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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
Stopped

Registration date
04/02/2025

Overall study status
Stopped

Last Edited
07/05/2026

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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?
gordon@drvegan.com

Contact information

Type(s)
Scientific, Public, Principal investigator

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Additional identifiers

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.

Primary study design
Interventional

Study design
Double-blind placebo-controlled interventional study

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

Reason abandoned (if study stopped)
Objectives no longer viable

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
0

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

England

Study participating centre
-
-
-
England
-

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