

Tear off section:

Please visit our website at www.approvetrial.org.au if you would like more information about the trial.

If you think you would be interested in joining the **APProve study**, you can contact us in one of four ways:

1. E-mail: approve.probiotic@sydney.edu.au
2. Phone: (02) 9462 9796
3. Text: 0417 725 052
4. Complete your details and return to:
Fax: (02) 9462 9058
Post: APProve Trial Coordinator
Level 2, Building 52, RNSH
St. Leonard's NSW 2065

Name: _____

Street Address: _____

City: _____

Postcode: _____

Phone (mobile): _____

Email: _____

My baby is due on: ____ / ____ / ____
(dd) (mm) (yy)

APProve Study

This study is being conducted at the Royal North Shore Hospital by researchers at the Kolling Institute, University of Sydney.

APProve Investigators

Professor Jonathan Morris
Associate Professor Natasha Nassar
Ms Diana Bond

www.approvetrial.org.au



For further information contact the APProve Study Team:

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E-mail: approve.probiotic@sydney.edu.au

APProve

CAn
Probiotics
ImProve
Breastfeeding
Outcomes?



- Are you currently 36 weeks pregnant or more?
- Do you intend to breastfeed your baby after you give birth?
- Do you own a smartphone?

If you have answered yes to the above questions, then this trial could be suitable for you!

Providing
Optimal
Care
Through
Clinical
Research

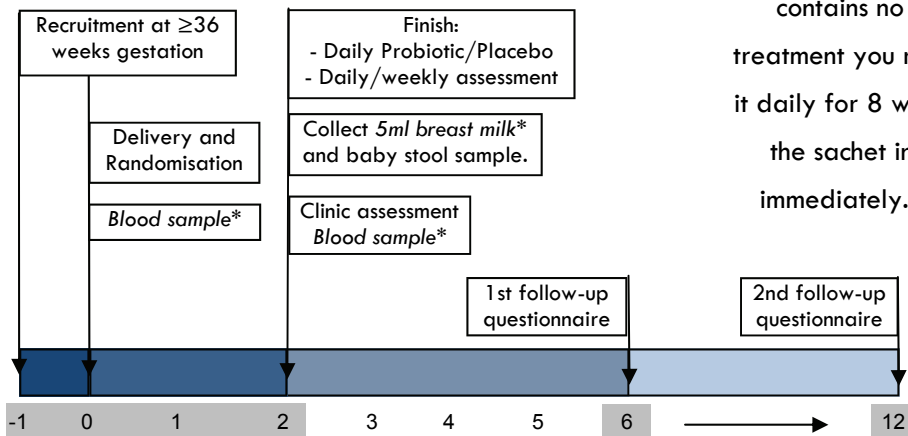


What you need to know about the APProve study...

The **purpose** of this study is to investigate whether taking oral probiotics are effective for improving breastfeeding outcomes during the first two months after you deliver. Research shows that probiotics can treat certain infections in mothers and infants, but their role in preventing disease and improving health in relation to breastfeeding has not yet been explored.



APProve Study Timeline



Time in months

*These samples MAY be collected.

What does this study involve?

If you agree to participate in this study, you will be asked to sign the Participant Consent Form and be willing to receive SMS texts via our mobile phone application system. mHealth is a novel way to access information about the **APProve** study, as well as collect information about you and your baby's health. It will even remind you if you forget to take your treatment!



After your baby is born, you will be randomly assigned to either the **"probiotic"** group or the **"placebo"** group. A placebo is a dummy treatment that looks like the genuine product but contains no active ingredient. Whichever treatment you receive, you will be asked to take it daily for 8 weeks by dissolving the contents of the sachet into a cold drink and drinking it immediately. You may be asked to collect a small sample of breast milk 2 months after the birth of your baby, along with a stool (poo) sample taken from your baby's nappy.

At this time we will conduct a health and well-being check with you and your baby. A small blood sample may be collected from you at the beginning and end of the treatment.

How much will it cost?

Absolutely nothing! All treatment sachets and collection tubes are supplied free of charge. We will also provide you with a parking voucher for your 2 month visit.



Is the APProve Study safe for me and my baby?

We do not anticipate that you will suffer any unexpected risks as a result of this study. The probiotics used in this trial are listed on the Australian Register of Therapeutic Goods and are not associated with any adverse effects.