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Effects of dietary supplements and nutrition on intestinal bacteria in healthy women and women with recurrent urinary tract infections

Submission date 02/11/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 02/11/2026	**Overall study status** Completed	
Last Edited 02/11/2026	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

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Study information

Scientific Title
Intestinal microbiota modulation following a combined essential oil–caprylic acid and synbiotic intervention in healthy women and women with recurrent urinary tract infections: a prospective, non-randomized, single-arm clinical study

Study objectives
Primary objective:
To evaluate changes in selected cultivable intestinal microbial populations following a three-month combined intervention with an essential oil–caprylic acid formulation, a multi-strain synbiotic, and dietary and hygiene recommendations in healthy premenopausal women and women with a history of recurrent urinary tract infections (rUTIs)

Secondary objectives:
1. To compare the direction and magnitude of microbiological changes between the healthy and rUTI cohorts
2. To investigate changes in selected potentially pathogenic and commensal intestinal bacterial populations following the intervention
3. To explore whether baseline clinical status (healthy versus rUTI) is associated with differential

microbiological responsiveness
4. To assess participant-reported gastrointestinal symptoms, intervention adherence, and tolerability, as documented through study questionnaires

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/02/2024, Research Ethics Committee, Faculty of Medicine and Pharmacy, University of Oradea (10 Piața 1 Decembrie Street, Faculty of Medicine and Pharmacy, University of Oradea, Oradea, 410073, Romania; +40259408559; fmf@uoradea.ro), ref: CEFMF/1

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Basic science

Study type(s)

Health condition(s) or problem(s) studied
Comparison of intestinal microbiota composition and dysbiosis in premenopausal women, including healthy women and women with a history of recurrent urinary tract infections

Interventions
This prospective, longitudinal, open-label, non-randomized, single-arm interventional clinical study involved two predefined cohorts of premenopausal women aged 18–45 years: healthy women without a history of urinary tract infections and otherwise healthy women with recurrent urinary tract infections (rUTIs).

Both cohorts received the same combined intervention for three months.

Intervention components
GX Assist® (dōTERRA International LLC, Pleasant Grove, UT, USA): a dietary supplement containing caprylic acid and essential oils of oregano, tea tree, lemon, lemongrass, peppermint, and thyme.

PB Restore™ ProBiome Complex (dōTERRA International LLC, Pleasant Grove, UT, USA): a synbiotic formulation providing approximately 18×10^9 colony-forming units (CFU) from 24

active cultures representing 22 bacterial species per capsule, together with fructooligosaccharides (FOS), a heat-inactivated postbiotic strain, and a defined bacteriophage blend.

Dietary and hygiene recommendations: participants received nutritional and behavioral guidance throughout the intervention period, including measures aimed at supporting intestinal health and reducing modifiable risk factors associated with recurrent urinary tract infections.

Study procedures
At baseline, participants completed medical, nutritional, lifestyle, gastrointestinal health, and urinary tract infection history questionnaires. Stool samples were collected and analyzed at Bioclinica Laboratories, Romania, using laboratory-based assessment of selected cultivable intestinal microbial populations.

Following the three-month intervention, stool microbiota analysis was repeated within approximately 14 days of intervention completion, using the same laboratory assessment approach.

Participant adherence, tolerability, and self-reported effects were assessed through study questionnaires.

Changes in microbial populations were evaluated within each cohort and compared between the healthy and rUTI cohorts.

No randomization, placebo, untreated control group, or crossover assignment was implemented.

Intervention Type
Supplement

Primary outcome(s)
1. Selected cultivable intestinal microbial populations measured using quantitative culture-based stool microbiological analysis (intestinal dysbiosis test) performed at Bioclinica Laboratories, Romania, with laboratory-reported bacterial abundance measures at baseline (before intervention) and post-intervention (within 14 days after completion of the three-month supplementation protocol)

Key secondary outcome(s)
1. Laboratory-derived intestinal Flora Index measured using the unitless Flora Index score reported by GANZIMMUN Diagnostics, with laboratory-defined dysbiosis categories (1–5: mild; 6–12: intermediate; greater than 12: pronounced, at baseline and within 14 days after completion of the three-month intervention

2. Faecal pH measured using the laboratory's stool analysis method and reported on the unitless pH scale, at baseline and within 14 days after completion of the three-month intervention

Completion date
16/03/2026

Eligibility

Key inclusion criteria

1. Female participants aged 18–45 years
2. Premenopausal status, defined as at least 10 menstrual periods per year
3. Provision of written informed consent prior to study participation
4. Otherwise healthy women belonging to one of two predefined clinical cohorts:
4.1. Healthy cohort: women without a history of urinary tract infections.
4.2. rUTI cohort: women with a history of recurrent urinary tract infections, defined as at least two episodes within the preceding six months or at least three episodes within the preceding 12 months
5. Absence of chronic medical conditions
6. No ongoing medication or other dietary supplement use at enrolment, or a minimum 14-day interval since previous use of any over-the-counter sporadic medication or supplement, as specified in the study protocol

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Total final enrolment
173

Key exclusion criteria
1. Recurrent urinary tract infections secondary to underlying medical conditions
2. Chronic diseases, including diabetes mellitus, oncological or hematological disorders, autoimmune diseases, gastrointestinal disorders, or malabsorption syndromes
3. Current medication or dietary supplement use, or use within the preceding 14 days
4. Pregnancy
5. Known allergies relevant to study participation
6. Failure to provide written informed consent

Date of first enrolment
01/03/2024

Date of final enrolment
27/11/2025

Locations

Countries of recruitment
Romania

Sponsor information

Organisation
S.C. HOLOMED NUTRITION S.R.L.

Organisation
Universitatea de Medicină, Farmacie, Științe și Tehnologie „George Emil Palade” din Târgu Mureș

ROR
https://ror.org/03gwbzf29

Funder(s)

Funder type

Funder Name
S.C. HOLOMED NUTRITION S.R.L.

Funder Name
Universitatea de Medicină, Farmacie, Științe și Tehnologie "George Emil Palade" din Târgu Mureș

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Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Romania

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available