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OPAL-3

Determining the Optimal Dose of Omega-3 Fatty Acids in Pregnancy for Women with Moderate Status

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Study Information for GPs

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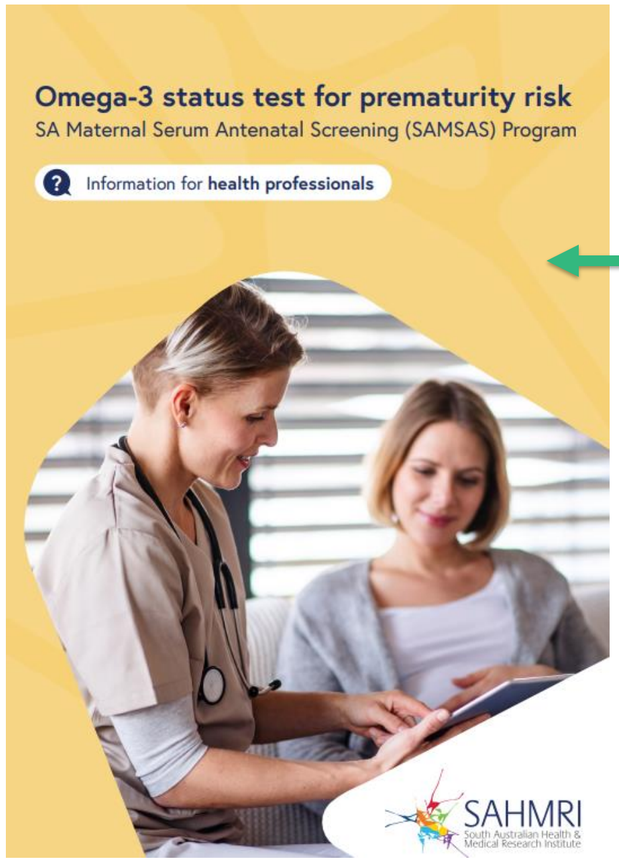

Background

The omega-3 test, delivered through SAMSAS as a part of the **Omega-3 Test-and-Treat Program** measures a woman's omega-3 status.

What <u>we know</u> about omega-3, pregnancy and preterm birth

- Pregnant women with **low total omega-3 status** early in pregnancy are at a **higher risk of early preterm birth** and may benefit from omega-3 supplementation.
- Conversely, women with **sufficient total omega-3 status** are at a **lower risk**, and additional omega-3 supplementation might not be advantageous.

What <u>we don't know</u> about omega-3, pregnancy and preterm birth

- **We lack guidance for women with moderate omega-3 status** regarding the appropriate omega-3 dose. Currently the advice we provide to women in this range is 'no action required'.

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Omega-3 status test results: how to advise women

Omega-3 status[4,5]	Guidance to incorporate into pregnancy care plan
Less than 3.7% (low status)	**Take omega-3 fatty acid supplements** until 37 weeks, to reduce the risk of early preterm birth. Suggested dose: 800 mg DHA and 100 mg EPA per day. Typical suitable supplements include Infantem (Pharmamark)* and Omega Brain (Blackmores).
Between 3.7 and 4.3% (moderate status)	**No action required.** If already taking omega-3 fatty acids as part of a multivitamin and mineral supplement or a standalone supplement, this may continue.
Above 4.3% (sufficient status)	**Omega-3 supplements are not required** and provide no benefit to risk of early preterm birth. If women are already taking omega-3 fatty acids as part of a multivitamin and mineral supplement and wish to continue, the dose of DHA+EPA should not exceed 250 mg per day.

*Vegan algal oil supplement of DHA and EPA.

Importance of the OPAL-3 Study

Moderate omega-3 status and pregnancy?

- Women in the **moderate omega-3 group are halfway towards achieving sufficient status** and may require a lower dose compared to those with low omega-3 to reach the desired sufficient level.
- Conducting a **dose-response study is the logical next step** to determine the precise dosage needed for these women to attain sufficient omega-3 levels.
- The OPAL-3 Study **aims to identify the optimal DHA and EPA dose for pregnant women** with **moderately low omega-3 status** to match the profile of women with the lowest risk of preterm birth.
- This study serves as a crucial step in **finding the right omega-3 dose** for women with moderate omega-3 status to **further reduce prematurity rates**

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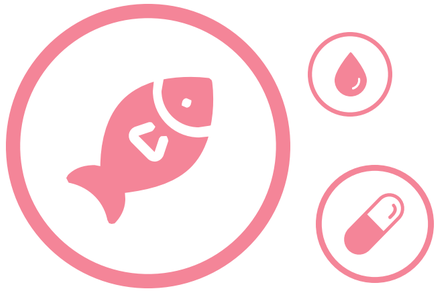
Study Design

- This is an omega-3 dose-response study in pregnant women.
- In this randomised controlled trial, our specific focus is on **women with omega-3 status in the lower half of the moderate range** (≥3.7 to ≤4.0% in blood serum), rather than those in the higher end of this moderate range.
- In a previous study (ORIP), the low moderate group did not show statistically significant benefits, but there were **indications that they might still gain advantages from supplementation** to reduce their risk of early birth.



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What's Required from Participants

- Participants involved in this study will receive **one of four omega-3 doses** from ≤ 21 weeks to 37 weeks' gestation:
  - Control/No DHA+EPA
  - 200mg DHA, 25mg EPA
  - 400mg DHA, 50mg EPA
  - 800mg DHA, 100mg EPA

- The study also includes **Low** and **Sufficient** reference **groups** (not supplemented).

- Participants need to collect **3 x blood spots** during pregnancy and complete short **online surveys**. No in-person visits are required. **1 x breastmilk sample** is also collected post-partum.

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What's Required From GPs

- For GPs: **Your role in this study is to recruit participants**, you do not need to provide any study advice to women. Regardless of whether participants are in the randomised groups or reference groups, they should continue following the usual guidance of the Test and Treat Program. The only difference is that some women in this study will be taking additional supplements. **More information on how to recruit is provided in the next slides**.

- The **OPAL-3 team will be responsible for maintaining ongoing contact with participants after you have recruited them**. GPs will then receive a letter indicating that their patient has enrolled in the study. You are not responsible for ongoing communication with them about this study.

Study Eligibility

- Pregnant women
- Singleton pregnancy
- Less than 21 weeks pregnant
- Known omega-3 results

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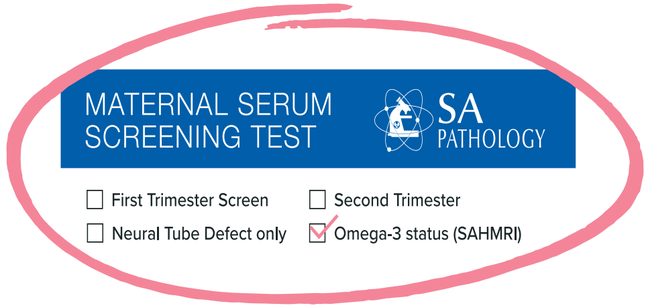
How You Can Help Us to Recruit Participants

Step 1: Request Omega-3 Testing

- When interacting with your pregnant patients, request omega-3 testing on the SAMSAS form by ticking 'omega-3 test' before 21 weeks' gestation.



Step 2: Discuss Omega-3 Results and Study

- During your discussion about the omega-3 test results, also explain the opportunity for your patients to participate in the OPAL-3 study and provide them with a study brochure.

"Would you be interested in hearing more about a study that's investigating the optimal dosage of omega-3 supplementation for pregnant women, with a particular focus on those with moderate omega-3 levels."

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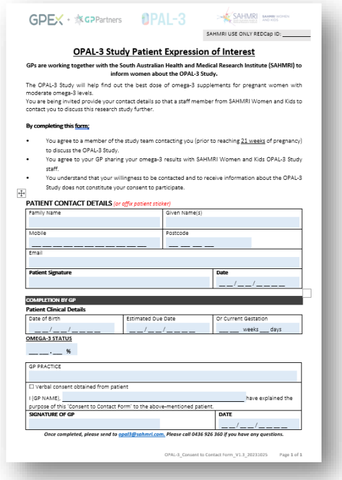
How Can You Help Us to Recruit Participants

Step 3:
Provide Patient 'Expression of Interest' Form

- If your patient wants to participate or is interested in obtaining more information, provide them with an 'Expression of Interest' form and encourage them to complete it and sign it during their visit with you.

- Let them know that your role is solely to inform them about the study, and that you'll share their details, including the 'Expression of Interest' form with the OPAL-3 team who will follow-up with them about the study and their potential participation.



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OPAL-3 Study Patient Expression of Interest

GPs are working together with the South Australian Health and Medical Research Institute (SAHMRI) to inform women about the OPAL-3 Study.

The OPAL-3 Study will help find out the best dose of omega-3 supplements for pregnant women with moderate omega-3 levels.
You are being invited provide your contact details so that a staff member from SAHMRI Women and Kids to contact you to discuss this research study further.

By completing this form:

- You agree to a member of the study team contacting you (prior to reaching 21 weeks of pregnancy) to discuss the OPAL-3 Study.
- You agree to your GP sharing your omega-3 results with SAHMRI Women and Kids OPAL-3 Study staff.
- You understand that your willingness to be contacted and to receive information about the OPAL-3 Study does not constitute your consent to participate.

PATIENT CONTACT DETAILS *(or affix patient sticker)*

Family name | Given name(s)
Mobile | Postcode
Email
Patient Signature | **Date**

COMPLETION BY GP
Patient Clinical Details

Date of Birth | Estimated Due Date | Or Current Gestation ___ weeks ___ days
OMEGA-3 STATUS ___ . ___ %

GP PRACTICE
☐ Verbal consent obtained from patient
I (GP NAME) _____ have explained the purpose of this 'Consent to Contact Form' to the above-mentioned patient.
SIGNATURE OF GP | **DATE**

Once completed, please send to opal3@sahmri.com. Please call 0436 926 360 if you have any questions.

OPAL-3_Consent to Contact Form_V1.0_30231025 Page 1 of 1

Step 4:
Email the 'Expression of Interest' Form

- After your patient completes the 'Expression of Interest' form, kindly retain the form and email it to opal3@sahmri.com

- Once we have received the referral 'Expression of Interest' form, your involvement is complete. No further action is needed on your behalf and a referral payment will be automatically arranged for you.

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What Now?

Why Your Support Matters

- We rely on GPs like you to help us recruit participants.
- Your referrals are crucial in advancing our understanding of omega-3 supplementation during pregnancy.
- We're here to support you by providing a necessary 'pack' for your easy reference. This include brochures, ‘Expression of Interest’ forms, and a one-pager informational resource.
- You will also be provided with a referral payment, which will be automatically arranged for you for each patient you refer.

You will find all the items you need to begin making referrals in our ‘Study Pack’ envelope

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Questions