



Participant Information Statement



Health/Social Science Research – Parent/Caregiver Watch Me Grow-Integrated SWSLHD

| | |
|---|---|
| Title | Watch Me Grow Integrated approach – “WMG- I”: Changing practice to improve universal child health and developmental surveillance in the primary care setting |
| Short Title | Watch Me Grow Integrated approach |
| Protocol Number | 3.0 |
| Project Sponsor | National Health and Medical Research Council (NHMRC) |
| Coordinating Principal Investigators | Prof Valsamma Eapen, South Western Sydney Local Health District (SWSLHD); A/Prof Margo Pritchard, The University of Queensland Centre for Clinical Research (UQCCR) |
| Location | South Western Sydney Local Health District (SWSLHD) |

1 Introduction

You and your child are invited to take part in this research about child development and behaviour because the General Practitioner (GP) practice your child is attending is participating in this research project. We are inviting all parents/caregivers of children aged 16 to 24 months to participate.

This Participant Information Sheet explains the processes involved if you were to take part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding, you might want to talk about it further with a staff member. Participation is voluntary and **if you don't wish to take part, you don't have to.**

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to be involved in the research described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet to keep.

2 What is the purpose of this research?

At birth, all Australian children receive a Child Health Book outlining the times for immunisations and health and developmental checks in the preschool years. The purpose of this research is to test the effectiveness of our current system of monitoring children's development with a web-based program. In this study we have randomly assigned (i.e. in a way that involves equal chances for) 40 GP practices to either continue using the current system or to use the new web-based system. Your GP practice is participating in the web-based group (Watch Me Grow-Integrated: WMG-I) which we have outlined in more detail below. In this research we want to

Page 1 of 6

SWSLHD Parent WMG PISCF – V1, 30.11.2021
MASTER Parent WMG PISCF ETH01625 – V1.2, 17.11.2021

know which system is the best at identifying and managing children with developmental and behavioural concerns, and examine associated parent satisfaction and health costs.

3 What does participation in this research involve?

If you consent to participation in this research, we ask you to do four things when your child is:

- 1. About 18 months of age (range 16 to 24 months):** complete an online questionnaire about your child's birth/family, as well as the 18 month developmental and behavioural screening questions prior to seeing your GP whilst in the waiting room. This will take about 10 to 20 minutes. Once completed, screening results are immediately emailed to you and your GP. If you report any developmental concern (for example any concerns about speech or walking movements) when you complete the questionnaire, your GP will discuss this further with you, and if need be, refer your child to the study Child and Family Health Nurse (CFHN) whose role is to co-ordinate any further assessments and referrals for early intervention. You will be given a \$20 Coles/Myer gift voucher or parking voucher at survey completion.
- 2. 2 years of age:** All children with any concerns as identified in step one and 10% of those without any concern will be invited to the study centre to participate in a child-friendly play-based (social, attention, communication and cognition) assessment which will take 1.5 to 2 hours. We will ask to videotape the session for later analysis. You will receive a written report and your GP will receive a copy. You will be given a \$20 Coles/Myer gift voucher or parking voucher at the completion of the study visit. The GP practice will be given \$1000 for staff study time.
- 3. 3 years of age:** All participating parents will be invited via email/text to complete the WMG-I screening questions which are similar to the 18 month screening questions and take about 5-15 minutes to complete. You and your GP will immediately receive your child's results which you can discuss at your child's next appointment. In addition, online questions about your use and satisfaction with services, parent health, costs and understanding of health information will take about 10-20 minutes to complete. In total, participation at 3 years involves online questionnaires that may take between 15 and 35 minutes to complete. You will be given a \$20 Coles/Myer gift voucher or parking voucher at survey completion.
- 4. 4 years of age:** All participating parents will be texted/emailed the WMG-I screening questions to complete which are similar to the 3 years screening questions and take about 5-15 minutes to complete. Your GP will receive your child's results which you can discuss at your child's next appointment. In addition, at 4 years of age parents will be asked to complete online questions about your use and satisfaction with services, questionnaires about parent health, cost and understanding and use of health information which are similar to 3 years questionnaires and will take about 15-20 minutes to complete. All families will also complete an online measure of child behavioural development that will take about 10 minutes to complete. For children with possible behavioural concerns, parents will be invited to participate in a telephone interview at a time that is convenient that will take 5 to 30 minutes to complete. You will be given a \$20 Coles/Myer gift voucher or parking voucher at survey completion.

4 Do I have to take part in this research project?

Participation in any research project is voluntary. Also, if you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine care, your relationship with any staff at your GP practice or your relationship with your relevant health authority (state or health district), or the universities organising the study.

5 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, participating in this study may make you more aware of the early features of developmental problems or delay, regardless of whether your child is identified as having any problems. This

Page 2 of 6

SWSLHD Parent WMG PISCF – V1, 30.11.2021
MASTER Parent WMG PISCF ETH01625 – V1.2, 17.11.2021

information and knowledge may be of benefit in the future for your ongoing monitoring of your child's development or in your dealings with other children, friends or family members. All children with identified concerns and some families with no concerns will be invited to a FREE standardised developmental assessment at 24 months.

We hope to use information that we gain from this research study to benefit others by ensuring that identification of children with developmental or behavioural problems occurs early, and that children receive the right services and supports, which may enhance school readiness.

6 What are the possible risks and disadvantages of taking part?

There are no major disadvantages associated with participation, except your time. However, if you experience discomfort or distress, you can stop participating at any time. You can also tell a staff member at the GP practice or a member of the research team and they will provide you with information about locally available support services. There is a list of support services and their contact information at the end of this Participant Information Statement.

7 What if I withdraw from this research project?

You can withdraw from participation at any time and you can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of the Consent Form. Alternatively, you can call the research team and tell them you no longer want to participate. If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. Data collected up to the time you withdraw will form part of the research project results but if you do not want your data to be included, you must tell the researchers when you withdraw. Your decision whether to take part or not, or to withdraw, will not affect your routine care, your relationship with your GP or any other relevant health services or the research staff.

8 What happens when the research project ends?

We would be pleased to provide you with a summary of the results when the research project is completed. Please indicate in the Consent Form if you wish to receive the findings of the study.

9 What will happen to information about me?

By signing the Consent Form you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. The personal information that the research team collects is your name and your contact details (email address, telephone number and postal address). This information is only used to keep in touch with you throughout the study. Only the research study team will have access to your information, and this will be held securely at South Western Sydney Local Health District (SWSLHD), University of New South Wales (UNSW) or University of Queensland (UQ) in a non-identifiable format in REDCap servers, under Australian jurisdiction. When data is shared between team members, it will be secured via password protected files and encrypted file-sharing services. Your responses to questionnaires are anonymous and cannot identify you.

We are required to keep the data from this study until at least the time of your child's 25th birthday. We also ask your permission to keep the data indefinitely in case it is of benefit for use in future research studies. The scope for future use of this research data or any future research is currently unknown as developmental and psychological science advances quickly. Future research might involve asking different questions of the data, or even recontacting you to find out how your child is doing in future. Any time there is a request for the data to be used in a project that is unrelated to this current project, approval from a Human Research Ethics Committee will be required prior to use of the data. No research will take place using your information unless that research is first reviewed and approved by a Human Research Ethics

Page 3 of 6

Committee, which will make sure the benefits of the research outweigh the costs to you and your privacy. The video recording of the 2 year assessment will be deleted after data analysis.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that neither you nor your child can be identified.

In accordance with relevant Australian and/or Privacy and Personal Information Protection act 1998 (NSW), you have the right to request access to the information collected and stored by the research team. You also have the right for any information with which you disagree to be corrected. Please use the contact details at the end of this document if you would like to do so.

10 Who is organising and funding the research?

This research project is being led by Prof. Valsamma Eapen (NSW) and A/Prof. Margo Pritchard (QLD). It is being funded by the National Health and Medical Research Council (NHMRC).

11 Who has reviewed the research project?

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 research project have been approved by the HREC of SWSLHD. 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.

12 Further information and who to contact

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 you have any problems which may be related to your involvement in the project, you can contact the following member of the research team:

Name: Dr Christa Lam-Cassettari
Position: Clinical Trial Coordinator
Telephone: (02)96164269
Email: c.lamcassettari@unsw.edu.au

13 Support services contact details

If at any stage during the project you or your child becomes distressed or require additional support from someone not involved in the research, we will assist you in seeking an appointment with your GP or local community health nurse.

Other services you may wish to contact:

- Healthdirect Australia (nurse on call): 1800 022 222
- Karitane: 1300 227 464
- Raising Children Network: raisingchildren.net.au
- Parentworks: parentworks.org.au
- Perinatal mental health (including postnatal depression): 1300 726 306 panda.org.au
- Men's Helpline: 1300 78 99 78 mensline.org.au
- Parentline NSW: 1300 1300 52

14 Complaints contact person

This study has been approved by the South Western Sydney Local Health District Human Research Ethics Committee, any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on (02) 8738 8304, email: SWSLHD-Ethics@health.nsw.gov.au and quote project number [2020/STE03380].

**Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.**

PARENT/CAREGIVER CONSENT FORM**“Watch Me Grow Integrated approach - WMG- I”:
Changing practice to improve universal child health and developmental
surveillance in the primary care setting**

1. I agree to participate in the study described in the Participant Information Statement attached to this form.
2. I understand I am being asked to provide consent to allow my child to participate in this research project.
3. I acknowledge that I have read the **Participant Information Statement**, which explains why I have been selected, the aims of the study, the study requirements, and the possible risks of the research, and the Statement has been explained to me to my satisfaction.
4. I have had an opportunity to ask questions and I am satisfied with the answers that I have received.
5. I understand that I can withdraw from the study at any time during the project and withdrawal will not affect my relationship with my GP, any professional staff at the GP practice, or any of the named organisations and/or research team members.
6. I agree that research data gathered from the results of the study may be published, and I will not be identified.
7. I understand that I will be given a copy of this document (via email) to keep.

By clicking on the 'I agree' button, I consent to participation in this study

 I AGREE **I DO NOT AGREE**

Please enter your email address, so that a copy of the Participant Information Statement, the Consent Form and the Form for Withdrawal of Participation may be emailed to you.

Email Address: _____

I consent to the 2 year assessment being videotaped:

 YES **NO**

I would like to receive a copy of the study results when available. If you select YES, a copy of the results will be sent to you via email at the end of the 4 year study:

 YES **NO**

I agree to be contacted regarding any follow up research in the future (beyond the four year period of the current study):

 YES **NO**

PARENT/CAREGIVER CONSENT FORM

“Watch Me Grow Integrated approach - WMG- I”:
Changing practice to improve universal child health and developmental surveillance in
the primary care setting

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent for my child to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with my GP practice, relevant health authority (state or health district), or the researchers conducting the study. In withdrawing my consent, I would like any information collected from me or my child that has been provided for the purpose of this research project withdrawn.

Participant Signature

| | |
|-------------------------------------|--|
| Name of Participant (please print): | |
| Signature of Research Participant: | |
| Date: | |

The section for Withdrawal of Participation should be forwarded to:

| | |
|-----------------|--|
| CI Name: | Professor Valsamma Eapen |
| Email: | v.eapen@unsw.edu.au |
| Phone: | 9616 4205 |
| Postal Address: | ICAMHS, L1 MHC, Liverpool Hospital, Elizabeth Street, NSW 2170 |