



Research Article

Adjunctive Oral Probiotic Therapy for Preventing Recurrent Urinary Tract Infections in Women: A Randomized Clinical Trial

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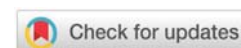
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Abstract

Background: Recurrent urinary tract infections (rUTIs) remain a common and clinically challenging condition among women, leading to repeated antibiotic exposure, increasing antimicrobial resistance, and impaired quality of life. Conventional preventive strategies often fail to prevent recurrence, highlighting the need for effective non-antibiotic adjunctive therapies. This study evaluated the effectiveness of adjunctive oral probiotic therapy in Libyan women with recurrent urinary tract infections.

Methods: An open-label, randomized, parallel-group clinical trial was conducted at a tertiary urology clinic in Libya between September 2022 and September 2025. A total of 365 women aged 18–60 years with recurrent urinary tract infections were randomly assigned to receive either conventional therapy alone (n = 182) or conventional therapy plus a daily oral probiotic containing *Lactobacillus rhamnosus* GR-1 and *Lactobacillus reuteri* RC-14 (5 × 10⁹ CFU each) for 3–6 months (n = 183). Participants were followed for 12 months. The primary outcome was recurrence of symptomatic urinary tract infections, while secondary outcomes included lower urinary tract symptoms, pain, quality of life, and adverse events.

Results: A total of 345 participants completed the study (169 conventional therapy and 176 probiotic therapy). Women receiving probiotics experienced significantly fewer recurrent urinary tract infections than those receiving conventional therapy alone. Overall, 63.1% of women in the probiotic group experienced ≤1 UTI during follow-up compared with 14.8% in the conventional group, whereas recurrent infections (≥4 episodes/year) occurred in 6.8% and 49.1% of participants, respectively ($\chi^2 = 96.84, p < 0.001$). Probiotic therapy also resulted in significantly greater resolution of burning symptoms (61.4% vs. 26.0%), pain reduction (74.4% vs. 34.3%), and improvement in quality of life (72.7% vs. 31.4%) (all $p < 0.001$). No serious adverse events related to probiotic supplementation were reported.

Conclusion: Adjunctive oral supplementation with *Lactobacillus rhamnosus* GR-1 and *Lactobacillus reuteri* RC-14 significantly reduced recurrent urinary tract infections and improved urinary symptoms and quality of life among Libyan women. These findings support probiotic therapy as a safe and effective complementary strategy for the prevention of recurrent urinary tract infections.

Abbreviations

GR-1: *Lactobacillus rhamnosus*; RC-14; *Lactobacillus reuteri*; LUTS: Lower Urinary Tract Symptoms; RUTIs: Recurrent Urinary Tract Infections

Introduction

Recurrent urinary tract infections (rUTIs) are among the most common bacterial infections affecting women worldwide

and continue to represent a major clinical and public health concern. Their high recurrence rate frequently necessitates repeated courses of antibiotic therapy, contributing to increasing antimicrobial resistance, greater healthcare utilization, and substantial impairment of patients' quality of life. Clinically, recurrent UTI is defined as the occurrence of at least three symptomatic episodes within 12 months or at least two episodes within 6 months. Despite advances in antimicrobial therapy, preventing recurrence remains a significant challenge, highlighting the need for safe, effective,

and sustainable non-antibiotic preventive strategies [1–3]. The urinary and vaginal microbiota play a fundamental role in maintaining urogenital health. Under normal physiological conditions, *Lactobacillus* species predominate within the female urogenital tract and contribute to host defense through several complementary mechanisms, including maintenance of an acidic microenvironment, inhibition of pathogen adherence to epithelial cells, production of antimicrobial substances such as bacteriocins and hydrogen peroxide, and modulation of local immune responses. Repeated exposure to antibiotics may disrupt this protective microbial ecosystem, facilitating colonization by uropathogenic bacteria, particularly *Escherichia coli*, which remains the principal causative organism of recurrent urinary tract infections [4–6]. Among the probiotic microorganisms investigated for urogenital health, *Lactobacillus rhamnosus* GR-1 and *Lactobacillus reuteri* RC-14 have received considerable attention because of their ability to restore a *Lactobacillus*-dominant microbiota and enhance natural defense mechanisms against uropathogens. Evidence from randomized clinical trials and systematic reviews suggests that probiotic supplementation may reduce the frequency of recurrent urinary tract infections while improving overall urogenital health. Nevertheless, reported outcomes remain variable across different populations, indicating that geographical, microbiological, behavioral, and healthcare-related factors may influence treatment effectiveness [6–8].

Although probiotic therapy has been evaluated in several countries, evidence from North African populations remains scarce, and no randomized clinical trial has specifically investigated its effectiveness among Libyan women with recurrent urinary tract infections. This evidence gap is particularly important given the increasing burden of antimicrobial resistance and the widespread reliance on repeated antibiotic therapy for recurrence prevention. Therefore, the present randomized clinical trial aimed to evaluate whether adjunctive oral supplementation with *Lactobacillus rhamnosus* GR-1 and *Lactobacillus reuteri* RC-14, in combination with conventional therapy, reduces the recurrence of urinary tract infections and improves urinary symptoms and health-related quality of life among Libyan women with recurrent UTIs.

Methods

Study design and setting

This study was designed as an open-label, randomized, parallel-group clinical trial to evaluate the effectiveness of adjunctive oral probiotic therapy in preventing recurrent urinary tract infections (rUTIs) among Libyan women. The study was conducted at a tertiary urology clinic in Libya between September 2022 and September 2025. The study protocol and procedures were developed to define participant eligibility, randomization, intervention administration, follow-up procedures, and outcome assessment. The study was conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT 2010) principles for randomized clinical trials.

The trial was registered under registration number GH125897. 1/9/2022. The statistical methods used for the

analysis of the collected study data are described in detail in Section 2.8. Ethical approval was obtained from the appropriate institutional ethics committee before participant recruitment. All participants provided written informed consent prior to enrollment, and the study was conducted in accordance with the ethical principles of the Declaration of Helsinki.

The study included women aged 18–60 years with a documented history of recurrent urinary tract infections. Participants were randomly allocated in a 1:1 ratio to either conventional therapy alone or conventional therapy plus daily oral probiotic supplementation containing *Lactobacillus rhamnosus* GR-1 and *Lactobacillus reuteri* RC-14. A total of 365 eligible women were enrolled and randomized, with 182 participants allocated to the conventional therapy group and 183 to the probiotic therapy group. Participants were followed for 12 months after randomization.

Participants

Women attending the participating urology clinic were screened for eligibility throughout the study period. Eligible participants were women aged 18–60 years with a documented history of recurrent urinary tract infections, defined as at least three symptomatic, culture-confirmed episodes during the preceding 12 months or at least two episodes during the preceding six months, according to the European Association of Urology (EAU) Guidelines.

Institutional Ethics Committee: Ethical approval for the study was obtained from [Sabratha Teaching Hospital] under approval number [JH 9834620], dated [1/9/2022]. The study was conducted in accordance with the Declaration of Helsinki, and written informed consent was obtained from all participants prior to the commencement of the study.

Trial Registration: The clinical trial was registered with [Sabratha Teaching Hospital] under registration number [GH125897] on [1/9/2022].

Inclusion Criteria

Participants were eligible if they:

- were female;
- were between 18 and 60 years of age;
- had recurrent urinary tract infections as defined above;
- were willing to participate throughout the study period; and
- provided written informed consent.

Exclusion Criteria

Participants were excluded if they:

- were pregnant or breastfeeding;
- had congenital or acquired urinary tract abnormalities;
- had neurogenic bladder dysfunction;

- had urinary tract malignancy;
- had severe chronic systemic disease requiring continuous hospitalization;
- had known immunodeficiency disorders;
- had received probiotic supplementation within the previous four weeks; or
- were unable to complete the scheduled follow-up period.

A total of 365 eligible women fulfilled the selection criteria and were enrolled in the study.

Randomization and allocation

Following enrollment, participants were randomly assigned in a 1:1 ratio to either the conventional therapy group (n = 182) or the conventional therapy plus probiotic group (n = 183).

Randomization was performed using a computer-generated random allocation sequence prepared before participant enrollment. The allocation sequence was implemented using sequential assignment to ensure balanced distribution between the two study groups. Because of the nature of the intervention, participant blinding was not feasible; therefore, the study was conducted using an open-label design. Nevertheless, all statistical analyses were performed using anonymized datasets to minimize analytical bias.

Interventions

Participants allocated to the control group received conventional management according to routine urological practice. Treatment consisted of culture-directed antibiotic therapy whenever indicated, together with urinary antiseptics, analgesics, and anti-inflammatory medications prescribed according to the treating physician's clinical judgment. Participants assigned to the intervention group received the same conventional treatment in addition to one oral probiotic capsule daily containing:

- *Lactobacillus rhamnosus* GR-1 (5×10^9 CFU)
- *Lactobacillus reuteri* RC-14 (5×10^9 CFU)

Probiotic supplementation was continued for a period ranging from three to six months according to the individual treatment plan.

Throughout the study, all participants received standardized counseling regarding adequate hydration, personal hygiene practices, and behavioral measures aimed at reducing the risk of recurrent urinary tract infections.

Outcome measures

Primary Outcome: The primary outcome was the frequency of symptomatic recurrent urinary tract infections during the 12-month follow-up period. A recurrent urinary tract infection

was defined as the presence of compatible urinary symptoms accompanied by a positive urine culture requiring antimicrobial treatment.

Secondary Outcomes

Secondary outcomes included:

- improvement in lower urinary tract symptoms (LUTS);
- reduction in dysuria severity;
- reduction in urinary pain;
- improvement in health-related quality of life; and
- occurrence of adverse events associated with probiotic supplementation.

Clinical outcomes were assessed at baseline and at the end of the follow-up period using a structured clinical assessment and standardized patient questionnaire.

Sample size

During the recruitment period, all women who fulfilled the predefined eligibility criteria were consecutively invited to participate in the study. A total of 365 eligible participants were enrolled and randomized. This sample size was considered adequate to provide sufficient statistical precision for detecting clinically meaningful differences between the intervention and control groups throughout the study period.

Follow-up

Participants were followed for 12 months after randomization.

Follow-up assessments were conducted according to the scheduled clinical visits. At each visit, information regarding recurrent urinary tract infections, urinary symptoms, treatment adherence, and adverse events was recorded. Participants who discontinued treatment or were lost to follow-up were documented, and the reasons for withdrawal were recorded whenever available.

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics version 20.0. Continuous variables were summarized as means $\pm$ standard deviations (SD), whereas categorical variables were expressed as frequencies and percentages. Comparisons between groups were performed using the independent-samples *t*-test for normally distributed continuous variables or the Mann-Whitney *U* test for non-normally distributed variables. Categorical variables were analyzed using Pearson's chi-square test or Fisher's exact test whenever appropriate.

All statistical tests were two-sided, and a *p*-value of < 0.05 was considered statistically significant. Data analysis was performed using the per-protocol approach based on participants who completed the scheduled follow-up.

Results

Participant flow and baseline characteristics

A total of 365 women meeting the eligibility criteria were enrolled and randomized to either the conventional therapy group (n = 182) or the conventional therapy plus probiotic group (n = 183). During the 12-month follow-up period, 20 participants were lost to follow-up (13 in the conventional therapy group and 7 in the probiotic group). Consequently, 345 participants completed the study and were included in the per-protocol analysis, comprising 169 women in the conventional therapy group and 176 women in the probiotic group. Baseline demographic and clinical characteristics were comparable between the two treatment groups. The mean age of participants was 38.9 ± 10.4 years in the conventional therapy group and 39.2 ± 9.8 years in the probiotic group ($p = 0.781$). The average number of recurrent urinary tract infection episodes during the preceding year was 4.3 ± 1.1 and 4.2 ± 1.0 , respectively ($p = 0.463$). No statistically significant differences were observed between the two groups for any baseline variable, indicating successful randomization (Table 1).

Primary outcome: Recurrence of urinary tract infections

During the 12-month follow-up, women receiving adjunctive oral probiotics experienced a significantly lower recurrence rate of urinary tract infections than those receiving conventional therapy alone. Overall, 63.1% of participants in the probiotic group experienced no more than one UTI episode during follow-up, compared with only 14.8% in the conventional therapy group. Conversely, recurrent infections (≥ 4 episodes/year) were substantially more frequent in the conventional therapy group (49.1%) than in the probiotic group (6.8%). The overall distribution of recurrence frequencies differed significantly between the two treatment groups ($\chi^2 = 96.84$, $p < 0.001$) (Table 2).

Secondary outcomes

Adjunctive probiotic therapy was also associated with significant improvements in lower urinary tract symptoms and patient-reported quality of life. Resolution of dysuria was achieved in 61.4% of women receiving probiotics compared with 26.0% in the conventional therapy group ($p < 0.001$). Similarly, urinary pain improved in 74.4% versus 34.3% of participants, respectively ($p < 0.001$). Quality-of-life improvement was reported by 72.7% of women in the probiotic group compared with 31.4% in the conventional therapy group ($p < 0.001$). No serious adverse events related to probiotic supplementation were observed during the study (Table 3).

Discussion

The present randomized clinical trial evaluated the effectiveness of adjunctive oral probiotic therapy containing *Lactobacillus rhamnosus* GR-1 and *Lactobacillus reuteri* RC-14 in reducing recurrent urinary tract infections among Libyan women. The findings demonstrated that the addition of probiotics to conventional therapy significantly reduced the frequency of recurrent urinary tract infections over the

Table 1: Baseline characteristics of study participants.

Characteristic	Conventional Therapy	Probiotic Therapy	p-value
	(n = 169)	(n = 176)	
Mean age (years $\pm$ SD)	38.9 ± 10.4	39.2 ± 9.8	0.781
Body mass index (kg/m ² $\pm$ SD)	27.4 ± 3.8	27.1 ± 3.6	0.512
Previous UTI episodes/year (mean $\pm$ SD)	4.3 ± 1.1	4.2 ± 1.0	0.463
Lost to follow-up, n	13	7	—
Participants analyzed, n	169	176	—

Table 2: Frequency of recurrent urinary tract infections during 12-month follow-up.

Recurrence category (episodes/year)	Conventional Therapy	Probiotic Therapy	p-value
	(n = 169)	(n = 176)	
≤ 1 episode	25 (14.8%)	111 (63.1%)	
2 episodes	32 (18.9%)	35 (19.9%)	
3 episodes	29 (17.2%)	18 (10.2%)	
≥ 4 episodes	83 (49.1%)	12 (6.8%)	
Chi-square test		$\chi^2 = 96.84$	<0.001

Table 3: Secondary clinical outcomes.

Outcome	Conventional Therapy	Probiotic Therapy	p-value
	(n = 169)	(n = 176)	
Burning symptoms resolved	44 (26.0%)	108 (61.4%)	<0.001
Pain reduction	58 (34.3%)	131 (74.4%)	<0.001
Quality of life improved	53 (31.4%)	128 (72.7%)	<0.001
Serious adverse events	0	0	—

12-month follow-up period. Women who received probiotic supplementation were more likely to experience one or fewer recurrent episodes and less likely to develop multiple recurrences compared with those receiving conventional therapy alone. These findings support the potential role of probiotics as an effective adjunctive strategy for preventing recurrent urinary tract infections and reducing dependence on repeated antibiotic therapy [2,3,6].

The beneficial effects observed in the present study are biologically plausible and consistent with the proposed mechanisms of probiotic action. *Lactobacillus* species contribute to maintaining a healthy urogenital microbiota through several complementary mechanisms, including maintenance of an acidic vaginal environment, inhibition of pathogen adhesion to epithelial cells, production of antimicrobial substances such as bacteriocins and hydrogen peroxide, and modulation of local immune responses. These mechanisms reduce colonization by uropathogenic microorganisms, particularly *Escherichia coli*, which remains the predominant pathogen responsible for recurrent urinary tract infections [2,3].

Although the direction of the findings is broadly consistent with previous investigations suggesting a potential preventive role for selected probiotic strains, the substantially larger effect observed in the present study warrants cautious interpretation and independent confirmation in larger and methodologically rigorous populations.

The present findings are consistent with previous randomized clinical trials investigating probiotic therapy for

recurrent urinary tract infections. Stapleton et al. reported that restoration of vaginal *Lactobacillus* colonization significantly reduced the recurrence of urinary tract infections among women at high risk of recurrence [1]. Similarly, Reid and Bruce concluded that probiotic therapy represents a promising non-antibiotic preventive approach capable of restoring the normal urogenital microbiota and reducing infection recurrence [2]. More recently, Gupta et al. conducted a systematic review and meta-analysis and reported that probiotic supplementation was associated with a lower incidence of recurrent urinary tract infections, although some variability among published studies remained because of differences in probiotic strains, treatment duration, and study populations [6]. An important finding of the present study was the relatively large difference in recurrence outcomes between the probiotic and conventional-therapy groups. During the 12-month follow-up, 63.1% of women in the probiotic group experienced no more than one UTI episode, compared with 14.8% in the conventional-therapy group, while four or more episodes occurred in 6.8% and 49.1% of participants, respectively. Although these differences were statistically significant, the magnitude of the observed treatment effect appears greater than that reported in several previous studies of probiotics for recurrent UTI prevention.

This discrepancy warrants cautious interpretation. Differences in study populations, baseline recurrence risk, probiotic strains and doses, duration of supplementation, adherence, definitions of recurrent UTI, microbiological confirmation, and background preventive treatment may contribute to variation in observed treatment effects. In particular, the present study evaluated a specific combination of *Lactobacillus rhamnosus* GR-1 and *Lactobacillus reuteri* RC-14 as an adjunct to conventional management, and the findings should therefore not be generalized to probiotics as a class.

The open-label design may also have influenced patient-reported outcomes and adherence, particularly for subjective measures such as urinary symptoms and quality of life. In addition, the study was conducted at a single urology center, and microbiological characterization of the vaginal or urinary microbiome was not performed. These factors may partly explain differences between the present findings and those reported internationally.

Accordingly, the magnitude of benefit observed in this study should be interpreted as a finding requiring independent confirmation rather than as evidence of a definitive treatment effect. Larger, multicenter, adequately blinded randomized controlled trials using standardized probiotic preparations, objective adherence measures, microbiological confirmation of recurrent episodes, and predefined outcome definitions are needed to determine the reproducibility and clinical magnitude of the observed effect.

In addition to reducing infection recurrence, adjunctive probiotic therapy produced significant improvements in lower urinary tract symptoms, urinary pain, and health-related quality of life. These improvements are clinically important because recurrent urinary tract infections adversely affect daily activities, psychological well-being, and healthcare

utilization. The observed improvement in patient-reported outcomes suggests that the benefits of probiotics extend beyond microbiological control of infection and contribute to overall patient well-being. Similar improvements in clinical symptoms have also been reported following restoration of the normal vaginal microbiota after probiotic supplementation [3,6].

Another important implication of the present findings relates to antimicrobial stewardship. Recurrent urinary tract infections frequently require repeated courses of antibiotics, increasing the risk of antimicrobial resistance and treatment failure. The World Health Organization has identified antimicrobial resistance as one of the major global public health challenges, emphasizing the importance of strategies that safely reduce unnecessary antibiotic exposure [5-11]. Therefore, adjunctive probiotic therapy may represent an effective complementary approach for decreasing antibiotic consumption while maintaining satisfactory clinical outcomes.

Despite these encouraging findings, several practical barriers should be considered before routine implementation. The relatively high cost of probiotic preparations, prolonged treatment duration, variation in product quality, and challenges related to long-term patient adherence may reduce effectiveness in routine clinical practice. Furthermore, reinfection associated with untreated sexual partners and behavioral risk factors may continue to contribute to recurrent urinary tract infections despite successful probiotic supplementation. Addressing these factors may further improve treatment outcomes in future clinical practice.

The present study has several strengths. It employed a randomized parallel-group clinical trial design with a relatively large sample size and a 12-month follow-up period, allowing comprehensive assessment of both recurrence and clinical outcomes. Baseline characteristics were well balanced between study groups, supporting the effectiveness of randomization. Furthermore, the consistency of improvements observed across both primary and secondary outcomes enhances confidence in the reliability of the findings.

Nevertheless, several limitations should be acknowledged. First, the study was conducted using an open-label design because blinding was not feasible, potentially introducing performance and reporting bias, particularly for subjective outcomes. Second, this was a single-center study, which may limit the generalizability of the findings to other healthcare settings and populations. Third, microbiome sequencing was not performed; therefore, direct confirmation of microbial changes following probiotic supplementation was not possible. Finally, adherence to probiotic therapy was assessed through follow-up interviews rather than objective compliance measures, which may have resulted in some overestimation of treatment adherence.

Future randomized multicenter clinical trials with double-blind designs, larger sample sizes, microbiome characterization using molecular techniques, and cost-effectiveness analyses are recommended to confirm these findings. Further research

should also investigate the optimal duration of probiotic therapy, compare different probiotic strains and dosages, and evaluate combined preventive strategies that integrate probiotics with behavioral and lifestyle interventions for women at high risk of recurrent urinary tract infections.

Conclusion

Adjunctive oral probiotic therapy containing *Lactobacillus rhamnosus* GR-1 and *Lactobacillus reuteri* RC-14 significantly reduced recurrent urinary tract infections and improved urinary symptoms and quality of life among Libyan women when administered alongside conventional therapy. The findings support the incorporation of probiotic supplementation as a complementary strategy for preventing recurrent urinary tract infections, particularly in women at high risk of recurrence. Nevertheless, additional large-scale multicenter randomized clinical trials are warranted before routine implementation in clinical guidelines.

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Disclosure statement

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Conflict of interest

The authors declare that there are no conflicts of interest regarding the publication of this study. All authors confirm that the research was conducted objectively and that no personal, financial, or professional interests influenced the study outcomes or interpretation of data.

Author's contributions

MOAD Almednini and Ahmed EBshena are conducting studies, interpreted the data, and drafted the manuscript. Both authors approved the paper for publication.

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