

The overall effectiveness of a targeted supplement of botanicals, isoflavones, vitamins and minerals on perimenopausal and postmenopausal women and the most common symptoms.

Submission date 24/01/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/02/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 04/02/2025	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This is a study to test the effects of a food supplement formula called PeriMenoFriend. An estimated 13 million women are going through menopause in the UK. According to NHS data, less than 20% of women going through menopause choose to take HRT. Therefore, 80% choose not to take HRT or cannot take HRT, and turn to changes in their diet, lifestyle, exercise, cognitive behavioural therapy, food supplements, or a combination of these and other changes to enjoy a more comfortable menopause. PeriMenoFriend is a food supplement formula that includes isoflavones, botanicals, minerals and vitamins designed to support natural regulation of hormones through menopause for a more comfortable menopause.

Who can participate?

Perimenopausal (have had a period in the last 12 months and are of menopausal age) and postmenopausal (have been 12 consecutive months without a period and are of menopausal age) healthy volunteer women who are experiencing at least one symptom of menopause.

What does the study involve?

Participants will confirm they meet study requirements and confirm they do not meet any criteria that exclude them from taking food supplements. Participants will receive their 90-day supply of supplements in the post in one delivery, and begin taking their supplements as per the recommended dosage and instructions they receive as soon as they receive their supplements. Participants will be asked to complete a short questionnaire on the first day and on days 14, 30, 60 and 90.

What are the possible benefits and risks of participating?

The potential benefit is feeling better through menopause and relief from some symptoms of menopause.

There are no known risks associated with participating in this study for those who meet qualifying criteria.

Where is the study run from?
Virtually by Talk Health Partnership Ltd.

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

Who is funding the study?
DR.VEGAN LTD

Who is the main contact?
The third-party organisation running the trial, TalkHealth Partnership Ltd, are the main point of contact: Catriona Williams, catriona.williams@talkhealthpartnership.com

Contact information

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Public, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

DRV_PMF_DBPRCT_001

Study information

Scientific Title

For peri and postmenopausal women does the blind use of the PeriMenoFriend supplement formula compared to a placebo improve their menopause experience and menopause symptoms.

Study objectives

Women in perimenopause and postmenopause who take PeriMenoFriend for 90 days find it effective for their wellbeing and common symptoms of menopause.

Ethics approval required

Ethics approval not required

Ethics approval(s)

This is a randomised controlled trial in healthy volunteers of a food supplement that is already available for sale in the UK and does not require ethics approval under the UK's law.

Study design

Double-blind placebo-controlled interventional study

Primary study design

Interventional

Study type(s)

Efficacy

Health condition(s) or problem(s) studied

Perimenopause, postmenopause

Interventions

This is a double-blind placebo-controlled interventional study of perimenopausal and postmenopausal women taking a food supplement formula versus a placebo, assessing self-reported changes in wellbeing and common symptoms of menopause during the 90-day trial.

In the recruitment phase, participants are invited to confirm:

- their age
- if they are a) perimenopausal or b) post-menopausal

- symptoms of menopause they are experiencing on a 5-point scale (none, mild, moderate, severe, very severe)
- age their symptoms began

Format: PeriMenoFriend® and placebo formulas in capsule (Size 00) format

Delivery to participants: Delivered in the post to participants' homes in 3 x pouches containing 60 capsules each (3 months supply).

Dosage: 2 capsules per day, each day. Capsules are to be taken together, in the morning, daytime or evening, with food.

Duration of Intervention: 90 days

How taken: At home by individuals recruited onto the study. Participants take the supplements at a time of their choosing and convenience.

Personalisation: None

Modifications: None

Adherence: Intervention adherence or fidelity was not monitored.

Intervention Type

Supplement

Primary outcome(s)

The overall effectiveness of PeriMenoFriend for menopause symptoms and wellbeing over the previous 5 days (if participants feel a difference in menopause symptoms; if participants feel better in themselves) will be measured using self-assessed questionnaires on Days 0, 14, 30, 60 and 90

Key secondary outcome(s)

The following secondary outcome measures will assess self-reported changes in symptoms and variances between perimenopausal and post-menopausal women using self-assessed questionnaires on Days 0, 14, 30, 60 and 90:

1. The overall effectiveness of PeriMenoFriend for menopause symptoms and wellbeing over the previous 5 days in perimenopausal women
2. The overall effectiveness of PeriMenoFriend for menopause symptoms and wellbeing over the previous 5 days in postmenopausal women

Completion date

30/04/2025

Eligibility

Key inclusion criteria

1. Experiencing at least one symptom of menopause
2. Perimenopausal Women (have had a period in the last 12 months and are of menopausal age)
3. Postmenopausal Women (have been 12 consecutive months without a period and are of menopausal age)

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Mixed

Sex

Female

Total final enrolment

280

Key exclusion criteria

1. Have had or are at risk of oestrogen-positive breast cancer
2. Pregnancy or breastfeeding
3. Taking the combined contraceptive pill (containing oestrogen and progesterone)
4. Taking any of these medications: Tamoxifen, Methotrexate, Levodopa, Carbidopa, Warfarin, Benzodiazepines eg Diazepam (Valium) and Clonazepam (Klonopin), Antidepressants.
5. Taking any medications or under medical supervision, please consult a doctor or healthcare professional before joining this study if you are chosen
6. Taking any supplements for menopause and associated symptoms

Date of first enrolment

10/12/2024

Date of final enrolment

08/01/2025

Locations**Countries of recruitment**

United Kingdom

Study participating centre

-

United Kingdom

-

Sponsor information**Organisation**

DR.VEGAN LTD

Funder(s)**Funder type**

Industry

Funder Name

DR.VEGAN LTD

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			31/01/2025	No	Yes