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Effectiveness of web-based interventions for women with urinary incontinence: Protocol for a systematic review and meta-analysis of randomized controlled trials

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Complete List of Authors:	Xu, Xuefen; Women's Hospital, Zhejiang University School of Medicine Guo, Pingping; Women's Hospital School of Medicine Zhejiang University Xu, Ping; Women's Hospital, Zhejiang University School of Medicine Chen, Dan; Faculty of Nursing, Zhejiang University School of Medicine Chen, Weijing; Department of Obstetrics, The First Affiliated Hospital of Wenzhou Medical University Wang, Hongyan; Women's Hospital, Zhejiang University School of Medicine Jin, Ying; Women's Hospital, Zhejiang University School of Medicine Wang, Xiaojuan; Women's Hospital, Zhejiang University School of Medicine Zhang, Wei; Women's Hospital, Zhejiang University School of Medicine Xie, Fang; Women's Hospital, Zhejiang University School of Medicine Mao, Minna; Women's Hospital, Zhejiang University School of Medicine Zhao, Rujia; Women's Hospital, Zhejiang University School of Medicine Feng, Suwen; Women's Hospital School of Medicine Zhejiang University,
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Title Page

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Names of Authors:

1. Xuefen Xu[a†],
E-mail: *5613024@zju.edu.cn*
2. Pingping Guo[a,b†],
E-mail: *12118394@zju.edu.cn*
[†]Xuefen Xu and Pingping Guo contributed equally to this work and should be considered as joint first authors.
3. Ping Xu[a,b],
E-mail: *12018383@zju.edu.cn*
4. Dandan Chen[b],
E-mail: *11918475@zju.edu.cn*
5. Weijing Chen[c],
E-mail: *2270712704@qq.com*
6. Hongyan Wang[a],
E-mail: *whysammy@163.com*
7. Ying Jin[a],
E-mail: jinyin@zju.edu.cn
8. Xiaojuan Wang[a,b],
E-mail: *11818206@zju.edu.cn*
9. Wei Zhang[a,b],
E-mail: *12018379@zju.edu.cn*
10. Fang Xie[a,b],

E-mail: *fangxie@zju.edu.cn*

11. Minna Mao[a,b],

E-mail: *22118796@zju.edu.cn*

12. Rujia Zhao[a,b],

E-mail: *zhaorujia0721@163.com*

13. **Corresponding author:** Suwen Feng[a*], Professor of Nursing, tutor for graduates

[*] Corresponding author at: Women's Hospital, Zhejiang University School of Medicine, No.1 Xue Shi Road, Hangzhou, Zhejiang Province 310006, China.

E-mail addresses: *fengsw@zju.edu.cn.*

Telephone：+86 *139 5716 8708*

Addresses of the Institutions:

[a]Women's Hospital, Zhejiang University School of Medicine, Hangzhou, China.

[b]Faculty of Nursing, Zhejiang University School of Medicine, Hangzhou, China.

[c]Department of Obstetrics, The First Affiliated Hospital of Wenzhou Medical University, Wenzhou, China.

Effectiveness of web-based interventions for women with urinary incontinence: Protocol for a systematic review and meta-analysis of randomized controlled trials

Abstract

Introduction Urinary incontinence (UI) is one of the most common chronic diseases among women, which can endanger their physical and mental health and incur a heavy financial burden on both individuals and society. Web-based interventions (WBIs) have been applied to manage women's UI, but their effectiveness has remained inconclusive. This systematic review and meta-analysis aims to explore the effectiveness of WBIs on self-reported symptom severity, condition-specific quality of life, adherence to pelvic floor muscle training (primary outcomes), and other extensive secondary outcomes among women with UI. We also aimed to investigate whether intervention characteristics (format, interactivity, and main technology) have impacts on the effectiveness of primary outcomes.

Methods and analysis This systematic review protocol is developed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols guidelines. Ten electronic databases will be comprehensively searched from their inception to January 1, 2024, along with gray literature searches and manual reviews of relevant reference lists to identify eligible randomized controlled trials. The methodological quality of the included studies will be assessed by two reviewers based on the Cochrane Risk of Bias Tool. Meta-analyses will be conducted via Stata 12.0. Leave-one-out sensitivity analyses will be performed, and publication bias will be evaluated using funnel plots and Egger's test. Subgroup analyses regarding intervention format, interactivity, and main technology will be carried out.

Ethics and dissemination No ethics approval is needed for this review since no primary data are to be collected. The results of this review will be helpful in developing an optimal WBI for women with UI, thereby providing them with maximum benefits. The findings will be disseminated via a peer-reviewed journal or a conference presentation.

PROSPERO Registration Number: CRD42023435047.

STRENGTHS AND LIMITATIONS OF THIS STUDY

► This systematic review protocol strictly adheres to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols guidelines to ensure quality in all aspects of study planning, execution, and reporting.

► We will apply a broad and comprehensive search strategy to search ten electronic databases.

► Subgroup analyses regarding intervention format, interactivity, and main technology will be conducted if possible to provide scientific evidence for researchers and healthcare professionals to optimize the web-based intervention regimen.

► Anticipated high heterogeneity across available studies may increase the difficulty in interpreting a meta-analysis.

► Another potential limitation of this systematic review may be the introduction of language bias, since the search will be restricted to studies published in English and Chinese.

INTRODUCTION

Urinary incontinence (UI) is defined by The International Urogynecological Association and the International Continence Society as "complaints of any involuntary leakage of urine" [1]. It is one of the common chronic diseases that endanger women's health, affecting at least 200 million women around the world [2]. Estimates of the prevalence of UI are contested and vary widely depending on the definition applied, population investigated, and measurement tools used [3]. According to the data of the 6th International Continence on Incontinence, which is considered relatively authoritative, 10%–39% of women globally suffered from UI [4]. Worse still, this prevalence is expected to be higher among women who have risk factors such as being overweight or obese and having a higher parity, and estimates rise with each decade of life as a consequence of the aging population [5]. In short, UI has become a key public health and social problem around the world.

Although UI is not life-threatening, it can be a debilitating condition that significantly impacts quality of life in both physical and psychological aspects for the majority of women affected. Evidence reveals that UI interferes with women's daily lives, including work, household duties, recreational life, and even sleep, and makes

them suffer from psychological distress (such as embarrassment, low self-esteem, and depression) [6]. It is also closely associated with numerous severe medical conditions (e.g., urinary tract infections, perineal dermatitis, and pressure wounds) [7]. In the medium or long term, UI in older women significantly increases the risk of falls and nursing-home admissions [7]. Furthermore, women with UI often find themselves socially isolated and relatively inactive [6], leading to an increased risk of suicide [8]. From the perspective of economics, UI imposes a considerable financial burden on both individuals and the healthcare system. For example, the USA allocates approximately $12 billion annually to cover expenses related to therapeutic management, absenteeism, and disability associated with UI [9], and in the UK, the expenditure exclusively on UI containment products, such as absorbent pads, amounts to approximately £80 million per year [10]. Considering the substantial adverse consequences that UI may cause, it is crucial to take measures to manage UI effectively.

Existing evidence-based UI treatments can be broadly separated into surgeries, pharmaceutical therapies, and conservative pelvic floor rehabilitation treatments (hereinafter referred to as conservative treatments) [11]. Incontinence surgeries and pharmaceutical therapies often exhibit only modest effectiveness but commonly lead to several side effects [12]. In contrast, conservative treatments, which mainly include pelvic floor muscle training (PFMT), lifestyle intervention (such as weight loss, smoking cessation, and fluid intake management), bladder training, and electrical stimulation, are considered to be relatively low-risk and can be initiated by most women without extensive preliminary evaluation; they are also cheaper and more attractive than surgeries and pharmaceutical therapies [12]. Substantial evidence has demonstrated that conservative treatments can cure or ameliorate symptoms in about two-thirds of patients with UI [13, 14], thereby reducing disease burden and optimizing health outcomes. It is particularly noteworthy that PFMT has been recommended by the International Continence Society as the first-line treatment for UI since 2005 [13]. Most conservative treatments are currently typically administered through "face-to-face" sessions by professional physiotherapists or registered nurses

in clinics or hospitals [12]; however, the uptake of such treatments is poor. It is reported that only a small percentage (around 25%-30%) of UI women seek professional help [15], with the incorrect perception of UI, stigma, inconvenient traffic, time constraints, and high medical costs being the main obstacles for them to uptake [16-18]. Meanwhile, most healthcare settings do not routinely provide treatments and management practices for patients with UI due to limited human and material resources [19]. Given the multiple deficiencies of the traditional mode of UI management, it is imperative to identify a more feasible, expandable, sustainable, affordable, and privacy-friendly mode of care to manage UI among women effectively and simultaneously alleviate the healthcare system's burden without affecting its current services or compromising care quality.

Web-based interventions (WBIs), referring to achieving specific health objectives via web-connected devices like smartphones, computers, and laptops [16, 20], might be an effective complement and alternative to narrow the aforementioned gaps and manage women's UI more effectively through an innovative delivery mode. The benefits of interventions that delivered via the web include anonymity, relatively low cost, and convenience because they enable individuals to receive interventions anytime and anywhere without face-to-face contact with professionals [21-23], thereby reducing stigma, transportation costs, and waiting time for treatments, which are particularly suitable for those with busy schedules or who require flexibility owing to work and family responsibilities. Moreover, with the rapid growth of internet access rates worldwide and the popularization of web-based devices, the practical feasibility of WBIs has increased [16, 24, 25]. In recent years, the increasing number of randomized controlled trials (RCTs) [26-30] related to WBIs on women's UI, in particular in the context of the COVID-19 pandemic, has demonstrated a growing need for supplementary strategies that can enhance existing services and provide better assistance to UI management for women.

Recent systematic reviews have indicated that WBIs can enhance health outcomes among patients with chronic diseases such as diabetes [25] and dementia [24]. Nevertheless, the findings about the effects of WBIs on ameliorating health

outcomes for UI women are not consistent. For instance, some trials reported that, compared with the control group, WBIs significantly improved self-reported symptom severity [27, 29], condition-specific quality of life (QoL) [26], and adherence to PFMT [26, 29] for women with UI. On the contrary, some studies [28, 30] found no significant differences in self-reported symptom severity, condition-specific QoL, or adherence to PFMT between the WBIs and control groups.

Currently, there are five systematic reviews of WBIs for women with UI. Two reviews only focus on the effects of mobile applications on UI. Among them, Widdison et al. [23] included four articles from three RCTs, and Leme Nagib et al. [20] included three RCTs, both of which indicated that WBIs had significant improvements on self-reported symptom severity, condition-specific QoL, and adherence to PFMT. Yet, both reviews included male and female UI patients but did not report outcomes separately for women. Similarly, Hou et al. [31] (n = 6 RCTs) only assessed the effectiveness of mobile application-delivered PFMT for stress UI in women and reported significant improvement in self-reported symptom severity, condition-specific QoL, adherence to PFMT, and the global impression of improvement. Nevertheless, the certainty of the findings from above three reviews is limited, as the authors only provided a narrative description of the results but did not conduct any quantitative syntheses. In another systematic review and meta-analysis conducted by Huang et al. [21] (n = 7 RCTs), the effects of telemedicine for UI in women was investigated, with the results indicating reductions in self-reported symptom severity, anxiety, and depression, as well as improvements in QoL, self-efficacy of PFMT, and the global impression of improvement for the targeted population. However, caution should be exercised when interpreting the results of this review, as it conflated early mobile technologies (such as telephone call) with web-based technologies. Interestingly, the results of Papanikolaou et al.'s systematic review and meta-analysis [22] (n = 10 RCTs) contradicted the above four reviews by showing no significant difference in self-reported symptom severity, condition-specific QoL, or adherence to PFMT between WBIs and the control group. On the whole, the findings across existing systematic reviews pertaining to this topic

are lacking in congruity, with certain outcomes such as pelvic floor muscle contractility, incontinence episode frequency, usage rate of incontinence aids, and satisfaction with intervention being rarely evaluated. Moreover, all of these reviews incorporated a restricted quantity of primary studies ($n \leq 10$), while an increasing number of RCTs [26-30] concerning this topic were being published after them, which could offer novel evidence. Accordingly, the effects of WBIs on women with UI need further exploration.

OBJECTIVES

The purpose of this systematic review and meta-analysis is to investigate the effectiveness of WBIs for women with UI based on all available evidence from RCTs. Specifically, our proposed review seeks to answer the following questions: (a) Whether WBIs can effectively mitigate self-reported symptom severity, improve condition-specific QoL, and increase adherence to PFMT (primary question); (b) Whether specific types of intervention format, intervention interactivity, and main technology have beneficial effects on these outcomes (secondary question 1); and (c) Are WBIs effective on other extensive secondary outcomes among women with UI (secondary question 2).

METHODS AND ANALYSIS

Registration

This systematic review and meta-analysis has been prospectively registered on the platform of the International Prospective Register of Systematic Reviews (PROSPERO). The registration number is CRD42023435047. Any future changes to the study protocol will be registered as amendments.

Eligibility criteria

The PICOS approach will be used for eligibility criteria. The details are described as follows:

P (Population)

Female adults diagnosed with any types of UI will be considered eligible. However, women affected by UI arising from non-urinary tract factors will be excluded, such as cancer or radiotherapy-induced symptoms, neurological, cognitive

or psychological disorders, and diseases hindering independent mobility. Also, studies that involved women with various types of lower urinary tract symptoms but did not report the data specific to women with UI separately will be excluded.

I (Intervention)

The intervention should be in a digital format using any web-based technologies, including but not limited to websites and mobile applications, with or without an intravaginal digital device's connection. Nevertheless, studies will be excluded if they solely utilize WBIs to observe the maintenance effects of previously administered health interventions, compare different types of program- or module-specific WBIs, involve face-to-face components in addition to the same routine care received by the control group, or do not conduct real WBIs (such as by adopting telephone call, short message, or digital video disk for intervention).

C (Control)

The control group can be usual care, a waitlist, no treatment, or minimal WBIs (such as hyperlinks to brief informational websites or an application that delivers concise information).

O (Outcome)

The primary outcomes are self-reported symptom severity, condition-specific QoL, and adherence to PFMT. Secondary outcomes will include pelvic floor muscle contractility evaluated by digital palpation (focusing on four out of the six domains of the PERFECT assessment scheme: power, endurance, repetition, and fast), incontinence episode frequency, urine leakage volume (measured via the pad-weighing test), usage rate of incontinence aids, the global impression of improvement, disease-related knowledge, self-efficacy of PFMT, mental health (anxiety and depression), and satisfaction with intervention. Studies that assess at least one of the aforementioned outcomes will be recognized as qualified.

S (Study design)

This systematic review will only include RCTs with full-text research papers available. Studies published in English and Chinese will be included.

Information sources and search strategy

The three-step approach to literature search recommended by the Joanna Briggs Institute will be used to identify studies that are relevant to the review questions. Step 1: An initial search has been conducted only on PubMed and CNKI, followed by an analysis of the text words in the titles and abstracts of the retrieved publications, as well as the corresponding Medical Subject Heading (MeSH) terms to describe them. Step 2: Based on the results of the initial search modification and additional keywords, we will collaborate with an academic librarian to develop customized search strategies for each electronic database. A combination of MeSH terms and free text keywords will be applied where appropriate to represent the definitions of WBIs, UI, and RCT is possible. Table 1 shows the detailed search strategies of PubMed and CNKI. Ten electronic databases are anticipated to be comprehensively searched from their inception to January 1, 2024, by two authors independently, including six English databases (PubMed, Embase, the Cochrane Library, Web of Science, PsycINFO, and CINAHL) and four Chinese databases (CNKI, Wanfang Data, VIP, and SinoMed). Step 3: Google Scholar and Baidu Library sources will be searched for gray literatures. The reference lists of all eligible articles and relevant reviews will be manually examined to expand the scope of our search and retrieve additional eligible studies.

Table 1. Literature search strategy.

Electronic database	Search terms
Pubmed	**#1** "Mobile Applications"[Mesh] OR "Telemedicine"[Mesh] OR "Internet"[Mesh] OR "Computers"[Mesh] OR "Telecommunications"[Mesh] OR "Online Systems"[Mesh] OR "Software"[Mesh] OR "Wireless Technology"[Mesh] OR "Cell Phone"[Mesh] OR app[Title/Abstract] OR apps[Title/Abstract] OR application[Title/Abstract] OR applications[Title/Abstract] OR ipad[Title/Abstract] OR blog[Title/Abstract] OR blogging[Title/Abstract] OR computer[Title/Abstract] OR computer interface[Title/Abstract] OR cell phones[Title/Abstract] OR cell phone[Title/Abstract] OR cellular phone[Title/Abstract] OR digital[Title/Abstract] OR digital health[Title/Abstract] OR digital-health[Title/Abstract] OR ehealth[Title/Abstract] OR e-health[Title/Abstract] OR e-mail[Title/Abstract] OR electronic[Title/Abstract] OR E-learning[Title/Abstract] OR Facebook[Title/Abstract] OR health, mobile[Title/Abstract] OR health technolog[Title/Abstract] OR health app[Title/Abstract] OR Internet[Title/Abstract] OR Internet forum[Title/Abstract] OR iphone[Title/Abstract] OR i phone[Title/Abstract] OR i-phone[Title/Abstract] OR ipad[Title/Abstract] OR i pad[Title/Abstract] OR i-pad[Title/Abstract] OR laptop[Title/Abstract] OR linkedin[Title/Abstract] OR

	mobile[Title/Abstract] OR mobile application[Title/Abstract] OR mobile apps[Title/Abstract] OR mobile app[Title/Abstract] OR mobile phone[Title/Abstract] OR mobile phones[Title/Abstract] OR mhealth[Title/Abstract] OR m-health[Title/Abstract] OR mobile health[Title/Abstract] OR mobile electronic device[Title/Abstract] OR mobile technolog[Title/Abstract] OR mobile communication[Title/Abstract] OR mobile computing[Title/Abstract] OR network[Title/Abstract] OR online[Title/Abstract] OR online intervention[Title/Abstract] OR online interventions[Title/Abstract] OR platform[Title/Abstract] OR personal computer[Title/Abstract] OR personal digital assistant[Title/Abstract] OR QQ[Title/Abstract] OR remote[Title/Abstract] OR smartphone[Title/Abstract] OR smart phone[Title/Abstract] OR social media[Title/Abstract] OR social networking[Title/Abstract] OR telehealth[Title/Abstract] OR tele-health[Title/Abstract] OR telephone[Title/Abstract] OR telemedicine[Title/Abstract] OR tele-medicine[Title/Abstract] OR tele-care[Title/Abstract] OR telecare[Title/Abstract] OR telecommunication[Title/Abstract] OR telemonitor[Title/Abstract] OR tele-monitor[Title/Abstract] OR telemonitoring[Title/Abstract] OR twitter[Title/Abstract] OR web[Title/Abstract] OR web-based[Title/Abstract] OR website[Title/Abstract] OR wireless[Title/Abstract] OR WeChat[Title/Abstract] **#2** "Urinary Incontinence"[Mesh] OR "Urinary Incontinence, Urge"[Mesh] OR "Urinary Incontinence, Stress"[Mesh] OR urine incontinence[Title/Abstract] OR urinary incontinence[Title/Abstract] OR urinary incontinence*[Title/Abstract] OR urine incon*[Title/Abstract] OR incontinence, urinary[Title/Abstract] OR urinary incontinence, stress[Title/Abstract] OR urinary stress incontinence[Title/Abstract] OR incontinence, urinary stress[Title/Abstract] OR stress incontinence, urinary[Title/Abstract] OR stress incontinence[Title/Abstract] OR urinary incontinence, urge[Title/Abstract] OR urinary urgency[Title/Abstract] OR urinary urge incontinence[Title/Abstract] OR urge urinary incontinence[Title/Abstract] OR urgency urinary incontinence[Title/Abstract] OR incontinence, urge[Title/Abstract] OR urge incontinence[Title/Abstract] OR urinary reflex incontinence[Title/Abstract] OR incontinence, urinary reflex[Title/Abstract] OR reflex incontinence[Title/Abstract] OR mixed incontinence[Title/Abstract] OR mixed urinary incontinence[Title/Abstract] OR involuntary leakage[Title/Abstract] **#3** "Randomized Controlled Trial" [Publication Type] OR "Randomized Controlled Trials as Topic"[Mesh] OR Clinical Trials, Randomized[Title/Abstract] OR Trials, Randomized Clinical[Title/Abstract] OR Controlled Clinical Trials, Randomized[Title/Abstract] OR RCT[Title/Abstract] **#1** AND **#2** AND **#3** Filters applied: Female.
CNKI	SU=('远程医疗'+'远程健康'+'电子健康'+'移动健康'+'移动医疗'+'互联网医疗'+'远程咨询'+'远程医疗咨询'+'可穿戴电子设备'+'社交媒体'+'多媒体'+'App'+'移动应用'+'移动应用程序'+'移动设备'+'手机'+'智能手机'+'电话'+ '电子游戏'+'计算机游戏'+'基于互联网'+'基于网络'+'基于计算机'+'视频会议'+'网站'+'网络'+'社交网络'+'网络平台'+'移动网络'+'在线'+'线上'+'互联网'+'微信'+'QQ'+'论坛'+'平台') and SU=('失禁'+'尿失禁'+'漏尿'+'压力性尿失禁'+'急迫性尿失禁'+'混合性尿失禁') and TKA=('随机对照试验'+'随机分配'+'随机'+'临床应用')

Screening and selection procedures for eligible studies

EndNote X9 will be used to manage the retrieved studies, where duplicate references will be identified and removed by using the automated “Find Duplicates”

function. A two-stage process will be used to determine the eligibility of each publication. In the first stage, two independent reviewers will screen the titles and abstracts of the papers retrieved, and an article will be temporarily retained if either of the two reviewers considers it to be potentially eligible for inclusion. The authors of potentially eligible studies for which the full text is not available will be contacted via email to seek either the full text or their research data. In the second stage, the full texts of the remaining studies will be read. Discussions will be used to reach a consensus if there are any discrepancies at the full-text level. Consultation by a third reviewer will be performed if necessary when an agreement cannot be reached through discussion alone. The article selection process and reasons for excluding studies will be showed in a PRISMA flow diagram (Figure 1).

Data abstraction

Two different reviewers will extract the data into a purpose-built, structured sheet, and any discrepancies will be resolved through arbitration and consensus among the members of our research team. Beforehand, the data extraction sheet will be first piloted with a subsample of included studies and then revised and refined as necessary. If studies report outcomes at different time points, the outcomes evaluated at immediate post-intervention termination will be extracted, for the effect sizes observed at the end of the intervention are considered the most pertinent measures of potential benefits. The following information will be collected from eligible studies:

(1) The general information of the study: first author, study country, and publication year;

(2) The baseline characteristics of participants: type of UI, diagnostic criteria, mean age, and sample size;

(3) The details of the WBIs: the intervention's name, detailed regimen, duration, format (personalized or non-personalized), interactivity (interactive or non-interactive), and main technology;

(4) The intervention regimen of the control group;

(5) The details of the outcome: data on outcomes, measurement tools, between-group difference (+ /-), evaluation time points;

(6) Adverse events;

and (7) The attrition rate.

Quality appraisal

The quality of the included studies will be assessed independently by two investigators through the Cochrane Collaboration's tool [32]. This tool consists of seven items: random sequence generation (selection bias), concealment of allocation (selection bias), blinding of the subjects and personnel (performance bias), outcome assessor blinding (detection bias), completeness of follow-up (attrition bias), selective reports (reporting bias), and other biases. Each item will be rated as 'low', 'unclear', or 'high' risk of bias. Any disagreements will be settled by discussion with a third reviewer.

Statistics analysis

Data synthesis

Where possible, meta-analysis will be conducted to combine the data. We will utilize mean differences with 95% confidence intervals for continuous variables that were assessed with the same instrument and standardised mean differences with 95% confidence intervals when a similar outcome was measured with different instruments. The mean differences/standardised mean differences between the intervention and control groups will be calculated based on the $\text{Mean}_{\text{change}}$ ($\text{Mean}_{\text{change}} = \text{Mean}_{\text{after}} - \text{Mean}_{\text{baseline}}$) and the corresponding standard deviation $(\text{SD})_{\text{change}}$ ($\text{SD}_{\text{change}} = \sqrt{[\text{SD}^2_{\text{baseline}} + \text{SD}^2_{\text{after}} - (2 * 0.5 * \text{SD}_{\text{baseline}} * \text{SD}_{\text{after}})]}$) [33]. The effect size of standardized mean differences is reported as small (<0.2), moderate (0.2–0.8), or large (>0.8) based on Cohen's definition [33]. Regarding binary variables, we will choose relative risks with 95% confidence intervals as the point estimate, with the cut-off values of 1.22, 1.86, and 3.00 denoting small, medium, and large effects, respectively [34]. The Mantel-Haenszel method will be employed to combine dichotomous outcome data, and the Inverse Variance method will be employed for pooling continuous outcome data. All statistical analyses will be performed using Stata, version 12.0 (Stata Corp., College Station, TX, USA). Statistical significance will be defined as a p value < 0.05. For outcomes that cannot be quantitatively

synthesized in a meta-analysis because of insufficient data (less than three studies report the data), high heterogeneity of effect measures, or other reasons, a narrative approach will be utilized for describing and summarizing.

Assessment of heterogeneity

The degree of heterogeneity across studies will be assessed using both the χ^2 test and the I^2 test. According to the Cochrane Handbook, Higgins I^2 from 0% to 40% means that there is insignificant heterogeneity, from 30% to 60% indicates that there is moderate heterogeneity, from 50% to 90% represents that there is substantial heterogeneity, and > 75% manifests that there is high heterogeneity [33]. A fixed-effects model will be chosen for analysis only when no substantial heterogeneity exists ($p \geq 0.1$ and $I^2 \leq 50\%$), whereas a random-effects model will be used if there is significant heterogeneity ($p < 0.1$ and $I^2 > 50\%$), since it can provide more cautious summary effect estimates and is preferred when there is unexplained heterogeneity across studies [33].

Sensitivity analysis

Sensitivity analyses will be performed by excluding one study at a time to determine if any individual study has a significant impact on the merged results. A comparison will be made between the merged results prior to the modifications and the adjusted results in order to identify the potential sources of heterogeneity.

Publication bias

Publication bias assessment of an outcome will be detected by using the funnel plot and Egger test when the number of included studies reaches or exceeds ten.

Subgroup analyses

Three subgroup analyses will be carried out to investigate the influence of the type of format (personalised and non-personalised), type of interactivity (interactive and non-interactive), and main technology (such as mobile applications and websites) on the effects of WBIs on primary outcomes, thereby attempting to explore an optimal WBIs regimen for women with UI.

Patient and public involvement

This review will be based solely on publicly accessible studies. Thus, no patient

or member of the public will direct involvement in the design, implementation, reporting, or dissemination of the study.

Validity, reliability, and rigour

The present study protocol was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Protocol Statement Guidelines (PRISMA-P) (see Supplemental file). We will conduct and report the systematic review strictly in accordance with the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions and the guidelines of the PRISMA statement to ensure its validity, reliability, and rigor.

DISCUSSION

As one of the most common chronic diseases among women, UI can cause many physical, mental, and social discomforts for individuals and result in huge financial burdens on families and society as a whole [6-10]. Although the traditional face-to-face mode of UI management is effective [12], it demands substantial human and financial inputs [18, 19]. WBIs have drawn great attention from the medical and hygiene fields due to their advantages of high accessibility and efficiency [16, 24, 25]. Recently, some researchers have attempted to use WBIs to manage UI for women, but the effectiveness of WBIs among this crowd has remained inconclusive [26-30], and even the existing relevant systematic reviews failed to arrive at a consensus on this matter [20-23, 31], which impedes clinical decision-making and limits the widespread application of WBIs. Accordingly, this paper presents a protocol for a systematic review and meta-analyses that will summarize the related evidence by systematically reviewing previous RCTs regarding the effectiveness of WBIs in women with UI. It is anticipated that the findings of the future systematic review will allow for more considerate and insightful recommendations when advising UI women with effective management strategies.

With regard to selecting outcomes, since self-reported symptom severity and condition-specific QoL can appropriately reflect the impacts of UI on women's physical health, mental health, and social engagement and play crucial roles in determining whether additional treatments are warranted [35], and adherence to

PFMT represents a fundamental element of the effectiveness of a PFMT program [13], the future systematic review will adopt self-reported symptom severity, condition-specific QoL, and adherence to PFMT as the primary outcomes. In the meantime, a wide range of secondary outcomes will also be evaluated to enhance the overall comprehension of the WBIs' effectiveness in managing UI for women. Consequently, the findings of this review will provide more solid evidence and comprehensive references on whether WBIs should be extensively suggested in the future for women's UI management in clinical settings.

Additionally, subgroup analyses based on the interactivity, format, and main technology of WBIs will be conducted. It is expected that the corresponding results can aid healthcare providers in developing and implementing an optimal WBIs program for UI women, thereby generating maximum benefits for the intended audiences, medical staff, and other related stakeholders.

Nonetheless, we have recognized some potential limitations of this review. Firstly, the use of web-based technologies in healthcare is a developing field, so there might be limited studies available on this topic. Secondly, some studies in other languages can be overlooked because this review will only include RCTs published in English and Chinese. Thirdly, heterogeneity will exist inevitably in meta-analysis in terms of the variation of clinical and methodological characteristics. For instance, the diversity of UI types and duration of WBI characteristics will lead to heterogeneity. Thus, we intend to carry out leave-one-out sensitivity analysis to evaluate the stability of pooled results and identify potential sources of heterogeneity.

ETHICS AND DISSEMINATION

Ethical approval and participant consent will not be required since this study will consist of a secondary analysis of published evidence and not contain any private information about participants.The findings will be disseminated via a peer-reviewed journal or an international conference.

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Contributors Xuefen Xu: Conceptualization, Visualization, Investigation, Writing - original draft. Pingping Guo: Conceptualization, Visualization, Writing - review & editing. Ping Xu: Investigation, Writing - review & editing. Dandan Chen: Investigation, Writing - review & editing. Weijing Chen: Formal analysis, Writing - review & editing. Hongyan Wang: Formal analysis, Writing - review & editing. Ying Jin: Formal analysis, Writing - review & editing. Xiaojuan Wang: Funding acquisition, Writing - review & editing. Wei Zhang: Funding acquisition, Writing - review & editing. Fang Xie: Funding acquisition, Writing - review & editing. Rujia Zhao: Funding acquisition, Writing - review & editing. Minna Mao: Funding acquisition, Writing - review & editing. Suwen Feng: Conceptualization, Visualization, Writing - review & editing.

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ORCID ID

Xuefen Xu https://orcid.org/0009-0004-4637-6617

Pingping Guo https://orcid.org/0000-0002-5091-9387

Ping Xu https://orcid.org/0000-0002-2434-8437

Dandan Chen https://orcid.org/0000-0003-4488-5624

Ying Jin https://orcid.org/0000-0003-4073-1732

Xiaojuan Wang https://orcid.org/0000-0002-1947-5140

Wei Zhang https://orcid.org/0000-0001-9884-0494

Fang Xie https://orcid.org/0000-0002-5327-764X

Minna Mao https://orcid.org/0000-0001-7413-1554

Rujia Zhao https://orcid.org/0009-0002-1624-5427

Suwen Feng https://orcid.org/0000-0002-0883-0418

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580

Figure Legend

Figure 1. Flow diagram of article selection process.

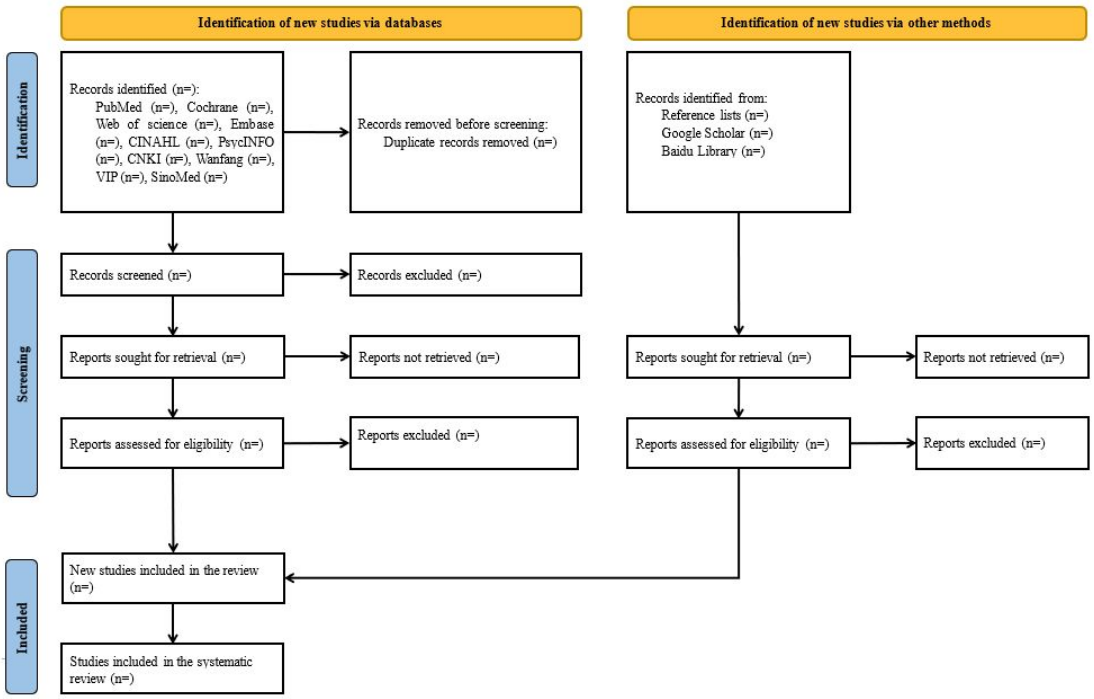

FIGURE 1 Flow diagram of article selection process.

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

Section/Topic	Item No	Item	Reported on Page Number/Line Number (P/L)	Reported on Section/Paragraph
ADMINISTRATIVE INFORMATION				
Title	1a	Identification - identify the report as a protocol of a systematic review	P3/L44	Title
	1b	Update - if the protocol is for an update of a previous systematic review, identify as such	Non-update	Non-update
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	P3/L71	Abstract/Cover Letter
Authors	3a	Contact - provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Title page	Title page
	3b	Contributions - describe contributions of protocol authors and identify the guarantor of the review	P17/L425	Contributions
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	Non-amendments	Non-amendments
Support	5a	Sources - indicate sources of financial or other support for the review	P17/L436-440	Funding
	5b	Sponsor - provide name for the review funder and/or sponsor	P17/L436-440	Funding
	5c	Role of sponsor or funder - describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	P17/L436-440	Funding
INTRODUCTION				
Rationale	6	Describe the rationale for the review in the context of what is already known	P4-8/L87-199	Introduction
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants,interventions, comparators, and outcomes (PICO)	P8/L201-209	Objectives
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	P8-9/L217-251	Eligibility criteria
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	P9-11/L252-271	Information sources and search strategy
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	P10-11/L2[illegible]	Table 1
Study records	11a	Data management - describe the mechanism(s) that will be used to manage records and data throughout the review	P12-13/L286-306	Data abstraction
	11b	Selection process - state the process that will be used for selecting studies (such as two independent	P11-12/L272-285	Screening and

		reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)		selection procedures for eligible studies
	11c	Data collection process - 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	P12-13/L286-306	Data abstraction
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	P12-13/L286-306	Data abstraction
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	P9/L233-238 P15-16/L377-402	Eligibility criteria Discussion
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	P13/L315-325	Quality appraisal
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	P13/L327-333	Statistics analysis
	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)	P13/L327-333	Statistics analysis
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	P14/L349-353, L357-362	Statistics analysis
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	P13-14/L334-337	Statistics analysis
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	P14/L354-356	Statistics analysis
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Not conducted	Not conducted

* 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.

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.

BMJ Open

Effectiveness of web-based interventions for women with urinary incontinence: Protocol for a systematic review and meta-analysis of randomized controlled trials

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Title Page

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Names of Authors:

1. Xuefen Xu[a†],
E-mail: *5613024@zju.edu.cn*
2. Pingping Guo[a,b†],
E-mail: *12118394@zju.edu.cn*
[†]Xuefen Xu and Pingping Guo contributed equally to this work and should be considered as joint first authors.
3. Ping Xu[a,b],
E-mail: *12018383@zju.edu.cn*
4. Dandan Chen[b],
E-mail: *11918475@zju.edu.cn*
5. Weijing Chen[c],
E-mail: *2270712704@qq.com*
6. Hongyan Wang[a],
E-mail: *whysammy@163.com*
7. Ying Jin[a],
E-mail: jinyin@zju.edu.cn
8. Xiaojuan Wang[a,b],
E-mail: *11818206@zju.edu.cn*
9. Wei Zhang[a,b],

E-mail: *12018379@zju.edu.cn*

10. Fang Xie[a,b],

E-mail: *fangxie@zju.edu.cn*

11. Minna Mao[a,b],

E-mail: *22118796@zju.edu.cn*

12. Rujia Zhao[a,b],

E-mail: *zhaorujia0721@163.com*

13. **Corresponding author:** Suwen Feng[a*], Professor of Nursing, tutor for graduates

[*] Corresponding author at: Women's Hospital, Zhejiang University School of Medicine, No.1 Xue Shi Road, Hangzhou, Zhejiang Province 310006, China.

E-mail addresses: *fengsw@zju.edu.cn.*

Telephone：+86 *139 5716 8708*

Addresses of the Institutions:

[a]Women's Hospital, Zhejiang University School of Medicine, Hangzhou, China.

[b]Faculty of Nursing, Zhejiang University School of Medicine, Hangzhou, China.

[c]Department of Obstetrics, The First Affiliated Hospital of Wenzhou Medical University, Wenzhou, China.

Effectiveness of web-based interventions for women with urinary incontinence: Protocol for a systematic review and meta-analysis of randomized controlled trials

Abstract

Introduction Urinary incontinence (UI) is one of the most common chronic diseases among women, which can endanger their physical and mental health and incur a heavy financial burden on both individuals and society. Web-based interventions (WBIs) have been applied to manage women's UI, but their effectiveness has remained inconclusive. This systematic review and meta-analysis aims to explore the effectiveness of WBIs on self-reported symptom severity, condition-specific quality of life, adherence to pelvic floor muscle training (primary outcomes), and other extensive secondary outcomes among women with UI. We also aimed to investigate whether intervention characteristics (format, interactivity, and main technology) have impacts on the effectiveness of primary outcomes.

Methods and analysis This systematic review protocol was developed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols guidelines. Ten electronic databases will be comprehensively searched from their inception to May 1, 2024, along with grey literature searches and manual reviews of relevant reference lists to identify eligible randomized controlled trials. The methodological quality of the included studies will be assessed by two reviewers based on the Cochrane Risk of Bias Tool. Meta-analyses will be conducted via Stata 12.0. Leave-one-out sensitivity analyses will be performed, and publication bias will be evaluated using funnel plots and Egger's test. Subgroup analyses regarding intervention format, interactivity, and main technology will be carried out.

Results Whether WBIs are effective for women's UI management and which type of intervention regimen is optimal will be reported upon the completion of this study.

Ethics and dissemination No ethics approval is needed for this review since no primary data are to be collected. The results of this review will help develop an

optimal WBI for women with UI, thereby providing them with maximum benefits. The findings will be disseminated via a peer-reviewed journal or conference presentation.

PROSPERO Registration Number: CRD42023435047.

STRENGTHS AND LIMITATIONS OF THIS STUDY

► This systematic review protocol strictly adheres to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols guidelines to ensure quality in all aspects of study planning, execution, and reporting.

► We will apply a broad search strategy to search ten electronic databases.

► Subgroup analyses regarding intervention format, interactivity, and main technology will be conducted if possible to provide scientific evidence for researchers and healthcare professionals to optimize the web-based intervention regimen.

► Anticipated high heterogeneity across available studies may increase the difficulty in interpreting a meta-analysis.

► Another potential limitation of this systematic review may be the introduction of language bias since the search will be restricted to studies published in English and Chinese.

INTRODUCTION

Urinary incontinence (UI) is defined by the International Urogynecological Association and the International Continence Society as “complaints of any involuntary leakage of urine” [1]. It is one of the common chronic diseases that endanger women's health, affecting at least 200 million women around the world [2]. Estimates of the prevalence of UI are contested and vary widely (from 5% to 70% globally) depending on the definition applied, population investigated, and measurement tools used [3], with most studies reporting a prevalence of any UI in the range of 25–45% [4]. Worse still, this prevalence is expected to be higher among women who have risk factors such as being overweight or obese and having a higher

parity, and estimates rise with each decade of life as a consequence of the aging population [5]. In short, UI has become a key public health and social problem around the world.

Although UI is not life-threatening, it can be a debilitating condition that significantly impacts the quality of life in both physical and psychological aspects for the majority of women affected. Evidence reveals that UI interferes with women's daily lives, including work, household duties, recreational life, and even sleep, and makes them suffer from psychological distress (such as embarrassment, low self-esteem, and depression) [6]. It is also closely associated with numerous severe medical conditions (e.g., urinary tract infections, perineal dermatitis, and pressure wounds) [7]. In the medium or long term, UI in older women significantly increases the risk of falls and being referred to nursing homes [7]. Furthermore, women with UI often find themselves socially isolated and relatively inactive [6], leading to an increased risk of suicide [8]. From the perspective of economics, UI imposes a considerable financial burden on both individuals and the healthcare system. For example, the USA allocates approximately $12 billion annually to cover expenses related to therapeutic management, absenteeism, and disability associated with UI [9], and in the UK, the expenditure exclusively on UI containment products, such as absorbent pads, amounts to approximately £80 million per year [10]. Considering the substantial adverse consequences that UI may cause, it is crucial to take measures to manage UI effectively.

Existing evidence-based UI treatments can be broadly separated into surgeries, pharmaceutical therapies, and conservative pelvic floor rehabilitation treatments (hereinafter referred to as conservative treatments) [11]. Incontinence surgeries and pharmaceutical therapies often exhibit only modest effectiveness but commonly lead to several side effects [12]. In contrast, conservative treatments, which mainly include pelvic floor muscle training (PFMT), lifestyle intervention (such as weight loss,

smoking cessation, and fluid intake management), bladder training, and electrical stimulation, are considered to be relatively low-risk, cheaper, and can be initiated by most women without extensive preliminary evaluation [12]; these advantages make them seem more attractive in UI treatments than surgeries and pharmaceutical therapies [13]. Substantial evidence has demonstrated that conservative treatments can cure or ameliorate symptoms in about two-thirds of patients with UI [14, 15], thereby reducing disease burden and optimizing health outcomes. It is particularly noteworthy that PFMT has been recommended by the International Continence Society as the first-line treatment for UI since 2005 [14]. However, despite the existence of several effective UI treatments, the uptake of professional treatments is poor. It is reported that only a small percentage (around 25%–30%) of women with UI seek professional help [16], which could be attributed to the fact that most UI treatments are currently typically administered through "face-to-face" sessions by professional physiotherapists or registered nurses in clinics or hospitals [12], with the stigma of UI, inconvenient traffic, time constraints, and high medical costs constituting the main obstacles to their uptake [17-19]. Meanwhile, most healthcare settings do not routinely provide treatments and management practices for patients with UI due to limited human and material resources [20]. Given the multiple deficiencies of the traditional mode of UI management, it is imperative to identify a more feasible, expandable, sustainable, affordable, and privacy-friendly mode of care to manage UI among women effectively and simultaneously alleviate the healthcare system's burden without affecting its current services or compromising care quality.

Web-based interventions (WBIs), referring to achieving specific health objectives via web-connected devices like smartphones, computers, and laptops [17, 21], might be an effective complement and alternative to narrow the aforementioned gaps and manage women's UI more effectively through an innovative delivery mode. The benefits of interventions that are delivered via the web include anonymity, relatively

low cost, and convenience because they enable individuals to receive interventions at anytime and anywhere without face-to-face contact with professionals [22-24], thereby reducing stigma, transportation costs, and waiting time for treatments, which are particularly suitable for those with busy schedules or who require flexibility owing to work and family responsibilities. Recent systematic reviews have demonstrated that WBIs can enhance health outcomes among patients with chronic diseases such as diabetes [25] and dementia [26].

Moreover, with the rapid growth of internet access rates worldwide and the popularization of web-based devices, the practical feasibility of WBIs has increased [17, 25, 26]. In recent years, the increasing number of randomized controlled trials (RCTs) [27-31] related to WBIs on women's UI, in particular in the context of the COVID-19 pandemic, has demonstrated a growing need for supplementary strategies that can enhance existing services and provide better assistance to UI management for women. Nevertheless, the findings about the effects of WBIs on ameliorating health outcomes for UI women are not consistent. For instance, some trials reported that, compared with the control group, WBIs significantly improved self-reported symptom severity [28, 30], condition-specific quality of life (QoL) [27], and adherence to PFMT [27, 30] for women with UI. On the contrary, some studies [29, 31] found no significant differences in self-reported symptom severity, condition-specific QoL, or adherence to PFMT between the WBIs and control groups.

Currently, there are five systematic reviews of WBIs for women with UI. Two reviews only focus on the effects of mobile applications on the UI. Among them, Widdison et al. [24] included four trials, and Leme Nagib et al. [21] included three RCTs, both of which indicated that WBIs had significant improvements in self-reported symptom severity, condition-specific QoL, and adherence to PFMT. Yet, both reviews included male and female UI patients but did not report outcomes separately for women. Similarly, Hou et al. [32] included six RCTs and only assessed

the effectiveness of mobile application-delivered PFMT for stress UI in women and reported significant improvement in self-reported symptom severity, condition-specific QoL, adherence to PFMT, and the global impression of improvement. Nevertheless, the certainty of the findings from the above three reviews is limited, as the authors only provided a narrative description of the results but did not conduct any quantitative syntheses, mainly due to the limited number of studies for each outcome. In another systematic review and meta-analysis conducted by Huang et al. [22] (n = 7 RCTs), the effects of telemedicine for UI in women were investigated, with the results indicating reductions in self-reported symptom severity, anxiety, and depression, as well as improvements in QoL, self-efficacy of PFMT, and the global impression of improvement for the targeted population. However, caution should be exercised when interpreting the results of this review, as it conflated early mobile technologies (such as telephone calls) with web-based technologies. Interestingly, the results of Papanikolaou et al.'s systematic review and meta-analysis [23] (n = 10 RCTs) contradicted the above four reviews by showing no significant difference in self-reported symptom severity, condition-specific QoL, or adherence to PFMT between WBIs and the control group. On the whole, the findings across existing systematic reviews pertaining to this topic are lacking in congruity, with certain outcomes such as pelvic floor muscle contractility, incontinence episode frequency, usage rate of incontinence aids, and satisfaction with the intervention being rarely evaluated. Moreover, all of these reviews incorporated a restricted quantity of primary studies (n ≤ 10), while an increasing number of RCTs [27-31] concerning this topic were being published after them, which could offer novel evidence. Accordingly, the effects of WBIs on women with UI need further exploration.

OBJECTIVES

The purpose of this systematic review and meta-analysis is to investigate the

effectiveness of WBIs for women with UI based on all available evidence from RCTs. Specifically, our proposed review seeks to answer the following questions: (a) Whether WBIs can effectively mitigate self-reported symptom severity, improve condition-specific QoL, and increase adherence to PFMT (primary question); (b) Whether specific types of intervention format, intervention interactivity, and main technology have beneficial effects on these outcomes (secondary question 1); and (c) Are WBIs effective on other extensive secondary outcomes among women with UI (secondary question 2).

METHODS AND ANALYSIS

Registration

This systematic review and meta-analysis has been prospectively registered on the platform of the International Prospective Register of Systematic Reviews (PROSPERO). The registration number is CRD42023435047. Any future changes to the study protocol will be registered as amendments.

Eligibility criteria

The PICOS approach will be used for eligibility criteria. The details are described as follows:

P (Population)

Female adults diagnosed with any type of UI will be considered eligible. However, women affected by UI arising from non-urinary tract factors will be excluded, such as cancer or radiotherapy-induced symptoms, neurological, cognitive or psychological disorders, and diseases hindering independent mobility. Also, studies that involved women with various types of lower urinary tract symptoms but did not report the data specific to women with UI separately will be excluded.

I (Intervention)

The intervention should be in a digital format using any web-based technologies, including but not limited to websites and mobile applications, with or without an

intravaginal digital device connection. Nevertheless, studies will be excluded if they solely utilize WBIs to observe the maintenance effects of previously administered health interventions, compare different types of program- or module-specific WBIs, involve face-to-face components in addition to the same routine care received by the control group, or do not conduct real WBIs (such as by adopting telephone call, short message, or digital video disk for intervention).

C (Control)

The control group can be usual care, a waitlist, no treatment, or minimal WBIs (such as hyperlinks to brief informational websites or an application that delivers concise information).

O (Outcome)

The primary outcomes are self-reported symptom severity, condition-specific QoL, and adherence to PFMT. Secondary outcomes will include pelvic floor muscle contractility evaluated by digital palpation (focusing on four out of the six domains of the PERFECT assessment scheme: power, endurance, repetition, and fast), incontinence episode frequency, urine leakage volume (measured via the pad-weighing test), usage rate of incontinence aids, the global impression of improvement, disease-related knowledge, self-efficacy of PFMT, mental health (anxiety and depression), and satisfaction with intervention. Studies that assess at least one of the aforementioned outcomes will be recognized as qualified.

S (Study design)

This systematic review will only include RCTs with full-text research papers available. Studies published in English and Chinese will be included.

Information sources and search strategy

The three-step approach to literature search recommended by the Joanna Briggs Institute will be used to identify studies that are relevant to the review questions. Step 1: An initial search has been conducted only on PubMed and CNKI, followed by an

analysis of the text words in the titles and abstracts of the retrieved publications, as well as the corresponding Medical Subject Heading (MeSH) terms to describe them. Step 2: Based on the results of the initial search modification and additional keywords, we will collaborate with an academic librarian to develop customized search strategies for each electronic database. A combination of MeSH terms and free text keywords will be applied where appropriate to represent the definitions of WBIs, UI, and RCT if possible. Table 1 shows the detailed search strategies of PubMed and CNKI. Ten electronic databases are anticipated to be comprehensively searched from their inception to May 1, 2024, by two authors independently, including six English databases (PubMed, Embase, the Cochrane Library, Web of Science, PsycINFO, and CINAHL) and four Chinese databases (CNKI, Wanfang Data, VIP, and SinoMed). Step 3: Google Scholar and Baidu Library sources will be searched for grey literature. The reference lists of all eligible articles and relevant reviews will be manually examined to expand the scope of our search and retrieve additional eligible studies.

Table 1. Literature search strategy.

Electronic database	Search terms
Pubmed	**#1** "Mobile Applications"[Mesh] OR "Telemedicine"[Mesh] OR "Internet"[Mesh] OR "Computers"[Mesh] OR "Telecommunications"[Mesh] OR "Online Systems"[Mesh] OR "Software"[Mesh] OR "Wireless Technology"[Mesh] OR "Cell Phone"[Mesh] OR app[Title/Abstract] OR apps[Title/Abstract] OR application[Title/Abstract] OR applications[Title/Abstract] OR ipad[Title/Abstract] OR blog[Title/Abstract] OR blogging[Title/Abstract] OR computer[Title/Abstract] OR computer interface[Title/Abstract] OR cell phones[Title/Abstract] OR cell phone[Title/Abstract] OR cellular phone[Title/Abstract] OR digital[Title/Abstract] OR digital health[Title/Abstract] OR digital-health[Title/Abstract] OR ehealth[Title/Abstract] OR e-health[Title/Abstract] OR e-mail[Title/Abstract] OR electronic[Title/Abstract] OR E-learning[Title/Abstract] OR Facebook[Title/Abstract] OR health, mobile[Title/Abstract] OR health technolog[Title/Abstract] OR health app[Title/Abstract] OR Internet[Title/Abstract] OR Internet forum[Title/Abstract] OR iphone[Title/Abstract] OR i phone[Title/Abstract] OR i-phone[Title/Abstract] OR ipad[Title/Abstract] OR i pad[Title/Abstract] OR i-pad[Title/Abstract] OR laptop[Title/Abstract] OR linkedin[Title/Abstract] OR mobile[Title/Abstract] OR mobile application[Title/Abstract] OR mobile apps[Title/Abstract] OR mobile app[Title/Abstract] OR mobile phone[Title/Abstract] OR mobile phones[Title/Abstract] OR

	mhealth[Title/Abstract] OR m-health[Title/Abstract] OR mobile health[Title/Abstract] OR mobile electronic device[Title/Abstract] OR mobile technolog[Title/Abstract] OR mobile communication[Title/Abstract] OR mobile computing[Title/Abstract] OR network[Title/Abstract] OR online[Title/Abstract] OR online intervention[Title/Abstract] OR online interventions[Title/Abstract] OR platform[Title/Abstract] OR personal computer[Title/Abstract] OR personal digital assistant[Title/Abstract] OR QQ[Title/Abstract] OR remote[Title/Abstract] OR smartphone[Title/Abstract] OR smart phone[Title/Abstract] OR social media[Title/Abstract] OR social networking[Title/Abstract] OR telehealth[Title/Abstract] OR tele-health[Title/Abstract] OR telephone[Title/Abstract] OR telemedicine[Title/Abstract] OR tele-medicine[Title/Abstract] OR tele-care[Title/Abstract] OR telecare[Title/Abstract] OR telecommunication[Title/Abstract] OR telemonitor[Title/Abstract] OR tele-monitor[Title/Abstract] OR telemonitoring[Title/Abstract] OR twitter[Title/Abstract] OR web[Title/Abstract] OR web-based[Title/Abstract] OR website[Title/Abstract] OR wireless[Title/Abstract] OR WeChat[Title/Abstract] **#2** "Urinary Incontinence"[Mesh] OR "Urinary Incontinence, Urge"[Mesh] OR "Urinary Incontinence, Stress"[Mesh] OR urine incontinence[Title/Abstract] OR urinary incontinence[Title/Abstract] OR urinary incontinence*[Title/Abstract] OR urine incon*[Title/Abstract] OR incontinence, urinary[Title/Abstract] OR urinary incontinence, stress[Title/Abstract] OR urinary stress incontinence[Title/Abstract] OR incontinence, urinary stress[Title/Abstract] OR stress incontinence, urinary[Title/Abstract] OR stress incontinence[Title/Abstract] OR urinary incontinence, urge[Title/Abstract] OR urinary urgency[Title/Abstract] OR urinary urge incontinence[Title/Abstract] OR urge urinary incontinence[Title/Abstract] OR urgency urinary incontinence[Title/Abstract] OR incontinence, urge[Title/Abstract] OR urge incontinence[Title/Abstract] OR urinary reflex incontinence[Title/Abstract] OR incontinence, urinary reflex[Title/Abstract] OR reflex incontinence[Title/Abstract] OR mixed incontinence[Title/Abstract] OR mixed urinary incontinence[Title/Abstract] OR involuntary leakage[Title/Abstract] **#3** "Randomized Controlled Trial" [Publication Type] OR "Randomized Controlled Trials as Topic"[Mesh] OR Clinical Trials, Randomized[Title/Abstract] OR Trials, Randomized Clinical[Title/Abstract] OR Controlled Clinical Trials, Randomized[Title/Abstract] OR RCT[Title/Abstract] **#1** AND **#2** AND **#3** Filters applied: Female.
CNKI	SU=('远程医疗'+'远程健康'+'电子健康'+'移动健康'+'移动医疗'+'互联网医疗'+'远程咨询'+'远程医疗咨询'+'可穿戴电子设备'+'社交媒体'+'多媒体'+'App'+'移动应用'+'移动应用程序'+'移动设备'+'手机'+'智能手机'+'电话'+ '电子游戏'+'计算机游戏'+'基于互联网'+'基于网络'+'基于计算机'+'视频会议'+'网站'+'网络'+'社交网络'+'网络平台'+'移动网络'+'在线'+'线上'+'互联网'+'微信'+'QQ'+'论坛'+'平台') and SU=('失禁'+'尿失禁'+'漏尿'+'压力性尿失禁'+'急迫性尿失禁'+'混合性尿失禁') and TKA=('随机对照试验'+'随机分配'+'随机'+'临床应用')

Screening and selection procedures for eligible studies

EndNote X9 will be used to manage the retrieved studies, where duplicate references will be identified and removed by using the automated “Find Duplicates”

function. A two-stage process will be used to determine the eligibility of each publication. In the first stage, two independent reviewers will screen the titles and abstracts of the papers retrieved and an article will be temporarily retained if either of the two reviewers considers it to be potentially eligible for inclusion. The authors of potentially eligible studies for which the full text is not available will be contacted via email to seek either the full text or their research data. In the second stage, the full texts of the remaining studies will be read. Discussions will be used to reach a consensus if there are any discrepancies at the full-text level. Consultation by a third reviewer will be performed if necessary when an agreement cannot be reached through discussion alone.

Data abstraction

Two different reviewers will extract the data into a purpose-built, structured sheet, and any discrepancies will be resolved through arbitration and consensus among the members of our research team. Beforehand, the data extraction sheet will be first piloted with a subsample of included studies and then revised and refined as necessary. If studies report outcomes at different time points, the outcomes evaluated at immediate post-intervention termination will be extracted, for the effect sizes observed at the end of the intervention are considered the most pertinent measures of potential benefits. The following information will be collected from eligible studies:

(1) The general information of the study: first author, study country, and publication year;

(2) The baseline characteristics of participants: type of UI, diagnostic criteria, mean age, and sample size;

(3) The details of the WBIs: the intervention's name, detailed regimen, duration, format (personalized or non-personalized), interactivity (interactive or non-interactive), and main technology;

(4) The intervention regimen of the control group;

(5) The details of the outcome: data on outcomes, measurement tools, between-group difference (+ /-), evaluation time points;

(6) Adverse events;

and (7) The attrition rate.

Quality appraisal

The quality of the included studies will be assessed independently by two investigators through the Cochrane Collaboration tool [33]. This tool consists of seven items: random sequence generation (selection bias), concealment of allocation (selection bias), blinding of the subjects and personnel (performance bias), outcome assessor blinding (detection bias), completeness of follow-up (attrition bias), selective reports (reporting bias), and other biases. Each item will be rated as 'low', 'unclear', or 'high' risk of bias. Any disagreements will be settled by discussion with a third reviewer.

Statistics analysis

Data synthesis

Where possible, meta-analyses will be conducted to combine the data. We will utilize mean differences with 95% confidence intervals for continuous variables that were assessed with the same instrument and standardized mean differences with 95% confidence intervals when a similar outcome was measured with different instruments. The mean differences/standardized mean differences between the intervention and control groups will be calculated based on the $\text{Mean}_{\text{change}}$ ($\text{Mean}_{\text{change}} = \text{Mean}_{\text{after}} - \text{Mean}_{\text{baseline}}$) and the corresponding standard deviation $(\text{SD})_{\text{change}}$ ($\text{SD}_{\text{change}} = \sqrt{[\text{SD}^2_{\text{baseline}} + \text{SD}^2_{\text{after}} - (2 * r * \text{SD}_{\text{baseline}} * \text{SD}_{\text{after}})]}$) [34]. r is the correlation between the matched pairs of pre- and post-intervention assessments. In fact, it has been demonstrated that there are no significant differences in the calculated effect size between correlations = 0, 0.3, and 0.7 [34]. In this study, a r of 0.5 was assumed for all analyses as it is the most commonly used for calculation [35, 36]. The

effect size of standardized mean differences is reported as small (<0.2), moderate (0.2–0.8), or large (>0.8) based on Cohen's definition [37]. Regarding binary variables, we will choose relative risks with 95% confidence intervals as the point estimate, with the cut-off values of 1.22, 1.86, and 3.00 denoting small, medium, and large effects, respectively [38]. The Mantel-Haenszel method will be employed to combine dichotomous outcome data, and the Inverse Variance method will be employed for pooling continuous outcome data. All statistical analyses will be performed using Stata, version 12.0 (Stata Corp., College Station, TX, USA). Statistical significance will be defined as a p-value < 0.05. For outcomes that cannot be quantitatively synthesized in a meta-analysis because of insufficient data (less than three studies report the data), high heterogeneity of effect measurement tools, or other reasons, a narrative approach will be utilized for describing and summarizing.

Assessment of heterogeneity

The degree of heterogeneity across studies will be assessed using both the χ^2 test and the I^2 test. According to the Cochrane Handbook, Higgins I^2 from 0% to 40% means that there is insignificant heterogeneity, from 30% to 60% indicates that there is moderate heterogeneity, from 50% to 90% represents that there is substantial heterogeneity, and > 75% manifests that there is high heterogeneity [37]. A fixed-effects model will be chosen for analysis only when no substantial heterogeneity exists ($p \geq 0.1$ and $I^2 \leq 50\%$), whereas a random-effects model will be used if there is significant heterogeneity ($p < 0.1$ and $I^2 > 50\%$) since it can provide more cautious summary effect estimates and is preferred when there is unexplained heterogeneity across studies [37].

Sensitivity analysis

Sensitivity analyses will be performed by excluding one study at a time to determine if any individual study has a significant impact on the merged results. A comparison will be made between the merged results prior to the modifications and

the adjusted results in order to identify the potential sources of heterogeneity.

Publication bias

Publication bias assessment of an outcome will be detected by using the funnel plot and Egger test when the number of included studies reaches or exceeds ten.

Subgroup analyses

Three subgroup analyses will be carried out to investigate the influence of the type of format (personalized and non-personalized), type of interactivity (interactive and non-interactive), and main technology (such as mobile applications and websites) on the effects of WBIs on primary outcomes, thereby attempting to explore an optimal WBIs regimen for women with UI.

Patient and public involvement

This review will be based solely on publicly accessible studies. Thus, no patient or member of the public will be directly involved in the design, implementation, reporting, or dissemination of the study.

Validity, reliability, and rigor

The present study protocol was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Protocol Statement Guidelines (PRISMA-P) (see Supplemental material). We will conduct and report the systematic review strictly in accordance with the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions and the guidelines of the PRISMA statement to ensure its validity, reliability, and rigor.

RESULTS

The article selection process and reasons for excluding studies will be shown in a PRISMA flow diagram (Figure 1). Table 2 presents the mock data extraction result sheet for the review studies. Table 3 provides an example of the methodological quality appraisal checklist that will be conducted by the reviewers.

TABLE 2 The mock data extraction result of the included studies.

First author, Country, Publication Year, Citation	Subtype of UI/ Diagnostic criteria of UI	Mean age/ Sample size (IG/ CG)	**Web-based interventions** 1. Name 2. Detailed regimen 3. Format 4. Interactivity 5. Main technology	Control group intervention	Primary outcome (Measurement tool, +/-) Secondary outcome (Measurement tool, +/-)	Outcome evaluation time point	Adverse events	Attrition rate
Study 1								
Study 2								
Study 3								
…								

Abbreviations: CG, control group; IG, intervention group; UI, urinary incontinence; +, significant between-group difference; -: non-significant between-group difference.

TABLE 3 Quality assessment for included studies.

	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessors	Incomplete outcome data	Selective reporting	Other bias
Study 1							
Study 2							
Study 3							
…							

DISCUSSION

As one of the most common chronic diseases among women, UI can cause many physical, mental, and social discomforts for individuals and result in huge financial burdens on families and society as a whole [6-10]. Although the traditional face-to-face mode of UI management is effective [12], it demands substantial human and financial inputs [19, 20]. WBIs have drawn great attention from the medical and hygiene fields due to their advantages of high accessibility and efficiency [17, 25, 26]. Recently, some researchers have attempted to use WBIs to manage UI for women, but the effectiveness of WBIs among this crowd has remained inconclusive [27-31], and even the existing relevant systematic reviews failed to arrive at a consensus on this matter [21-24, 32], which impedes clinical decision-making and limits the widespread

application of WBIs. Accordingly, this paper presents a protocol for a systematic review and meta-analyses that will summarize the related evidence by systematically reviewing previous RCTs regarding the effectiveness of WBIs in women with UI. It is anticipated that the findings of the future systematic review will allow for more considerate and insightful recommendations when advising UI women with effective management strategies.

With regard to selecting outcomes, since self-reported symptom severity and condition-specific QoL can appropriately reflect the impacts of UI on women's physical health, mental health, and social engagement and play crucial roles in determining whether additional treatments are warranted [39], and adherence to PFMT represents a fundamental element of the effectiveness of a PFMT program [14], the future systematic review will adopt self-reported symptom severity, condition-specific QoL, and adherence to PFMT as the primary outcomes. In the meantime, a wide range of secondary outcomes will also be evaluated to enhance the overall comprehension of the WBIs' effectiveness in managing UI for women. Consequently, the findings of this review will provide more solid evidence and comprehensive references on whether WBIs should be extensively suggested in the future for women's UI management in clinical settings. Furthermore, we will also collect information about the attrition rate of participants and adverse events that happened during WBIs in the data abstraction process to find out the possible disadvantages of WBIs, although they were not set as the secondary outcomes for this review, which may provide useful information for improving the WBIs regimen.

Additionally, subgroup analyses based on the interactivity, format, and main technology of WBIs will be conducted. It is expected that the corresponding results can aid healthcare providers in developing and implementing an optimal WBI program for UI women, thereby generating maximum benefits for the intended audiences, medical staff, and other related stakeholders.

Nonetheless, we have recognized some potential limitations of this review. Firstly, the use of web-based technologies in healthcare is a developing field, so there might be limited studies available on this topic. Secondly, some studies in other languages can be overlooked because this review will only include RCTs published in English and Chinese. Thirdly, heterogeneity will exist inevitably in meta-analysis in terms of the variation of clinical and methodological characteristics. For instance, the diversity of UI types and the duration of WBI characteristics will lead to heterogeneity. Thus, we intend to carry out leave-one-out sensitivity analyses to evaluate the stability of the pooled results and identify potential sources of heterogeneity.

ETHICS AND DISSEMINATION

Ethical approval and participant consent will not be required since this study will consist of a secondary analysis of published evidence and not contain any private information about participants. The findings will be disseminated via a peer-reviewed journal or an international conference.

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Contributors Xuefen Xu: Conceptualization, Visualization, Investigation, Writing - original draft. Pingping Guo: Conceptualization, Visualization, Writing - review & editing. Ping Xu: Investigation, Writing - review & editing. Dandan Chen: Investigation, Writing - review & editing. Weijing Chen: Formal analysis, Writing - review & editing. Hongyan Wang: Formal analysis, Writing - review & editing. Ying Jin: Formal analysis, Writing - review & editing. Xiaojuan Wang: Funding acquisition, Writing - review & editing. Wei Zhang: Funding acquisition, Writing - review & editing. Fang Xie: Funding acquisition, Writing - review & editing. Rujia Zhao: Funding acquisition, Writing - review & editing. Minna Mao: Funding

acquisition, Writing - review & editing. Suwen Feng: Conceptualization, Visualization, Writing - review & editing.

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ORCID ID

Xuefen Xu https://orcid.org/0009-0004-4637-6617

Pingping Guo https://orcid.org/0000-0002-5091-9387

Ping Xu https://orcid.org/0000-0002-2434-8437

Dandan Chen https://orcid.org/0000-0003-4488-5624

Ying Jin https://orcid.org/0000-0003-4073-1732

Xiaojuan Wang https://orcid.org/0000-0002-1947-5140

Wei Zhang https://orcid.org/0000-0001-9884-0494

Fang Xie https://orcid.org/0000-0002-5327-764X

Minna Mao https://orcid.org/0000-0001-7413-1554

Rujia Zhao https://orcid.org/0009-0002-1624-5427

Suwen Feng https://orcid.org/0000-0002-0883-0418

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Figure Legend

Figure 1. Flow diagram of the article selection process.

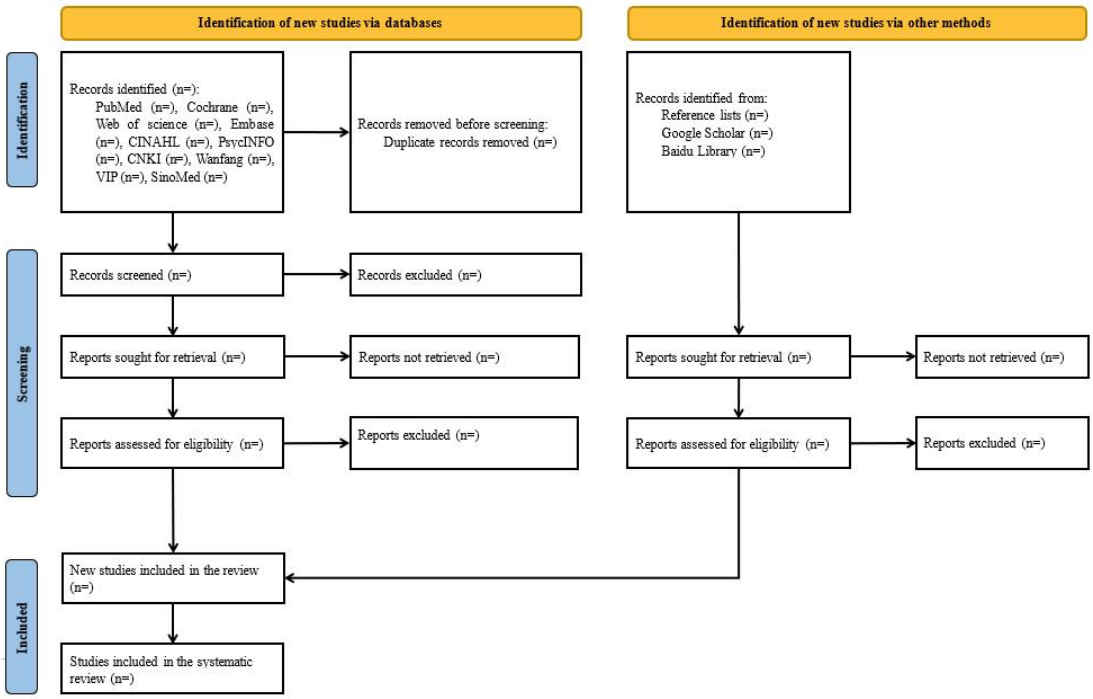

Figure 1. Flow diagram of the article selection process.

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

Section/Topic	Item No	Item	Reported on Page Number/Line Number (P/L)	Reported on Section/Paragraph
ADMINISTRATIVE INFORMATION				
Title	1a	Identification - identify the report as a protocol of a systematic review	P3/L44	Title
	1b	Update - if the protocol is for an update of a previous systematic review, identify as such	Non-update	Non-update
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	P3/L73	Abstract
Authors	3a	Contact - provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Title page	Title page
	3b	Contributions - describe contributions of protocol authors and identify the guarantor of the review	P19-20/L440-450	Contributions
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	Non-amendments	Non-amendments
Support	5a	Sources - indicate sources of financial or other support for the review	P20/L451-456	Funding
	5b	Sponsor - provide name for the review funder and/or sponsor	P20/L451-456	Funding
	5c	Role of sponsor or funder - describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	P20/L451-456	Funding
INTRODUCTION				
Rationale	6	Describe the rationale for the review in the context of what is already known	P4-8/L87-201	Introduction
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants,interventions, comparators, and outcomes (PICO)	P8-9/L202-211	Objectives
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	P9-10/L212-253	Eligibility criteria
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	P10-11/L254-271	Information sources and search strategy
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	P11/L272	Table 1
Study records	11a	Data management - describe the mechanism(s) that will be used to manage records and data throughout the review	P13-14/L286-306	Data abstraction
	11b	Selection process - state the process that will be used for selecting studies (such as two independent	P12-13/L273-285	Screening and

		reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)		selection procedures for eligible studies
	11c	Data collection process - 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	P13-14/L286-306	Data abstraction
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	P13-14/L286-306	Data abstraction
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	P10/L221-230 P18/L422-413	Eligibility criteria Discussion
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	P14/L335-345	Quality appraisal
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	P14-15/L338-352	Statistics analysis
	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)	P14-15/L338-352	Statistics analysis
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	P15-16/L338-357, 361-368,	Statistics analysis
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	P15/L338-341	Statistics analysis
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	P16/L358-360	Statistics analysis
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Not conducted	Not conducted

* 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.

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.

BMJ Open

Effectiveness of web-based interventions for women with urinary incontinence: Protocol for a systematic review and meta-analysis of randomized controlled trials

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Names of Authors:

1. Xuefen Xu[a†],
E-mail: *5613024@zju.edu.cn*
2. Pingping Guo[a,b†],
E-mail: *12118394@zju.edu.cn*
[†]Xuefen Xu and Pingping Guo contributed equally to this work and should be considered as joint first authors.
3. Ping Xu[a,b],
E-mail: *12018383@zju.edu.cn*
4. Dandan Chen[b],
E-mail: *11918475@zju.edu.cn*
5. Weijing Chen[c],
E-mail: *2270712704@qq.com*
6. Hongyan Wang[a],
E-mail: *whysammy@163.com*
7. Ying Jin[a],
E-mail: jinyin@zju.edu.cn
8. Xiaojuan Wang[a,b],
E-mail: *11818206@zju.edu.cn*
9. Wei Zhang[a,b],

E-mail: *12018379@zju.edu.cn*

10. Fang Xie[a,b],

E-mail: *fangxie@zju.edu.cn*

11. Minna Mao[a,b],

E-mail: *22118796@zju.edu.cn*

12. Rujia Zhao[a,b],

E-mail: *zhaorujia0721@163.com*

13. **Corresponding author:** Suwen Feng[a*], Professor of Nursing, tutor for graduates

[*] Corresponding author at: Women's Hospital, Zhejiang University School of Medicine, No.1 Xue Shi Road, Hangzhou, Zhejiang Province 310006, China.

E-mail addresses: *fengsw@zju.edu.cn.*

Telephone：+86 *139 5716 8708*

Addresses of the Institutions:

[a]Women's Hospital, Zhejiang University School of Medicine, Hangzhou, China.

[b]Faculty of Nursing, Zhejiang University School of Medicine, Hangzhou, China.

[c]Department of Obstetrics, The First Affiliated Hospital of Wenzhou Medical University, Wenzhou, China.

Revised manuscript (The latest version)

Effectiveness of web-based interventions for women with urinary incontinence: Protocol for a systematic review and meta-analysis of randomized controlled trials

Abstract

Introduction Urinary incontinence (UI) is one of the most common chronic diseases among women, which can endanger their physical and mental health and incur a heavy financial burden on both individuals and society. Web-based interventions (WBIs) have been applied to manage women's UI, but their effectiveness has remained inconclusive. This systematic review and meta-analysis aims to explore the effectiveness of WBIs on self-reported symptom severity, condition-specific quality of life, adherence to pelvic floor muscle training (primary outcomes), and other extensive secondary outcomes among women with UI. We also aimed to investigate whether intervention characteristics (format, interactivity, and main technology) have impacts on the effectiveness of primary outcomes.

Methods and analysis This systematic review protocol was developed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols guidelines. Ten electronic databases will be comprehensively searched from their inception to May 1, 2024, along with grey literature searches and manual reviews of relevant reference lists to identify eligible randomized controlled trials. The methodological quality of the included studies will be assessed by two reviewers based on the Cochrane Risk of Bias Tool. Meta-analyses will be conducted via Stata 12.0. Leave-one-out sensitivity analyses will be performed, and publication bias will be evaluated using funnel plots and Egger's test. Subgroup analyses regarding intervention format, interactivity, and main technology will be carried out.

Ethics and dissemination No ethics approval is needed for this review since no primary data are to be collected. The results of this review will help develop an optimal WBI for women with UI, thereby providing them with maximum benefits.

The findings will be disseminated via a peer-reviewed journal or conference presentation.

PROSPERO Registration Number: CRD42023435047.

STRENGTHS AND LIMITATIONS OF THIS STUDY

► This systematic review protocol strictly adheres to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols guidelines to ensure quality in all aspects of study planning, execution, and reporting.

► We will apply a broad search strategy to search ten electronic databases.

► Subgroup analyses regarding intervention format, interactivity, and main technology will be conducted if possible to provide scientific evidence for researchers and healthcare professionals to optimize the web-based intervention regimen.

► Anticipated high heterogeneity across available studies may increase the difficulty in interpreting a meta-analysis.

► Another potential limitation of this systematic review may be the introduction of language bias since the search will be restricted to studies published in English and Chinese.

INTRODUCTION

Urinary incontinence (UI) is defined by the International Urogynecological Association and the International Continence Society as “complaints of any involuntary leakage of urine” [1]. It is one of the common chronic diseases that endanger women's health, affecting at least 200 million women around the world [2]. Estimates of the prevalence of UI are contested and vary widely (from 5% to 70% globally) depending on the definition applied, population investigated, and measurement tools used [3], with most studies reporting a prevalence of any UI in the range of 25–45% [4]. Worse still, this prevalence is expected to be higher among women who have risk factors such as being overweight or obese and having a higher parity, and estimates rise with each decade of life as a consequence of the aging

population [5]. In short, UI has become a key public health and social problem around the world.

Although UI is not life-threatening, it can be a debilitating condition that significantly impacts the quality of life in both physical and psychological aspects for the majority of women affected. Evidence reveals that UI interferes with women's daily lives, including work, household duties, recreational life, and even sleep, and makes them suffer from psychological distress (such as embarrassment, low self-esteem, and depression) [6]. It is also closely associated with numerous severe medical conditions (e.g., urinary tract infections, perineal dermatitis, and pressure wounds) [7]. In the medium or long term, UI in older women significantly increases the risk of falls and being referred to nursing homes [7]. Furthermore, women with UI often find themselves socially isolated and relatively inactive [6], leading to an increased risk of suicide [8]. From the perspective of economics, UI imposes a considerable financial burden on both individuals and the healthcare system. For example, the USA allocates approximately $12 billion annually to cover expenses related to therapeutic management, absenteeism, and disability associated with UI [9], and in the UK, the expenditure exclusively on UI containment products, such as absorbent pads, amounts to approximately £80 million per year [10]. Considering the substantial adverse consequences that UI may cause, it is crucial to take measures to manage UI effectively.

Existing evidence-based UI treatments can be broadly separated into surgeries, pharmaceutical therapies, and conservative pelvic floor rehabilitation treatments (hereinafter referred to as conservative treatments) [11]. Incontinence surgeries and pharmaceutical therapies often exhibit only modest effectiveness but commonly lead to several side effects [12]. In contrast, conservative treatments, which mainly include pelvic floor muscle training (PFMT), lifestyle intervention (such as weight loss, smoking cessation, and fluid intake management), bladder training, and electrical

stimulation, are considered to be relatively low-risk, cheaper, and can be initiated by most women without extensive preliminary evaluation [12]; these advantages make them seem more attractive in UI treatments than surgeries and pharmaceutical therapies [13]. Substantial evidence has demonstrated that conservative treatments can cure or ameliorate symptoms in about two-thirds of patients with UI [14, 15], thereby reducing disease burden and optimizing health outcomes. It is particularly noteworthy that PFMT has been recommended by the International Continence Society as the first-line treatment for UI since 2005 [14]. However, despite the existence of several effective UI treatments, the uptake of professional treatments is poor. It is reported that only a small percentage (around 25%–30%) of women with UI seek professional help [16], which could be attributed to the fact that most UI treatments are currently typically administered through "face-to-face" sessions by professional physiotherapists or registered nurses in clinics or hospitals [12], with the stigma of UI, inconvenient traffic, time constraints, and high medical costs constituting the main obstacles to their uptake [17-19]. Meanwhile, most healthcare settings do not routinely provide treatments and management practices for patients with UI due to limited human and material resources [20]. Given the multiple deficiencies of the traditional mode of UI management, it is imperative to identify a more feasible, expandable, sustainable, affordable, and privacy-friendly mode of care to manage UI among women effectively and simultaneously alleviate the healthcare system's burden without affecting its current services or compromising care quality.

Web-based interventions (WBIs), referring to achieving specific health objectives via web-connected devices like smartphones, computers, and laptops [17, 21], might be an effective complement and alternative to narrow the aforementioned gaps and manage women's UI more effectively through an innovative delivery mode. The benefits of interventions that are delivered via the web include anonymity, relatively low cost, and convenience because they enable individuals to receive interventions at

anytime and anywhere without face-to-face contact with professionals [22-24], thereby reducing stigma, transportation costs, and waiting time for treatments, which are particularly suitable for those with busy schedules or who require flexibility owing to work and family responsibilities. Recent systematic reviews have demonstrated that WBIs can enhance health outcomes among patients with chronic diseases such as diabetes [25] and dementia [26].

Moreover, with the rapid growth of internet access rates worldwide and the popularization of web-based devices, the practical feasibility of WBIs has increased [17, 25, 26]. In recent years, the increasing number of randomized controlled trials (RCTs) [27-31] related to WBIs on women's UI, in particular in the context of the COVID-19 pandemic, has demonstrated a growing need for supplementary strategies that can enhance existing services and provide better assistance to UI management for women. Nevertheless, the findings about the effects of WBIs on ameliorating health outcomes for UI women are not consistent. For instance, some trials reported that, compared with the control group, WBIs significantly improved self-reported symptom severity [28, 30], condition-specific quality of life (QoL) [27], and adherence to PFMT [27, 30] for women with UI. On the contrary, some studies [29, 31] found no significant differences in self-reported symptom severity, condition-specific QoL, or adherence to PFMT between the WBIs and control groups.

Currently, there are five systematic reviews of WBIs for women with UI. Two reviews only focus on the effects of mobile applications on the UI. Among them, Widdison et al. [24] included four trials, and Leme Nagib et al. [21] included three RCTs, both of which indicated that WBIs had significant improvements in self-reported symptom severity, condition-specific QoL, and adherence to PFMT. Yet, both reviews included male and female UI patients but did not report outcomes separately for women. Similarly, Hou et al. [32] included six RCTs and only assessed the effectiveness of mobile application-delivered PFMT for stress UI in women and

reported significant improvement in self-reported symptom severity, condition-specific QoL, adherence to PFMT, and the global impression of improvement. Nevertheless, the certainty of the findings from the above three reviews is limited, as the authors only provided a narrative description of the results but did not conduct any quantitative syntheses, mainly due to the limited number of studies for each outcome. In another systematic review and meta-analysis conducted by Huang et al. [22] (n = 7 RCTs), the effects of telemedicine for UI in women were investigated, with the results indicating reductions in self-reported symptom severity, anxiety, and depression, as well as improvements in QoL, self-efficacy of PFMT, and the global impression of improvement for the targeted population. However, caution should be exercised when interpreting the results of this review, as it conflated early mobile technologies (such as telephone calls) with web-based technologies. Interestingly, the results of Papanikolaou et al.'s systematic review and meta-analysis [23] (n = 10 RCTs) contradicted the above four reviews by showing no significant difference in self-reported symptom severity, condition-specific QoL, or adherence to PFMT between WBIs and the control group. On the whole, the findings across existing systematic reviews pertaining to this topic are lacking in congruity, with certain outcomes such as pelvic floor muscle contractility, incontinence episode frequency, usage rate of incontinence aids, and satisfaction with the intervention being rarely evaluated. Moreover, all of these reviews incorporated a restricted quantity of primary studies (n ≤ 10), while an increasing number of RCTs [27-31] concerning this topic were being published after them, which could offer novel evidence. Accordingly, the effects of WBIs on women with UI need further exploration.

OBJECTIVES

The purpose of this systematic review and meta-analysis is to investigate the effectiveness of WBIs for women with UI based on all available evidence from RCTs.

Specifically, our proposed review seeks to answer the following questions: (a) Whether WBIs can effectively mitigate self-reported symptom severity, improve condition-specific QoL, and increase adherence to PFMT (primary question); (b) Whether specific types of intervention format, intervention interactivity, and main technology have beneficial effects on these outcomes (secondary question 1); and (c) Are WBIs effective on other extensive secondary outcomes among women with UI (secondary question 2).

METHODS AND ANALYSIS

Registration

This systematic review and meta-analysis has been prospectively registered on the platform of the International Prospective Register of Systematic Reviews (PROSPERO). The registration number is CRD42023435047. Any future changes to the study protocol will be registered as amendments.

Eligibility criteria

The PICOS approach will be used for eligibility criteria. The details are described as follows:

P (Population)

Female adults diagnosed with any type of UI will be considered eligible. However, women affected by UI arising from non-urinary tract factors will be excluded, such as cancer or radiotherapy-induced symptoms, neurological, cognitive or psychological disorders, and diseases hindering independent mobility. Also, studies that involved women with various types of lower urinary tract symptoms but did not report the data specific to women with UI separately will be excluded.

I (Intervention)

The intervention should be in a digital format using any web-based technologies, including but not limited to websites and mobile applications, with or without an intravaginal digital device connection. Nevertheless, studies will be excluded if they

solely utilize WBIs to observe the maintenance effects of previously administered health interventions, compare different types of program- or module-specific WBIs, involve face-to-face components in addition to the same routine care received by the control group, or do not conduct real WBIs (such as by adopting telephone call, short message, or digital video disk for intervention).

C (Control)

The control group can be usual care, a waitlist, no treatment, or minimal WBIs (such as hyperlinks to brief informational websites or an application that delivers concise information).

O (Outcome)

The primary outcomes are self-reported symptom severity, condition-specific QoL, and adherence to PFMT. Secondary outcomes will include pelvic floor muscle contractility evaluated by digital palpation (focusing on four out of the six domains of the PERFECT assessment scheme: power, endurance, repetition, and fast), incontinence episode frequency, urine leakage volume (measured via the pad-weighing test), usage rate of incontinence aids, the global impression of improvement, disease-related knowledge, self-efficacy of PFMT, mental health (anxiety and depression), and satisfaction with intervention. Studies that assess at least one of the aforementioned outcomes will be recognized as qualified.

S (Study design)

This systematic review will only include RCTs with full-text research papers available. Studies published in English and Chinese will be included.

Information sources and search strategy

The three-step approach to literature search recommended by the Joanna Briggs Institute will be used to identify studies that are relevant to the review questions. Step 1: An initial search has been conducted only on PubMed and CNKI, followed by an analysis of the text words in the titles and abstracts of the retrieved publications, as

well as the corresponding Medical Subject Heading (MeSH) terms to describe them. Step 2: Based on the results of the initial search modification and additional keywords, we will collaborate with an academic librarian to develop customized search strategies for each electronic database. A combination of MeSH terms and free text keywords will be applied where appropriate to represent the definitions of WBIs, UI, and RCT if possible. Table 1 shows the detailed search strategies of PubMed and CNKI. Ten electronic databases are anticipated to be comprehensively searched from their inception to May 1, 2024, by two authors independently, including six English databases (PubMed, Embase, the Cochrane Library, Web of Science, PsycINFO, and CINAHL) and four Chinese databases (CNKI, Wanfang Data, VIP, and SinoMed). Step 3: Google Scholar and Baidu Library sources will be searched for grey literature. The reference lists of all eligible articles and relevant reviews will be manually examined to expand the scope of our search and retrieve additional eligible studies.

Table 1. Literature search strategy.

Electronic database	Search terms
Pubmed	**#1** "Mobile Applications"[Mesh] OR "Telemedicine"[Mesh] OR "Internet"[Mesh] OR "Computers"[Mesh] OR "Telecommunications"[Mesh] OR "Online Systems"[Mesh] OR "Software"[Mesh] OR "Wireless Technology"[Mesh] OR "Cell Phone"[Mesh] OR app[Title/Abstract] OR apps[Title/Abstract] OR application[Title/Abstract] OR applications[Title/Abstract] OR ipad[Title/Abstract] OR blog[Title/Abstract] OR blogging[Title/Abstract] OR computer[Title/Abstract] OR computer interface[Title/Abstract] OR cell phones[Title/Abstract] OR cell phone[Title/Abstract] OR cellular phone[Title/Abstract] OR digital[Title/Abstract] OR digital health[Title/Abstract] OR digital-health[Title/Abstract] OR ehealth[Title/Abstract] OR e-health[Title/Abstract] OR e-mail[Title/Abstract] OR electronic[Title/Abstract] OR E-learning[Title/Abstract] OR Facebook[Title/Abstract] OR health, mobile[Title/Abstract] OR health technolog[Title/Abstract] OR health app[Title/Abstract] OR Internet[Title/Abstract] OR Internet forum[Title/Abstract] OR iphone[Title/Abstract] OR i phone[Title/Abstract] OR i-phone[Title/Abstract] OR ipad[Title/Abstract] OR i pad[Title/Abstract] OR i-pad[Title/Abstract] OR laptop[Title/Abstract] OR linkedin[Title/Abstract] OR mobile[Title/Abstract] OR mobile application[Title/Abstract] OR mobile apps[Title/Abstract] OR mobile app[Title/Abstract] OR mobile phone[Title/Abstract] OR mobile phones[Title/Abstract] OR mhealth[Title/Abstract] OR m-health[Title/Abstract] OR mobile health[Title/Abstract] OR mobile electronic device[Title/Abstract] OR mobile technolog[Title/Abstract] OR mobile

	communication[Title/Abstract] OR mobile computing[Title/Abstract] OR network[Title/Abstract] OR online[Title/Abstract] OR online intervention[Title/Abstract] OR online interventions[Title/Abstract] OR platform[Title/Abstract] OR personal computer[Title/Abstract] OR personal digital assistant[Title/Abstract] OR QQ[Title/Abstract] OR remote[Title/Abstract] OR smartphone[Title/Abstract] OR smart phone[Title/Abstract] OR social media[Title/Abstract] OR social networking[Title/Abstract] OR telehealth[Title/Abstract] OR tele-health[Title/Abstract] OR telephone[Title/Abstract] OR telemedicine[Title/Abstract] OR tele-medicine[Title/Abstract] OR tele-care[Title/Abstract] OR telecare[Title/Abstract] OR telecommunication[Title/Abstract] OR telemonitor[Title/Abstract] OR tele-monitor[Title/Abstract] OR telemonitoring[Title/Abstract] OR twitter[Title/Abstract] OR web[Title/Abstract] OR web-based[Title/Abstract] OR website[Title/Abstract] OR wireless[Title/Abstract] OR WeChat[Title/Abstract] **#2** "Urinary Incontinence"[Mesh] OR "Urinary Incontinence, Urge"[Mesh] OR "Urinary Incontinence, Stress"[Mesh] OR urine incontinence[Title/Abstract] OR urinary incontinence[Title/Abstract] OR urinary incontinence*[Title/Abstract] OR urine incon*[Title/Abstract] OR incontinence, urinary[Title/Abstract] OR urinary incontinence, stress[Title/Abstract] OR urinary stress incontinence[Title/Abstract] OR incontinence, urinary stress[Title/Abstract] OR stress incontinence, urinary[Title/Abstract] OR stress incontinence[Title/Abstract] OR urinary incontinence, urge[Title/Abstract] OR urinary urgency[Title/Abstract] OR urinary urge incontinence[Title/Abstract] OR urge urinary incontinence[Title/Abstract] OR urgency urinary incontinence[Title/Abstract] OR incontinence, urge[Title/Abstract] OR urge incontinence[Title/Abstract] OR urinary reflex incontinence[Title/Abstract] OR incontinence, urinary reflex[Title/Abstract] OR reflex incontinence[Title/Abstract] OR mixed incontinence[Title/Abstract] OR mixed urinary incontinence[Title/Abstract] OR involuntary leakage[Title/Abstract] **#3** "Randomized Controlled Trial" [Publication Type] OR "Randomized Controlled Trials as Topic"[Mesh] OR Clinical Trials, Randomized[Title/Abstract] OR Trials, Randomized Clinical[Title/Abstract] OR Controlled Clinical Trials, Randomized[Title/Abstract] OR RCT[Title/Abstract] **#1** AND **#2** AND **#3** Filters applied: Female.
CNKI	SU=('远程医疗'+'远程健康'+'电子健康'+'移动健康'+'移动医疗'+'互联网医疗'+'远程咨询'+'远程医疗咨询'+'可穿戴电子设备'+'社交媒体'+'多媒体'+'App'+'移动应用'+'移动应用程序'+'移动设备'+'手机'+'智能手机'+'电话'+ '电子游戏'+'计算机游戏'+'基于互联网'+'基于网络'+'基于计算机'+'视频会议'+'网站'+'网络'+'社交网络'+'网络平台'+'移动网络'+'在线'+'线上'+'互联网'+'微信'+'QQ'+'论坛'+'平台') and SU=('失禁'+'尿失禁'+'漏尿'+'压力性尿失禁'+'急迫性尿失禁'+'混合性尿失禁') and TKA=('随机对照试验'+'随机分配'+'随机'+'临床应用')

Screening and selection procedures for eligible studies

EndNote X9 will be used to manage the retrieved studies, where duplicate references will be identified and removed by using the automated “Find Duplicates” function. A two-stage process will be used to determine the eligibility of each

publication. In the first stage, two independent reviewers will screen the titles and abstracts of the papers retrieved and an article will be temporarily retained if either of the two reviewers considers it to be potentially eligible for inclusion. The authors of potentially eligible studies for which the full text is not available will be contacted via email to seek either the full text or their research data. In the second stage, the full texts of the remaining studies will be read. Discussions will be used to reach a consensus if there are any discrepancies at the full-text level. Consultation by a third reviewer will be performed if necessary when an agreement cannot be reached through discussion alone. The article selection process and reasons for excluding studies will be showed in a PRISMA flow diagram (Figure 1).

Data abstraction

Two different reviewers will extract the data into a purpose-built, structured sheet, and any discrepancies will be resolved through arbitration and consensus among the members of our research team. Beforehand, the data extraction sheet will be first piloted with a subsample of included studies and then revised and refined as necessary. If studies report outcomes at different time points, the outcomes evaluated at immediate post-intervention termination will be extracted, for the effect sizes observed at the end of the intervention are considered the most pertinent measures of potential benefits. The following information will be collected from eligible studies:

(1) The general information of the study: first author, study country, and publication year;

(2) The baseline characteristics of participants: type of UI, diagnostic criteria, mean age, and sample size;

(3) The details of the WBIs: the intervention's name, detailed regimen, duration, format (personalized or non-personalized), interactivity (interactive or non-interactive), and main technology;

(4) The intervention regimen of the control group;

(5) The details of the outcome: data on outcomes, measurement tools, between-group difference (+ /-), evaluation time points;

(6) Adverse events;

and (7) The attrition rate.

Quality appraisal

The quality of the included studies will be assessed independently by two investigators through the Cochrane Collaboration tool [33]. This tool consists of seven items: random sequence generation (selection bias), concealment of allocation (selection bias), blinding of the subjects and personnel (performance bias), outcome assessor blinding (detection bias), completeness of follow-up (attrition bias), selective reports (reporting bias), and other biases. Each item will be rated as 'low', 'unclear', or 'high' risk of bias. Any disagreements will be settled by discussion with a third reviewer.

Statistics analysis

Data synthesis

Where possible, meta-analyses will be conducted to combine the data. We will utilize mean differences with 95% confidence intervals for continuous variables that were assessed with the same instrument and standardized mean differences with 95% confidence intervals when a similar outcome was measured with different instruments. The mean differences/standardized mean differences between the intervention and control groups will be calculated based on the $\text{Mean}_{\text{change}}$ ($\text{Mean}_{\text{change}} = \text{Mean}_{\text{after}} - \text{Mean}_{\text{baseline}}$) and the corresponding standard deviation $(\text{SD})_{\text{change}}$ ($\text{SD}_{\text{change}} = \sqrt{[\text{SD}^2_{\text{baseline}} + \text{SD}^2_{\text{after}} - (2 * r * \text{SD}_{\text{baseline}} * \text{SD}_{\text{after}})]}$) [34]. r is the correlation between the matched pairs of pre- and post-intervention assessments. In fact, it has been demonstrated that there are no significant differences in the calculated effect size between correlations = 0, 0.3, and 0.7 [34]. In this study, a r of 0.5 was assumed for all analyses as it is the most commonly used for calculation [35, 36]. The

effect size of standardized mean differences is reported as small (<0.2), moderate (0.2–0.8), or large (>0.8) based on Cohen's definition [37]. Regarding binary variables, we will choose relative risks with 95% confidence intervals as the point estimate, with the cut-off values of 1.22, 1.86, and 3.00 denoting small, medium, and large effects, respectively [38]. The Mantel-Haenszel method will be employed to combine dichotomous outcome data, and the Inverse Variance method will be employed for pooling continuous outcome data. All statistical analyses will be performed using Stata, version 12.0 (Stata Corp., College Station, TX, USA). Statistical significance will be defined as a p-value < 0.05. For outcomes that cannot be quantitatively synthesized in a meta-analysis because of insufficient data (less than three studies report the data), high heterogeneity of effect measurement tools, or other reasons, a narrative approach will be utilized for describing and summarizing.

Assessment of heterogeneity

The degree of heterogeneity across studies will be assessed using both the χ^2 test and the I^2 test. According to the Cochrane Handbook, Higgins I^2 from 0% to 40% means that there is insignificant heterogeneity, from 30% to 60% indicates that there is moderate heterogeneity, from 50% to 90% represents that there is substantial heterogeneity, and > 75% manifests that there is high heterogeneity [37]. A fixed-effects model will be chosen for analysis only when no substantial heterogeneity exists ($p \geq 0.1$ and $I^2 \leq 50\%$), whereas a random-effects model will be used if there is significant heterogeneity ($p < 0.1$ and $I^2 > 50\%$) since it can provide more cautious summary effect estimates and is preferred when there is unexplained heterogeneity across studies [37].

Sensitivity analysis

Sensitivity analyses will be performed by excluding one study at a time to determine if any individual study has a significant impact on the merged results. A comparison will be made between the merged results prior to the modifications and

the adjusted results in order to identify the potential sources of heterogeneity.

Publication bias

Publication bias assessment of an outcome will be detected by using the funnel plot and Egger test when the number of included studies reaches or exceeds ten.

Subgroup analyses

Three subgroup analyses will be carried out to investigate the influence of the type of format (personalized and non-personalized), type of interactivity (interactive and non-interactive), and main technology (such as mobile applications and websites) on the effects of WBIs on primary outcomes, thereby attempting to explore an optimal WBIs regimen for women with UI.

Patient and public involvement

This review will be based solely on publicly accessible studies. Thus, no patient or member of the public will be directly involved in the design, implementation, reporting, or dissemination of the study.

Validity, reliability, and rigor

The present study protocol was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Protocol Statement Guidelines (PRISMA-P) (see Supplemental material). We will conduct and report the systematic review strictly in accordance with the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions and the guidelines of the PRISMA statement to ensure its validity, reliability, and rigor.

DISCUSSION

As one of the most common chronic diseases among women, UI can cause many physical, mental, and social discomforts for individuals and result in huge financial burdens on families and society as a whole [6-10]. Although the traditional face-to-face mode of UI management is effective [12], it demands substantial human and financial inputs [19, 20]. WBIs have drawn great attention from the medical and

hygiene fields due to their advantages of high accessibility and efficiency [17, 25, 26]. Recently, some researchers have attempted to use WBIs to manage UI for women, but the effectiveness of WBIs among this crowd has remained inconclusive [27-31], and even the existing relevant systematic reviews failed to arrive at a consensus on this matter [21-24, 32], which impedes clinical decision-making and limits the widespread application of WBIs. Accordingly, this paper presents a protocol for a systematic review and meta-analyses that will summarize the related evidence by systematically reviewing previous RCTs regarding the effectiveness of WBIs in women with UI. It is anticipated that the findings of the future systematic review will allow for more considerate and insightful recommendations when advising UI women with effective management strategies.

With regard to selecting outcomes, since self-reported symptom severity and condition-specific QoL can appropriately reflect the impacts of UI on women's physical health, mental health, and social engagement and play crucial roles in determining whether additional treatments are warranted [39], and adherence to PFMT represents a fundamental element of the effectiveness of a PFMT program [14], the future systematic review will adopt self-reported symptom severity, condition-specific QoL, and adherence to PFMT as the primary outcomes. In the meantime, a wide range of secondary outcomes will also be evaluated to enhance the overall comprehension of the WBIs' effectiveness in managing UI for women. Consequently, the findings of this review will provide more solid evidence and comprehensive references on whether WBIs should be extensively suggested in the future for women's UI management in clinical settings. Furthermore, we will also collect information about the attrition rate of participants and adverse events that happened during WBIs in the data abstraction process to find out the possible disadvantages of WBIs, although they were not set as the secondary outcomes for this review, which may provide useful information for improving the WBIs regimen.

Additionally, subgroup analyses based on the interactivity, format, and main technology of WBIs will be conducted. It is expected that the corresponding results can aid healthcare providers in developing and implementing an optimal WBI program for UI women, thereby generating maximum benefits for the intended audiences, medical staff, and other related stakeholders.

Nonetheless, we have recognized some potential limitations of this review. Firstly, the use of web-based technologies in healthcare is a developing field, so there might be limited studies available on this topic. Secondly, some studies in other languages can be overlooked because this review will only include RCTs published in English and Chinese. Thirdly, heterogeneity will exist inevitably in meta-analysis in terms of the variation of clinical and methodological characteristics. For instance, the diversity of UI types and the duration of WBI characteristics will lead to heterogeneity. Thus, we intend to carry out leave-one-out sensitivity analyses to evaluate the stability of the pooled results and identify potential sources of heterogeneity.

ETHICS AND DISSEMINATION

Ethical approval and participant consent will not be required since this study will consist of a secondary analysis of published evidence and not contain any private information about participants. The findings will be disseminated via a peer-reviewed journal or an international conference.

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Contributors Xuefen Xu: Conceptualization, Visualization, Investigation, Writing - original draft. Pingping Guo: Conceptualization, Visualization, Writing - review & editing. Ping Xu: Investigation, Writing - review & editing. Dandan Chen: Investigation, Writing - review & editing. Weijing Chen: Formal analysis, Writing -

review & editing. Hongyan Wang: Formal analysis, Writing - review & editing. Ying Jin: Formal analysis, Writing - review & editing. Xiaojuan Wang: Funding acquisition, Writing - review & editing. Wei Zhang: Funding acquisition, Writing - review & editing. Fang Xie: Funding acquisition, Writing - review & editing. Rujia Zhao: Funding acquisition, Writing - review & editing. Minna Mao: Funding acquisition, Writing - review & editing. Suwen Feng: Conceptualization, Visualization, Writing - review & editing.

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Competing interests statement None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer-reviewed.

ORCID ID

Xuefen Xu https://orcid.org/0009-0004-4637-6617

Pingping Guo https://orcid.org/0000-0002-5091-9387

Ping Xu https://orcid.org/0000-0002-2434-8437

Dandan Chen https://orcid.org/0000-0003-4488-5624

Ying Jin https://orcid.org/0000-0003-4073-1732

Xiaojuan Wang https://orcid.org/0000-0002-1947-5140

Wei Zhang https://orcid.org/0000-0001-9884-0494

Fang Xie https://orcid.org/0000-0002-5327-764X

Minna Mao https://orcid.org/0000-0001-7413-1554

Rujia Zhao https://orcid.org/0009-0002-1624-5427

Suwen Feng https://orcid.org/0000-0002-0883-0418

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Figure Legend

Figure 1. Flow diagram of the article selection process.

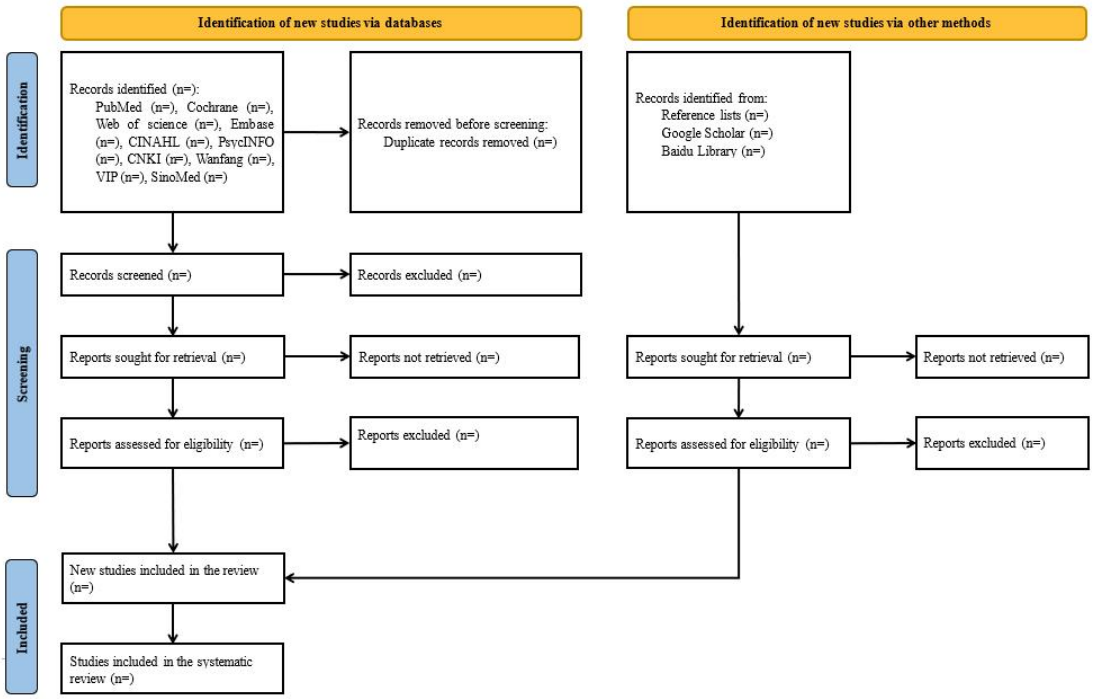

Figure 1. Flow diagram of the article selection process.

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

Section/Topic	Item No	Item	Reported on Page Number/Line Number (P/L)	Reported on Section/Paragraph
ADMINISTRATIVE INFORMATION				
Title	1a	Identification - identify the report as a protocol of a systematic review	P3/L44-46	Title
	1b	Update - if the protocol is for an update of a previous systematic review, identify as such	Non-update	Non-update
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	P4/L72	Abstract
Authors	3a	Contact - provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	Title page	Title page
	3b	Contributions - describe contributions of protocol authors and identify the guarantor of the review	P18-19/L438-443	Contributions
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	Non-amendments	Non-amendments
Support	5a	Sources - indicate sources of financial or other support for the review	P19/L444-449	Funding
	5b	Sponsor - provide name for the review funder and/or sponsor	P19/L444-449	Funding
	5c	Role of sponsor or funder - describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	P19/L444-449	Funding
INTRODUCTION				
Rationale	6	Describe the rationale for the review in the context of what is already known	P4-8/L86-200	Introduction
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants,interventions, comparators, and outcomes (PICO)	P8-9/L201-210	Objectives
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	P9-10/L212-253	Eligibility criteria
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	P9-10/L212-252	Information sources and search strategy
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	P10-11/L254	Table 1
Study records	11a	Data management - describe the mechanism(s) that will be used to manage records and data throughout the review	P13-14/L286-306	Data abstraction
	11b	Selection process - state the process that will be used for selecting studies (such as two independent	P12-13/L272-285	Screening and

		reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)		selection procedures for eligible studies
	11c	Data collection process - 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	P13-14/L286-306	Data abstraction
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	P13-14/L286-306	Data abstraction
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	P10/L210-249 P17/L396-406	Eligibility criteria Discussion
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	P14/L315-325	Quality appraisal
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	P15/L328-338	Statistics analysis
	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)	P14-15/L328-338, 342-355	Statistics analysis
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	P15-16/L338-357, 361-368	Statistics analysis
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	P15/L328-341	Statistics analysis
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	P16/L358-360	Statistics analysis
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	Not conducted	Not conducted

* 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.

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.