ISRCTN56831337 https://doi.org/10.1186/ISRCTN56831337

Impact of a probiotic supplement on menopause

Submission date
08/08/2025

Recruitment status
No longer recruiting

Registration date
12/08/2025

Overall study status
Ongoing

Last Edited
12/08/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Menopause can have a significant impact on the quality of life. Many women struggle with mental and physical menopause symptoms, including problems with sleeping, forgetfulness and mood swings. Hormone replacement therapy is an effective solution for helping with menopause symptoms, but a balanced diet and exercise can also help. There is some evidence suggesting that menopause may reduce the diversity of the gut microbiome, which is the microorganisms living in the gut. However, more research is needed to understand the possible benefits of gut health supplements such as probiotics during menopause. This pilot study aims to assess the impact of a gut supplement called Symprove on early menopause symptoms. Symprove is a water-based solution that contains billions of live and active bacteria, which can help stimulate the good bacteria already in the gut.

Who can participate?
Perimenopausal women who are experiencing symptoms related to perimenopause.

What does the study involve?
All participants will be recruited through Harley Street at Home (https://www.harleystathome.com). This is a virtual study that does not involve any study visits or allocation to groups. After providing consent to take part using an online consent form, all participants will receive a 12-week course of Symprove to take once a day. Participants will also receive a link to complete an online study survey about their perimenopause and gut symptoms at the beginning of the study before starting Symprove (Baseline), and at weeks 4, 8 and 12 (follow-up). To assess the impact of Symprove on menopause symptoms, we will compare the follow-up data to the Baseline.

What are the possible benefits and risks of participating?
Although participants may not receive any health benefit from taking part, research like this can improve our understanding of menopause and help develop new ways to manage it in the future.

A small number of people may experience mild gut disturbances (such as bloating or a change in bowel habit) when they first start taking Symprove. Disturbances will usually resolve in the first few weeks.

Where is the study run from?
Symprove Ltd, UK

When is the study starting and how long is it expected to run for?
December 2024 to December 2025

Who is funding the study?
Symprove Ltd, UK

Who is the main contact?
Mr Nigel Denby, nigel@harleystathome.com

Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
352166

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A single-arm, virtual, real-world evidence pilot study to assess the impact of Symprove in women with perimenopause symptoms

Study objectives
To explore the effects of Symprove (70 ml per day) in perimenopausal women

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/05/2025, North West - Preston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048364; preston.rec@hra.nhs.uk), ref: 25/NW/0123

Study design
Single-arm virtual real-world evidence pilot study

Primary study design
Interventional

Study type(s)
Quality of life, Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Menopause

Interventions
All participants will receive a 12-week course of Symprove to take 70ml once a day. Symprove is a gut supplement that contains billions of live and active bacteria.

Intervention Type
Supplement

Primary outcome(s)
Quality of life measured using the Menopause-Specific Quality of Life (MENQOL) questionnaire at baseline, and weeks 4, 8 and 12 (follow-up)

Key secondary outcome(s))
The following secondary outcome measures are assessed at baseline, and weeks 4, 8 and 12 (follow-up):

1. Quality of life measured using the Menopause-Specific Quality of Life (MENQOL) questionnaire
2. Gastrointestinal symptoms measured using the Gastrointestinal Symptom Index for Midlife Women (MSI-GI)
3. Other perimenopausal symptoms measured using the Midlife Women's Symptom Index (MSI)
4. Sleep disturbances measured using the Sleep Regularity Questionnaire (SRQ)

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Had a period in the last 12 months
2. Experienced menstrual cycles of variable length, skipped cycles and/or had no period for 60 days or more
3. Experiencing regular (e.g. daily or weekly) symptoms related to perimenopause (e.g. night sweats, hot flushes, gut symptoms, mood changes, trouble with concentration/memory, sleep disturbances, headaches) NB: this is not an exhaustive
list
4. Symptoms are affecting quality of life

Participant type(s)
Service user, Other

Healthy volunteers allowed
No

Age group
Mixed

Sex
Female

Key exclusion criteria
1. Currently taking probiotics or prebiotics supplements (e.g. Bimuno) or yogurts containing probiotics (e.g. Yakult, Actimel)
2. Took Symprove in the last 6 months
3. Started taking hormone replacement therapy (HRT) within the last 3 months
4. Diagnosed with gut conditions other than Irritable Bowel Syndrome, such as inflammatory bowel disease (e.g. Crohn’s disease or ulcerative colitis), coeliac disease, hepatitis, gallstones, acid reflux/dyspepsia. NOTE: Irritable Bowel Syndrome is not an exclusion criterion
5. Diagnosed with any significant psychological issues (such as depression, bipolar illness, psychosis)
6. Diagnosed with any significant heart, lung or kidney issues
7. Receiving treatment for cancer
8. Currently pregnant or breastfeeding

Date of first enrolment
11/08/2025

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Harley Street at Home
Unit 8a Wingbury Courtyard Business Village
Wingrave
Aylesbury
United Kingdom
HP22 4LW

Sponsor information

Organisation
Symprove Ltd

Funder(s)

Funder type
Industry

Funder Name
Symprove Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (Symprove Ltd).

IPD sharing plan summary
Stored in non-publicly available repository