Efficacy of bladder training in the overactive bladder symptoms improvement: systematic review protocol

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Research Article

**Keywords:** Behavior Therapy, Exercise Therapy, Rehabilitation, Urinary Bladder, Overactive, Urinary Incontinence, Conservative Treatment.

**Posted Date:** October 14th, 2022

**DOI:** https://doi.org/10.21203/rs.3.rs-1507551/v1

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Abstract

Background

The International Continence Society recommends that first-line treatment of overactive bladder syndrome symptoms and urgency urinary incontinence is performed by conservative interventions. Bladder training is considered one of the types of behavioral intervention, which is characterized by health education associated with scheduled voiding regimen with gradually adjusted voiding intervals. The aim of this study will be to investigate and update whether bladder training can promote improvement of symptoms of individuals with overactive bladder with or without urgency urinary incontinence.

Methods

A bibliographic search will be conducted in eight databases, no data or language restrictions: PubMed, PEDro, SciELO, LILACS, Cochrane Library, Web of Science, EMBASE, CINAHL, by handing searching. A combination of search terms including ‘bladder training’, ‘overactive bladder’, ‘urinary incontinence’ and ‘urinary urgency incontinence’ with common Boolean operators will be used. Specific search terms will be combined with either MeSH and search descriptors terms and appropriate permutations for each database. Search findings will be imported into the Reference Management Software (Mendeley 2.67.0) then uploaded where two reviewers will screen the titles, abstracts and retrieved full text. In case of conflicts and moderate consensus discussions, a third reviewer will be available. The Mixed Methods Appraisal Tool (MMAT) will be used to appraise the quality of mixed studies (quantitative and qualitative) by limiting them to criteria. The primary outcome will be the improvement of OAB symptoms and the secondary outcomes will be the quality of life, functional assessment and adverse events, which can be assessed by questionnaires and measurement instruments. Meta-analysis, if plausible, will be performed by the software Review Manager 5.4. Cochrane RoB 2 assesses the risk of bias for randomized trials and quality of evidence will be assessed by GRADE.

Discussion

This study is a review of randomized controlled studies to analyze the efficacy of bladder training improving overactive bladder syndrome symptoms. The study design of randomized controlled trials for a higher level of scientific evidence was chosen. The aim is to obtain results that allow further studies and evidence that this intervention generates beneficial effects in the sample studied.

Systematic review registration: PROSPERO CRD42022301522.

Background

According to the International Continence Society (ICS), overactive bladder (OAB) is a multifactorial clinical syndrome associated with intrinsic and extrinsic factors, and is defined as the presence of symptoms of urinary urgency, daytime voiding frequency and/or nocturia, with urinary incontinence (OAB-wet) or without (OAB-dry), in the absence of urinary tract infection or other detectable disease [1–5]. OAB tends to directly impact the quality of life of individuals, affecting self-esteem and interpersonal relationships, and contributing to social isolation [6, 7]. However, the search for treatment is usually delayed due to embarrassment and lack of knowledge [8].

Its prevalence in the general population is quite variable (2–53%), reaching approximately 35% in the male and 41% in the female population, increasing with age in both genders. [7, 9, 10, 11]. Furthermore, OAB is a dynamic condition, with a remission rate of 49% in OAB-dry and 26% in OAB-wet female, which tends to be costly for public health. The higher prevalence of the female population may be related to different factors, which was suggested by Peyronnet et al. (2019) [12], which highlights the relevance of phenotypes for a better understanding of the trigger mechanisms and the importance of the individualized approach.

According to international guidelines, low-cost and low-complexity therapeutic strategies are recommended as first-line treatment, aiming to promote a good cost-benefit relationship as well as quality of life in individuals with OAB [3, 5, 6, 7, 13–16].

The first-line conservative approach to the symptoms of OAB-wet or OAB-dry includes behavioral interventions, which consists of strategies that modify lifestyle, life habits, and patient environment, with scheduled voiding regimens, including bladder training (BT) and pelvic floor muscle training (PFMT) [14–17]. BT has been shown to be important, not only for the results presented, but because it has low cost, low complexity and reduced side effects [18].

BT consists of a set of techniques that help individuals to delay voiding through activities that require mental concentration, such as relaxation or distraction techniques, often associated with repeated contractions of pelvic floor muscles (PFM), which provide an inhibitory reflex of the detrusor (Urethosphincteric guarding reflex) [16, 19, 20]. Therefore, while the individual delay voiding, the voluntary contractions of PFM activate afferent stimulus, via the pudendal nerve to the sacral center of the urination with inhibitory responses to the detrusor through the pelvic nerve (Perineodetrusor inhibitory reflex), resulting in increased intervals between the voidings [20].
The first Cochrane review from 2004 about bladder training suggests that BT may be helpful for the treatment of individuals with OAB symptoms, but there was also not enough evidence to determine whether BT was useful as a supplement to another therapy, either by the quality of evidence of the studies or by the sample size, confidence interval or estimates of effect. In this study, it was observed that there is limited evidence available in the individuals with Urinary Incontinence related to OAB symptoms and it is necessary to add more evidence about BT in individuals with OAB symptoms wet or dry [21].

Considering this context, the aim of this paper is to outline the protocol for a systematic review of a bladder training and its role in the improvement of symptoms of OAB-dry and OAB-wet available randomized clinical trials (RCTs) through of two objectives: (i) To determine the effect of BT on individuals with symptoms of overactive bladder; (ii) to compare BT against other interventions for the treatment of individuals with overactive bladder (OAB-wet or OAB-dry).

**Methods**

**Design**

This systematic review protocol was developed in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols 2015 statement (PRISMA-P) of the Enhancing the Quality and Transparency Of health Research (EQUATOR-network), as the Prisma-P Table below at (Additional file 1) (PRISMA-P) [22–24], will be reported in accordance with the PRISMA statement [25] and registered on the International Prospective Register of Systematic Reviews (PROSPERO) (CRD42022301522).

To contemplate the aim of this study will be performed a systematic review following the Cochrane methodology of randomized controlled trials [26].

**Eligibility criteria**

For this study the eligibility criteria will be according to the model by the Population, Intervention, Comparison, Outcome (PICO) [27].

**Types of studies**

Primary quantitative research studies published in English or Spanish with no date restriction will be considered. There was and there is an increase in the production of scientific evidence about OAB and improvement of its symptoms. In this study will be included RCTs with adults over 18 years old with OAB, with or without urgency urinary incontinence, receiving any kind of BT intervention with or without supervision, to prevent and/or reduce the OAB symptoms.

**Population**

The population of interest is women and men, aged 18 years or over with OAB-wet or OAB-dry symptoms.

**Intervention**

BT will be the intervention of interest. BT consists of a set of techniques that help individuals to delay voiding through activities that require mental concentration, such as relaxation or distraction techniques, often associated with repeated contractions of pelvic floor muscles (PFM), which provide an inhibitory reflex of the detrusor (Urethrosphincteric guarding reflex). Usually a health professional (usually a physiotherapist) teaches and guides the patient to perform bladder training during moments of urgency urinary.

**Comparator**

Will be used like a comparator group, another intervention or a non-exposed control/placebo group.

**Outcome**

The primary outcome will be the improvement of OAB symptoms (urinary urgency with daytime voiding frequency, nocturia with or without urgency urinary incontinence), which can be assessed by tools such as urodynamic study, voiding diary, and questionnaires and others instruments that make it possible to assess quantitatively.

The secondary outcome will be the quality of life, functional assessment and adverse events, which can be assessed by questionnaires and measurement instruments.

**Exclusion criteria**

For this protocol will be excluded all studies that may show design the case studies, cross-over studies, non-comparative study, non-controlled studies, observational cohort, case-control, cohort, cross-sectional and single group observational studies, abstract, opinion piece, integrative mixed methods and systematic reviews, grey literature studies, studies that do not have the separation of the groups nor details of the adequate
protocol, or studies that do not present bladder training alone as an endpoint will be given the primary aim of the review is to assess BT in adults with OAB-wet or dry.

Regarding the intervention, studies demonstrating an online orientation, treatment, previous demonstration and orientation about bladder training or having already been previously treated or with urinary tract infection, detrusor overactivity or any other lower urinary tract pathology, bladder or urethral abnormalities, pre, peri and immediate post-operative, uncontrolled metabolic disorders, children, women during pregnancy and puerperium, will be excluded. Similarly, RCTs published that are not shown in English will be excluded.

### Information sources and search strategy

Systematic review protocol will be carried out by following the Cochrane methodology of Randomized Controlled Trials. Databases to be searched with no date restriction and no language restrictions, include PubMed Central (PMC)/MEDLINE, Physiotherapy Evidence Database (PEDro), Scientific Electronic Library Online (Scielo), Latin American and Caribbean Literature in Health Sciences (LILACS), Central Cochrane Library, Web of Science, Excerpta Medica database (EMBASE), Cumulative Index to Nursing and Allied Health Literature (CINAHL), and by handing searching to identify studies involving the above-mentioned interventions. MeSH terms and search descriptors that will be used for our searches are "Bladder Training", "Bladder Drill", "Bladder Re-education", "Bladder Retraining", "Bladder Discipline", "Overactive Bladder", "Bladder, Overactive", "Overactive Urinary Bladder", "Urinary Bladder", "Overactive, Urinary Bladder", "Bladder, Urinary", "Urinary Bladder Disease", "Bladder Disease", "Bladder Detrusor Muscle", "Detrusor Muscle, Bladder", "Randomized Controlled trial", "controlled clinical trial", "Randomly" and "RCT", as shown in Table 1.

<table>
<thead>
<tr>
<th>Mesh headings and Searches terms</th>
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<tbody>
<tr>
<td>1  Bladder Training</td>
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<tr>
<td>2  Bladder Drill</td>
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<tr>
<td>3  Bladder Re-education</td>
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<td>4  Bladder Retraining</td>
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<td>5  Bladder Discipline</td>
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<td>6  1 OR 2 OR 3 OR 4 OR 5</td>
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<td>7  Overactive Bladder</td>
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<td>8  Bladder, Overactive</td>
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<td>9  Overactive Urinary Bladder</td>
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<td>10 MH “Urinary Bladder”</td>
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<td>11 Overactive, Urinary Bladder</td>
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<td>12 Bladder, Urinary</td>
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<td>13 MH “Urinary Bladder Disease”</td>
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<td>14 Bladder Disease</td>
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<td>15 Bladder Detrusor Muscle</td>
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<td>16 Detrusor Muscle, Bladder</td>
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<td>17 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16</td>
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<tr>
<td>18 MH “Randomized Controlled Trial”</td>
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<td>19 MH “Controlled Clinical Trial”</td>
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<td>21 RCT</td>
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<td>22 6 AND 17 AND 18 AND 19 AND 20 AND 21</td>
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The Table shown how the search will be conducted, this model will be conducted at model PUBMED base.
This search will be conducted by AKLR with the assistance of a librarian from the institution. Each term will be combined with the term of the intervention (bladder training, its variations and other terms), combined with the term of the health condition studied (overactive bladder) combined then with the term referring to the type and design of study that will be chosen for the analysis. Primary search terms include ‘bladder training’, ‘overactive bladder’, ‘urinary incontinence’ and ‘urinary urgency incontinence’, with common Boolean operators and symbols as illustrated in Table 2. These terms will be searched using MeSH or search descriptors with appropriate changes for each database.

<table>
<thead>
<tr>
<th>Concept 1</th>
<th>Concept 2</th>
<th>Concept 3</th>
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<tr>
<td>Bladder Training</td>
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<td>MH &quot;Randomized Controlled Trial&quot;</td>
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<td>OR</td>
<td>OR</td>
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<tr>
<td>Bladder Drill</td>
<td>Bladder, Overactive</td>
<td>MH &quot;Controlled Clinical Trial&quot;</td>
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<td>OR</td>
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<td>OR</td>
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<tr>
<td>Bladder Re-education</td>
<td>Overactive Urinary Bladder</td>
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<td>Bladder Retraining</td>
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<td></td>
<td>Detrusor Muscle, Bladder</td>
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</tr>
</tbody>
</table>

Each concept will be combined with "AND".

### Data management, selection and screening

Database search results will be imported into the reference management software Mendeley Reference Management 2.67.0. Mendeley is the program or software that supports collaborative title and abstract screening, full-text, screening [28]. In this study, for each search strategy, two reviewers will evaluate the studies gathered from the databases in the order: title, abstract and full reading. All studies potentially eligible for inclusion in the review will be selected for full reading. In case of disagreement, a third reviewer will be consulted. Therefore, after the screening outcomes will be saved, documented and shown in a flow diagram recommended by PRISMA Statement [25].

### Data extraction

Data extraction for eligible studies will be performed by two reviewers (AKLR e DPVS) who will extract data from articles that meet the inclusion criteria. A standardized form will be used to extract the following information: study characteristics (design, randomization method, blinding, allocation generation and concealment, statistics), which will be assessed for risk of bias and quality of evidence, and in relation to the profile of the participants and the variables that will be extracted as shown in Table 3.
Data items

Will be included from the selected studies the title, author, year, country, study setting, design element, aim, number of participants per group, inclusion and exclusion criteria, type and unit of allocation, start and end dates of the study, duration, baseline group differences, follow-up, satisfaction with treatment, improvement of symptoms, outcome measure and OAB symptoms, others outcomes of self-reported that allow measures and data to be drawn up for comparison as a comparator group and interventions to compare with bladder training, as shown in Table 3.

Outcomes and prioritisation

The outcome that will be prioritised is the effect of BT in the improvement of OAB symptoms. Outcomes will be compared between the groups who do and do not participate in a BT intervention. The Secondary outcomes will be quality of life, functional assessment and adverse events, which can be assessed by questionnaires and measurement instruments. If any discrepancy data is observed, an email will be sent to the authors of the studies to be analyzed.

Risk of bias in individual studies

In this study the methodological quality the risk of bias will be measure by the Cochrane Handbook of Interventions Systematic Reviews, which assesses the following domains: allocation generation; concealment of allocation; blinding (of participants and researchers) and blinding of outcome assessment; the presence of incomplete data; reporting bias of information and other types of bias. The results to these domains may be "High", "Low" or "Uncertain". The final grade of the study will be based on the responses given to the first three domains and will be classified as having high, low or uncertain risk of bias. In case of doubt or a tie between the ability of the two reviewers to give an opinion on the individual risk of bias of each study, a third evaluator will be inserted for further information. If there is any doubt as to whether the study did or did not comply with the risk of bias it will be stated that the author did not make it clear and therefore the authors of this study will contact the authors of the study in question for further information on the methodology and data. The RoB 2, will be used for specific outcomes assessed for the risk of biased domains, including signaling issues that may influence a risk of biased judgments and may lead to an overall biased and unreliable risk judgment [29].

Quality appraisal

In this stage, two authors (AKLR and DV) will check and evaluate each of the articles by using the Mixed Methods Appraisal Tool (MMAT) [30]. Therefore, this method verifies the studies regarding their methodology, however, there will not be a score to verify the quality of each study, thus, an analysis will be used to complete the quality of the studies regarding their outcomes and methodologies [30].

Data synthesis

For between-study analyses, the odds ratio, mean differences or the standardised mean difference will be calculated. In case of missing data, we will try to contact the primary authors to obtain relevant information. We will provide summaries of intervention effects, calculating odds ratio for dichotomous outcomes (with 95% confidence interval), for continuous outcomes, the mean differences or the standardised mean difference, when outcomes are measured using scales not compatible (with 95% CI). Therefore, if possible, due to the range of different outcomes measured across the small number of existing trials, will conduct a meta-analysis. However, if it is possible to have a study with the same type of intervention, a comparator, and the same outcome measure, we can reproduce a random-effects meta-analysis with standardized mean differences outcomes and risk ratios for binary outcomes. Ninety-five percent (95%) confidence intervals and two-sided p-values for each
outcome. Review Manager software (RevMan) will be used for all analyses, including meta-analysis with more of two studies will be illustrated using forest plots [26, 31].

To verify the heterogeneity between studies, the effect measures will be evaluated using both the χ² test and the I² statistic [32]. Therefore, will be considered a value of I² greater than 50% to indicate satisfactory heterogeneity. Low heterogeneity will be considered between 0 and 40%, moderate heterogeneity between 30 and 60%, heterogeneity between 50 and 90% and significant heterogeneity between 75 and 100% [33]. An analysis will be carried out to verify the sub-groups Stratified meta-analyses will be used to assess estimates of heterogeneity according to: study quality, populations studied, logistics of intervention, and content of the intervention.

**Meta-bias**

The selection of studies for this systematic review protocol will be driven by the PICO model and the full step by step of this protocol. Hand searching will be used to reduce the possibility of publication bias [34, 36]. Therefore, the protocol has been registered to provide transparency and that it can be replicable and intelligible. In this sense, two reviewers will be selected to assess the quality of the studies of low quality studies and will be excluded if they may interfere with the results [22].

**Confidence in cumulative evidence**

The overall effectiveness and the improvement in individuals with OAB symptoms will be assessed by The Grading of Recommendations Assessment, Development and Evaluation (GRADE) that will verify the quality of evidence of the analyzed studies [35]. To assess the quality of evidence, two authors will evaluate each outcome measure through discussion and consensus. If the data for meta-analysis will be pooled and a narrative analysis performed, the GRADE criteria will be used to evaluate each analytical grouping. The GRADE system assesses the limitations of the study, inconsistencies, indirect evidence, inaccuracies, and publication biases, classifying the level of evidence of the reviewed studies as high, moderate, low, or very low [23, 36, 37].

**Discussion**

First-line conservative interventions for OAB-wet or OAB-dry may generate benefits for individuals with this syndrome. BT may show and have been showing positive results due to its low complexity requiring simple technology, furthermore it involves behavioral changes in relation to voiding behavior and health habits, and finally due to its low cost for its effectiveness in prescription and treatment [5, 14–18].

This study design was chosen because it can assess and update the highest level of evidence available. In a Cochrane review in 2004, it was noted that BT may be helpful for the treatment of individuals with OAB symptoms, but there was also not enough evidence to determine whether BT was useful as a supplement to another therapy [21]. There is a need for more studies and more current research to be conducted to support clinical practice, in addition to promoting other higher quality studies on this topic [21].

In this way, we can obtain solid and conclusive evidence, whether or not there is evidence to support clinical practice, in addition to promoting high quality studies on the subject.

**Abbreviations**

ICS - International Continence Society; BT - Bladder Training; OAB - Overactive Bladder; OAB-wet - Overactive bladder with urinary incontinence; OAB-dry - Overactive bladder without urinary incontinence; UUI - Urgency Urinary Incontinence

RCTs - Randomized Clinical Trials; PFMT - Pelvic Floor Muscle Training; PFM - Pelvic Floor Muscle

**Declarations**

**Ethics approval and consent to participate**

This review does not require ethics approval, and as there are no active participants, consent is not relevant.

**Consent for publication**

Not applicable.

**Availability of data and materials**

Datasets generated by searches will be made available upon reasonable request.

**Competing interests**
All authors don’t have conflicts of interest with the present study.

**Funding**

This study is supported by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brazil (CAPES) through the Graduate Program in Rehabilitation Sciences, UroPhysiotherapy Laboratory of the Postgraduate Program in Rehabilitation Sciences - Federal University of Alfenas, UNIFAL-MG, Brazil and the Postgraduate Program in Surgical Science, School of Medical Sciences of the State University of Campinas (UNICAMP), Campinas, São Paulo, Brazil, as well as the Fundação de Amparo à Pesquisa do Estado de Minas Gerais – FAPEMIG and Research Incentive Fund, PUC MINAS, MG, Brazil, for the design, implementation, interpretation, and publication of the study. The funders had not and will not have a role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**Authors’ contributions**

AKLR, SEM, CR, SB, and LV participated in the acquisition of data and revision of the manuscript. AKLR, SEM, CR, SB, DV and MPV conceived the study, determined the design and interpreted the data. AKLR, SEM, CR, SB, MPV drafted the manuscript. All authors read and gave final approval for the version submitted for publication.

**Acknowledgements**

We thank you the groups of the all universities - UNIFAL-MG, UNICAMP-SP and PUC-MG as well as the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brazil (CAPES) - Finance Code 001, Fundação de Amparo à Pesquisa do Estado de Minas Gerais (FAPEMIG), through PPM-00471-18 and Research Incentive Fund (FIP/PUC Minas, MG, Brazil).

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**References**


**Supplementary Files**

This is a list of supplementary files associated with this preprint. Click to download.

- PRISMAPProtocolSROABBT.pdf