STUDY INFORMATION SHEET

A randomised, double-blind, placebo-controlled clinical study to evaluate the efficacy and safety of LactoSpore® (*Heyndrickxia coagulans* MTCC 5856) in perimenopausal women.

Principal Investigator:	**Dr Adrian Lopresti**
Contact Person(s):	**Dr Adrian Lopresti and Dr Stephen Smith**
Address	**38 Arnisdale Rd, Duncraig WA 6023**
Telephone No.	**(08) 9448 7376**

Background

Preliminary research suggests that probiotics may help reduce menopausal symptoms. Therefore, the aim of this study is to investigate the effects of a probiotic, LactoSpore®, on menopause-related quality of life in perimenopausal women with persistent symptoms. We will examine whether LactoSpore® improves a range of common perimenopausal symptoms, including changes in mood, sleep, energy, hot flushes and night sweats, cognition, libido, digestion, joint discomfort, and overall wellbeing. In addition, to help understand how LactoSpore® may work, we will measure changes in several blood markers that may be associated with menopausal symptoms over time

This study will be conducted by Dr Adrian Lopresti and Dr Stephen Smith (Clinical Research Australia).

Information about the funding source and declaration of interests

This study is funded by Sabinsa Corporation, the company that produces LactoSpore®. However, this study is being independently managed by Clinical Research Australia (CRA) without external influence from the study sponsor.

What does participation involve? **(see study flow chart on page 3)**

This study will comprise several steps as outlined below:

Step 1: Completion of initial online screening

This questionnaire takes approximately 10 minutes to complete. It provides us with information relating to the eligibility criteria. If, based on the screening questionnaire results, you are assessed as 'likely' eligible, you will be contacted for a phone interview. Ineligible volunteers will be informed by email that they do not fulfil the eligibility criteria.

Step 2: Phone Interview for an assessment of eligibility

If you are potentially eligible to participate in the study, you will be interviewed by a researcher. The interview will be conducted over the phone (approx. 20 minutes). The purpose of this interview is to obtain relevant background information (e.g., medication use, current treatments, menopausal symptoms, general health, etc.) and assess other relevant eligibility criteria. We will also provide you with further details about the study. If you meet our eligibility criteria and agree to participate in the study, you will proceed to the next step.

Step 3: VISIT 1 (Day 0): Face-to-face assessment (total time approx. 45 mins)

The face-to-face assessment will comprise the following:

a. Completion of informed consent form
b. Measurement of vital signs and body measurements: A researcher will measure your sitting blood pressure, pulse, height, weight, and temperature.
c. Completion of self-report questionnaires: You will complete a series of questionnaires.
d. Provision of a 12-week supply of the study capsules: You will be given one bottle containing capsules with either LactoSpore® or a placebo.
e. Provision of Gift Voucher. You will be given a $30 gift voucher.

Step 4: DAY 0: Collect a blood sample

Immediately after your visit, a fasting blood sample will need to be collected. This will be collected at a Western Diagnostics Pathology (WDP) clinic located near our office. This blood sample will be used to assess changes in your sex hormones, thyroid function, blood lipids, blood sugar balance, liver function, renal function and blood count.

Step 5: DAYS 1 TO 84: Start taking your capsules

In this study, we will be using a randomised, double-blind, placebo-controlled design. This means that half of the participants will be given placebo capsules, and the other half will be given capsules containing LactoSpore®.

Neither you nor the investigator will know which group you have been placed in. This random allocation is important for assessing the true effects of the probiotic supplement.

You will be required to take **ONE** capsule, approximately 30 minutes before breakfast. If you don't have breakfast, you can take it with your first meal of the day (e.g., lunch). It is extremely important that you take these capsules every day.

* Placebo involves providing a substance with no known treatment effects. In this case, the placebo will contain maltodextrin (a plant starch).

Step 6: DAY 28: questionnaires (online)

You will complete questionnaires online, which will take approximately 5 to 10 minutes

Step 7: DAY 56: questionnaires (online)

You will complete questionnaires online, which will take approximately 5 to 10 minutes

Step 8: DAY 60 Onwards: Blood collection

After you have taken the capsules for at least 60 days, we will contact you when your second fasting blood test is due. Please do not attend pathology until we have instructed you to do so. Where possible, the sample will be collected 1–7 days after menstrual bleeding begins. If you do not experience bleeding before Visit 2, the blood sample will be collected at Visit 2.

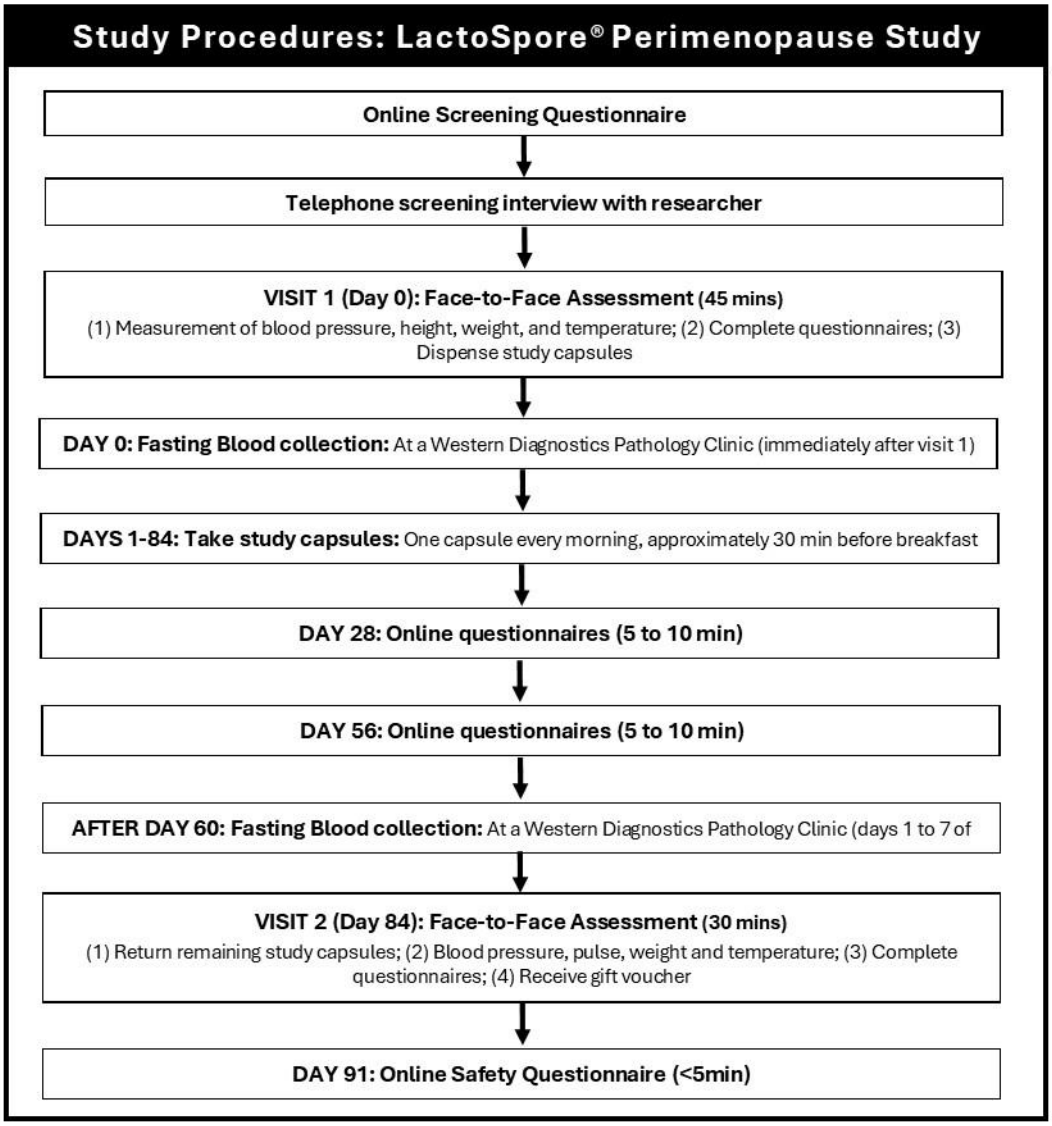
Step 9: VISIT 2 (Day 84): Face-to-face assessment (total time approx. 30 mins)

The face-to-face assessment is similar to visit 1 and will comprise the following:

a. You will need to return your study bottles/ capsules
b. Measurement of vital signs and anatomical measurements: A researcher will measure your sitting blood pressure, pulse, weight, and temperature.
c. Completion of self-report questionnaires: You will complete several questionnaires.
d. Provision of Gift Voucher. You will be given a $140 gift voucher

Step 10: DAY 91 (1-week Safety Follow-up): Online questionnaire (approx. 2–3 minutes)

Approximately one week after your final study visit, we will email you a brief online questionnaire to complete. The purpose of this questionnaire is to determine whether you have experienced any new or ongoing side effects since completing the study.



Compensation for participating in this study

To compensate participants for travel costs and time associated with participating in this study, you will receive a $30 gift voucher at visit 1 and a $140 gift voucher at visit 2.

At the end of the study, volunteers in the placebo group will also be offered a complimentary 12-week supply of LactoSpore® to try.

Criteria for inclusion/ exclusion in this study

To participate in this study, you must meet all of the following inclusion criteria:

1. You are a female aged 40 to 55 years
2. For at least 2 months, you have experienced changes in your menstrual cycle consistent with perimenopause.
3. You are experiencing ongoing perimenopause-related symptoms that are affecting your quality of life.
4. You have been a non-smoker for at least 12 months
5. You have a body mass index between 18 and 35 kg/m^2
6. You have no plan to commence new treatments over the study period.
7. You understand, are willing and able to comply with all study procedures.
8. You are willing to provide a personally signed and dated informed consent form detailing all pertinent aspects of the trial.

If any of the exclusion criteria below are met, you will not be suitable for participation in this study:

1. Your menopause was induced by surgery, chemotherapy, radiation treatment or medication.
2. You have had a partial or total hysterectomy

3. You are currently receiving any treatment for your menopausal symptoms
4. You have a recently diagnosed, unmanaged or clinically significant medical condition that may affect your safety or ability to participate.
5. You have a history of cancer
6. You have a gastrointestinal, liver or kidney condition, or another condition that may affect how the study product is absorbed or processed by your body.
7. You have a significant neurological condition or injury, or a major psychiatric condition that substantially affects daily functioning.
8. You have recently experienced an acute infection.
9. You currently use probiotic supplements or have used them recently.
10. You have recently commenced or changed medications, including antibiotics, that may affect the study outcomes, or expect to change them during the study.
11. You have recently commenced or changed nutritional or herbal supplements that may affect the study outcomes, or expect to change them during the study.
12. You have a sensitivity, intolerance, or allergy to probiotics or other excipients in the capsules
13. You plan on making major lifestyle or dietary change during the study period.
14. Your alcohol intake is greater than 14 standard drinks per week
15. You have a current or 12-month history of regular illicit drug use
16. You are pregnant, breastfeeding, or intend to become pregnant during the study period.
17. In the last year, you have had a significant surgery that affects your general health or daily function, or you have a planned surgery during the study period.
18. You have participated in any other clinical trial in the last month

Voluntary participation and withdrawal from the study

It is essential that you understand your involvement in this study is entirely voluntary. While we appreciate your participation, we respect your right to decline. There will be no consequences to you if you decide not to participate, and this will not affect any future treatment/service. If you decide to discontinue participation at any time, you may do so without providing an explanation. If you withdraw, any assessments already conducted may continue to be used for analysis.

If you need to commence a new medication, supplement or treatment during the study, please inform the research team. Depending on the treatment, you may be withdrawn from the study. Your health and access to appropriate treatment will always take priority.

Your privacy

Your participation and all information you provide will be treated confidentially. Your name and identifying information will not appear in reports or publications arising from the study. Study data will be assigned a participant identification number and stored securely for 15 years in accordance with applicable research requirements. Documents linking your identity with your participant number will be stored separately and securely, with access restricted to authorised study personnel.

Possible benefits

Distressing menopausal symptoms, including hot flushes and night sweats, are experienced by up to 80% of women. Therefore, identifying safe and effective methods to alleviate menopausal symptoms is crucial. If LactoSpore® supplementation is effective, it will provide us with a natural option to help reduce menopausal symptoms in women experiencing perimenopause.

Possible risks

Participation in this study carries minimal risk, and numerous measures will be in place to minimise the likelihood of potential risks. LactoSpore® is an over-the-counter supplement available in several countries and is well-tolerated with no reports of serious adverse reactions. Several studies conducted on LactoSpore® have shown that it is well-tolerated with limited adverse effects. However, mild adverse and typically transient gastrointestinal reactions are possible with probiotics, including gas, bloating, and diarrhoea.

In this study, we will collect a blood sample from your vein (venepuncture). Although venepunctures are very safe, there is a possibility of bruising at the site of the needle puncture. This usually appears within 24 hours and may range in size from a small spot to a large purple bruise. While bruising can be unsightly, it is not dangerous and typically disappears over a few days. Very rarely, a small artery that contains blood at a much higher pressure than in veins will lie unusually close to, or underneath, a vein. In this situation, the artery may be accidentally punctured during venepuncture. Bruising

on the lower arm may develop over the next 2 to 3 days. Again, this is not dangerous and will gradually disappear over a couple of weeks. Although extremely rare, some people may have a small branch of one of the sensory nerves in the arm running over the surface of a vein. Rarely, the needle will hit this tiny nerve on the way into the vein. This may cause a sharp, electric-shock-type pain. This may be all that occurs, but in some cases, a tingling type of pain may persist for 1 to 4 weeks as the nerve heals. This is inconvenient and may be unpleasant, but it eventually subsides. Another rare complication is the formation of a small clot (or thrombus) in the vein at the site of the venepuncture. This is noticed as a small firm lump just under the skin at the venepuncture site. The lump may be tender, and it will typically subside over a couple of weeks. Finally, although extremely rare, an infection can occur at the site of puncture. Please notify us immediately if this occurs. To minimise all these risks, blood collections will be collected by a qualified and experienced phlebotomist using current best practices.

What to do if you experience significant side effects

If you experience any significant illness, injury, or side effect that has commenced since starting your capsules, please contact Dr Adrian Lopresti or Dr Stephen Smith immediately (contact details are below). You may be asked to stop participating in the study and to seek medical advice.

Dr Stephen Smith: Ph: 9448 7376 | Mob: 0412 813 518 | Email: steve@clinicalresearch.com.au

Dr Adrian Lopresti: Ph: 9448 7376 | Mob: 0411 969 797 | Email: adrian@clinicalresearch.com.au

Feedback on study results

It is estimated that the results of this study will be finalised in late 2026. A summary of the results obtained from all participants in this study will be emailed to you when they have been published in a peer-reviewed journal (usually 6 to 12 months after the completion of the study).

Questions

If you would like to discuss any aspect of this study, please contact the principal investigator, Dr Adrian Lopresti, on 08 9448 7376 or email adrian@clinicalresearch.com.au

This study has been approved by the National Institute of Integrative Medicine (NIIM) Human Research Ethics Committee (HREC) (Trial Reference Number: 0164E_2026). If you have any reservations or complaints about the ethical conduct of this research and wish to talk with an independent person, you may contact the NIIM Research Ethics Office (Tel. 03 9804 0646) or email hrec@niim.com.au). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.