilitation, Vocational"[Mesh] OR "Telerehabilitation"[Mesh] OR "Occupational Therapy"[Mesh] OR "Self Care"[Mesh] OR "Urinary Incontinence/rehabilitation"[Mesh] OR "Pelvic Floor/therapy"[Mesh] OR "self care"[TIAB] OR</p>

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EMBASE (via Embase.com interface)	13/12/2016	<p>1. 'bladder tumor'/exp OR 'urinary tract carcinoma'/exp OR 'bladder surgery'/exp OR 'transitional cell carcinoma'/exp OR 'bladder cancer':ab,ti OR 'bladder cancers':ab,ti OR 'bladder carcinoma':ab,ti OR 'bladder carcinomas':ab,ti OR 'bladder malignancy':ab,ti OR 'bladder malignancies':ab,ti OR 'bladder neoplasm':ab,ti OR 'bladder neoplasms':ab,ti OR 'bladder tumor':ab,ti OR 'bladder tumors':ab,ti OR 'bladder tumour':ab,ti OR 'bladder tumours':ab,ti OR 'transitional cell carcinoma':ab,ti OR 'transitional cell carcinomas':ab,ti OR 'transitional cell cancer':ab,ti OR 'transitional cell cancers':ab,ti OR 'transitional cell malignancies':ab,ti OR 'transitional cell tumor':ab,ti OR 'transitional cell tumors':ab,ti OR 'transitional cell tumour':ab,ti OR 'transitional cell tumours':ab,ti OR 'urothelial cancer':ab,ti OR 'urothelial cancers':ab,ti OR 'urothelial carcinoma':ab,ti OR 'urothelial carcinomas':ab,ti OR 'urothelial malignancy':ab,ti OR 'urothelial malignancies':ab,ti OR 'urothelial tumor':ab,ti OR 'urothelial tumors':ab,ti OR 'urothelial tumour':ab,ti OR 'urothelial tumours':ab,ti OR 'urinary tract carcinoma':ti,ab OR 'urinary tract carcinomas':ti,ab OR 'urinary tract cancer':ti,ab OR 'urinary tract cancers':ti,ab OR 'urinary tract malignance':ti,ab OR 'urinary tract malignancy':ti,ab OR 'urinary tract malignancies':ti,ab OR 'urinary tract tumor':ti,ab OR 'urinary tract tumors':ti,ab OR 'urinary tract tumour':ti,ab OR 'urinary tract tumours':ti,ab</p> <p>2. 'physical activity'/exp OR 'exercise'/exp OR 'physiotherapy'/exp OR 'kinesiotherapy'/exp OR 'fitness'/exp OR 'sport'/exp OR 'bladder training'/exp OR 'cancer rehabilitation'/exp OR 'cognitive rehabilitation'/exp OR 'functional training'/exp OR 'geriatric rehabilitation'/exp OR 'muscle training'/exp OR 'home rehabilitation'/exp OR 'occupational therapy'/exp OR 'pelvic floor muscle training'/exp OR 'self care':ab,ti OR 'exercise':ab,ti OR 'exercising':ab,ti OR 'exercises':ab,ti OR 'sport':ab,ti OR 'sports':ab,ti OR 'physical activity':ab,ti OR 'physical activities':ab,ti OR 'physiotherapy':ab,ti OR 'kinesiotherapy':ab,ti OR 'physical conditioning':ab,ti OR 'physical education*':ab,ti OR 'physical fitness':ab,ti OR 'running':ab,ti OR 'swimming':ab,ti OR 'walking':ab,ti OR 'jogging':ab,ti OR 'weight lifting':ab,ti OR 'dancing':ab,ti OR 'dance':ab,ti OR 'tai chi':ab,ti OR 'tai ji':ab,ti OR 'yoga':ab,ti OR 'pilates':ab,ti OR 'gymnastic':ab,ti OR 'gymnastics':ab,ti OR 'resistance training':ab,ti OR 'aerobic training':ab,ti OR 'anaerobic training':ab,ti OR 'muscle training':ab,ti OR 'stretching':ab,ti OR 'aerobic':ab,ti OR 'aerobics':ab,ti OR 'rehabilitation':ab,ti OR 'pre-habilitation':ab,ti OR 'prehabilitation':ab,ti OR 'aquagym':ab,ti OR 'football':ab,ti OR 'soccer':ab,ti OR 'circuit training':ab,ti OR 'fitness':ab,ti OR 'bladder training':ab,ti OR 'incontinence management':ab,ti OR 'urinary management':ab,ti</p> <p>3. 'psychosocial rehabilitation'/exp OR 'recreational therapy'/exp OR 'sociotherapy'/exp OR 'telerehabilitation'/exp OR 'vocational rehabilitation'/exp OR 'caregiver support'/exp OR 'psychosocial care'/exp OR 'social support'/exp OR 'spiritual care'/exp OR 'psychotherapy'/exp OR 'preoperative education'/exp OR 'psychoeducation'/exp OR 'patient education'/exp OR 'health promotion'/exp OR 'reinforcement'/exp OR 'patient participation'/exp OR 'counseling'/exp OR 'problem solving'/exp OR 'home physiotherapy'/exp OR 'cancer prevention'/exp OR 'learning'/exp OR 'rehabilitation care'/exp OR 'bladder and bowel management'/exp OR 'empowerment'/exp OR 'coping behavior'/exp OR 'social interaction'/exp OR 'social participation'/exp OR 'behavior change'/exp OR 'lifestyle'/exp OR 'psychosocial intervention*':ab,ti OR 'psychologic intervention*':ab,ti OR 'psychological intervention*':ab,ti OR 'psychology intervention*':ab,ti OR 'social intervention*':ab,ti OR 'psychosocial therap*':ab,ti OR 'psychologic therap*':ab,ti OR 'psychological therapy':ab,ti OR 'psychological therapies':ab,ti OR 'psychology therapies':ab,ti OR 'psychotherapy':ab,ti OR 'tertiary health care':ab,ti OR 'tertiary prevention':ab,ti OR 'social support':ab,ti OR 'social behav*':ab,ti OR 'support care':ab,ti OR 'supportive</p>

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Web of Science	13/12/2016	<p>1. TS=("bladder cancer") OR TS=("bladder cancers") OR TS=("bladder carcinoma") OR TS=("bladder carcinomas") OR TS=("bladder malignancy") OR TS=("bladder malignancies") OR TS=("bladder neoplasm") OR TS=("bladder neoplasms") OR TS=("bladder tumor") OR TS=("bladder tumors")OR TS=("bladder tumour") OR TS=("bladder tumours") OR TS=("transitional cell carcinoma") OR TS=("transitional cell carcinomas") OR TS=("transitional cell cancer") OR TS=("transitional cell cancers") OR TS=("transitional cell malignancies") OR TS=("transitional cell tumor") OR TS=("transitional cell tumors") OR TS=("transitional cell tumour") OR TS=("transitional cell tumours") OR TS=("urothelial cancer") OR TS=("urothelial cancers") OR TS=("urothelial carcinoma") OR TS=("urothelial carcinomas")OR TS=("urothelial malignancy") OR TS=("urothelial malignancies") OR TS=("urothelial tumor") OR TS=("urothelial tumors")OR TS=("urothelial tumour") OR TS=("urothelial tumours") OR TS=("urinary tract carcinoma") OR TS=("urinary tract carcinomas") OR TS=("urinary tract cancer") OR TS=("urinary tract cancers") OR TS=("urinary tract malignancy") OR TS=("urinary tract malignancies") OR TS=("urinary tract tumor") OR TS=("urinary tract tumors") OR TS=("urinary tract tumour") OR TS=("urinary tract tumours")</p> <p>2. TS=("self care") OR TS=(exercise) OR TS=(exercising) OR TS=(exercises) OR TS=(sport) OR TS=(sports) OR TS=("physical activity") OR TS=("physical activities") OR TS=(physiotherapy) OR TS=(kinesiotherapy) OR TS=("physical conditioning") OR TS=("physical education*") OR TS=("physical fitness") OR TS=(running) OR TS=(swimming) OR TS=(walking) OR TS=(jogging) OR TS=("weight lifting") OR TS=(dancing) OR TS=(dance) OR TS=("tai chi") OR TS=("tai ji") OR TS=(yoga) OR TS=(pilates) OR TS=(gymnastic) OR TS=(gymnastics) OR TS=("resistance training") OR TS=("aerobic training") OR TS=("anaerobic training") OR TS=("muscle training") OR TS=(stretching) OR TS=(aerobic) OR TS=(aerobics) OR TS=(rehabilitation) OR TS=("pre-habilitation") OR TS=(prehabilitation) OR TS=(aquagym) OR TS=(football) OR TS=(soccer)</p>

- OR TS=("circuit training") OR TS=(fitness) OR TS=("bladder training") OR TS=("incontinence management") OR TS=("urinary management")
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PEDro 13/12/2016 Title/abstract: bladder cancer

The **cited and citing** articles of the included studies, retrieved with the above searches, will be screened through **Web of Science** to potentially identify other studies.

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		line number; page number
Title:		
Identification	1a	Identify the report as a protocol of a systematic review 2-3; 1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number 62; 2
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author 4-22; 1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review 410-413; 13
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources	5a	Indicate sources of financial or other support for the review 415-416; 13
Sponsor	5b	Provide name for the review funder and/or sponsor 415; 13
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol 415-416; 13
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known 92-199; 4-6
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) 200-206; 6-7
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) 215-273; 7-9 and report characteristics (such as years considered 276; 9, language 293-295; 10, publication status 295-297; 10) to be used as criteria for eligibility for the review
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage 276-283; 9
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated Supplementary file 1 Supplementary file 1

Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review 286-288; 9-10
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review 288-292; 9-10
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators 299-302; 10
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications 303-325; 10
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale 250-270; 8
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis 327-334; 10
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised 345-351; 11-12
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ) 349-351; 11, 356-361; 10-11
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) 362-370; 12
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned 356; 11
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies) 352-354; 11
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE) 334-335; 11

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

BMJ Open

Rehabilitation interventions to improve patient reported outcomes and physical fitness in survivors of muscle invasive bladder cancer: a systematic review protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-016054.R2
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Primary Subject Heading:	Urology
Secondary Subject Heading:	Evidence based practice, Oncology, Rehabilitation medicine
Keywords:	Muscle invasive bladder cancer, Exercise, Psychosocial intervention, systematic review, Rehabilitation

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Manuscripts

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3 **Rehabilitation interventions to improve patient reported outcomes and**
4 **physical fitness in survivors of muscle invasive bladder cancer: a systematic**
5 **review protocol**
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8 Elke Rammant¹, Renée Bultijnck¹, Nora Sundahl¹, Piet Ost¹, Nele S. Pauwels², Benedicte
9 Deforche³, Ronny Pieters⁴, Karel Decaestecker⁴, Valérie Fonteyne¹
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13
14 **Affiliations:**

- 15
16 1. Department of Radiation Oncology and Experimental Cancer Research, Ghent
17 University Hospital, Ghent, Belgium
18 2. Knowledge Center Ghent, Ghent University Hospital, Ghent, Belgium
19 3. Department of Public Health, Ghent University, Ghent, Belgium
20 4. Department of Urology, Ghent University Hospital, Ghent, Belgium
21
22
23
24

25 **Corresponding Author:**

26
27
28 Elke Rammant, MSc.
29 Department of Radiation Oncology and Experimental Cancer Research,
30 Ghent University Hospital
31 De Pintelaan 185, B-9000 Ghent, Belgium
32 Tel: +32 9 33 21552
33 E-mail: elke.rammant@ugent.be
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ABSTRACT

Introduction

Survivors of muscle invasive bladder cancer (MIBC) experience physical and psychosocial side effects of cancer diagnosis and treatment. These negative side effects have a crucial impact on their health-related quality of life (HRQoL). To date, there is evidence that rehabilitation interventions such as physical activity and psychosocial support have a positive effect on the HRQoL of cancer survivors. Unfortunately, there are no specific guidelines for rehabilitation or survivorship programs for MIBC survivors. Therefore, this systematic review aims to assess the effects of exercise-based and psychosocial rehabilitation interventions on MIBC survivors.

Methods and analysis

The approach of this review is consistent with the Cochrane methodology. Randomized controlled trials and non-randomized studies will be included. The population of interest is patients (≥ 18 years of age) with diagnosis of MIBC or high risk non-MIBC for whom a radical cystectomy is indicated. There will be two eligible intervention types for inclusion: exercise-based and psychosocial rehabilitation interventions. The primary outcome measures are patient reported outcomes (e.g. HRQoL, fatigue, pain) and physical fitness. Studies will be identified independently by two review authors by searching the Cochrane Central Register of Controlled Trials, MEDLINE, Embase, Web of Science and the Physiotherapy Evidence Database. A third reviewer will be asked by disagreements. Risk of bias will be assessed using the Cochrane Collaboration tool and the Newcastle-Ottawa Scale. Data will be summarized descriptively. If homogeneity of the studies is sufficient, meta-analysis will be undertaken. The broad scope of this review (i.e. different interventions and study designs) is needed to have a comprehensive view on effective rehabilitation interventions.

Ethics and dissemination

Ethics approval is not required, as no primary data will be collected. Results will be disseminated through a peer-reviewed publication.

PROSPERO registration number: CRD42017055306

Keywords

Bladder neoplasm— exercise – psychosocial intervention – rehabilitation

Strengths and limitations of this study

Strengths

- The overall approach of this review is consistent with the methodology described in the Cochrane Handbook for Systematic reviews of Interventions
- It's an innovative topic in the field of bladder cancer.
- Actual problem because the incidence of bladder cancer is rising.

Limitations

- Possible paucity of studies meeting the inclusion criteria.

BACKGROUND

Description of the condition

Bladder cancer (BC) is the 11th most common cancer worldwide. When both genders are considered separately, BC in men is rising to the 7th place whilst BC in women is dropping to the 17th place of most common cancer worldwide^{1,2}. Since BC is mainly diagnosed at more advanced age, the incidence is expected to raise due to an increased life expectancy.^{3,4} Thirty percent of the BC patients are diagnosed with muscle invasive BC (MIBC, stages T2-T4)⁵ and up to 45% of patients with non-MIBC (NMIBC) will eventually progress to MIBC⁶. The standard treatment of MIBC is neo-adjuvant chemotherapy followed by radical cystectomy combined with an extended pelvic lymph node dissection and urinary diversion (continent or incontinent bladder replacement). Also patients with high-risk NMIBC can be offered a radical cystectomy.¹ This aggressive approach is associated with a variety of negative side effects, mainly hampering urinary, gastro-intestinal and sexual function. This can lead to a loss of health-related quality of life (HRQoL), which refers to the patients' own perceptions of their health and ability to function⁷ encompassing physical, psychological, social, and spiritual dimensions⁸. Bladder preserving radiochemotherapy is an alternative for radical cystectomy. Both radiotherapy and chemotherapy can also be used in the adjuvant or palliative setting and can cause important treatment related side effects. Therefore, follow-up care beyond the acute diagnosis and treatment phase is necessary⁹.

Description of the intervention

The World Health Organisation (WHO) has defined rehabilitation as "the use of all means aimed at reducing the impact of disabling and handicapping conditions at enabling people with disabilities to achieve optimal social integration"¹⁰. A more specific definition of rehabilitation in the setting of cancer is the following: "cancer rehabilitation is a concept that is defined by the patient and involves helping a person with cancer to obtain maximum physical, social, psychological, and vocational functioning within the limit by the disease and its treatment"¹¹. Therefore, cancer rehabilitation needs to comprise different intervention approaches^{12,13}.

Physical activity (PA) is seen as one of the rehabilitation interventions to improve patients quality of life (QoL) and survival outcomes. PA is defined as "any movement created by the skeletal muscles that causes a substantial increase in energy expenditure"¹⁴. It is important to point out that 'physical activity' and 'exercise' are not similar. PA can be seen as an overarching term that includes exercise as well as other activities which involve bodily movement and are done as part of playing, working, active transportation, house chores and recreational activities. Exercise on the other hand, is a subcategory of PA. It is planned, structured, repetitive and purposeful to improve or maintain one or more components of

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3 physical fitness (cardiorespiratory fitness, muscular strength, muscular endurance, flexibility
4 and body composition)¹⁵. These components represent important outcomes in cancer
5 survivors that may mediate the influence of exercise on other outcomes¹⁴.
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8 Psychosocial interventions are another important focus in rehabilitation. These sort of
9 interventions aim to help patients cope with negative side effects of cancer diagnosis and
10 treatment¹⁶. Based on a framework proposed by Buffart et al., there are five categories of
11 interventions: patient education, social support, coping skills training, psychotherapy and
12 spiritual/existential therapy¹⁷.
13

14 15 **How the intervention might work**

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17 In order to explain how cancer rehabilitation interventions might work, the revised Wilson
18 and Cleary Model for HRQoL will be used as a conceptual framework¹⁸. This is useful to
19 explain the pathways between different patient outcomes¹⁹. The model proposes five types
20 of patient outcome measurements (biological function, symptoms, functional status, health
21 perception and overall QOL), which have a causal relationship^{18 20}. These five patient
22 outcome measurements can be influenced by individual and environment characteristics.
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26 In case of bladder cancer, morbidity associated with the disease and its treatment can lead
27 to complications related to urinary diversion, urinary incontinence or constipation, sexual
28 dysfunction²¹, fatigue, and psychological distress²². This can potentially lead to a loss of
29 physical, social, psychological and role function, which affects activities in daily life. As a
30 consequence, the general health perceptions of the patient can be damaged which can
31 finally lead to an overall impaired QOL. All of these outcomes can be influenced by
32 environment and individual characteristics.
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36 Offering cancer rehabilitation can be seen as a physical environment characteristic. Since it
37 has been proven in other cancer populations that cancer rehabilitation interventions have
38 a positive influence on for example physical fitness²³, muscle capacity²⁴, fatigue and
39 emotional distress²⁵, we can conclude, according to the revised Wilson and Cleary Model for
40 HRQoL, that cancer rehabilitation interventions can have a positive influence on other
41 patient outcomes such as HRQoL¹⁸.
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45 Individual characteristics, such as advanced age and the associated increased risk of co
46 morbidities, are important factors to take into account in BC patients. These characteristics
47 are associated with poorer health²⁶ such as functional and psychosocial declines²⁷. Although
48 this supports the need for cancer rehabilitation, the older age of BC patients creates
49 challenges in recommending rehabilitation interventions. Potential difficulties are the lack of
50 social support in older patients and the need for extra time and resources to enroll these
51 patients²⁸. Additionally, the high prevalence of urinary complications and problems with
52 body image in BC patients can act as potential barriers to participate in exercise
53 interventions²⁶. According to Karvinen et al., exercise interventions for BC survivors should
54 focus on offering enjoyable activities, education on the benefits of regular exercise,
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3 improving activity levels in important others and targeting perceived barriers. They also note
4 that adjuvant therapy, age and invasiveness of the tumor may affect exercise participation²⁶.
5 Furthermore, BC survivors seem to be most interested in walking and home-based,
6 individual exercises that are not supervised²⁹.
7

8 9 **Why it is important to do this review**

10
11 With an increasing number of cancer survivors, cancer rehabilitation will become imperative
12 in cancer survivorship. In order to develop evidence-based rehabilitation programs for BC
13 patients, who received a curative treatment it is essential to have a global picture of
14 effective rehabilitation interventions. Therefore, a systematic review assessing the effects of
15 exercise-based and psychosocial rehabilitation interventions for BC patients is needed. A
16 previous systematic review assessed the effects of lifestyle factors (diet, smoking and
17 physical activity) on HRQoL in BC survivors. Findings of this review concluded that there was
18 limited evidence to support a positive association between HRQoL and physical activity in BC
19 survivors³⁰. Our review differs with previous review in several aspects. First we want to
20 identify well-defined interventions that are effective. In previous review, they evaluated the
21 physical activity pattern of the patient, which is not the same as an exercise intervention.
22 Furthermore, this review will not only focus on HRQoL, we will also assess the effects of
23 rehabilitation interventions on other outcomes (explained below). Additionally, to our
24 knowledge, there is no systematic review that has summarized the evidence of psychosocial
25 rehabilitation interventions for MIBC survivors in a systematic manner.
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32 So far, no specific guidelines exist for exercise-based and/or psychosocial rehabilitation
33 interventions for MIBC survivors. This review could give guidance to the development of
34 specific evidence-based guidelines. Although this review focuses only on the exercise and
35 psychosocial part of rehabilitation, it is important to note that rehabilitation of cancer
36 patients requires also other interventions such as diet counseling, smoking cessation, etc.¹².
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40 It should also be noticed that providing cancer rehabilitation is an often-neglected facet of
41 cancer care in terms of health policy and infrastructure³¹. Frequently reported barriers to
42 rehabilitation interventions are the lack of expertise, inappropriate referrals by physicians,
43 funding issues^{24 31} and availability of rehabilitation resources³². The results of this review
44 may increase the awareness of physicians and funders of the importance of cancer
45 rehabilitation.
46

47 48 **AIMS AND OBJECTIVES**

49 50 **Primary objective**

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52 1. Assessing the effects of rehabilitation interventions (exercise-based and psychosocial
53 interventions) on patient reported outcomes (PROs) (e.g. QoL, fatigue, pain) and physical
54 fitness of MIBC survivors.
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Secondary objective

1. Identifying significant moderators of the intervention effects.

METHODS

The overall approach of this review is consistent with the methodology described in the Cochrane Handbook for Systematic reviews of Interventions³³ and is described below. Reports of current systematic review protocol adhere to the preferred items for systematic reviews and meta-analysis protocol (PRISMA-P) checklist³⁴. The systematic review itself will adhere to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)³⁵.

Criteria for considering studies for this review

Types of studies

Because of the anticipated low amount of randomized controlled trials (RCTs), RCTs and non-randomized studies (NRS) (i.e., cohort studies, case-control studies, cross-sectional studies and quasi-randomized controlled clinical trials (CCTs)) will be considered as appropriate study designs. Results from RCTs and NRS will be presented separately.

Types of participants

The population of interest will be adults (≥ 18 years of age) with medically confirmed diagnosis of localized MIBC or high risk NMIBC for whom a radical cystectomy is indicated. Studies with a majority of patients with metastasized BC will be excluded. Demographic factors are no exclusion criteria except for age (< 18 years of age). Studies involving participants with a range of cancers or other diagnoses that report results specifically for patients with MIBC will be included. Studies involving participants with urologic cancers where data is not provided separately for MIBC patients will be excluded.

Types of interventions

Exercise-based rehabilitation interventions considered for this review will be aerobic or endurance activities, strength or resistance training, balance exercises, flexibility exercises (with inclusion of yoga and Pilates), exercises specific to address sexual functioning and pelvic floor exercises in case of bladder preserving strategies or bladder reconstruction after radical cystectomy. Generalized advice to engage in regular PA activity will not be considered as an exercise-based rehabilitation intervention. In this review, the focus will be placed on exercise in a planned, structured, repetitive and purposeful rehabilitation intervention. PA as part of playing, working, active transportation, house chores or recreational activities will not be included.

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3 Psychosocial rehabilitation interventions eligible for inclusion will be based on the
4 framework proposed by Buffart et al.: patient education (e.g. stoma management,
5 generalized advice to engage in PA activity), social support, coping skills training,
6 psychotherapy and spiritual/existential therapy¹⁷. Alternative medicine and therapies will
7 not be included in this review.
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9

10 Both intervention types can either be individual or in group, hospital-based or home-based
11 (with follow up by a professional), supervised by a physiotherapist or not and can be given
12 before, during and/or after treatment. No limits will be placed on the timing, frequency,
13 intensity and duration of rehabilitation interventions. The interventions will be compared
14 with an inactive control intervention (e.g. no treatment, standard care or a waiting list
15 control).
16
17

18 19 Types of outcome measures

20
21 For both primary and secondary outcome measures, there will be no exclusion based on
22 length of follow up.
23

24 25 *Primary outcomes*

26
27 1. PROs including overall HRQoL, specific HRQoL domains including symptoms such as
28 fatigue, pain, urinary incontinence, sexual dysfunction, gastro-intestinal dysfunction and
29 psychological factors such as anxiety, depression, stress and self-esteem. Due to the wide
30 range of questionnaires used for PROs and the non-consensus of using one standardized
31 questionnaire, only studies using the standardized and validated measurement instruments
32 for PRO, found in Table 1^{36 37 38 39 40 41 42 43 44 45 46 47 48} will be included. All studies using other
33 measurement instruments will be excluded, unless proof of their validation can be found in
34 literature.
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38 2. Physical fitness assessed by VO₂ peak, VO₂ max, 6- or 12-minute walk test, 400-m walk
39 test, handgrip strength tests, sit and reach tests or other proven to be validated instruments.
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41 42 *Secondary outcomes*

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44 1. Cancer recurrence, cancer-specific survival, progression-free survival, overall survival,
45 mortality, years of life lost or 5-year survival.
46

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48 2. Body composition assessed by height, weight, body mass index, muscle capacity, fat mass,
49 lean body mass, thickness of skin folds, body fat, arm circumference, waist circumference,
50 hip circumference or waist-hip ratio.

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52 3. Bone mineral density or fracture risk assessed by fracture risk assessment tool (FRAX)⁴⁹.

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54 4. Karnofsky performance score (KPS)⁵⁰.
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Table 1 – standardized and validated measurement instruments for the included patient reported outcomes

Patient reported outcome	Validated measurement instrument
HRQOL	EQ-5D visual analogue scale, MID: 7 points, SF-36, Ferrans and Powers Quality of Life Index, World Health Organization Quality of Life, SF-12, Padilla QLI, 20-item short form health survey and Satisfaction With Life Scale
Cancer specific QOL	FACT-G, EORTC QLQ-C30, Functional Living Index-Cancer, Selby's QLI, Cleary's QLI and Cancer Rehabilitation Evaluation System –SF
Bladder cancer specific QOL	QLQ-BLM30, BCI and FACT-BI
Sexual function	IIEF-5 and FSFI
Gastro-intestinal function	GIQLI
Urinary incontinence	BCI supplement, ICIQ-UI SF, IPSS
Psychological factors	
Depression	BSI-18, BDI,ISR-depression scale
Anxiety	STAI anxiety scales, numeric rating scales or visual analogue scale
Stress	Perceived Stress Scale
Self-esteem	Rosenberg self-esteem scale

Search methods for identification of studies

Electronic searches

The following electronic databases will be searched from inception until the search date: the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (using the PubMed interface), Embase (using the embase.com interface), Web of Science and the Physiotherapy Evidence Database (PEDro). The search strategies will be evaluated using the PRESS checklist⁵¹ and will be monitored and peer reviewed by an information specialist (NSP). The search strategies are presented in 'Supplementary File 1'.

Searching other resources

The cited and citing references of the included studies will be checked via Web of Science.

Data collection and analysis

Selection of studies

All references found through the search process will be downloaded in a database created by reference management software (Endnote). After removing duplicates in Endnote, all

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3 references will be imported into Covidence for screening purposes. Obviously irrelevant
4 studies, based on title and abstract, will independently be excluded by two review authors
5 (ER and VF). After screening titles and abstracts, two review authors (ER and VF) will
6 independently assess full-text reports for eligibility. Discrepancies will be discussed with a
7 third review author (NS). Reasons for exclusion of full-texts will be documented. Studies will
8 be excluded if no full-text is available. Abstracts in any other language than English will be
9 excluded. There will be no language restriction for full texts and translations will be carried
10 out if necessary. If studies have multiple publications with the same outcome(s) reported,
11 manuscripts with the longest follow-up will be selected for inclusion. Older publications
12 referred to in included articles will be accessed to clarify methods if required.

16 Data extraction

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19 A modified EPOC data collection form of the Cochrane collaboration will be used and pilot
20 tested with at least three studies in the review⁵². After pilot testing the form, adjustments
21 can be made. Data extraction will be performed independently by two review authors (ER
22 and VF). At least following data will be extracted for each study:

- 25 • **General information:** date form completed, name of person extracting data, report
26 title, report ID, authors' names, source, country, contact address, language of
27 publication, year of publication.
 - 28 • **Population and setting:** population description (from which study participants are
29 drawn), setting (e.g. inpatient, outpatient, hospital setting, home setting,
30 combination), inclusion and exclusion criteria.
 - 31 • **Methods:** aim of study, design, unit of allocation, start and end date, duration of
32 participation.
 - 33 • **Participants:** number of participants in intervention and control groups, details of
34 clusters if applicable, baseline imbalances, participant demographics such as sex and
35 age, disease related characteristics such as stage of disease, received treatment(s)
36 and comorbidities.
 - 37 • **Intervention:** type of intervention (exercise-based, psychosocial or combination),
38 details of intervention type (e.g. aerobic, pelvic floor exercises, counseling, patient
39 education), co-intervention(s), type of control intervention, frequency, duration and
40 providers of the intervention.
 - 41 • **Outcomes:** outcome name, time points measured and reported, outcome definition,
42 person measuring/reporting, upper and lower limits of scales, unit measurement if
43 relevant, if outcome/tool is validated, imputation of missing data and assumed risk
44 estimate if reported.
 - 45 • **Results:** outcome, measurement effects (please see data analyses below) for
46 intervention and comparison group, baseline data, number of missing participants
47 and reasons, and statistical methods used.
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Assessment of risk of bias in included studies

The Cochrane Collaboration's tool for assessing risk of bias will be used for RCTs. Assessment of risk of bias in NRS will be done using the Newcastle-Ottawa Scale for observational studies. The assessment of risk of bias will be done independently by two reviewers (ER and NSP). Differences will be discussed and a third reviewer (NS) will be consulted when needed. Results will be summarized both in a graph and a narrative summary. In order to evaluate selective reporting, the reviewers will check clinical trial registries or search any protocols of the studies for a priori reported primary and secondary outcome measures. The strength of the body of evidence will be assessed according to the GRADE approach.

Dealing with missing data

If essential data is not available in the publication, we will first attempt to contact the study authors. If this is not possible, we will try to back-calculate from the data presented. If data will be obtained from other study authors, this will be reported in the review in a transparent manner. This way, we can keep in mind that this missing data obtained from study authors was not peer reviewed. Studies assessing lifestyle interventions may have issues with compliance. Therefore, reasons for missing data (e.g. dropouts, losses to follow-up and withdrawals) will be carefully reported.

Assessment of heterogeneity

First, there will be a critical consideration of the heterogeneity between the different interventions and outcomes to evaluate whether there is clinical diversity or not. Based on this evaluation, there will be a decision if a meta-analysis can be conducted. When there's no clinical heterogeneity, statistical heterogeneity will be quantified using the I^2 statistic. We will consider the statistical heterogeneity to be high if $I^2 > 50\%$. Depending on the heterogeneity of the studies and their results, we will further decide if a meta-analysis can be conducted. We will attempt to explain any observed heterogeneity in the review.

Assessment of reporting bias

Funnel plots will be used to assess publication bias when ten or more studies are included in a meta-analysis.

Data synthesis

The findings from the included studies will be summarized descriptively. For dichotomous outcomes, measurement of treatment effect will be reported as risk ratios (RRs) and 95 % confidence intervals (CIs). For continuous outcomes, we will calculate mean differences and 95 % CIs when results are reported on the same scale (or can be converted to the same scale) or standardized mean differences and 95 % CIs if results are reported on different scales.

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3 There will be an attempt to identify significant moderators, based on the most important
4 demographical and clinical characteristics in this population. In order to do this, there will be
5 a subgroup analysis for age and urinary diversion type. To prevent co-intervention bias,
6 there will also be a subgroup analysis based on the type of intervention (only exercised-
7 based interventions, only psychosocial interventions or a combination).
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10 When homogeneity of the studies is sufficient, random-effects meta-analysis will be
11 undertaken separately for each type of study design. Only studies with low risk of bias will be
12 included in meta-analyses. Therefore, we will perform sensitivity analyses to investigate how
13 conclusions might be affected if studies at high or unclear risk of bias were included.
14
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16 **Ethics and dissemination**

17
18 Ethics approval is not required, as no primary data will be collected. Results will be
19 disseminated through a peer-reviewed publication.
20

21
22 The scope of this review is broad (i.e., different rehabilitation interventions and study
23 designs). Although this means that heterogeneity might be present between the studies,
24 evaluation of different intervention approaches is needed to develop optimal rehabilitation
25 or survivorship programs. Caution will be present in the interpretation of the results because
26 of the fact that evidence from RCTs is higher than evidence from NRS. Therefore, the results
27 derived from RCTs will be seen as the primary evidence. Results from NRS will be seen as
28 additional evidence to support the results from RCTs.
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32 This systematic review has several strengths. First, the overall approach of this review is
33 consistent with the methodology described in the Cochrane Handbook for Systematic
34 reviews of Interventions. Secondly, rehabilitation interventions are an innovative topic in the
35 field of BC so this review ensures an absolute value. A third strength is the fact that MIBC is
36 an actual problem because of the potentially rising incidence of MIBC due to the aging
37 population.
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41 The results of this systematic review could also have potential limitations in terms of biased
42 results due to the nature of exercise and psychosocial interventions. It is impossible for such
43 interventions to blind participants and personnel. Therefore, 'blinding of participants and
44 personnel' will not be taken into account in the risk of bias assessment because of the
45 thought that this will not necessarily affect the study quality. On the other hand, attrition
46 and adherence biases and selective reporting biases are other common concerns around
47 high risk of bias that would affect the study quality⁵³. Therefore, it's important that the risk
48 of bias assessment will be carried out very carefully. Another limitation of this review could
49 be the possible paucity of studies meeting the inclusion criteria.
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54 In spite of these anticipated limitations, it's important to conduct this review because of the
55 expected implications for health care, research and survivorship. To date, there are no
56 specific guidelines for exercise-based or psychosocial rehabilitation interventions for MIBC
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3 survivors. This systematic review is expected to provide guidance to the development of
4 specific guidelines and evidence-based rehabilitation or survivorship programs for MIBC
5 survivors. Development of such programs could have further implications for health care if
6 they will be translated into daily clinical practice.
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9 By identifying those interventions that have a positive effect on patient outcomes and which
10 underlying factors ensure the success of such rehabilitation interventions, new interventions
11 can be developed that can contribute to further research. The positive influence of physical
12 activity on survivorship is already suggested in different tumor types⁵⁴. The results of this
13 systematic review can contribute to patient survivorship from the hypothesis that this
14 positive association is also applicable in MIBC.
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17 **Authors' contribution**

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19 ER drafted the manuscript and developed the methods and analyses strategy. VF coordinated the process. NSP
20 and NS aided in developing the search strategy. VF, PO and KD provided uro-oncology specific expertise. RB and
21 BD gave valuable input concerning rehabilitation.
22

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24
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26 or analysis.
27

28 **Competing interests statement**

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30 None declared.
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Search Strategy		
Database	Data last searched	Search Syntax
The Cochrane Central Register of Controlled Trials (CENTRAL)	13/12/2016	<ol style="list-style-type: none"> [mh "Urinary Bladder Neoplasms"] OR [mh "Carcinoma, Transitional Cell"] OR ("bladder cancer"):ti,ab,kw OR ("bladder carcinoma"):ti,ab,kw OR ("bladder malignancy"):ti,ab,kw OR ("bladder neoplasm"):ti,ab,kw OR ("bladder tumor"):ti,ab,kw OR ("transitional cell carcinoma"):ti,ab,kw OR ("transitional cell cancer"):ti,ab,kw OR ("transitional cell malignancies"):ti,ab,kw OR ("transitional cell tumor"):ti,ab,kw OR ("urothelial cancer"):ti,ab,kw OR ("urothelial carcinoma"):ti,ab,kw OR ("urothelial malignancy"):ti,ab,kw OR ("urothelial tumor"):ti,ab,kw OR ("urinary tract carcinoma"):ti,ab,kw OR ("urinary tract cancer"):ti,ab,kw OR ("urinary tract malignancy"):ti,ab,kw OR ("urinary tract tumor"):ti,ab,kw [mh "exercise"] OR [mh "Exercise Movement Techniques"] OR [mh "Sports"] OR [mh "Physical Fitness"] OR [mh "Physical Exertion"] OR [mh "Exercise Therapy"] OR [mh "Dance Therapy"] OR [mh "Recreation Therapy"] OR [mh "Rehabilitation, Vocational"] OR [mh "Telerehabilitation"] OR [mh "Occupational Therapy"] OR [mh "Self Care"] OR [mh "Urinary Incontinence/rehabilitation"] OR [mh "Pelvic Floor/therapy"] OR ("self care"):ti,ab,kw OR (exercise):ti,ab,kw OR (sport):ti,ab,kw OR ("physical activity"):ti,ab,kw OR (physiotherapy):ti,ab,kw OR (kinesiotherapy):ti,ab,kw OR ("physical conditioning"):ti,ab,kw OR ("physical education"):ti,ab,kw OR ("physical fitness"):ti,ab,kw OR (running):ti,ab,kw OR (swimming) :ti,ab,kw OR (walking):ti,ab,kw OR (jogging):ti,ab,kw OR ("weight lifting"):ti,ab,kw OR (dance):ti,ab,kw OR ("tai chi"):ti,ab,kw OR (yoga):ti,ab,kw OR (pilates):ti,ab,kw OR (gymnastic):ti,ab,kw OR ("resistance training"):ti,ab,kw OR ("aerobic training"):ti,ab,kw OR ("anaerobic training"):ti,ab,kw OR ("muscle training"):ti,ab,kw OR (stretching):ti,ab,kw OR (aerobic):ti,ab,kw OR (rehabilitation):ti,ab,kw OR ("pre-rehabilitation"):ti,ab,kw OR (prehabilitation):ti,ab,kw OR (aquagym):ti,ab,kw OR (football) :ti,ab,kw OR (soccer):ti,ab,kw OR ("circuit training"):ti,ab,kw OR (fitness):ti,ab,kw OR ("bladder training"):ti,ab,kw OR ("incontinence management"):ti,ab,kw OR ("urinary management"):ti,ab,kw [mh "Tertiary Prevention"] OR [mh "Social Support"] OR [mh "Psychiatric Rehabilitation"] OR [mh "Health Promotion"] OR [mh "Psychotherapy"] OR [mh "Counseling"] OR [mh "Patient Education as Topic"] OR [mh "Sex Education"] OR [mh "Sexuality/rehabilitation"] OR [mh "Health Literacy"] OR [mh "psychology/education"] OR [mh "psychology/therapy"] OR [mh "Problem Solving"] OR [mh "Mind-body therapies"] OR [mh "patient participation"] OR [mh "Existentialism"] OR [mh "spiritual therapies"] OR [mh "problem-based learning"] OR [mh "Sedentary Lifestyle"] OR ("psychosocial intervention"):ti,ab,kw OR ("psychologic intervention"):ti,ab,kw OR ("psychological intervention"):ti,ab,kw OR ("psychology intervention"):ti,ab,kw OR ("social intervention"):ti,ab,kw OR ("psychosocial therapy"):ti,ab,kw OR ("psychologic therapy"):ti,ab,kw OR ("psychological therapy"):ti,ab,kw OR ("psychology therapies"):ti,ab,kw OR (psychotherapy):ti,ab,kw OR ("tertiary health care"):ti,ab,kw OR ("tertiary prevention"):ti,ab,kw OR ("social support"):ti,ab,kw OR ("social behavior"):ti,ab,kw OR ("support care"):ti,ab,kw OR ("supportive care"):ti,ab,kw OR ("behavior treatment"):ti,ab,kw OR ("behavior therapy"):ti,ab,kw OR ("cognitive treatment"):ti,ab,kw OR ("cognitive

therapy):ti,ab,kw OR (counseling):ti,ab,kw OR ("patient education"):ti,ab,kw OR ("patient participation"):ti,ab,kw OR ("health education"):ti,ab,kw OR ("sex education"):ti,ab,kw OR ("sexual education"):ti,ab,kw OR (psychoeducation):ti,ab,kw OR ("sex therapy"):ti,ab,kw OR ("sexual therapy"):ti,ab,kw OR ("stoma education"):ti,ab,kw OR ("stoma therapy"):ti,ab,kw OR ("health literacy"):ti,ab,kw OR ("health promotion"):ti,ab,kw OR ("health behavior"):ti,ab,kw OR ("cognitive behavior"):ti,ab,kw OR ("behavior training"):ti,ab,kw OR ("behavioral training"):ti,ab,kw OR (CBT) OR ("complementary therapy"):ti,ab,kw OR ("mind body therapy"):ti,ab,kw OR ("spiritual therapy"):ti,ab,kw OR ("relaxation therapy"):ti,ab,kw OR ("relaxation training"):ti,ab,kw OR ("client centered therapy"):ti,ab,kw OR (conditioning):ti,ab,kw OR ("stoma management"):ti,ab,kw OR ("bowel management"):ti,ab,kw OR (coping):ti,ab,kw OR (mindfulness):ti,ab,kw OR (empowerment):ti,ab,kw OR ("self-monitoring"):ti,ab,kw OR ("motivation therapy"):ti,ab,kw OR ("motivational therapy"):ti,ab,kw OR ("motivation interviewing"):ti,ab,kw OR ("motivational interviewing"):ti,ab,kw OR ("motivation treatment"):ti,ab,kw OR ("motivational treatment"):ti,ab,kw OR (psychology):ti,ab,kw OR ("problem solving"):ti,ab,kw OR ("psychosocial care"):ti,ab,kw OR ("psychological care"):ti,ab,kw OR ("psychologic care"):ti,ab,kw OR ("caregiver support"):ti,ab,kw OR (sociotherapy):ti,ab,kw OR ("occupational therapy"):ti,ab,kw OR ("care delivery"):ti,ab,kw OR ("functional therapy"):ti,ab,kw OR ("functional training"):ti,ab,kw OR (existentialism):ti,ab,kw OR ("spiritual healing"):ti,ab,kw OR ("spiritual therapy"):ti,ab,kw OR ("transcultural care"):ti,ab,kw OR ("life style"):ti,ab,kw

4. 2 OR 3

5. 1 AND 4

MEDLINE (via PubMed interface) 13/12/2016

1. "Urinary Bladder Neoplasms"[MESH] OR "Urinary Bladder/abnormalities"[MESH] OR "Urinary bladder/surgery"[MESH] OR "Carcinoma, Transitional Cell"[Mesh] OR "bladder cancer"[TIAB] OR "bladder cancers"[TIAB] OR "bladder carcinoma"[TIAB] OR "bladder carcinomas"[TIAB] OR "bladder malignancy"[TIAB] OR "bladder malignancies"[TIAB] OR "bladder neoplasm"[TIAB] OR "bladder neoplasms"[TIAB] OR "bladder tumor"[TIAB] OR "bladder tumors"[TIAB] OR "bladder tumour"[TIAB] OR "bladder tumours"[TIAB] OR "transitional cell carcinoma"[TIAB] OR "transitional cell carcinomas"[TIAB] OR "transitional cell cancer"[TIAB] OR "transitional cell cancers"[TIAB] OR "transitional cell malignancies"[TIAB] OR "transitional cell tumor"[TIAB] OR "transitional cell tumors"[TIAB] OR "transitional cell tumour"[TIAB] OR "transitional cell tumours"[TIAB] OR "urothelial cancer"[TIAB] OR "urothelial cancers"[TIAB] OR "urothelial carcinoma"[TIAB] OR "urothelial carcinomas"[TIAB] OR "urothelial malignancy"[TIAB] OR "urothelial malignancies"[TIAB] OR "urothelial tumor"[TIAB] OR "urothelial tumors"[TIAB] OR "urothelial tumour"[TIAB] OR "urothelial tumours"[TIAB] OR "urinary tract carcinoma"[TIAB] OR "urinary tract carcinomas"[TIAB] OR "urinary tract cancer"[TIAB] OR "urinary tract cancers"[TIAB] OR "urinary tract malignancy"[TIAB] OR "urinary tract malignancies"[TIAB] OR "urinary tract tumor"[TIAB] OR "urinary tract tumors"[TIAB] OR "urinary tract tumour"[TIAB] OR "urinary tract tumours"[TIAB]
2. "exercise"[MESH] OR "Exercise Movement Techniques"[Mesh] OR "Sports"[Mesh] OR "Physical Fitness"[Mesh] OR "Physical Exertion"[Mesh] OR "Exercise Therapy"[Mesh] OR "Dance Therapy"[Mesh] OR "Recreation Therapy"[Mesh] OR "Rehabilitation, Vocational"[Mesh] OR "Telerehabilitation"[Mesh] OR "Occupational Therapy"[Mesh] OR "Self Care"[Mesh] OR "Urinary Incontinence/rehabilitation"[Mesh] OR "Pelvic Floor/therapy"[Mesh] OR "self care"[TIAB] OR

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- “exercise”[TIAB] OR “exercising”[TIAB] OR “exercises”[TIAB] OR “sport”[TIAB] OR “sports”[TIAB] OR “physical activity”[TIAB] OR “physical activities”[TIAB] OR “physiotherapy”[TIAB] OR “kinesiotherapy”[TIAB] OR “physical conditioning”[TIAB] OR physical education*[TIAB] OR “physical fitness”[TIAB] OR “running”[TIAB] OR “swimming”[TIAB] OR “walking”[TIAB] OR “jogging”[TIAB] OR “weight lifting”[TIAB] OR “dancing”[TIAB] OR “dance”[TIAB] OR “tai chi”[TIAB] OR “tai ji”[TIAB] OR “yoga”[TIAB] OR “pilates”[TIAB] OR “gymnastic”[TIAB] OR “gymnastics”[TIAB] OR “resistance training”[TIAB] OR “aerobic training”[TIAB] OR “anaerobic training”[TIAB] OR “muscle training”[TIAB] OR “stretching”[TIAB] OR “aerobic”[TIAB] OR “aerobics”[TIAB] OR “rehabilitation”[TIAB] OR “pre-habilitation”[TIAB] OR “prehabilitation”[TIAB] OR “aquagym”[TIAB] OR “football”[TIAB] OR “soccer”[TIAB] OR “circuit training”[TIAB] OR “fitness”[TIAB] OR “bladder training”[TIAB] OR “incontinence management”[TIAB] OR “urinary management”[TIAB]
3. "Tertiary Prevention"[Mesh] OR "Social Support"[Mesh] OR "Psychiatric Rehabilitation"[Mesh] OR "Health Promotion"[Mesh] OR "Psychotherapy"[Mesh] OR "Counseling"[Mesh] OR "Patient Education as Topic"[Mesh] OR "Sex Education"[Mesh] OR "Sexuality/rehabilitation"[Mesh] OR "Health Literacy"[Mesh] OR "psychology/education"[MESH] OR "psychology/therapy"[MESH] OR "Problem Solving"[MESH] OR "Mind-body therapies"[Mesh] OR "patient participation"[MESH] OR "Existentialism"[MESH] OR "spiritual therapies"[MESH] OR "problem-based learning"[MESH] OR "Sedentary Lifestyle"[Mesh] OR psychosocial intervention*[TIAB] OR psychologic intervention*[TIAB] OR psychological intervention*[TIAB] OR psychology intervention*[TIAB] OR social intervention*[TIAB] OR psychosocial therap*[TIAB] OR psychologic therap*[TIAB] OR "psychological therapy"[TIAB] OR "psychological therapies"[TIAB] OR "psychology therapies"[TIAB] OR "psychotherapy"[TIAB] OR "tertiary health care"[TIAB] OR "tertiary prevention"[TIAB] OR "social support"[TIAB] OR social behav*[TIAB] OR "support care"[TIAB] OR "supportive care"[TIAB] OR behavior treatment*[TIAB] OR behavioral treatment*[TIAB] OR behavior therap*[TIAB] OR behavioral therap*[TIAB] OR cognitive treatment*[TIAB] OR cognitive therap*[TIAB] OR "counseling"[TIAB] OR patient education*[TIAB] OR "patient participation"[TIAB] OR health education*[TIAB] OR sex education*[TIAB] OR sexual education*[TIAB] OR psychoeducation*[TIAB] OR sex therap*[TIAB] OR sexual therap*[TIAB] OR stoma education*[TIAB] OR stoma therap*[TIAB] OR health literac*[TIAB] OR health promotion*[TIAB] OR health behavio*[TIAB] OR "cognitive behavior"[TIAB] OR "behavior training"[TIAB] OR "behavioral training"[TIAB] OR "behavioural training"[TIAB] OR CBT[TIAB] OR complementary therap*[TIAB] OR mind body therap*[TIAB] OR spiritual therap*[TIAB] OR relaxation therap*[TIAB] OR "relaxation training"[TIAB] OR client centered therap*[TIAB] OR conditioning[TIAB] OR stoma management[TIAB] OR bowel management[TIAB] OR coping [TIAB] OR mindfulness[TIAB] OR empowerment[TIAB] OR empowering[TIAB] OR self-monitoring*[TIAB] OR motivation therap*[TIAB] OR motivational therap*[TIAB] OR motivation interview[TIAB] OR motivation interviewing[TIAB] OR motivational interview[TIAB] OR motivational interviewing[TIAB] OR motivation treatment*[TIAB] OR motivational treatment*[TIAB] OR psychology[TIAB] OR problem solv*[TIAB] OR "psychosocial care"[TIAB] OR "psychological care"[TIAB] OR "psychologic care"[TIAB] OR caregiver support*[TIAB] OR sociotherap*[TIAB] OR occupational therap*[TIAB] OR care deliver*[TIAB] OR functional therap*[TIAB] OR "functional training"[TIAB] OR existentialism[TIAB] OR "spiritual healing"[TIAB] OR spiritual therap*[TIAB] OR "transcultural care"[TIAB] OR "life style"[TIAB]
4. 2 OR 3

		5. 1 AND 4
EMBASE (via Embase.com interface)	13/12/2016	<p>1. 'bladder tumor'/exp OR 'urinary tract carcinoma'/exp OR 'bladder surgery'/exp OR 'transitional cell carcinoma'/exp OR 'bladder cancer':ab,ti OR 'bladder cancers':ab,ti OR 'bladder carcinoma':ab,ti OR 'bladder carcinomas':ab,ti OR 'bladder malignancy':ab,ti OR 'bladder malignancies':ab,ti OR 'bladder neoplasm':ab,ti OR 'bladder neoplasms':ab,ti OR 'bladder tumor':ab,ti OR 'bladder tumors':ab,ti OR 'bladder tumour':ab,ti OR 'bladder tumours':ab,ti OR 'transitional cell carcinoma':ab,ti OR 'transitional cell carcinomas':ab,ti OR 'transitional cell cancer':ab,ti OR 'transitional cell cancers':ab,ti OR 'transitional cell malignancies':ab,ti OR 'transitional cell tumor':ab,ti OR 'transitional cell tumors':ab,ti OR 'transitional cell tumour':ab,ti OR 'transitional cell tumours':ab,ti OR 'urothelial cancer':ab,ti OR 'urothelial cancers':ab,ti OR 'urothelial carcinoma':ab,ti OR 'urothelial carcinomas':ab,ti OR 'urothelial malignancy':ab,ti OR 'urothelial malignancies':ab,ti OR 'urothelial tumor':ab,ti OR 'urothelial tumors':ab,ti OR 'urothelial tumour':ab,ti OR 'urothelial tumours':ab,ti OR 'urinary tract carcinoma':ti,ab OR 'urinary tract carcinomas':ti,ab OR 'urinary tract cancer':ti,ab OR 'urinary tract cancers':ti,ab OR 'urinary tract malignance':ti,ab OR 'urinary tract malignancy':ti,ab OR 'urinary tract malignancies':ti,ab OR 'urinary tract tumor':ti,ab OR 'urinary tract tumors':ti,ab OR 'urinary tract tumour':ti,ab OR 'urinary tract tumours':ti,ab</p> <p>2. 'physical activity'/exp OR 'exercise'/exp OR 'physiotherapy'/exp OR 'kinesiotherapy'/exp OR 'fitness'/exp OR 'sport'/exp OR 'bladder training'/exp OR 'cancer rehabilitation'/exp OR 'cognitive rehabilitation'/exp OR 'functional training'/exp OR 'geriatric rehabilitation'/exp OR 'muscle training'/exp OR 'home rehabilitation'/exp OR 'occupational therapy'/exp OR 'pelvic floor muscle training'/exp OR 'self care':ab,ti OR 'exercise':ab,ti OR 'exercising':ab,ti OR 'exercises':ab,ti OR 'sport':ab,ti OR 'sports':ab,ti OR 'physical activity':ab,ti OR 'physical activities':ab,ti OR 'physiotherapy':ab,ti OR 'kinesiotherapy':ab,ti OR 'physical conditioning':ab,ti OR 'physical education*':ab,ti OR 'physical fitness':ab,ti OR 'running':ab,ti OR 'swimming':ab,ti OR 'walking':ab,ti OR 'jogging':ab,ti OR 'weight lifting':ab,ti OR 'dancing':ab,ti OR 'dance':ab,ti OR 'tai chi':ab,ti OR 'tai ji':ab,ti OR 'yoga':ab,ti OR 'pilates':ab,ti OR 'gymnastic':ab,ti OR 'gymnastics':ab,ti OR 'resistance training':ab,ti OR 'aerobic training':ab,ti OR 'anaerobic training':ab,ti OR 'muscle training':ab,ti OR 'stretching':ab,ti OR 'aerobic':ab,ti OR 'aerobics':ab,ti OR 'rehabilitation':ab,ti OR 'pre-habilitation':ab,ti OR 'prehabilitation':ab,ti OR 'aquagym':ab,ti OR 'football':ab,ti OR 'soccer':ab,ti OR 'circuit training':ab,ti OR 'fitness':ab,ti OR 'bladder training':ab,ti OR 'incontinence management':ab,ti OR 'urinary management':ab,ti</p> <p>3. 'psychosocial rehabilitation'/exp OR 'recreational therapy'/exp OR 'sociotherapy'/exp OR 'telerehabilitation'/exp OR 'vocational rehabilitation'/exp OR 'caregiver support'/exp OR 'psychosocial care'/exp OR 'social support'/exp OR 'spiritual care'/exp OR 'psychotherapy'/exp OR 'preoperative education'/exp OR 'psychoeducation'/exp OR 'patient education'/exp OR 'health promotion'/exp OR 'reinforcement'/exp OR 'patient participation'/exp OR 'counseling'/exp OR 'problem solving'/exp OR 'home physiotherapy'/exp OR 'cancer prevention'/exp OR 'learning'/exp OR 'rehabilitation care'/exp OR 'bladder and bowel management'/exp OR 'empowerment'/exp OR 'coping behavior'/exp OR 'social interaction'/exp OR 'social participation'/exp OR 'behavior change'/exp OR 'lifestyle'/exp OR 'psychosocial intervention*':ab,ti OR 'psychologic intervention*':ab,ti OR 'psychological intervention*':ab,ti OR 'psychology intervention*':ab,ti OR 'social intervention*':ab,ti OR 'psychosocial therap*':ab,ti OR 'psychologic therap*':ab,ti OR 'psychological therapy':ab,ti OR 'psychological therapies':ab,ti OR 'psychology therapies':ab,ti OR 'psychotherapy':ab,ti OR 'tertiary health care':ab,ti OR 'tertiary prevention':ab,ti OR 'social support':ab,ti OR 'social behav*':ab,ti OR 'support care':ab,ti OR 'supportive</p>

care':ab,ti OR 'behavior treatment*':ab,ti OR 'behavioral treatment*':ab,ti OR 'behavior therap*':ab,ti OR 'behavioral therap*':ab,ti OR 'cognitive treatment*':ab,ti OR 'cognitive therap*':ab,ti OR 'counseling':ab,ti OR 'patient education*':ab,ti OR 'patient participation':ab,ti OR 'health education*':ab,ti OR 'sex education*':ab,ti OR 'sexual education*':ab,ti OR 'psychoeducation*':ab,ti OR 'sex therap*':ab,ti OR 'sexual therap*':ab,ti OR 'stoma education*':ab,ti OR 'stoma therap*':ab,ti OR 'health literac*':ab,ti OR 'health promotion*':ab,ti OR 'health behavio*':ab,ti OR 'cognitive behavior':ab,ti OR 'behavior training':ab,ti OR 'behavioral training':ab,ti OR 'behavioural training':ab,ti OR 'CBT':ab,ti OR 'complementary therap*':ab,ti OR 'mind body therap*':ab,ti OR 'spiritual therap*':ab,ti OR 'relaxation therap*':ab,ti OR 'relaxation training':ab,ti OR 'client centered therap*':ab,ti OR 'conditioning':ab,ti OR 'stoma management':ab,ti OR 'bowel management':ab,ti OR 'coping':ab,ti OR 'mindfulness':ab,ti OR 'empowerment':ab,ti OR 'empowering':ab,ti OR 'self-monitoring*':ab,ti OR 'motivation therap*':ab,ti OR 'motivational therap*':ab,ti OR 'motivation interview':ab,ti OR 'motivation interviewing':ab,ti OR 'motivational interview':ab,ti OR 'motivational interviewing':ab,ti OR 'motivation treatment*':ab,ti OR 'motivational treatment*':ab,ti OR 'psychology':ab,ti OR 'problem solv*':ab,ti OR 'psychosocial care':ab,ti OR 'psychological care':ab,ti OR 'psychologic care':ab,ti OR 'caregiver support*':ab,ti OR 'sociotherap*':ab,ti OR 'occupational therap*':ab,ti OR 'care deliver*':ab,ti OR 'functional therap*':ab,ti OR 'functional training':ab,ti OR 'existentialism':ab,ti OR 'spiritual healing':ab,ti OR 'spiritual therap*':ab,ti OR 'transcultural care':ab,ti OR 'life style':ab,ti

4. 2 OR 3

5. 1 AND 4

Web of Science

13/12/2016

1. TS=("bladder cancer") OR TS=("bladder cancers") OR TS=("bladder carcinoma") OR TS=("bladder carcinomas") OR TS=("bladder malignancy") OR TS=("bladder malignancies") OR TS=("bladder neoplasm") OR TS=("bladder neoplasms") OR TS=("bladder tumor") OR TS=("bladder tumors")OR TS=("bladder tumour") OR TS=("bladder tumours") OR TS=("transitional cell carcinoma") OR TS=("transitional cell carcinomas") OR TS=("transitional cell cancer") OR TS=("transitional cell cancers") OR TS=("transitional cell malignancies") OR TS=("transitional cell tumor") OR TS=("transitional cell tumors") OR TS=("transitional cell tumour") OR TS=("transitional cell tumours") OR TS=("urothelial cancer") OR TS=("urothelial cancers") OR TS=("urothelial carcinoma") OR TS=("urothelial carcinomas")OR TS=("urothelial malignancy") OR TS=("urothelial malignancies") OR TS=("urothelial tumor") OR TS=("urothelial tumors")OR TS=("urothelial tumour") OR TS=("urothelial tumours") OR TS=("urinary tract carcinoma") OR TS=("urinary tract carcinomas") OR TS=("urinary tract cancer") OR TS=("urinary tract cancers") OR TS=("urinary tract malignancy") OR TS=("urinary tract malignancies") OR TS=("urinary tract tumor") OR TS=("urinary tract tumors") OR TS=("urinary tract tumour") OR TS=("urinary tract tumours")
2. TS=("self care") OR TS=(exercise) OR TS=(exercising) OR TS=(exercises) OR TS=(sport) OR TS=(sports) OR TS=("physical activity") OR TS=("physical activities") OR TS=(physiotherapy) OR TS=(kinesiotherapy) OR TS=("physical conditioning") OR TS=("physical education*") OR TS=("physical fitness") OR TS=(running) OR TS=(swimming) OR TS=(walking) OR TS=(jogging) OR TS=("weight lifting") OR TS=(dancing) OR TS=(dance) OR TS=("tai chi") OR TS=("tai ji") OR TS=(yoga) OR TS=(pilates) OR TS=(gymnastic) OR TS=(gymnastics) OR TS=("resistance training") OR TS=("aerobic training") OR TS=("anaerobic training") OR TS=("muscle training") OR TS=(stretching) OR TS=(aerobic) OR TS=(aerobics) OR TS=(rehabilitation) OR TS=("pre-habilitation") OR TS=(prehabilitation) OR TS=(aquagym) OR TS=(football) OR TS=(soccer)

- OR TS=("circuit training") OR TS=(fitness) OR TS=("bladder training") OR TS=("incontinence management") OR TS=("urinary management")
3. TS=("psychosocial intervention*")OR TS=("psychologic intervention*") OR TS=("psychological intervention*")OR TS=("psychology intervention*")OR TS=("social intervention*") OR TS=("psychosocial therap*")OR TS=("psychologic therap*")OR TS=("psychological therapy")OR TS=("psychological therapies") OR TS=("psychology therapies") OR TS=(psychotherapy) OR TS=("tertiary health care") OR TS=("tertiary prevention") OR TS=("social support") OR TS=("social behav*") OR TS=("support care") OR TS=("supportive care") OR TS=("behavior treatment*") OR TS=("behavioral treatment*")OR TS=("behavior therap*")OR TS=("behavioral therap*") OR TS=("cognitive treatment*") OR TS=("cognitive therap*") OR TS=(counseling) OR TS=("patient education*")OR TS=("patient participation")OR TS=("health education*")OR TS=("sex education*") OR TS=("sexual education*")OR TS=(psychoeducation*)OR TS=("sex therap*")OR TS=("sexual therap*") OR TS=("stoma education*")OR TS=("stoma therap*")OR TS=("health literac*") OR TS=("health promotion*")OR TS=("health behavio*") OR TS=("cognitive behavior") OR TS=("behavior training") OR TS=("behavioral training") OR TS=("behavioural training") OR TS=(CBT) OR TS=("complementary therap*")OR TS=("mind body therap*")OR TS=("spiritual therap*")OR TS=("relaxation therap*")OR TS=("relaxation training") OR TS=("client centered therap*")OR TS=(conditioning)OR TS=("stoma management")OR TS=("bowel management") OR TS=(coping) OR TS=(mindfulness)OR TS=(empowerment) OR TS=(empowering) OR TS=("self-monitoring*")OR TS=("motivation therap*")OR TS=("motivational therap*")OR TS=("motivation interview") OR TS=("motivation interviewing") OR TS=("motivational interview") OR TS=("motivational interviewing") OR TS=("motivation treatment*")OR TS=("motivational treatment*")OR TS=(psychology)OR TS=("problem solv*")OR TS=("psychosocial care")OR TS=("psychological care")OR TS=("psychologic care")OR TS=("caregiver support*")OR TS=(sociotherap*) OR TS=("occupational therap*") OR TS=("care deliver*")OR TS=("functional therap*")OR TS=("functional training") OR TS=(existentialism)OR TS=("spiritual healing") OR TS=("spiritual therap*")OR TS=("transcultural care") OR TS=("life style")
4. 2 OR 3
5. 1 AND 4

PEDro 13/12/2016 Title/abstract: bladder cancer

The **cited and citing** articles of the included studies, retrieved with the above searches, will be screened through **Web of Science** to potentially identify other studies.