Pharmacoscript

Suzana et al./Pharmacoscript, Volume 8, No, 2, August 2025, 461-478

P-ISSN : 2622-4941 | E-ISSN : 2685-1121

THE ROLE OF *TRIBULUS TERRESTRIS* ON MALE INFERTILITY BASED ON CLINICAL TRIALS PERSPECTIVE: A NARRATIVE REVIEW

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Received: 24/03/2025, Revised: 09/07/2025, Accepted: 13/08/2025, Published: 31/08/2025

ABSTRACT

Tribulus terrestris is a widely recognized herb with potential applications in healthcare. Male factor infertility, often stemming from testicular disorders, is frequently linked to inadequate sperm quantity and quality. While botanical products, including herbal medicines, have shown both positive and negative effects on male fertility and testicular function in the literature, this narrative review specifically aimed to identify clinical trials investigating the potential benefits of *Tribulus terrestris* in reducing male infertility and enhancing semen and hormonal parameters. A literature review methodology was employed, utilizing Scopus, PubMed, and Cochrane databases to gather full-text accessible published works from 2013 to 2022. Initially, 28 studies were identified; 24 were excluded, leaving three for full-text evaluation. Ultimately, three articles met the inclusion criteria and were included in this review. Based on the reviewed articles, *Tribulus terrestris* extract appears to influence the quantity and quality of spermatozoa, as well as reproductive hormone levels. Two articles reported a significant increase in sperm parameters and hormone levels. However, one article indicated no meaningful correlation between *Tribulus terrestris* use and an increase in testosterone levels. Further data are needed to definitively determine the efficacy of *Tribulus terrestris* as an infertility treatment.

***Keywords**: Clinical Trials, Herbal Medicine, Male Infertility, Sperm Quality, Tribulus terrestris*

INTRODUCTION

The global interest in herbal medicines has significantly increased. Laboratory studies have extensively investigated the pharmacological properties of bioactive compounds derived from plants and their potential to treat various human and animal illnesses. The integration of traditional medicine and ethnopharmacology has led to the introduction of numerous innovative medications into the international market (Saeed et al., 2024). Herbal medicines are gaining traction as potential alternatives to conventional synthetic treatments due to their perceived low side effects, safety, and efficacy in managing human ailments (Shepherd et al., 2022). While synthetic medications often yield rapid results,

concerns regarding their side effects persist. A substantial number of modern medicines originate from plant-derived chemicals. Therefore, research is crucial to identify the active components of medicinal plants used in traditional medicine, enabling their utilization as phytomedicines. This extensive collection of phytoproducts includes many herbs purported to address human sexual dysfunction (Shahid et al., 2022).

Infertility is defined as the inability to conceive after one year of unprotected sexual activity, affecting 8% to 12% of couples worldwide. Both men and women contribute to conception difficulties, with male infertility accounting for 40% to 50% of cases (Shih et al., 2019). Initial assessment of male factor infertility typically involves semen analysis, which evaluates sperm motility, morphology, and concentration. Sperm motility, the ability of sperm to move correctly towards an oocyte, is widely recognized as a critical determinant of semen quality (Wren et al., 2023). Insufficient sperm motility is considered a primary contributor to subfertility or infertility. Beyond motility, sperm viability, and DNA fragmentation are increasingly acknowledged as significant factors affecting fertilization potential (Kaiyal et al., 2023)

The use of herbs and spices in medicine has seen a steady rise in developing nations, driven by their perceived benefits. Despite extensive research on numerous medicinal plants for improving male infertility, only a few have been traditionally employed for this purpose (Khaleghi et al., 2017). Early reports consistently highlight the growing interest in herbal antioxidants, given the significant antioxidant capacity of many medicinal plants. For instance, plant species like *Tribulus terrestris* have been studied in nutrition and medicine to develop natural antioxidant formulations (Li et al., 2022). In Europe and Asia, *Tribulus terrestris*, a plant from the Zygophyllaceae family, has been successfully used to treat sexual dysfunction. This plant contains numerous physiologically active substances, including tannins, steroids, saponins, flavonoids, alkaloids, unsaturated Tribulus terrestrisy acids, and vitamins (Elahi et al., 2013). Protodioscins, a type of furostanol saponin, are considered the primary active ingredients in *Tribulus terrestris*. These compounds have been widely utilized for various ailments, including cardiovascular and urinary disorders. Several studies indicate that *Tribulus terrestris* extract increases spermatogenesis and libido in both humans and animals (Shalaby & Hammouda, 2014).

Given its potent antioxidant content and lipoperoxidation inhibitory activity, *Tribulus terrestris* may be beneficial in treating infertility. Studies have shown that *Tribulus terrestris* extract improved sperm count and motility while reducing aberrant morphology in mice (Zhu et al., 2017). Understanding the causes and risk factors of male infertility is crucial for developing effective prevention strategies and therapies. The use of *Tribulus terrestris* represents a holistic approach to male infertility, aiming to stimulate and restore reproductive organ function (Garolla et al., 2022). This narrative review specifically aims to identify clinical trials that have investigated the potential benefits of *Tribulus terrestris* in reducing male infertility and enhancing semen and hormonal parameters.

Male infertility is a significant health concern, and various herbal therapies have been explored as potential interventions. Tribulus terrestris has been widely studied for its possible effects on male reproductive parameters, but the evidence from clinical trials remains varied and sometimes inconclusive. Therefore, it is important to systematically review and synthesize the available clinical data to provide a clearer understanding of its efficacy.

The main problem addressed in this review is: "Is *Tribulus terrestris* effective in improving male fertility parameters, particularly sperm quality, based on clinical trial evidence?"

This review aims to analyze and discuss the clinical findings regarding the use of *Tribulus terrestris* in male infertility, with a focus on its potential application in pharmaceutical practice and herbal therapy development.

METHODS

This study employed a narrative literature review approach. The aim was to synthesize and describe findings from selected clinical trials investigating the role of *Tribulus terrestris* in male infertility. References to PRISMA guidelines are mentioned only to ensure clarity and transparency in article selection, not to imply full adherence to systematic review standards (Page et.al., 2021)

Research Path

1. Data sources and selection criteria

A comprehensive literature search was conducted using the PubMed, Scopus, and Cochrane databases for English-language articles published between January 1, 2013, and November 15, 2022. The search focused on identifying clinical trials that evaluated

the effects of *Tribulus terrestris* on male fertility parameters, such as sperm quality and hormonal levels. Exclusion criteria included non-clinical studies, animal experiments, reviews, editorials, conference proceedings, and articles without accessible full text.

In the identification phase of the study, a total of 28 records were obtained through database searches, comprising 3 from Scopus, 4 from Cochrane, and 21 from PubMed. After screening, 24 records were selected for review. Documents were excluded for the following reasons: non-article types, such as books, proceedings, or reviews (n = 12), unavailable PDFs (n = 5), duplicate records (n = 6), and those not in English (n = 1). This left 4 documents assessed for eligibility. One full-text article was excluded because it did not use a randomized controlled trial (RCT) design. Finally, 3 studies met the inclusion criteria and were included in the review.

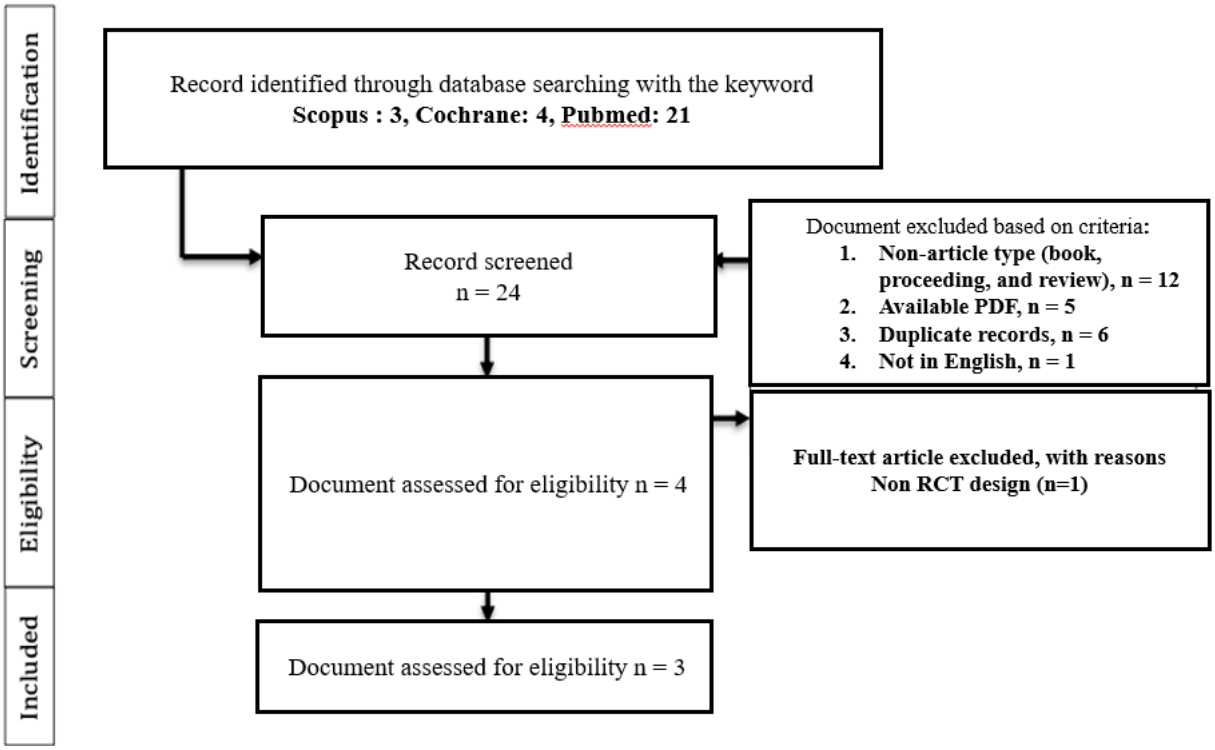

Figure 1. PRISMA 2020 Flow diagram of eligible research searching with keywords

2. Data extraction and analysis

Key data extracted from each article included the study title, authors, publication year, study design, sample characteristics, intervention dosage, outcome parameters, and main findings. The analysis focused on identifying *Tribulus terrestris* and trends in the reported effects of *Tribulus terrestris* on

male reproductive health, particularly concerning hormonal outcomes and sperm quality indicators.

RESULTS AND DISCUSSION

Tribulus terrestris is widely recognized as a traditional remedy for various sexual disorders, such as decreased libido, sterility, and menopausal symptoms.

Commercial preparations derived from Tribulus terrestris extracts are often recommended for addressing issues like erectile dysfunction, low libido, hot flashes in women, and metabolic disorders (Bouabdallah et al., 2024; Khaleghi et al., 2017).

Research indicates that protodioscin (PD) is the primary active compound responsible for the fundamental activities of *Tribulus terrestris*. PD is believed to support the treatment of male sterility and enhance muscle strength (Akhtari et al., 2014; Pokrywka et al., 2014). This compound is thought to influence cell membrane functions, thereby contributing to overall health improvement. PD has been shown to increase testosterone levels and facilitate its conversion into potent dehydrotestosterone (Maleki-Saghooni et al., 2020).

Table 1. Published studies on the effects of *tribulus terrestris* on male fertility parameters

No.	Reference	Study Design	Subject & Number of Participants	Dose	Parameter	Result
1	Roaiah et.al., 2016	Randomized controlled study	Thirty men, ages 30 to 50, who had idiopathic infertility for more than a year without any apparent cause.	250 mg extract three times a day for three months	Serum levels of both free and total testosterone, LH, motility, and abnormal sperm form	A marked increase in serum testosterone levels (from a mean of 2.31 ± 0.84 ng/mL to 3.45 ± 0.46 ng/mL, $p < 0.001$) and a significant enhancement in erectile function, as measured by IIEF questionnaire (scores increased from 13.4 ± 1.2 to 20.3 ± 1.5, $p < 0.001$). No adverse effects were reported, suggesting that *Tribulus terrestris* is a safe and potentially effective botanical intervention for alleviating symptoms of PADAM, particularly low

No.	Reference	Study Design	Subject & Number of Participants	Dose	Parameter	Result
						testosterone and erectile dysfunction.
2	Salgado et al.,2017	Randomized, double-blind, placebo-controlled clinical trial.	65 infertile males (aged 18-50) without chronic illnesses or hormonal imbalances, exhibiting altered sperm parameters	250 mg dry extract three times a day for three months	• Sperm concentration • Motility • Morphology • Testosterone levels • FSH and LH • Body Fat Index	The treatment group exhibited notable increases in sperm concentration (from 8.2 to 16.7 million/mL) and progressive sperm motility (from 12.3% to 20.9%), while sperm morphology remained unchanged. Participants receiving the extract experienced a significant reduction in body fat index (from 27.1% to 25.0%), suggesting potential metabolic benefits.
3	GamalEl Din et al., 2018	Prospective randomized controlled studies, placebo-controlled study	Seventy older, randomly assigned patients, aged 40–70, with lower urinary tract symptoms and erectile dysfunction	250 mg extract three times a day for three months	Testosterone-alanine-transaminase, AST, TRIBULUS TERRESTRIS, IIEF-5, PSA-T	The *Tribulus terrestris* group demonstrated a marked increase in IIEF-5 scores (from 13.1 ± 1.8 to 20.3 ± 1.5, $p < 0.001$) and a reduction in IPSS (from 19.3 ± 2.1 to 8.2 ± 1.3, $p < 0.001$), alongside a significant rise in serum testosterone levels (from 2.8 ± 0.4 ng/mL to 4.2 ± 0.5 ng/mL, $p < 0.001$). In contrast, the placebo group showed no statistically meaningful changes in IIEF-5, IPSS, or testosterone levels

Abbreviation:
LH: luteinizing hormone; AST: aspartate transaminase; TRIBULUS TERRESTRIS: total testosterone; IIEF-5: 5-item version of the International Index of Erectile Function; PSA-t: total prostate-specific antigen, IPSS: International Prostate Symptom Scores. PADAM: Partial Androgen Deficiency of the Aging Male

Tribulus terrestris (TT) has attracted significant scientific interest for its purported effects on male reproductive health, particularly its role in managing erectile

dysfunction (ED) and enhancing testosterone levels. Clinical trials involving aging men with partial androgen deficiency have shown promising improvements in both erectile function and serum testosterone following TT supplementation (Roaiah et al., 2016). Similar benefits were observed in patients with late-onset hypogonadism (GamalEl Din et al., 2018). However, these positive findings are contradicted by systematic reviews and randomized controlled trials, which found no significant difference between TT and placebo in terms of testosterone elevation or ED management in eugonadal men (de Oliveira Vilar Neto et al., 2025).

Beyond its hormonal effects, TT has also been explored for its influence on male fertility indicators such as sperm quality and concentration. Certain studies report improved sperm motility, liquefaction time, and concentration after TT supplementation (Salgado et al., 2017; Sanagoo et al., 2019). Additionally, TT has been associated with increased dihydrotestosterone levels and reduced body fat, potentially enhancing reproductive outcomes. However, inconsistent results exist, including studies that found no significant hormonal or semen-related changes post-treatment (Roaiah et al., 2017).

In its traditional medicinal use, TT has been used both as a fertility booster and an aphrodisiac, although its scientific validity remains debated. Some studies show improvements in sperm shape and quantity, while others reveal no hormonal changes, especially in cases of unexplained infertility. The inconsistent results suggest that TT's effectiveness may vary depending on the specific reproductive condition. Therefore, well-controlled clinical trials are necessary to better identify which populations might benefit from TT therapy.

The potential therapeutic effects of TT are attributed to its rich phytochemical content, including flavonoids, alkaloids, lignans, glycosides, and steroidal saponins. These compounds are believed to exert physiological effects through modulation of the hypothalamic-pituitary-gonadal (HPG) axis. Notably, TT appears to stimulate testosterone production without affecting adrenal hormone levels. Enhanced blood circulation via increased red blood cell production may further support improved sexual performance.

One 12-week clinical study using Tribestan, a commercial TT product, demonstrated improved sexual desire and conception outcomes in men with hypoactive sexual function. Participants also reported a

favorable safety profile and ease of use. Interestingly, TT also demonstrated efficacy in boosting libido in postmenopausal women by influencing spermatogenesis and estrogen balance (Ismail et al., 2014). These findings imply that TT's therapeutic potential may extend beyond male reproductive health.

In vitro analyses have provided additional evidence supporting TT's reproductive benefits. For example, incubating human semen with TT extract significantly improved parameters such as sperm motility, morphology, and concentration (Ahmad & Al-Murshidi, 2022). These results are believed to stem from the plant's antioxidant properties, which protect spermatozoa from oxidative stress. Such effects support the idea that TT can enhance sperm vitality at a cellular level.

Clinical research employing t-tests on pre- and post-intervention data has demonstrated significant improvements in sperm count and testosterone levels following *Tribulus terrestris* (TT) administration (Hossein et al., 2018). Traditionally used as an aphrodisiac, TT has long been associated with enhancements in reproductive health across both sexes. A key compound responsible for these effects is protodioscin, a prominent steroidal saponin found in TT, which is recognized for its potential to act as a testosterone precursor and modulate reproductive hormone levels (Villa et al., 2022; Neumann et al., 2024). Experimental models further support these claims, showing that protodioscin can enhance spermatogenesis in males and may also facilitate ovulatory function in females through multiple endocrine pathways (Neumann et al., 2024; Amer et al., 2021).

Multiple studies further substantiate TT's aphrodisiac properties by demonstrating its ability to elevate key sex hormones involved in reproductive function. TT has been shown to increase libido in both men and women, likely through a combination of hormonal regulation and improved vascular function. In one notable study, administration of TT extract resulted in a significant increase in luteinizing hormone (LH) and testosterone levels, underscoring its endocrine-modulating potential (Pavin et al., 2018). These findings highlight TT as a promising herbal agent for supporting reproductive health through hormonal optimization and libido enhancement.

Flavonoids, another class of phytochemicals prevalent in TT, contribute to its antioxidant properties, thereby promoting overall health, which can indirectly support reproductive functions

(Gracia et al., 2021). The presence of flavonoids and saponins has been linked to numerous biological activities, including anti-inflammatory responses, which may suggest broader implications for reproductive health (Yang et al., 2022; Kamalli et al., 2021). For instance, the flavonoid components have been associated with protective roles against oxidative stresses, thereby improving cellular health in reproductive tissues (Gracia et al., 2021; Patel et al., 2021).

Furthermore, TT has shown a protective effect against reproductive toxicity caused by certain pharmaceuticals. It has been found to prevent cyclophosphamide-induced testicular damage, preserving fertility parameters (Pavin et al., 2018). Similarly, TT mitigates the adverse reproductive effects of metronidazole, a drug known to impair spermatogenesis (Ara et al., 2023). These findings underscore TT's role not just in enhancing fertility but also in preserving reproductive function under stress conditions.

Recent meta-analyses of both human and animal trials suggest that *Tribulus terrestris* (TT) may positively influence male reproductive health by enhancing key parameters such as sperm viability, motility, and hormonal balance. Specifically, TT has been reported to elevate testosterone levels and improve sperm function, supporting its potential role as a therapeutic agent in managing male infertility. A study by Meybodi et al. (2024) involving male mice demonstrated significant increases in testosterone levels, along with marked improvements in sperm motility and count following TT extract administration. These findings reinforce the idea that TT could serve as a viable supplementary treatment for male reproductive disorders.

Despite these encouraging results, caution remains necessary when interpreting TT's therapeutic potential. Several systematic reviews, including that of GamalEl Din (2018), have emphasized the limitations of existing studies, citing issues such as small sample sizes, inconsistent dosages, and varied outcome measures. Furthermore, many trials lack methodological rigor and standardization, which weakens the reliability and generalizability of their conclusions. Therefore, although TT shows promise in enhancing male fertility, its clinical application should be approached with careful consideration and further validated through robust, controlled research.

One notable clinical trial investigated the effects of a 12-week TT regimen (Androsten®) on 65 men with abnormal semen parameters. Patients demonstrated marked improvement in sperm motility, concentration, and lean muscle mass following treatment (Fernández-Lázaro et al., 2022). However, the study's lack of strict inclusion criteria limits its external validity. Still, the results suggest that TT could be useful in ART settings.

The therapeutic potential of *Tribulus terrestris* (TT) in addressing male reproductive issues has been explored in various studies, particularly for conditions such as oligoasthenozoospermia and azoospermia. While some studies have reported no significant alterations in body fat or total weight among participants, it is critical to note that TT's reproductive benefits may function independently of changes in body composition (Semerdjieva & Zheljazkov, 2019). In a study involving participants diagnosed with male infertility, treatment with TT extracts showed improvements in semen quality, specifically in sperm concentration and motility, while body composition changes were minimal (Salgado et al., 2016; , Hossein et al., 2018). This suggests that TT may specifically enhance seminal parameters without impacting overall body metrics, underscoring its targeted efficacy on reproductive health.

Furthermore, extracts of *Tribulus terrestris* have demonstrated an influence on hormonal pathways, which may contribute to improved spermatogenesis. A notable mechanism involves the enhancement of testosterone production via estradiol glycosides, particularly protodioscin, present in the extract. This may lead to increased spermatogenic activity, providing potential therapeutic effects for identifiable semen abnormalities (Rajabi & Jashni, 2014). In populations experiencing oligoasthenozoospermia, TT has been associated with significant improvements in seminal quality parameters according to various studies (Ara et al., 2023; , Hossein et al., 2018).

A randomized controlled trial (RCT) conducted by Roaiah et al. (2016) evaluated the efficacy of *Tribulus terrestris* (TT) in elderly men with erectile dysfunction (ED) and lower urinary tract symptoms (LUTS). The study revealed significant improvements in testosterone levels and erectile function following TT administration, while LUTS remained unaffected. These findings suggest that TT may exert selective effects on reproductive pathways without influencing urinary function. Moreover, mild elevations

in liver enzymes and prostate-specific antigen (PSA) levels were reported, emphasizing the necessity for ongoing clinical monitoring during therapy.

Similar outcomes were reported in another RCT by Din et al. (2018), which also examined the effects of TT in elderly men with ED and LUTS. The study found a notable enhancement in erectile function, whereas no improvements were observed in LUTS. These results further support the notion that TT may selectively modulate pathways related to sexual health rather than having broader applications in urological management. This targeted pharmacological profile indicates TT's potential value in treating hormonal or fertility-related dysfunctions.

Supporting these findings, additional studies have demonstrated TT's potential in improving various reproductive health parameters. For instance, Hossein et al. (2018) reported enhancements in sperm quality among men diagnosed with oligospermia following TT supplementation. Nevertheless, conflicting evidence remains; studies such as those by Din et al. (2018) and Roaiah et al. (2016) showed no significant changes in hormonal profiles or semen parameters, challenging generalized claims about TT's effectiveness. These inconsistencies underscore the need for stratified research to identify specific populations that might benefit most from TT therapy.

Despite growing interest in TT as a therapeutic agent, safety concerns remain. Din et al. (2018) noted slight elevations in liver enzyme and PSA levels during the treatment period, underlining the importance of risk monitoring. These observations suggest that while TT may offer reproductive benefits, its use must be accompanied by a careful assessment of potential side effects. Consequently, future clinical trials should integrate comprehensive safety evaluations alongside efficacy outcomes.

Interest in developing TT into a standardized medicinal product remains high due to its observed reproductive benefits in select demographics. Advances in pharmacological research, including dose optimization and bioactive compound isolation, are essential to establishing TT's place in personalized medicine. However, limitations in existing literature—such as small sample sizes, heterogeneous methodologies, and short follow-up durations—persist (Din et al., 2018). This calls for well-designed, multicenter, placebo-controlled RCTs to generate robust evidence regarding TT's clinical value.

Recent studies into the underlying molecular mechanisms of Tribulus Terrestris (TT) have revealed insights into its therapeutic potential, particularly in male sexual and reproductive health. Investigations have highlighted the herb's influence on nitric oxide synthesis and androgen receptor (AR) expression. Increased AR expression and nitric oxide levels are linked to enhanced vasodilation and hormonal regulation, which may account for observed improvements in erectile function and sexual desire among users of TT (Moey et al., 2021; Meybodi et al., 2024). Such findings suggest a rationale for developing targeted formulations of TT aimed at optimizing sexual and reproductive functions.

Further advancing this discussion, studies propose that specific molecular biomarkers could be identified to predict individual patient responses to TT treatment. This personalized approach could enhance the efficacy of TT in clinical practices (Zeng et al., 2023). Moreover, recent research indicates that the efficacy of TT may be particularly pronounced in patients with certain endocrine disorders or fertility issues, underscoring the necessity for additional investigation into the herb's dosing standardization, long-term safety, and detailed mechanistic pathways governing its action (Delfani et al., 2021). The integration of these variables could bolster TT's positioning as an effective complementary treatment in evidence-based integrative reproductive medicine.

Evidence supporting the influence of TT on reproductive health includes various studies documenting its effects on testosterone levels and implications for fertility. Findings suggest that TT can elevate testosterone production an effect attributed to its specific saponin content, notably protodioscin, which interacts with androgen receptors or modulates hormone metabolism to influence reproductive parameters (Moey et al., 2021; Meybodi et al., 2024). This reinforces the idea that TT presents significant opportunities for therapeutic exploration and application, particularly in contexts of male infertility and hypogonadism.

CONCLUSIONS

This review indicates that *Tribulus terrestris* demonstrates positive potential for enhancing male fertility. Based on the clinical trials reviewed, *Tribulus terrestris* appears to influence male sex hormone levels, sperm quality, and libido. However, this study also highlights significant

variations in methodology and outcomes across the included studies, underscoring the critical need for more regulated and standardized research, even amidst promising findings. While acknowledging the necessity for further investigation into the effects and mechanisms of action of *Tribulus terrestris*, the conclusions of this review support the notion that this plant could be a viable natural therapeutic option for male infertility issues.

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