Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work; Participant Information and Consent Form for (1.) the Formula-feeding group and (2.) the Breastfeeding group

Supplement to:

Infant formula supplemented with milk-fat-globule membrane compared with standard infant formula for the cognitive development of healthy term-born formula-fed infants; a protocol for a randomised controlled trial

Participant Information Sheet/Consent Form – Parent/Guardian

Formula Feeding Group

Women's & Children's Hospital, North Adelaide, South Australia

Lay Title	Infant nutrition with milk fat globule membrane for infant cognition in early life
Short Title	Infant Feeding Study
Protocol Number	3.0
Project Sponsor	Fonterra Cooperative Group Limited
Principal Investigator	Professor Maria Makrides (SAHMRI Women and Kids)
Local Principal Investigator	Dr Andrew McPhee and Dr Jacqueline Gould (SAHMRI Women and Kids) (Chief Investigator)
Associate Investigator(s)	Professor Robert Gibson, Dr Lisa Yelland (SAHMRI Women and Kids) and Professor John Colombo (University of Kansas, USA)

1. Introduction

The first year of life is an important time for the way a baby's brain grows and develops. This growth and development are partly influenced by a nurturing environment and partly by the quality of nutrition. The nutrition needed for optimal development are met via breastmilk, baby formula, or a mixture of both. One of the complex nutrients found in breastmilk is a mix of protein and fat called the milk fat globule membrane (MFGM). Although standard baby formula is a good substitute for breastmilk, it contains only trace amounts of MFGM.

The purpose of this study is to determine whether supplementing baby formula with additional MFGM is beneficial to the way healthy babies develop. To do this, we plan to compare the growth and development of babies that are fed breastmilk, standard baby formula or a formula supplemented with additional MFGM.

Approximately 600 babies will be enrolled in this study; 200 in the standard infant formula group, 200 in the MFGM-supplemented infant formula group and 200 in the breast-fed reference group. This study is being conducted by SAHMRI in South Australian Hospitals and in the community through the Child and Family Health Service.

This Participant Information Sheet/Consent Form tells you about the study. Please read this information carefully. Ask questions about anything that you don't understand or would like to know more about.

2. What is the purpose of this research?

Sometimes we don't know which treatment is best and to find out, we need to compare different treatments. It is known that MFGM is present in breastmilk and may play a role in both brain and immune development. We would like to look at whether supplementing standard baby formula with additional MFGM can improve health and development in formula fed babies.

We are also interested in looking at infant feeding practices among Australian mothers of term born babies.

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3. What does participation in this research involve?

Your baby will be randomly assigned (like tossing a coin) to either the 'standard formula' or a 'standard formula with additional MFGM' group. Your baby will have one in two chances of receiving either the 'standard formula' or the 'standard formula with additional MFGM' to feed to your baby from enrolment into the study (less than or equal to 60 days of age) until he or she is 12 months old.

Neither you, nor the research team, will be able to choose which group you are in or know which type of formula you have been assigned. All 'study formula' will be provided to you free of charge until your baby is 12 months of age. At the end of the study the results will be compared to see if one treatment is better than the other. We have also included a breastfed group to help us compare the formula fed groups.

If you have chosen to take part in this study we ask that you do not offer any solids or other drinks for at least 4 months following birth. If you choose to start breastfeeding your baby, please contact the research team.

We will ask you to attend some study visits and do some surveys, so we can assess the effects of the two study formulas.

Study Contact

All study contact is outlined in the flow chart on the next page. When you enrol into the study, we will ask you some questions about education, race and details about your pregnancy. We will also review your baby's blue book to determine information about your baby's growth, birth and health history. You will also receive a few phone calls in the first few weeks following enrolment to discuss formula commencement and current feeding practices.

The study visits involve answering some questions about how you are feeding your baby, your baby's health and development and doing some assessments with your baby. You will be reimbursed for your travel costs to attend these study visits. At each study visit we will collect your baby's measurements, ask some questions about feeding your baby, how windy or gassy your baby has been, your baby's bowel movements, any illnesses and childcare attendance.

You have the option of attending two study visits when your baby is 4 and 9 months of age where we can assess your baby's attention and heart rate at two of the study visits. These optional visits would involve showing your baby pictures of faces, while they are sitting on your lap (or in a highchair) and assessing your baby's attention to these faces (and how your baby's attention may change when seeing the same face or new different face). This will be done by measuring your baby's heart rate through a monitor on their chest and videorecording their eye movements whilst they look at the pictures. This takes between 5-15 minutes and is generally interesting for babies. If you prefer, the 4 and 9 month milestones can be done over the phone.

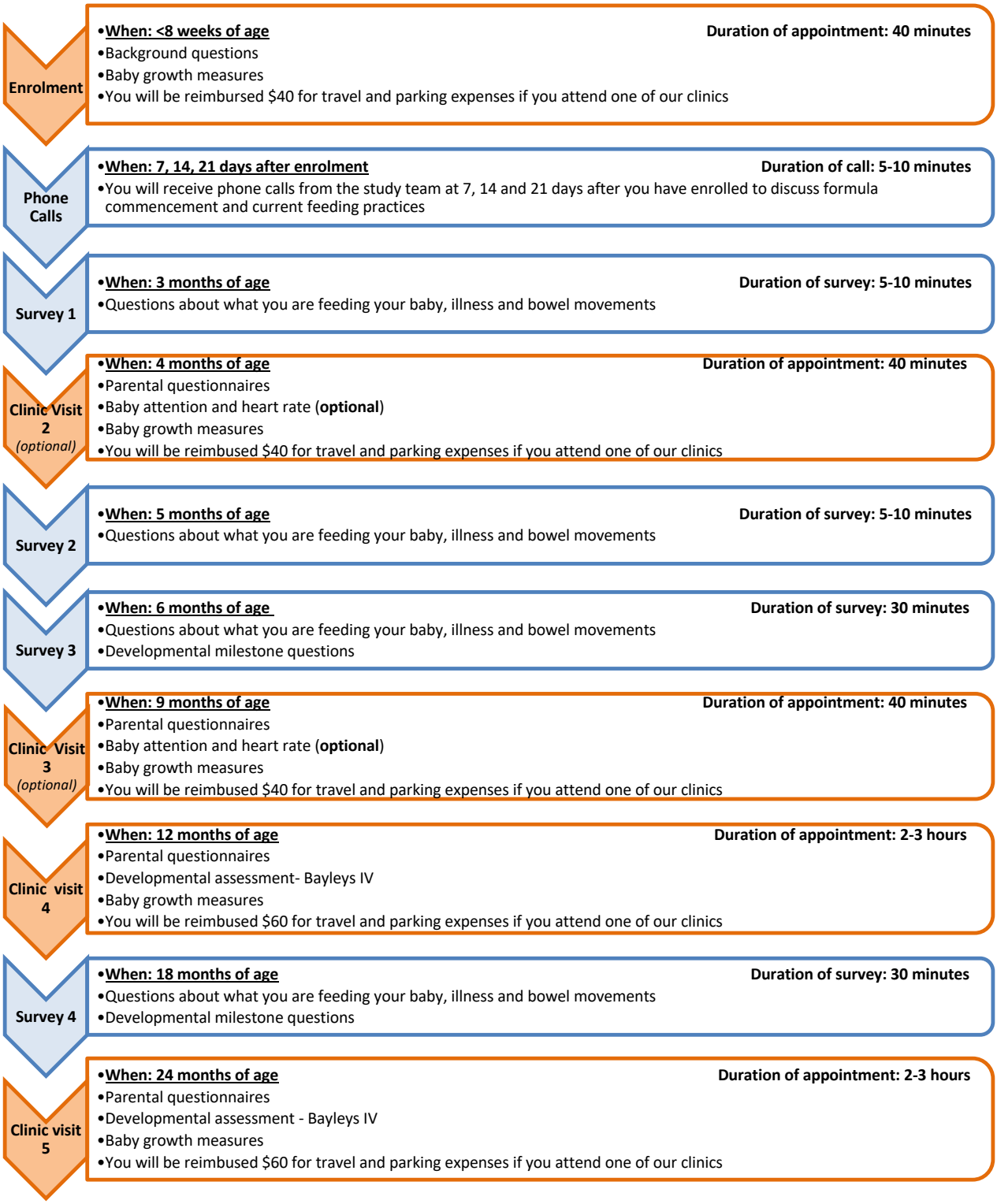
At 12 and 24 months of age we will assess your baby's development with the Bayley Scales of Infant and Toddler Development, fourth edition (Bayley-IV). This usually takes 1 hour with a research assistant and involves a series of games-like activities with toys and picture books that children generally enjoy. We also have some questionnaires for you to complete about your child's general development (Ages and Stages Questionnaire), language skills (MacArthur-Bates Communicative Development Inventories), and emotion and behaviour. We will give you the results of this assessment and if you have any concerns, we can offer you a referral to a GP.

We will also send you some questions via an online survey to your phone or email (or via telephone if you prefer) in between the study visits. There will be four online surveys to complete over a two-year period. They will take between 5-30 minutes and will include questions about feeding your baby, how windy or gassy your baby has been, your baby's bowel movements, any illnesses and childcare attendance. We will also collect some information about your baby's sleeping habits. Please note that we may contact you

Gould JF, *et al. BMJ Open* 2024; 14:e083399. doi: 10.1136/bmjopen-2023-083399

with some additional information that you might find helpful (e.g., safe sleeping practices), depending on how you respond to your surveys. Two of the surveys will also include questions about your child's general development (like whether they have started crawling or walking or speaking yet, or whether they are able to hold a crayon).

Outline of study contact



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4. What does my baby have to do?

We ask that you provide the study formula to your baby until 12 months of age.

We ask that you provide us with information about any use of any antibiotics or other medications prescribed or given to your baby during the study.

Whilst your baby is participating in this study, it is important to tell the study team about any treatments or medications you may give your baby, including over-the-counter medications, vitamins or herbal remedies. You should also tell the study team about any changes to these during your baby's participation in the research study.

We will be collecting information about the general health and development of your baby throughout the study and may access your medical records, if your baby has been admitted to hospital.

5. Other relevant information about the study

The standard formula and MFGM-supplemented formula are similar to infant formula that is currently sold within Australia. The formula used in this study are not currently sold in Australia or internationally.

Both the standard formula and MFGM-supplemented formula comply with all the requirements of the Australian and New Zealand Food Standards Code for infant formula and international regulations.

We will collect you and your partners contact details to enable us to communicate with you throughout the study. We will also collect details of up to four alternate contacts. We may contact one or more of the alternate contacts that you have provided to us in the event we have difficulties in reaching you throughout the study.

6. Does my baby have to take part in this study?

Participation in any study is voluntary. If you decide that your baby can take part and later change your mind, you are free to withdraw your baby from the project at any stage.

Your decision that your baby can or cannot take part, or that they can take part and then be withdrawn, will not affect their routine treatment, relationship with those treating them, their hospital or relationship with SAHMRI.

7. What are the possible benefits of taking part?

We cannot promise that your baby will receive any benefits from this research. The study assessments may assist in detecting a problem or delay with your baby's health or development. You will be supplied with formula to feed your baby until they are 12 months of age and reimbursed for attending clinic visits.

This study will lead to an improved understanding of whether supplementing infant formula with additional MFGM will benefit infant health and development.

8. What are the possible risks and disadvantages of taking part?

There are minimal risks for taking part in the study. As with any cow's milk formula, there may be rare occurrences of intolerance. Attending the clinic visits and participating in this study will involve a time commitment for you and your baby.

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9. What if I withdraw my baby from this study?

If you decide to withdraw your baby from the project, please notify a member of the research team before you withdraw them. This notice will allow that person or the research supervisor to further discuss any special requirements linked to withdrawing.

If you do withdraw your baby during the study, study staff will not collect additional personal information, although personal information already collected will be retained to ensure that the results of the study can be measured properly and to comply with law.

10. What happens when the study ends?

Following completion of this study, all records identifying you and your baby will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available.

The results of this study may be published in medical journals or presented at professional meetings, but you or your baby will not be identified in any way. We will send you a newsletter with the results of the study.

We may contact you following the completion of this study to see if you are interested in participating in any potential follow up studies, pending approval by the Human Research Ethics Committee.

11. What will happen to information about you and your baby?

You have a right to privacy, and all information that is collected because of this study is confidential. Your and your baby's data may be viewed by governments or ethics committees for auditing purposes, or by an external party for the purposes of monitoring data quality and adherence to the study protocol. To deliver study formula to you, your contact information, including your address will be provided to a warehouse. If you decide to take part in the attention and heart rate clinic assessment at 4 and 9 months, the video files of your baby will be sent to our international collaborators at the University of Kansas in the U.S.A. The video files are sent and stored and are destroyed at the completion of the study. All external parties involved in this project have signed agreements to ensure that your and your baby's information will be kept secure and confidential at all times.

In the case of a legal requirement, we may need to pass on personal information to authorised third parties. This requirement is standard and applies to information collected both in research and non-research situations. Such requests to access information are rare however, we have an obligation to inform you of this possibility.

In any publication and/or presentation, information will be provided in such a way that no participant can be identified. All data collected in the study may be stored for use in future research studies that may or may not be related to the original study. For example, to explore how baby's grow and develop over the first 24 months of life and patterns for the introduction of the first solid foods. Any stored data will be identified by a unique study number only, so that you and your baby cannot be identified and use of the data for research purposes would only occur if the research has been approved by the trial steering committee and the Human Research Ethics committee.

12. Complaints and Compensation

If your baby requires medical attention as a result of effects attributable to the consumption of any of the study formulas, you will be reimbursed for such medical costs by Fonterra Cooperative Group Limited. Such compensation shall be in accordance with the Australian Pharmaceutical Manufacturers Association (APMA) Clinical Trials Compensation Guidelines.

Gould JF, *et al. BMJ Open* 2024; 14:e083399. doi: 10.1136/bmjopen-2023-083399

13. Who is organising and funding the research?

This study is being conducted by SAHMRI Women and Kids and is funded by Fonterra Cooperative Group Limited. Fonterra Cooperative Group Limited is a dairy company that manufactures dairy-based ingredients, and dairy-based consumer products including infant formula. They may directly or indirectly benefit financially from knowledge acquired through analysis of your baby's data. You will not benefit financially from your baby's involvement in this study.

SAHMRI will receive payment from Fonterra Cooperative Group Limited to undertake this study. No member of the research team will receive a personal financial benefit from this study, or your baby's involvement in this study (other than their ordinary wages).

14. Who has reviewed the study?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the Women's & Children's Health Network.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15. Further information and who to contact

If you would like to contact us, the person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if the baby has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact a member of the study team on 8128 4436 or any of the following people:

Study related matters

Name	Dr Jacqueline Gould
Position	Chief Investigator
Telephone	
Email	

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	
HREC Executive Officer	
Telephone	
Email	

Local HREC Office contact (Single Site - Research Governance Officer)

Name	
Position	
Telephone	
Email	

Gould JF, *et al. BMJ Open* 2024; 14:e083399. doi: 10.1136/bmjopen-2023-083399

Infant Feeding Study CONSENT FORM

LAY TITLE: Infant Feeding Study

SCIENTIFIC TITLE: Infant nutrition with milk fat globule membrane for infant cognition in early life.

I _____

hereby consent to my child's involvement in the research study described above:

1. The nature and purpose of the study described on the attached Information Sheet has been explained to me. I understand it and agree to my child taking part.
2. I understand that my child may not directly benefit by taking part in this study.
3. I acknowledge that the possible risks and/or side effects, discomforts, and inconveniences, as outlined in the Information Sheet, have been explained to me.
4. I understand that I can withdraw my child from the study at any stage and that this will not affect medical care or any other aspects of my / my child's relationship with any healthcare service.
5. I understand that there will be no direct payment to me or my child for taking part in this study. I understand I will be reimbursed $40 for the first three study visits, and $60 for the final two study visits should they require travel to the hospital clinics. All visits completed in the home will not be reimbursed.
6. I have had the opportunity to discuss taking part in this study with a family member or friend, and/or have had the opportunity to have a family member or friend present whilst the researcher was explaining the study.
7. I am aware that I should retain a copy of the Consent Form, when completed, and the Information Sheet.
8. I agree to the accessing my child’s medical records, if they are hospitalised during the study period.
9. I understand that my and my child’s information will be kept confidential as explained in the Information Sheet except where there is a requirement for it to be shared with external parties for the purposes of monitoring, delivery of study formula, or when required by law.
10. I understand that the alternate contacts I have provided may be used to contact me as explained in the Information Sheet for study related purposes.
11. I understand that I may be contacted following the completion of this study to see if I am interested in participating in a follow-up of this study.

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Infant Feeding Study CONSENT FORM

14. I consent to my baby's de-identified data being used in other studies, provided the project has the approval of the Women's & Children's Hospital Research Ethics Committee.

Full name of Parent/Guardian: .....

Signature of Parent/Guardian: .....

Relationship to baby: .....

Full name of baby: .....

Dated: .....

I certify that I have explained the study to the parent / guardians and consider that he/she understands what is involved.

Researcher Name: .....

Researcher Signature: .....

Title: .....

Dated: .....

Gould JF, *et al. BMJ Open* 2024; 14:e083399. doi: 10.1136/bmjopen-2023-083399

Participant Information Sheet/Consent Form – Parent/Guardian

Breastfeeding Group

Women's & Children's Hospital, North Adelaide, South Australia

Lay Title	Infant nutrition with milk fat globule membrane for infant cognition in early life
Short Title	Infant Feeding Study
Protocol Number	3.0
Project Sponsor	Fonterra Cooperative Group Limited
Principal Investigator	Professor Maria Makrides (SAHMRI Women and Kids)
Local Principal Investigator	Dr Andrew McPhee, Dr Jacqueline Gould (SAHMRI Women and Kids) (Chief Investigator)
Associate Investigator(s)	Professor Robert Gibson, Dr Lisa Yelland (SAHMRI Women and Kids) and Professor John Columbo (University of Kansas, USA)

1. Introduction

The first year of life is an important time for the way a baby's brain grows and develops. This growth and development are partly influenced by a nurturing environment and partly by the quality of nutrition. The nutrition needed for optimal development are met via breastmilk, baby formula, or a mixture of both. One of the complex nutrients found in breastmilk is a mix of protein and fat called the milk fat globule membrane (MFGM). Although standard baby formula is a good substitute for breastmilk, it contains only trace amounts of MFGM.

The purpose of this study is to determine whether supplementing baby formula with additional MFGM is beneficial to the way healthy babies develop. To do this, we plan to compare the growth and development of babies that are fed breastmilk, standard baby formula or a formula supplemented with additional MFGM.

Approximately 600 babies will be enrolled in this study; 200 in the standard infant formula group, 200 in the MFGM-supplemented infant formula and 200 in the breast-fed reference group. This study is being conducted by SAHMRI in South Australian Hospitals and in the community through the Child and Family Health Service.

This Participant Information Sheet/Consent Form tells you about the study. Please read this information carefully. Ask questions about anything that you don't understand or would like to know more about.

2. What is the purpose of this research?

Sometimes we don't know which treatment is best and to find out, we need to compare different treatments. It is known that MFGM is present in breastmilk and may play a role in both brain and immune development. We would like to look at whether supplementing standard baby formula with additional MFGM can improve health and development in formula fed babies.

We are also interested in looking at infant feeding practices among Australian mothers of term born babies.

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3. What does participation in this research involve?

We want to work out whether we can improve on our current feeding practices for infants who are formula-fed. To do this, we will compare two groups of babies being fed two different infant formulas with a group of breastfed babies, the 'breastfeeding reference group'.

At the end of the study we will compare our results to see if one formula is better than the other at fulfilling the nutritional requirements of babies. We will also compare results with the breastfeeding baby group as this is the gold standard feeding method.

If you have chosen to take part in our breastfeeding group, we ask that you do not offer any solids or other drinks for at least 4 months following birth.

If you have difficulties with breastfeeding, we will offer the assistance of a lactation consultant whose services will be provided to you free of charge until your baby is 6 months of age.

Study Contact

All study contact is outlined in the flow chart on the next page. When you enrol into the study, we will ask you some questions about occupation, education, race and details about your pregnancy. We will also review your baby's blue book to determine information about your baby's growth, birth and health history. You will also receive a few phone calls in the first few weeks following enrolment to discuss your current feeding practices.

The study visits involve answering some questions about how you are feeding your baby, your baby's health and development and doing some assessments with your baby. You will be reimbursed for your travel costs to attend these study visits.

At each study visit we will collect your baby's measurements, ask some questions about feeding your baby, how windy or gassy your baby has been, your baby's bowel movements, any illnesses and childcare attendance.

You have the option of attending two study visits when your baby is 4 and 9 months of age where we can assess your baby's attention and heart rate at two of the study visits. These optional visits would involve showing your baby pictures of faces while they are sitting on your lap (or in a highchair) and assessing your baby's attention to these faces (and how your baby's attention may change when seeing the same face or new different face). This will be done by measuring your baby's heart rate through a monitor on their chest and videorecording their eye movements whilst they look at the pictures. This takes between 5-15 minutes and is generally interesting for babies. If you prefer, the 4 and 9 month milestones can be done over the phone.

At 12 and 24 months of age we will assess your baby's development with the Bayley Scales of Infant and Toddler Development, fourth edition (Bayley-IV). This usually takes 1 hour with a research assistant and involves a series of games-like activities with toys and picture books that children generally enjoy. We also have some questionnaires for you to complete about your child's general development (Ages and Stages Questionnaire), language skills (MacArthur-Bates Communicative Development Inventories), and emotion and behaviour. We will give you the results of this assessment and if you have any concerns, we can offer you a referral to a GP.

We will also send you some questions via an online survey to your phone or email (or via telephone if you prefer) in between the study visits. There will be four online surveys to complete over a two-year period. They will take between 5-30 minutes and will include questions about feeding your baby, how windy or gassy your baby has been, your baby's bowel movements, any illnesses and childcare attendance. We will also collect some information about your baby's sleeping habits. Please note that

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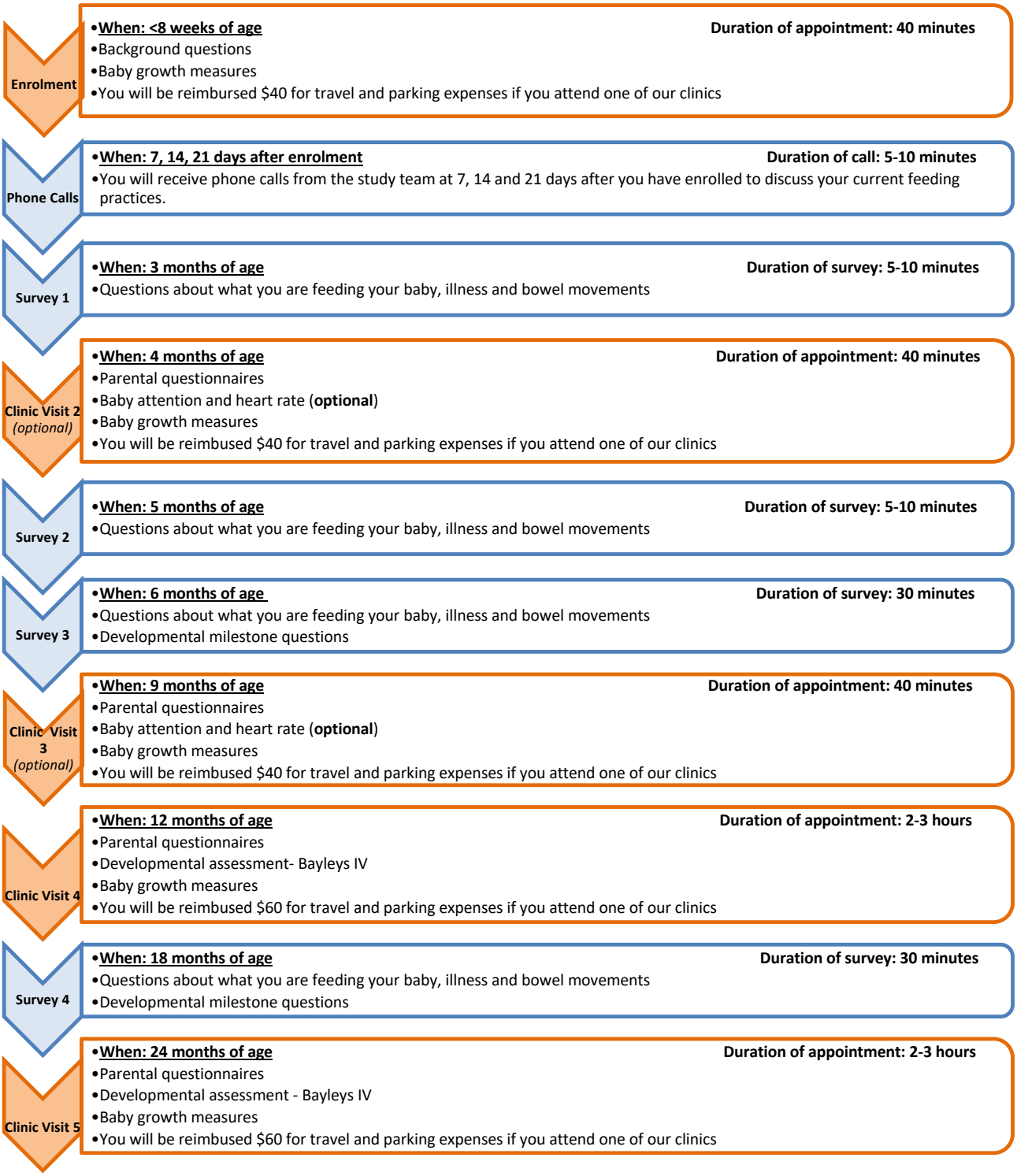
we may contact you with some additional information that you might find helpful (e.g., safe sleeping practices), depending on how you respond to your surveys. Two of the surveys will also include questions about your child's general development (like whether they have started crawling or walking or speaking yet, or whether they are able to hold a crayon).

Outline of study contact



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4. What does my baby have to do?

We ask that you provide us with information about any use of any antibiotics or other medications prescribed or given to your baby during the study.

Whilst your baby is participating in this study, it is important to tell the study team about any treatments or medications you may give your baby, including over-the-counter medications, vitamins or herbal remedies. You should also tell the study team about any changes to these during your baby's participation in the research study.

We will be collecting information about the general health and development of your baby throughout the study and may access your medical records if your baby has been admitted to hospital.

5. Other relevant information about the study

We will collect you and your partners contact details to enable us to communicate with you throughout the study. We will also collect details of up to four alternate contacts. We may contact one or more of the alternate contacts that you have provided to us in the event we have difficulties in reaching you throughout the study.

6. Does my baby have to take part in this study?

Participation in any study is voluntary. If you decide that your baby can take part and later change your mind, you are free to withdraw your baby from the project at any stage.

Your decision that your baby can or cannot take part, or that they can take part and then be withdrawn, will not affect their routine treatment, relationship with those treating them, their hospital or relationship with SAHMRI.

7. What are the possible benefits of taking part?

We cannot promise that your baby will receive any benefits from this research. We can offer you access to a lactation consultant until your baby is 6 months of age and the developmental assessments may assist in detecting a problem or delay.

This study will lead to an improved understanding of whether supplementing infant formula with additional MFGM will benefit infant health and development.

8. What are the possible risks and disadvantages of taking part?

There a minimal risks for taking part in this study. Attending the clinic visits and participating in this study will involve a time commitment for you and your baby.

9. What if I withdraw my baby from this study?

If you decide to withdraw your baby from the project, please notify a member of the research team before you withdraw them. This notice will allow that person or the research supervisor to further discuss any special requirements linked to withdrawing.

If you do withdraw your baby during the study, study staff will not collect additional personal information, although personal information already collected will be retained to ensure that the results of the study can be measured properly and to comply with law.

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10. What happens when the study ends?

Following completion of this study, all records identifying you and your baby will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available.

The results of this study may be published in medical journals or presented at professional meetings, but you or your baby will not be identified in any way. We will send you a newsletter with the results of the study.

We may contact you following the completion of this study to see if you are interested in participating in any potential follow up studies, pending approval by the Human Research Ethics Committee.

11. What will happen to information about you and your baby?

You have a right to privacy, and all information that is collected because of this study is confidential. Your and your baby's data may be viewed by governments or ethics committees for auditing purposes, or by an external party for the purposes of monitoring data quality and adherence to the study protocol. Should you request a lactation support, your contact information will be provided to a private lactation consultant. If you decide to take part in the attention and heart rate clinic assessment at 4 and 9 months, the video files of your baby will be sent to our international collaborators at the University of Kansas in the U.S.A. The video files are sent and stored and are destroyed at the completion of the study. All external parties involved in this project have signed agreements to ensure that your and your baby's information will be kept secure and confidential at all times.

In the case of a legal requirement, we may need to pass on personal information to authorised third parties. This requirement is standard and applies to information collected both in research and non-research situations. Such requests to access information are rare however, we have an obligation to inform you of this possibility.

In any publication and/or presentation, information will be provided in such a way that no participant can be identified. All data collected in the study may be stored for use in future research studies that may or may not be related to the original study. For example, to explore how baby's grow and develop over the first 24 months of life and patterns for the introduction of the first solid foods. Any stored data will be identified by a unique study number only, so that you and your baby cannot be identified and use of the data for research purposes would only occur if the research has been approved by the trial steering committee and the Human Research Ethics committee.

12. Complaints and Compensation

If your baby requires medical attention as a result of effects attributable to the consumption of any of the study formulas, you will be reimbursed for such medical costs by Fonterra Cooperative Group Limited. Such compensation shall be in accordance with the Australian Pharmaceutical Manufacturers Association (APMA) Clinical Trials Compensation Guidelines.

13. Who is organising and funding the research?

This study is being conducted by SAHMRI Women and Kids and funded by Fonterra Cooperative Group Limited. Fonterra Cooperative Group Limited is a dairy company that manufactures dairy-based ingredients, and dairy-based consumer products including the infant formula category. They may directly or indirectly benefit financially from knowledge acquired through analysis of your baby's data. You will not benefit financially from your baby's involvement in this study.

SAHMRI will receive payment from Fonterra Cooperative Group Limited to undertake this study. No member of the research team will receive a personal financial benefit from this study, or your baby's involvement in this study (other than their ordinary wages).

14. Who has reviewed the study?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the Women's & Children's Health Network.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15. Further information and who to contact

If you would like to contact us, the person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if the baby has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact a member of the study team on 8128 4436 or any of the following people:

Study related matters

Name	Dr Jacqueline Gould
Position	Chief Investigator
Telephone	
Email	

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	
HREC Executive Officer	
Telephone	
Email	

Local HREC Office contact (Single Site - Research Governance Officer)

Name	
Position	
Telephone	
Email	

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Infant Feeding Study CONSENT FORM

LAY TITLE: Infant Feeding Study

SCIENTIFIC TITLE: Infant nutrition with milk fat globule membrane for infant cognition in early life.

I _____

hereby consent to my child's involvement in the research study described above:

1. The nature and purpose of the study described on the attached Information Sheet has been explained to me. I understand it and agree to my child taking part.
2. I understand that my child may not directly benefit by taking part in this study.
3. I acknowledge that the possible risks and/or side effects, discomforts, and inconveniences, as outlined in the Information Sheet, have been explained to me.
4. I understand that I can withdraw my child from the study at any stage and that this will not affect medical care or any other aspects of my / my child's relationship with this healthcare service.
5. I understand that there will be no direct payment to me or my child for taking part in this study. I understand I will be reimbursed $40 for the first three study visits, and $60 for the final two study visits should they require travel to the hospital clinics. All visits completed in the home will not be reimbursed.
6. I have had the opportunity to discuss taking part in this study with a family member or friend, and/or have had the opportunity to have a family member or friend present whilst the researcher was explaining the study.
7. I am aware that I should retain a copy of the Consent Form, when completed, and the Information Sheet.
8. I agree to the accessing my child’s medical records if they are hospitalised during the study period.
9. I understand that my and my child’s information will be kept confidential as explained in the Information Sheet except where there is a requirement for it to be shared with external parties for the purposes of monitoring, delivery of study formula, or when required by law.
10. I understand that the alternate contacts I have provided may be used to contact me as explained in the Information Sheet for study related purposes.
11. I understand that I may be contacted following the completion of this study to see if I am interested in participating in a follow-up of this study.

Infant Feeding Study CONSENT FORM

14. I consent to my baby's de-identified data being used in other studies, provided the project has the approval of the Women's & Children's Hospital Research Ethics Committee.

Full name of Parent/Guardian: .....

Signature of Parent/Guardian: .....

Relationship to baby: .....

Full name of baby: .....

Dated: .....

I certify that I have explained the study to the parent/guardian and consider that he/she understands what is involved.

Researcher Name: .....

Researcher Signature: .....

Title: .....

Dated: .....

Gould JF, *et al. BMJ Open* 2024; 14:e083399. doi: 10.1136/bmjopen-2023-083399