

Milk consumption and cognitive function in children

INFORMATION SHEET

HUMAN RESEARCH ETHICS COMMITTEE NUMBER: 18/2016

INTRODUCTION

Each year the CSIRO performs a number of nutritional research projects involving human participants, including children. Nutrition plays a vital role in the development of the human brain and nutritional intakes are directly involved in the development of healthy cognitive function (including attention, memory and thinking). It is important to gain a better understanding of micronutrients (vitamins and minerals) and their role in the development of cognitive function in children.

Whilst some micronutrients are thought to provide benefits for cognitive development independently, it is common nutritional practice to provide micronutrients in combination. These micronutrient 'bundles' have been shown to be beneficial for cognitive development in children.

Research also shows that complex milk lipids have a role in supporting brain development and improving cognitive outcomes in infants. However, less is known about their effect on cognitive function in children aged 7-9 years, an age when children undergo a brain growth spurt.

This study is being funded by a commercial sponsor.

WHAT IS THE AIM OF THIS STUDY?

The aim of the present study is to investigate the effects of three milk drinks on cognitive function and physical growth and fitness in primary school children

1. a milk drink with an added micronutrient bundle plus Complex Milk Lipids
2. a milk drink with added micronutrients
3. a standard milk drink

HOW WILL THE STUDY BE CARRIED OUT?

Who can participate?

If you and your child would like to participate, you are asked to complete the online screening questionnaire (click on the NEXT button at the end of this information sheet). Before completing the questionnaire you are asked to consider the selection criteria below. If you have any concerns regarding the selection criteria please contact one of our research staff on 8303 8906. Your personal information will be stored on a secure survey server that is only accessible to members of the research team.

Inclusion Criteria

- Girls and boys
- Aged between 7 and 9.5 years at trial commencement (your child must have been born between November 1st, 2007 and May 1st, 2010)
- Low dairy consuming children (≤ 1 serve per day of core whole dairy food, e.g. milk, cheese, yoghurt)

Exclusion Criteria

- Children who don't consume Dairy for health reasons (e.g., Lactose intolerance),
- Children who won't consume Dairy because of a dislike, or for religious reasons,
- Children taking micronutrient supplements (e.g. Multivitamins, Calcium supplements),
- A diagnosed behavioural or other developmental disorder (e.g., Autism, ADHD, Specific Learning Disorder, Dyslexia),
- Blind,
- Deaf,
- Unable/unwilling to wear prescribed hearing aid &/or prescription glasses during the cognitive assessment,
- Primary language other than English,
- Diabetes (Type 1 or 2),
- Epilepsy ,
- A disorder or medical condition affecting physical movement (e.g., cerebral palsy, tremor, myoclonus, missing limb etc.).

On receipt of your questionnaire, eligibility of your family will be considered and you may be contacted by phone to confirm details. We expect to make a final selection of participants by February-March 2017. The study will commence during the April 2017 school holidays and conclude during the October 2017 school holidays.

What will be involved?

The study will run for 6 months. Participation in this study will involve coming to the CSIRO Research Clinic (located on North Terrace in the Adelaide CBD) on 2 occasions, at the beginning and end of the trial.

- All visits to the clinic will be organised with you by the study research officer.
- The visits at the beginning and end of the study will take approximately 4 hours and will take place in the mornings.
- You will be encouraged to leave your child in the care of the clinic staff, however you may be present to offer comfort if required.
- Your child will be required to fast from midnight prior to these two visits. Water will be allowed during fasting.
- An option of two breakfasts will be offered to your child approximately 1 hour into the clinic visit.

During the study, your child will be randomly allocated to one of three groups. The groups will differ in the type of milk drink that are provided. Your child will be asked to consume two serves of milk every day for the duration of the study. Each serve is 150ml and the two serves can be consumed at separate times or together. These milk drinks will come in Strawberry and Plain flavours and will be provided to you at no cost.

What will be measured?

At the start and end of the study the following tests will be conducted with your child:

1. **Body Composition:** Height and weight will be measured, Body Mass Index (BMI) calculated and tracked over time. Bioelectrical Impedance Analysis (BIA) will be used to assess body composition, including fat mass and fat-free mass. Using a commercial set of scales, your child will stand upright, positioning their bare feet on the footpads and their hands on the handles. Electrical impedance analysis is used to determine body composition which is calculated automatically by the inbuilt software.
2. **Blood Tests:** A venous fasting blood sample will be taken to measure haemoglobin, Vitamin D, Iron levels, inflammation (C-reactive protein), calcium and zinc. This will involve collecting a total of ~2 tablespoons of blood per visit. Bloods will be taken by a trained and experienced paediatric nurse.

3. Cognitive Measures: After breakfast your child will complete a set of cognitive tasks on paper and on the computer. A trained staff member will talk your child through each task to make sure they understand what to do before commencing. The cognitive tasks will measure memory, reasoning, reaction time and attention. These measures will take about 1 hour to complete.
4. Physical Fitness: After a break your child will be asked to perform a shuttle run, hand grip strength and a standing long jump.

As a parent/guardian you will be asked to complete the following measures:

1. Behavioural and Wellbeing: A questionnaire about your child's general behaviour and wellbeing will be completed on three occasions during the study (beginning, 3 months and end)
2. Dietary Intake: On three occasions (beginning, 3 months and end) you will be asked to complete 2 x 24 hour food recalls online with your child's assistance.
3. Consumption and Sickness Diaries: Throughout the study you (with your child's assistance) will be asked to complete weekly consumption and sickness diaries to monitor compliance and days off sick. One of the research staff will be in contact every 6 weeks to discuss your child's progress in the study.

At the end of the first visit you and your child will be provided with 3 months supply of the milk drinks. The final 3 months supply will be delivered to your residence (or preferred delivery address). All unused drinks are to be returned to the clinic at the final visit.

At the completion of the first visit you will be provided with a prepaid EFTPOS card to the value of \$60 to cover your travel and time. At the completion of the study you will be provided with a prepaid EFTPOS card to the value of \$240 to thank you for your family's participation in the study.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THE STUDY?

Your family may not benefit directly from participation in this study, but you will be providing a valuable contribution to the scientific knowledge in this field. You will not receive any personal results however the overall group results in the study will be mailed out to you approximately 6 months after the study is completed.

ARE THERE ANY RISKS INVOLVED?

- There may be some discomfort for children, including
 - The requirement to consume the milk drink during the study.
 - Completing the cognitive tasks and physical assessments.
 - Blood samples being collected. There is a very minor risk of bruising from venous blood sampling. Bloods will be taken by a trained and experienced paediatric nurse to minimise risk.
- There may be some inconvenience for parents, including
 - Attending the city based clinic during the study.
 - Completing the behavioural questionnaires, 24 hour food recalls and the consumption and sickness diary.

All human research undertaken by the CSIRO must comply with the values, principles, governance and review process specified in the *NH&MRC National Statement on Ethical Conduct in Human Research* (2007, Updated 2015). A copy of the National Statement can be found at www.nhmrc.gov.au/guidelines/ethics/human_research/index.htm

HOW WILL MY PRIVACY BE PROTECTED?

CSIRO is governed under the *Privacy Act 1988* (Cth). CSIRO is collecting your personal information for the purposes of conducting the study and related scientific research. CSIRO will only use and disclose your personal information in accordance with the Privacy Act 1988 and the *NH&MRC National Statement on Ethical Conduct in Human Research* (2007, Updated 2015) as amended from time to time, and as otherwise required by law.

In relation to studies conducted by CSIRO, it is customary for all personal information to be identified by a code and stored at CSIRO under lock and key for a period of 7 years (or 15 years in the case of a drug study). Except where otherwise required by law or a government body, at the end of this period your records will be destroyed or permanently de-identified.

You and, with your permission, your child's doctor will be notified of any medical condition deemed significant by the Clinical Research Unit Medical Officer. We will not use or disclose your information for direct marketing purposes.

CSIRO may publish study results and data in research publications and press releases, however, CSIRO will de-identify any personal information contained in the data and results so that you cannot be identified.

WHAT IF I WISH TO WITHDRAW?

Your child is free to withdraw at any time during the study. However, you will note in the consent form a request to maintain any data collected prior to your child's withdrawal from the study. Your child's data up until their withdrawal are an important part of the data set for analytical purposes. Your child's personal information will be kept with those of continuing participants until the end of the study.

It is also important to understand that we can choose to end your child's participation, too. That decision would be made if we decided that the study is not in your child's best interest, if they are unable to follow the protocol of the study, or if the study is discontinued. If we ever have to end your child's participation, we will make sure you and your child understand the reasons why.

YOUR OBLIGATIONS AS A PARTICIPANT.

You will need to inform a study staff member of any changes in your child's health as some changes could have an affect on their participation in the study and the study findings. Your child must also be able to attend all visits and undertake all relevant procedures during the study period.

IF YOU HAVE FURTHER QUESTIONS

Please call the Milk Kids Study Team on 8303 8906 or via email at MilkKids@csiro.au if you have any questions about participating in the study.

This study has been approved by the CSIRO Human Research Ethics Committee. If you would like to speak with someone with respect to ethical matters the Secretary of the Committee can be contacted via email at chmhrec@csiro.au .

If you wish to register a formal complaint about the conduct of this research project please contact the Office of the Centre Manager, CSIRO, PO Box 10041, Adelaide BC, SA 5000 or via email Bianca.Benassi@csiro.au.