INFORMED CONSENT FORM

Protocol Title	An investigation into the effect of a daily magnesium and melatonin based multi-ingredient dietary supplement on sleep quality in individuals with self-reported nighttime leg cramps.
Protocol Number / Version	V1.0 26May2026
Sponsor	StudySetGo Ltd
Principal Investigator	Dr David Church
Study Site / Location	Decentralized
Investigator Contact	Dr David Church Email: Dave_Church@alumni.baylor.edu
Coordinating Investigator and 24-Hour Emergency Contact	Dr Tom Jameson Email: Tom.Jameson@studysetgo.com 24-hour emergency contact: 8886119860
ICF Version / Date	V1.0 26May2026

Key Information About This Study

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.

Purpose: This study will investigate whether a multi-ingredient nutritional supplement containing magnesium and melatonin can improve sleep quality in adults who experience disrupted sleep due to nighttime leg cramps.

What participation involves: Participation lasts 8 weeks. You will be randomly assigned to take either the nutritional supplement or a placebo (inactive look-alike) every night before bed for 6 weeks. You will wear an Oura Ring wearable device on one finger continuously for 8 weeks throughout the study and complete short questionnaires using a smartphone app. The Oura ring and study supplement will be sent to your home address. You will never need to travel to a research centre; all contact with the research team will be by video call, phone, messaging, or email.

How long: Your total involvement will be 8 weeks, made up of a 2-week baseline period, and a 6-week supplementation period. Each day you will complete a short app-based questionnaire (approximately 1 minute). At the end of weeks 2, 4, 6, and 8 you will complete additional app-based questionnaires (approximately 10 minutes).

Main risks: The main risks are mild and temporary side effects that some individuals may experience due to the supplement, including drowsiness or grogginess on waking, headache, dizziness, nausea, and vivid dreams. The study has been designed to minimise these side effects.

Possible benefits: You may not benefit personally from taking part in this study. However, the results will help researchers understand whether nutritional supplements can improve sleep quality in people who experience nighttime leg cramps.

Voluntary participation: Taking part in this study is entirely voluntary. You may decide not to take part, or to stop at any time, without penalty or loss of benefits to which you are otherwise entitled.

1. Why is this research being done?

Nighttime leg cramps are sudden, painful muscle contractions that affect approximately half of adults over 60 years old. They frequently disrupt sleep, leading to reduced sleep quality and overall wellbeing. Despite being common, there are few effective non-drug treatments available for people who experience sleep disruption specifically caused by nighttime leg cramps.

Magnesium and melatonin have both been shown to help with sleep quality. Melatonin helps the body prepare for sleep, and magnesium may reduce the frequency and severity of leg cramps. A recent study showed that taking both magnesium and melatonin together improved sleep quality in adults with disturbed sleep. In addition, there are a number of other nutritional ingredients that show promise for improving sleep. However, no study has yet tested whether a supplement combining these ingredients can improve sleep specifically in people who have nighttime leg cramps.

This study aims to find out whether a commercially available multi-ingredient supplement, which contains magnesium and melatonin along with other ingredients, can improve sleep quality and reduce the frequency and severity of nighttime leg cramps compared to a placebo in adults aged 40 to 75 years.

2. Why am I being asked to take part?

You are being asked to take part because you are an adult aged between 40 and 75 years who reports poor sleep quality and experiences nighttime leg cramps at least four times per fortnight. People who are currently taking prescription medications, have a diagnosed sleep disorder, or have certain medical conditions are not eligible for this study.

Approximately 50 people will take part in this study.

3. What will happen if I take part?

This is a fully decentralised study which means you will not need to visit any research centre. All materials will be delivered to your home and all contact with the research team will take place remotely via messaging, email and video call. All data will be collected using an Oura ring

wearable device and a smartphone app which you will be asked to install on your personal smartphone.

Your participation will involve three main phases: screening, baseline, and the supplementation period.

Phase 1: Screening

After reading this consent form and agreeing to take part, you will be asked to complete electronic consent and identification verification. We will then arrange a short video call to confirm your eligibility. This will include questions about your health, medications, sleep habits, and nighttime leg cramp frequency. You will also complete the Pittsburgh Sleep Quality Index (PSQI), a questionnaire about your sleep, by using a smartphone app that you will be asked to install. The research team will review your responses and confirm whether you are eligible to take part.

If you are eligible, the research team will arrange for an Oura Ring sizing kit to be sent to your home. Once you confirm your ring size, an Oura Ring Generation 4 wearable device will be sent to you along with your assigned study supplement. Upon delivery of the supplement, you will be asked to submit a photograph of the delivered supplement bottle via the smartphone app. The research team will support you in setting up and charging the Oura ring and the smartphone apps.

Phase 2: Baseline period (2 weeks [14 days])

For 14 days before you start taking the supplement, you will wear the Oura Ring continuously night and day to collect baseline data. Each morning you will receive a push notification on your phone at approximately 9:00 AM asking you to complete a short questionnaire about any nighttime leg cramps you experienced the previous night. You will also be asked to open the Oura app on your smartphone to sync data from the ring to the app. At the end of the baseline period (Day 14) you will complete the PSQI and an additional quality-of-life questionnaire (SF-36) using the smartphone app. A member of the research team will be available remotely to support you with completing the questionnaire and to provide instructions before you begin the supplementation period.

Phase 3: Supplementation period (6 weeks [42 days])

For 6 weeks you will take your assigned supplement approximately 30 minutes before going to bed. Each morning you will complete a short questionnaire on the smartphone app recording the number of capsules you took the previous evening, any nighttime leg cramps, and any side effects you experienced. You will wear the Oura Ring continuously night and day to collect supplementation data and be asked to open the Oura app on your smartphone each morning to sync data from the ring to the app. At weeks 2, 4, and 6 of the supplementation period you will also complete the PSQI and SF-36 questionnaires. The research team will be in regular contact with you throughout by messaging, email, or video call. At the end of the supplementation period your participation will be complete and you will be asked to guess if you think you received the active supplement or placebo supplement. You will be asked to safely dispose of any remaining supplement.

Supplement

The study supplement is a commercially available multi-ingredient dietary supplement sold under the brand name Mag R&R and supplied by SaltWrap (Imagine Biolabs LLC). Each dose is

up to 3 capsules taken approximately 30 minutes before bedtime every night for 6 weeks. The supplement contains: melatonin (3 mg), magnesium bisglycinate chelate with magnesium oxide (162 mg elemental magnesium), KSM-66® Ashwagandha, Rhodiola rosea extract, 5-Hydroxytryptophan (5-HTP), Gamma-Aminobutyric Acid (GABA), Passion Flower Extract, and Vitamin B6. The product contains a gelatin capsule and milk-derived ingredients.

The placebo looks the same as the active supplement but contains long grain white rice flour in a hard vegetarian capsule (hypromellose).

If you are vegetarian, or have allergies to gelatin, milk, or any other ingredient in the active supplement, you are not eligible to take part.

To help minimise side effects, you will start at 3 capsules per evening. If you experience any bothersome side effects in the first week, the research team will reduce your dose to 2 capsules, and then to 1 capsule if needed.

Randomization and Blinding

You will be randomly assigned (like the flip of a coin) to take either the active supplement or a placebo. You will have an equal chance (50/50) of being in either group. Neither you nor any member of the research team will know which group you are in until the study is over. This helps ensure that the results of the study are accurate and unbiased.

4. How long will I be in the study?

Your total time in the study will be 8. This includes a 2-week baseline period, and a 6-week supplementation period. You will have scheduled remote contacts (video call or messaging) with the research team at the start of the study, at week 2 of baseline, and at weeks 2, 4, and 6 of the supplementation period.

5. What are the possible risks or discomforts?

Risks of the Supplement

The ingredient most likely to cause side effects is melatonin (3 mg per dose). Side effects are usually mild, temporary, and go away on their own. They may include:

- Drowsiness or grogginess on waking
- Headache
- Dizziness
- Nausea
- Vivid dreams or nightmares

You will be advised to take the supplement approximately 30 minutes before bedtime and not to drive or operate heavy machinery for at least 8 hours after taking it. If you need to get up during the night, you are advised to take your time; sit on the edge of the bed for a moment before standing, make sure you have adequate lighting, and move slowly, as the supplement may cause some temporary drowsiness or light-headedness.

The remaining ingredients (Magnesium, Ashwagandha, Rhodiola rosea, 5-HTP, GABA, Passion Flower Extract, Vitamin B6) are used at doses consistent with commercially available dietary supplements and are not expected to cause side effects in otherwise healthy adults.

5-HTP may interact with certain medications, particularly those that affect serotonin levels (such as SSRIs and MAOIs). Participants taking such medications are not eligible for this study.

A dose reduction procedure is in place during the first week to minimise the risk of side effects. You will rate any symptoms each morning, and your dose will be reduced if needed.

Risks of Study Procedures

This study involves no blood draws, injections, or any invasive procedures. The only procedure beyond questionnaires is wearing the Oura Ring wearable device. The Oura Ring is a consumer-grade non-medical device worn on one finger. It poses no known health risks. You will be advised not to wear the ring adjacent to other rings to avoid discomfort, and to contact the study team if you experience any skin irritation at the wear site.

Risks to Pregnancy or Reproduction

You will not be eligible to take part if you are pregnant, breastfeeding, or planning to become pregnant during the study period. The effects of the supplement on an unborn baby or breastfed infant are not fully known. If you become pregnant during the study, you should contact the research team immediately.

Risk of Loss of Confidentiality

As with any research study, there is a small risk that information about you could be seen by people who should not see it. The study team has put steps in place to protect your information, which are described in section 11 below.

Unknown Risks

Taking part in research may involve risks that are not yet known. The study team will let you know as soon as possible if any new information comes to light that may affect your willingness to continue.

6. What are the possible benefits?

You may not benefit personally from taking part in this study. If you are assigned to the active supplement group, you may experience improvements in sleep quality and a reduction in the frequency or severity of nighttime leg cramps, but this cannot be guaranteed.

The results of this study will contribute to scientific knowledge about whether nutritional supplements can help people who experience poor sleep due to nighttime leg cramps, which may benefit others in the future.

7. What other choices do I have?

Your alternative is simply not to take part in this study. If you are concerned about your sleep or nighttime leg cramps, you are encouraged to speak with your healthcare provider about other options available to you.

8. Will it cost me anything to take part?

There is no cost to you for taking part in this study. The study supplement or placebo, the Oura Ring wearable device, and all study materials will be provided and shipped to you at no charge. You will need a compatible smartphone (iOS 15 or higher, or Android 9 or higher) and an internet connection to use the study apps. The Oura ring requires charging using the provided USB charging cable and dock approximately once per week. Charging takes approximately 20-80 minutes.

9. Will I be paid for taking part?

You will not receive a cash payment for taking part in this study. As a gesture of appreciation for completing the study, you will be invited to keep the Oura Ring wearable device (retail value approximately $349 USD). Participants who do not wish to keep the ring may return it using a prepaid return envelope that will be provided.

Please note that if you decide to continue using the Oura Ring after the study ends, you will need to purchase an Oura membership independently and directly from Oura (approximately $5.99 per month). You are under no obligation to do so.

10. What happens if I am injured because of the study?

This study involves a commercially available dietary supplement and a non-invasive wearable device, so the overall risk is considered low. However, if you believe you have experienced a research-related injury, you should contact the Principal Investigator Dr David Church or Coordinating Investigator Dr Tom Jameson immediately using the contact details provided at the end of this form.

The study Sponsor (StudySetGo Ltd.) or Funder (SaltWrap / Imagine Biolabs LLC) do not provide payment or compensation for the costs of treating research-related injuries. You do not give up any of your legal rights by signing this consent form. If you require urgent medical attention, please contact your local emergency services or go to your nearest emergency room.

11. How will my information be kept private?

The research team takes the privacy of your information seriously. The following steps are in place to protect your data:

- You will be assigned a unique study ID number. Where possible, all research data will be linked to this number, not your name or personal details.
- Your questionnaire data and consent records will be transferred from the United States to the United Kingdom (UK), where they will be stored and processed by Trialflare, a clinical research platform, on behalf of StudySetGo Ltd., the organization responsible for this study.
- Your data is protected by UK data protection law and security measures described in this form.
- Your Oura ring will be collected and stored by Oura Health on servers in the United States. When you set up your Oura ring, you will be asked to accept Oura's Terms of Use and Privacy Policy. If there is any conflict between those terms and this consent form, this consent form takes precedence with regard to your research data.
- Your name, telephone number, email address and home address will be shared with Red Stag Fulfilment solely for the purposes of supplement delivery, and with Oura solely for

the purpose of Oura ring delivery. These disclosures are made for logistical purposes only and do not constitute research data sharing.

- No research data will be stored on personal or unencrypted devices.

Your study records may be reviewed by the Principal Investigator, the study sponsor (StudySetGo Ltd.), and the IRB. We will do our best to keep your information private, but we cannot guarantee absolute privacy. In the event of a data breach involving your personal information, you will be notified in accordance with applicable law.

Only anonymised individual and aggregated data will be shared with the study funder (SaltWrap / Imagine Biolabs LLC). No information that could identify you will be shared with the study funder or included in any publications or presentations arising from this research.

To complete the consent process, you will be asked to verify your identity using a third-party service called KYCAID. This requires a photograph of a government-issued ID and a short liveness check. You will be asked to agree to KYCAID's privacy policy before proceeding.

You have the right to ask questions about data handling and to receive a clear response from the research team at any point during the study.

12. Can I stop taking part?

Yes. Taking part is entirely voluntary. You can choose not to take part, and you can stop at any time, for any reason, without penalty or loss of any benefits to which you are otherwise entitled. If you decide to stop, please inform a member of the research team as soon as possible.

If you withdraw from the study, any data already collected about you will be retained as part of the study record, as required by research regulations. This will be explained to you when you sign this consent form.

The research team may also end your participation without your consent in certain circumstances, for example if a new safety concern arises, if you no longer meet the eligibility criteria, or if you do not take the supplement or wear the Oura Ring regularly as required by the study.

13. Will I be told about new information?

If the study team learns of any new information that might affect your decision to continue taking part, they will contact you as soon as possible. You may be asked to sign a new consent form before continuing in the study.

14. Optional and Additional Elements

Storage and Future Use of Data

All study records and data will be retained for a minimum of 10 years after the end of the study, as a single record linking Personally Identifiable Information (PII) to a participant code. After this 10 year period, the record linking PII to participant code shall be deleted, effectively rendering the data fully anonymized. Anonymized study data may be retained indefinitely by the Sponsor (StudySetGo Ltd.) and funder (SaltWrap / Imagine Biolabs LLC). This fully anonymized data

may be used for future research studies or shared with other researchers for research purposes. If this happens, your identity will not be revealed.

Commercial Profit

Your data may be used to develop new products. If this happens, you will not have rights to any profit from those products.

Return of Results

You will be provided with a summary of the main research findings once available upon completion of the study. You may request a copy of your individual raw data following completion of the study.

ClinicalTrials.gov Notice

A description of this clinical trial will be available on https://www.ClinicalTrials.gov before the first participant is enrolled. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

15. Who can I contact with questions?

If you have questions about...	Contact
The research, or you think you have a research-related injury	**Principal Investigator:** Dr David Church Email: Dave_Church@alumni.baylor.edu **Sponsor Contact:** Dr Tom Jameson Email: tom.jameson@studysetgo.com 24 hour phone number: 8886119860
Your rights as a research participant, complaints, or concerns	**Elemental IRB** 732 S. 6th St., STE N, Las Vegas, NV 89101 Phone number: 702-603-6851

16. Statement of Voluntary Participation

Taking part in this study is your choice. You may refuse to take part, or you may stop at any time, without losing any benefits to which you are otherwise entitled. Refusing to take part will not affect your relationship with the study team.

17. Consent to Take Part in the Study

By completing the electronic consent, I confirm that:

- I have read this form, or it has been read to me, and I have had a chance to ask questions.
- My questions have been answered to my satisfaction.
- I understand that taking part is voluntary and that I may stop at any time.
- I understand I will be asked to complete an identity verification process using a third-party service provider.
- I agree to take part in the study described in this form.
- I will be given a signed copy of this form to keep.