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Systematic Review

Exploring The Effect of Testosterone Hormonal Therapy on Sexual Problems in Postmenopausal Women: A Comprehensive Systematic Review on Clinical Trials

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ABSTRACT

Introduction: Sexual dysfunction is a common concern among postmenopausal women. Testosterone therapy has been proposed as a treatment option, yet evidence remains inconsistent.

Material and Methods: We searched PubMed, ScienceDirect, and EBSCOhost (January 2010–December 2024). Randomized controlled trials (RCTs) assessing testosterone versus placebo or control in postmenopausal women were included. Data extraction and synthesis were performed independently by two reviewers. Risk of bias was assessed using the Cochrane RoB 2 tool. RevMan 5.4 was used for meta-analysis.

Results: Seven articles were considered relevant for assessing the effect of testosterone or androgen therapy on sexual function and desire of postmenopausal women (n = 711). The testosterone group showed significant improvement in sexual activity or desire (OD: 3.18, 95% CI: 2.53 - 3.98, p< 0.00001). This result shows that testosterone therapy has the potential to improve sexual activity and desire in postmenopausal women.

Conclusion: Testosterone therapy may improve sexual function in postmenopausal women, but heterogeneity and limited long-term safety data warrant caution. Further high-quality RCTs are needed.

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INTRODUCTION

In postmenopausal women, sexual dysfunction is a prevalent issue that is often overlooked [1]. Menopause represents a fundamental biological event in the reproductive lifespan of women, denoted by the permanent cessation of menstruation due to ovarian follicular depletion and hormonal alterations, primarily involving declines in estrogen and progesterone levels [2,3]. Typically occurring in the late 40s to early 50s, menopause initiates a cascade of physiological changes encompassing various bodily systems [4,5]. These changes manifest clinically as a spectrum of symptoms, like hot flashes and night sweats as vasomotor symptoms, genitourinary symptoms such as dyspareunia, vaginal dryness, mood disturbances, and sleep disturbances [6–8].

Postmenopausal sexuality is affected by various factors, such as psychosocial, hormonal, also interpersonal and behavioral elements [9]. The sexual issues that most significantly affect the menopausal transition include decreased desire, sexual activity, and sexual response, along with the onset of dyspareunia and vaginal dryness [10,11]. Postmenopausal women are over twice as likely to encounter sexual dysfunction

compared to premenopausal women. A longitudinal study involving 436 women aged 35 to 47 at the start of the study, who were assessed annually, found that various aspects of sexual dysfunction, such as vaginal lubrication, pain during intercourse, reduced arousal, and decreased desire, deteriorate during the menopausal transition [12].

The use of testosterone in treating sexual and physical dysfunction in postmenopausal women is based on the conviction that the dose-response relationships for testosterone differ between men and women [13,14]. It is accepted that noteworthy health-related benefits can be securely achieved at testosterone measurements and levels much lower than those required to realize comparable impacts in men. In any case, these presumptions have not been thoroughly tested [15,16]. Testosterone is the essential male hormone directing sex differentiation, creating male sex characteristics, spermatogenesis, and fertility [17–19]. Hence, examination into the dose-response connections of testosterone in women is essential to determine whether improvements in sexual function, muscle mass and execution, and physical function can be accomplished at testosterone dosages and levels that don't lead to critical androgenic side effects.

Exceptionally few studies have examined the impacts of testosterone replacement on sexual issues in postmenopausal women. Additionally, impacts of testosterone organization on body composition, muscle execution, and physical work in women [10]. Common menopause is related to this with an increment in fat mass and a decrease in body mass index [20]. Furthermore, age-related declines in testosterone levels in older women have been associated with frailty. Hence, postmenopausal ladies who experience surgery at a low rate of testosterone levels may be at an increased risk of physical inability. Clinical trials utilizing different details and measurements of testosterone or other androgens have detailed a few advancements in body mass index and muscle strength [20]; however, this result has not been achieved consistently across studies, and none showed an improvement in physical performance. The impact of dosage of testosterone on skeletal muscle mass, muscle strength, and physical function has not been studied.

Currently, there's a need for precise surveys that comprehensively assess the potential testosterone hormonal treatment on the sexual issues in postmenopausal women, particularly with a clinical trial plan. Given the need for a comprehensive understanding with respect to the potential of testosterone hormonal treatment in postmenopausal women, this comprehensive systematic review aims to bridge this crevice by exploring its effect in postmenopausal women. In this manner, we utilized the most recent relevant clinical trials to conduct this precise audit, which aimed to investigate the potential of testosterone hormonal treatment in managing issues in postmenopausal women.

MATERIAL AND METHODS

This systematic review adopted the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.

Eligibility Criteria

The inclusion criteria include clinical trial research conducted in English. The sample population includes menopausal women. The PICO structure employed includes 1) Population: menopausal women; 2) Intervention: testosterone therapy; 3) Comparison: control group or placebo; 4) Outcome: sexual function or sexual desire. The exclusion criteria are: 1) premenopausal women; 2) studies involving non-human subjects; 3) studies not published in English; and 4) gray literature.

Search Strategy

The databases utilized are PubMed, EBSCOhost, and Science Direct. The selected keywords are ("Testosterone Therapy" OR "Androgen Therapy" OR "Hormonal Therapy") AND ("Menopausal" OR "Climacteric" OR "Postmenopausal") AND ("Sexual Problem" OR "Libido Problem" OR "Low Libido"), which are modified based on the specific features of each database. Article screening continued with a starting assessment of titles and abstracts to dispose of unimportant research, followed by a systematic appraisal of the entire content to decide compliance with the inclusion criteria.

Data Extraction and Analysis

Data extraction was accomplished by inputting data into a Google Sheet to evaluate its appropriateness and precision. A Google Sheet was used to record required study characteristics, including authors, study design, publication year, patient demographics, sample size, control group, and outcomes. The differences in opinion that formed during the writing process were settled through discussion.

Intervention of Interest

A recent research study shows that testosterone hormone therapy might improve sexual function or desire in menopausal women rather than placebo or control group. Therefore, this study was conducted to determine their efficacy in increasing patients' sexual function or desire.

and were analyzed quantitatively by meta-analysis, and

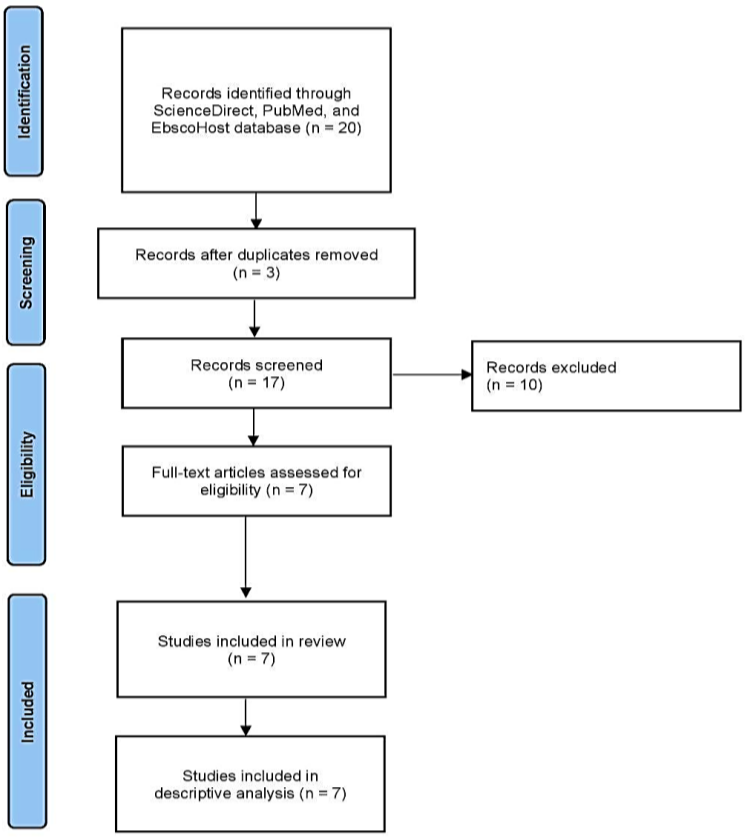


Fig. 1. PRISMA Flowchart

Outcome of Interest

Multiple research findings show that testosterone therapy can enhance sexual desire and activity, decrease psychological distress, and is generally well tolerated by naturally menopausal women experiencing hypoactive sexual desire disorder. Multiple outcomes have been assessed to enhance the comprehensiveness of this review regarding the impact of testosterone therapy on alterations in sexual function among menopausal women.

RESULTS

Overview of Literature Searching

After the literature review, 20 articles were distributed within the last ten years in three databases. A few articles were not included due to duplication of studies (n = 3). 10 articles were avoided due to ineligible information, such as books, review articles, and inaccessible articles due to subscriptions. Fig.1 presents the PRISMA flowchart. Thus, 7 articles that met the inclusion criteria were assessed in this systematic review the rest of the studies were analyzed qualitatively.

Study Characteristics

This review included seven studies with a clinical trial design. The testosterone interventions are used in various forms and doses, including testosterone patch 150 mcg or 300 mcg daily, testosterone intramuscular injection weekly, testosterone oral, a combination of 50 mg transdermal testosterone weekly and oral 1 mg estradiol valerate daily or only 1 mg estradiol valerate by oral daily, and oral testosterone undecanoate twice weekly and oral estradiol valerate daily as combination or placebo twice weekly and oral estradiol valerate daily. A total of 1.906 patients with a menopause condition were included as participants. All of the participants were in the post-menopausal stage, with a range of ages from 20 to 70 years old. The length of the medication administration ranges from 8 weeks to 13 months. The primary observed outcome was represented by mean changes. Mean changes refer to the alterations in sexual problems from pre- to post-intervention. Table 1 shows the studies that were assessed in this review.

less the sexual function of a person will become [22,28].

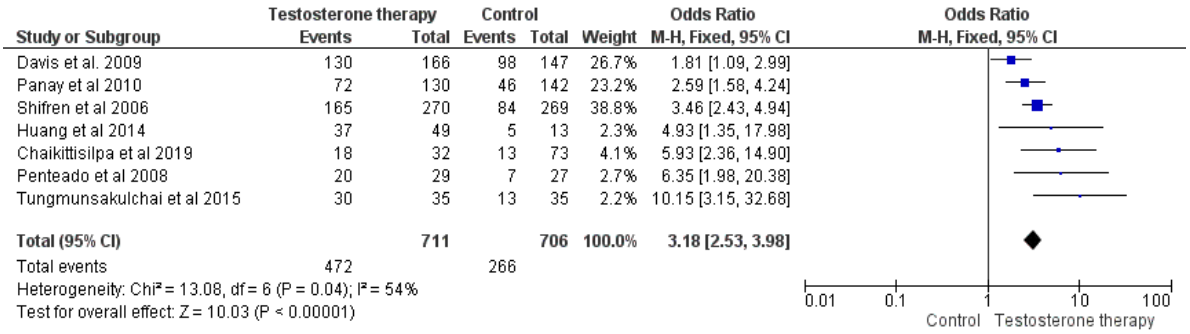


Fig.2. Forest Plot of Testosterone Therapy vs Placebo

Meta-analysis of Testosterone Potential vs Control in Postmenopausal Women

In this subgroup analysis, seven studies compared the alterations in sexual problems in postmenopausal women between the testosterone group and the placebo. Testosterone significantly improves sexual activity and sexual desire three times better than the placebo group (OD: 3.18, 95% CI: 3.15 to 32.68, p<0.00001), respectively. According to the analysis, testosterone was demonstrated to be predominant and may move forward sexual issues more effectively compared to placebo, as illustrated in Fig.2.

DISCUSSION

Menopause represents a complex physiological transition in a woman's life, involving significant hormonal changes and adaptations [21]. The decline of estrogen, progesterone, and androgen (e.g., testosterone) levels, coupled with alterations in other hormones such as luteinizing hormone (LH) and follicle-stimulating hormone (FSH), triggers the cessation of menstrual cycles [220,202,23]. The process of hormonal change in this case is able to lead to a wide range of physical symptoms, such as hot flashes, night sweats, vaginal dryness, and urinary tract changes. Additionally, menopause is often accompanied by psychological symptoms such as mood swings, anxiety, and depression, as well as cognitive changes like memory lapses and difficulty concentrating [20,24,25]. Beyond its immediate symptomatic manifestations, menopause also presents long-term health implications. The decline in estrogen levels can increase the risk of conditions such as osteoporosis, cardiovascular disease, and cognitive decline [2,17,26].

Moreover, this hormonal fluctuation will also gradually affect the sexual function and sexual desire of the woman [27]. The lower the hormonal level is, the One of the most important hormones that plays a role in managing sexual function and behavior in women is androgen or testosterone. Testosterone might act straightforwardly through androgen receptors (AR) as a progenitor hormone for estradiol (E2) generation in tissues such as the brain, bone, adipose, and vascular tissue, or by lowering SHBG and increasing free circulating levels of multiple sex steroids [29]. Female sexuality and libido are influenced by a variety of factors, such as the individual's health, her social and physical surroundings, education, cultural background, previous experiences, and her relationship with her partner. Androgens are also crucial, especially in promoting sexual motivation, sustaining optimal sexual desire, and potentially enhancing sexual satisfaction [30]. Low levels of testosterone are most unequivocally related to diminished coital recurrence and a decline in sexual desire [31,32].

The general effect of menopause on the sexual function and well-being of females underscores the importance of comprehensive management strategies that address the improvement of sexual function and long-term health considerations [33]. As our understanding of menopause continues to evolve, there's a developing emphasis on all-encompassing approaches that include lifestyle changes, dietary interventions, complementary treatments, and potentially, hormonal medications like testosterone therapy [25,34]. By addressing the multifaceted nature of menopause, healthcare providers can better support women through this significant life transition, promoting optimal health and well-being in the menopausal years and beyond [6,15,35].

In this study, testosterone therapy in either oral or transdermal medication has demonstrated health benefits across various physiological systems and sexual functions, supported by empirical evidence. The use of transdermal testosterone weekly for 8 weeks presents a critical improvement in the Female Sexual Function

Index (FSFI) score compared to placebo, which indicates an advancement within the sexual work of the tests [26,36]. Oral testosterone therapy also shows the same output as transdermal testosterone in improving the FSFI score [37]. Significant increments in sexual activity episodes, sexual desire, and sexual satisfaction are also reported in postmenopausal females who were given testosterone therapy [38,39]. Notably, the administration of testosterone therapy is three times more effective in improving sexual function and sexual desire of postmenopausal women compared with placebo.

Several biases in the included studies can be credited to the small sample size and the use of different testosterone doses and forms. The authors were aware of the study's limitations, primarily due to clinical heterogeneity caused by differences in the therapeutic regimens, such as dosages, preparations, administration intervals, and analyzed outcomes. Further research is needed to elucidate the optimal dosage, duration, and safety profile of testosterone supplementation, specifically for postmenopausal women. Addressing challenges related to testosterone's bioavailability and pharmacokinetics is crucial for translating these promising findings into effective clinical interventions for sexual problem management in postmenopausal individuals.

The review consolidates evidence from various clinical trials, indicating that testosterone therapy may have a good impact on sexual function in postmenopausal women experiencing low libido and other sexual dysfunctions. The studies included in the review consistently reported improvements in overall sexual satisfaction, arousal, and sexual desire among participants receiving testosterone therapy compared to those receiving a placebo or no treatment. These findings align with the biological understanding that testosterone plays a vital part in sexual wellbeing and working, especially in women who have experienced menopause and involve a characteristic decrease in hormone levels.

The implications of discoveries are critical for clinical practice. Given the prevalence of sexual dysfunction among postmenopausal women, testosterone therapy could be considered a viable treatment option for those who do not respond to conventional therapies, such as estrogen replacement or other pharmacological interventions. However, it is essential for healthcare providers to approach testosterone therapy with caution, considering the potential risks and side effects, including the possibility of androgenic effects, cardiovascular risks, and the long-term implications of hormone therapy.

Moreover, the review underscores the importance of individualized treatment plans. Not all postmenopausal women may benefit from testosterone therapy, and factors such as personal health history, the severity of sexual dysfunction, and patient preferences should guide treatment decisions. Healthcare providers should engage in shared decision-making with their patients, guaranteeing that they are well-informed about the potential benefits and dangers related to testosterone treatment.

The limitation of this study is that the journals used are several journals whose research was conducted within the last 5 years. So, this will be an inaccurate data source because the novelty and reliability of the conclusions drawn are not entirely accurate and correct.

CONCLUSION

Women who are undergoing menopausal or postmenopausal states will be affected by hormonal changes, especially in the sexual aspect. The sexual problems that most significantly affect the menopausal transition include decreased desire, diminished sexual response, reduced activity, and the onset of vaginal dryness and dyspareunia. These studies highlight the empowering potential of testosterone treatment for addressing sexual issues, particularly in postmenopausal women. Organization of testosterone in totally different shapes and measurements essentially makes strides in sexual activity and sexual desire in postmenopausal women. Subsequently, it can be expressed that testosterone treatment can be considered a potential treatment to address sexual issues in women with postmenopausal states, such as sexual activity and sexual desire.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

Availability of Data and Materials

All data sources described in this study are directed to the corresponding author.

Ethics Approval and Consent to Participate

No human subjects are in this article, and informed consent is not applicable.

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Table 1. Summaries included Studies

No.	Study (year)	Population	Duration	Intervention	Doses	Characteristics			Adverse effects
						Sample (n)	Sample mean age (SD)	Summary of Results	
1	Davis *et al.*, 2008 [24]	Postmenopausal women with hypoactive sexual desire disorder	52 weeks ~ 13 months	Testosterone patch 150 mcg or 300 mcg daily; or placebo	150 mcg, 300 mcg, placebo	814	20 - 70	The group receiving 300 µg of testosterone daily experienced a significantly larger increase in the number of satisfying sexual episodes over four weeks compared to the placebo group (2.1 episodes vs. 0.7; P <0.001). However, the increase in the group receiving 150 µg per day (1.2 episodes) was not statistically significant (P = 0.11) Compared to the placebo, both testosterone doses led to notable improvements in sexual desire (150 µg: P = 0.04; 300 µg: P <0.001) and reductions in distress related to sexual function (150 µg: P = 0.04; 300 µg: P <0.001)	No adverse effects were reported.
2	Huang *et al.*, 2014 [15]	Surgical menopause and natural menopause with total testosterone <31 ng/dL or free testosterone >3,5 pg/mL	24 weeks	Testosterone intramuscular injection weekly, or placebo	Testosterone enanthate 3 mg, 6,25 mg, 12,5 mg, or 25 mg weekly, placebo	71	21 - 60	Increments in free testosterone levels were essentially related to changes in different measures, including the composite Brief List of Sexual Working for Women, sexual thoughts/desire, excitement, frequency of sexual activity, body mass index, chest-press strength, and stair-climbing control. These advancements were significantly more prominent within the group receiving 25 mg compared to the placebo, but not within the lower-dose groups. Sexual activity increased by 2.7 experiences per week within the 25-mg group. The recurrence of androgenic unfavorable occasions was low.	No adverse effects were reported.
3	Lenharo Penteado *et al.*, 2008 [39]	Natural menopause with sexual complaints	12 months	Testosterone oral	Conjugated equine estrogen 0,625 mg and medroxyprogesterone acetate 2,5 mg plus either methyltestosterone 2,0 mg or placebo daily	60	42 - 60	Adding methyltestosterone to CEE/MPA therapy was significantly linked to increased sexual energy levels (p = 0.021). In any case, the treatment did not lead to a critical alteration in orgasmic ability.	No adverse effects were reported.
4.	Panay *et al.*, 2010 [40]	Natural menopause with low sexual desire	6 months	Testosterone patch	Transdermal testosterone patch 300 µg twice weekly; or placebo	272	40 -70	The TTP group illustrated critical changes in SSE (p=0.0089) as well as in sexual desire (p=0.0007) and decreased individual trouble (p=0.0024) versus placebo at 6 months (intent-to-treat analysis, n=247)	No adverse effects were reported.
5.	Shifren *et al.*, 2006 [22]	Natural menopause with low sexual desire	24 week ~ 6 months	Testosterone patch	Testosterone patch 300 µg	549	40 - 70	The increment within the number of fulfilling sexual scenes from baseline was altogether more prominent within the testosterone group compared to the	No adverse effects were reported.

No.	Study (year)	Population	Duration	Intervention	Doses	Characteristics			Adverse effects
						Sample (n)	Sample mean age (SD)	Summary of Results	
					twice weekly; or placebo			placebo group. Among members with standard sex hormone-binding globulin levels ≤160 nmol/L, the normal increment was 2.1 ± 0.28 nmol/L over four weeks with testosterone versus 0.5 ± 0.23 with placebo treatment (P < 0.0001). Within the intent-to-treat bunch, the normal increment was 1.9 ± 0.26 versus 0.5 ± 0.21 scenes (P < 0.0001). Testosterone is more driven to critical changes over placebo in all auxiliary results, including sexual desire and a reduction in individual trouble. The testosterone fix was, for the most part, well endured.	
6.	Chaikittisilpa *et al.*, 2019 [41]	Postmenopausal women with low sexual function	8 weeks	Weekly 50 mg transdermal testosterone + daily oral 1 mg estradiol valerate or only daily oral 1 mg estradiol valerate	Transdermal testosterone 50 mg; oral estradiol valerate 1 mg	70	40 - 60	Both groups demonstrated significant improvements in their FSFI scores compared to baseline after 8 weeks of treatment. The testosterone group had a significantly higher FSFI score than the control group (p = 0.038), with notable differences in score changes between the two groups (p = 0.024)	There were no serious adverse effects in this study; 42.4% of the testosterone group had acne, and 29.0% of the control group had acne (p = 0.26)
7.	Tungmunsakulchai *et al.*, 2015 [42]	Postmenopausal women with sexual complaints and Female Sexual Function Index (FSFI) ≤ 26.5	8 weeks	2x weekly oral testosterone undecanoate + PO estradiol valerate daily + PO estradiol valerate daily or 2x weekly placebo	Oral testosterone undecanoate 40 mg; oral estradiol valerate 1 mg; placebo 40 mg	70	40 - 60	After 8 weeks of therapy, both groups experienced a significant increase in their total FSFI scores compared to the start of the study. The group receiving testosterone had significantly higher total FSFI and arousal scores than the placebo group (p < 0.05).	There was no serious adverse effect in this study. The participants reported having mild acne and mild facial hair development, which were comparable between the two groups.