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Watch me grow integrated (WMG-I): Protocol for a cluster randomised controlled trial of a web-based surveillance approach for developmental screening in primary care settings

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ARTICLE SUMMARY

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The Cluster Randomised Controlled Trial methodology provides sound reliability and validity
- A strength of the study is the systematic and inclusive approach to recruitment by inviting all children in the eligible age group attending the participating General Practices
- An economic analysis embedded in the study will elucidate the cost-effectiveness of the program for service and policy translation
- Retention of the study participants will be critical in the success of the study
- A potential weakness is the bias in the nature of General Practices that participate in the study who may have characteristics that enable developmental surveillance

ABSTRACT

Introduction

The increasing prevalence of developmental disorders in early childhood poses a significant global health burden. Early detection of developmental problems is vital to ensure timely access to early intervention, and universal developmental surveillance is recommended best practice for identifying issues. Despite this, there is currently considerable variation in developmental surveillance and screening between Australian states and territories and low rates of developmental screening uptake by parents. This study aims to evaluate an innovative web-based developmental surveillance program and a sustainable approach to referral and care pathways, linking primary care General Practice (GP) services that fall under Federal policy responsibility, and State Government funded child health services.

Methods and Analysis

The proposed study describes a longitudinal Cluster Randomised Controlled Trial (c-RCT) comparing a "Watch Me Grow Integrated" (WMG-I) approach for developmental screening, to Surveillance as Usual (SaU) in GPs. Forty practices will be recruited across New South Wales and Queensland, and randomly allocated into either the 1) WMG-I or 2) SaU group. A cohort of 2000 children will be recruited during their 18-month vaccination visit or opportunistic visit to General Practices. At the end of the c-RCT, a qualitative study using focus groups/interviews will evaluate parent and practitioner views of the WMG-I program and inform national and state policy recommendations.

Ethics and Dissemination

The SWSLHD (2020/ETH01625), UNSW Sydney (2020/ETH01625) and University of Queensland (2021/HE000667) Human Research Ethics Committees independently reviewed and approved this study. Findings will be reported to the funding bodies, study institutes and partners; families and peer-reviewed conferences/publications. The trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR#12621000680864).

INTRODUCTION

Early child development, including speech and language, motor, and cognitive development, is an important predictor of health, mental wellbeing, and school attainment. Globally, the prevalence of developmental disorders in the early childhood period is increasing, posing a significant global health burden (1, 2) with an estimated 200 million children worldwide not reaching their developmental potential (3, 4). Data from the Australian Early Development Census (AEDC) indicate that around one in five children starting their first year of school are developmentally vulnerable (5) but that the detection of developmental problems is often delayed. In this regard, previous research has found the period from 12 months to 5 years of age to be a crucial "silent" period for assessing developmental issues including speech and language problems and Autism Spectrum Disorder (ASD) (6-9); resulting in missed opportunities for early intervention during a critical window of brain plasticity in the preschool years. Early intervention in the first few years of life is the most promising avenue to improve child development and mental health, and lower family stress and dysfunction. The last three decades have seen significant research data indicating that programs beginning in infancy and toddler years have the potential to affect key developmental outcomes (10, 11) and the earlier the intervention, the better the outcome (12).

Given the benefits of early identification, universal developmental surveillance is recommended best practice (13-17). Developmental surveillance is a continuous and cumulative process whereby knowledgeable healthcare professionals identify children who may have developmental problems (18, 19). There is, however, a significant gap between policy recommendations regarding developmental surveillance and clinical practice with the uptake being only 20% for the current Australian state-based surveillance programs in community health centres between one and four years of age (20). Variation in care of these children is also an issue, with evidence indicating that children from higher socioeconomic groups with developmental difficulties are more likely to be identified and to receive an appropriate referral, in contrast to those children from lower socioeconomic groups (21). In fact, there is evidence of an 'inverse care law' whereby those at highest risk (including mothers born overseas and of lower educational and income levels) are least likely to engage with health services and access the surveillance program, thereby exacerbating health inequalities (6, 9).

In addition, reviews of current practice in primary care have demonstrated that detection of developmental and behavioural disorders is occurring in an opportunistic, unstandardised fashion, rather than a systematic, proactive way (22). In Australia, developmental surveillance varies

considerably among states and territories, in terms of the surveillance and screening tools used, time points at which screening occurs and professionals providing the screening and surveillance (6). There are also substantial between- and within-state differences regarding pathways to diagnostic assessment following identification of children at developmental risk. In NSW, for example, the type of assessment that a child receives depends on the pathway that has been developed in his or her local health district and this can include referral to a paediatrician, GP or a local developmental clinic (6).

There is an urgent need to develop a contemporary standardised model of early childhood developmental screening and surveillance that engages parents, addresses existing inequalities and improves universal developmental surveillance in the preschool years. Delays in detection of developmental problems prevent access to early intervention. Consequently, this leads to adverse long-term outcomes. The current project will test a new web-based integrated-service approach to child developmental screening. The program is designed to address the current inequity in uptake of developmental surveillance and provide a system that is both parent-friendly and supports practitioners to use routine contact with preschool children as an opportunity for surveillance, rather than as a 'one-off' screen. This new integrated service approach will achieve these things by incorporating the screening program with vaccination visits at GP clinics, which has an uptake of over 90% (23). This project will also include an evaluation of an integrated care pathway achieved via a *'Triage and Review Team'* funded by the project and embedded in the state health system. The Triage and Review Team will receive referrals from the GPs following identification of developmental concerns and carry out further assessments and referral to appropriate services including early childhood education, early intervention and disability services. We will compare the new integrated service to surveillance as is usually provided by GPs to examine whether it (i) increases the proportion of children receiving scheduled surveillance checks; and (ii) improves child outcomes up to school age.

Aims

Cluster Randomised Control Trial

First, in a Cluster Randomised Controlled Trial (c-RCT) we aim to compare WMG Integrated (WMG-I), a web-based integrated-service approach to child developmental screening and surveillance, with Surveillance as Usual (SaU) in primary care GPs:

Primary Aim

1. To determine if WMG-I increases scheduled developmental screening completion rates at (a) 18 months of age and (b) from 18 months to 4 years of age compared to SaU.

Secondary Aims

2. To determine if WMG-I increases test accuracy for identifying diagnostic global developmental delay and autism at 2 years of age compared to SaU.

3. To determine if WMG-I increases parent and clinician satisfaction with child surveillance and parent health literacy at 3 years of age compared to SaU.

4. To determine if WMG-I improves child behavioural outcomes and school readiness at 4 years of age compared to SaU.

5. To determine whether WMG-I is more cost effective compared to SaU.

Qualitative evaluation

Second, a qualitative study using focus groups and in-depth interviews will examine parent and practitioner views around the results of the c-RCT, and about child surveillance and referral pathways more broadly. This qualitative study will inform the development of national policy recommendations regarding developmental surveillance for scaling up and wider dissemination.

METHODS AND ANALYSIS

Study design and setting

This study is a prospective, longitudinal cluster randomised controlled trial (c-RCT). General practices will be recruited across two locations: SWSLHD NSW and Brisbane South Primary Health Network (BSPHN) Queensland (20 per site) and randomly allocated into two groups: (1) SaU; 10per site, or (2) WMG-I; 10 per site.

Study locations reflect large health care service provision with almost 1 million people (24) in South Western Sydney Local Health District (SWSLHD) and 1.2 million people (25) in Brisbane South Primary Health Network. Both comprise a large Indigenous and culturally and linguistically diverse (CALD) community, with 43% of the SWSLHD and 30% of Brisbane South population born overseas, and almost one-third of the population (32%) of SWSLHD speaking a language other than English at home (24) and 19% born in a non-English speaking country from Brisbane South (25). Study locations are characterised as having high unemployment, and the accompanying health and psychosocial concerns of disadvantaged populations (24) (25).

Inclusion criteria

Practices located within the trial sites that offer child immunisation and have the capacity to recruit approximately 50 children in one year will be eligible for inclusion in the c-RCT. To ensure the groups are representative of the respective populations, all parents/caregivers of children aged 16 months to 24 months attending a participating General Practice will be eligible to participate in the c-RCT. For the qualitative study, parents/caregivers of children ≤ 4 years of age, clinicians and policy administrators involved in any aspect of child developmental surveillance will be eligible for inclusion. Figure 1 illustrates the recruitment process and measures.

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Figure 1. Study recruitment flow chart for the cluster RCT in New South Wales and Queensland.

Measures and Methods

Patient and public involvement

The acceptability and utility of the WMG-I weblink was developed and assessed with parents and health practitioners in a previous study (17). In the present study, potential participants will be approached by practice reception staff, nurses and GPs.

Sample size

Based on our previous work (6, 17) we estimate that uptake of developmental screening in the WMG-I and SaU groups will be 100% vs 50% at 18 months, 80% vs 30% at 3 years and 60% vs 10% at 4 years, respectively (Aim 1). A sample size of 2000 children comprised of 1000 children in each group is sufficient to detect a 30% improvement with minimum 80% power in complete developmental screening at 18 months and at 4 years assuming the SaU group completion rate is 50% and 10% respectively. There will be 20 general practices per arm, with an average of 50 children per general practice with a coefficient of variation= 0.65 to account for unequal number of children recruited per general practice, an intraclass correlation coefficient (ICC) = 0.3, statistical significance of 5%, and a 10% loss to follow up.

Randomisation

Randomisation will be conducted using minimisation across 2 factors, state and general practice size. This will be conducted in the statistical software R using the 'Minirand' package.

Recruitment and promotion

Forty practices will be recruited across two sites, SWSLHD NSW and BSPHN Queensland (20 per site). The study will be promoted to general practices via newsletters, GP events and flyers sent or emailed to general practices with an expression of interest form, along with Participant Information Statement and Consent Forms. Study Coordinators/Chief Investigators will respond to general practice responses and secure written informed consent. All parents/carers of children aged 16 to 24 months who present for their immunisation (or an opportunistic visit) will be invited to participate by the reception/health staff in participating general practices. All families will receive the information statement prior to providing consent on the weblink. Participants can withdraw consent at any time, without reason, by completing the withdrawal form at the end of the consent form and returning it to the research team.

Assessment procedure

All parents who consent to participate in the study will complete the following trial entry information using an iPad/smartphone before their appointment. Sociodemographic information about the *child* e.g., date of birth, sex, prematurity, birthweight; *parent* e.g., sex, country of birth, language spoken; *family* e.g., income, mental health of self/partner, substance use of self/partner, learning problems of self/partner; and *service use* (developmental checks, facility attended and satisfaction). Arabic, Vietnamese and Simplified Chinese language formats are available on the weblink.

After completion of the trial entry information, a parent/child attending a practice in the SaU group will be assessed by their GP according to their usual standard of care. The GP will complete a short

online questionnaire noting any screens used, developmental risk identified, and referrals/recommendations provided. Alternatively, a parent/child attending a practice in the WMG-I group will 1) complete the trial entry information and standardised developmental screens via the WMG-I web link (with automated feedback and anticipatory developmental guidance sent to the parent; and automated scoring sent to the GP); (2) receive a GP consultation and discuss the screening results and management options (if concerns were detected). Those who screen positive for developmental/behavioural concerns will be referred to the research Child and Family Health Nurse who will coordinate a 'Triage and Review Team' to recommend, implement and follow-up referral pathways with GPs and parents. The CFHN will record via an online case report form any referrals/recommendations provided to the family.

The primary screening measures used in the WMG-I web link are the:

- *Parent Evaluation of Developmental Status (PEDS)* (26), screens for global/cognitive, expressive language and articulation, receptive language, fine and gross motor, behaviour, self-help, socialisation and academic concerns. Scoring Path A (2 or more concerns) or Path B (1 predictive concern) indicate "at-risk" status and further screening is required.
- *Quantitative Checklist for Autism in Toddlers, 10-item (Q-CHAT-10)* (27), screens for behaviours/symptoms known to be typical in children with autistic disorder. Identification of 3 or more concerns indicates "at-risk" status and further screening is required.
- *Learn the Signs Act Early (LTSAE)* (28) seeks to identify social/emotional, language/communication; cognitive and movement/physical development concerns; Scoring 1 or more concerns indicate "at-risk" status and screening is required.
- Parents of children in WMG-I group who are identified "at-risk" of developmental concerns on the primary screens or tools (i.e., PEDS, Q-CHAT-10 and LTSAE) will also complete *a secondary screen* the *Ages and Stages Questionnaire-Third Edition (ASQ-3)* via the web link. The ASQ-3 screens for the child's Communication, Gross Motor, Fine Motor, Problem Solving, and Personal-Social skills. Standardised cut-off scores will be applied.
- Kessler Psychological Distress Scale (K6) (29, 30), a global measure of anxiety and depressive symptoms experienced by the parent.

From the time of the initial developmental screens (at child age 18 months) until the child is aged 4-years, automated emails/text-messages will be sent to parents to invite them to complete the recommended developmental tools (outlined in their child's Personal Health Record) via a web link and steps (1) and (2) above are repeated. Table 1 provides a summary of measures.

At the 2 year assessment, all children in WMG-I and SaU who screen positive for developmental risk (at 16-24 months) plus a random sample of 10% not at risk, will be invited to participate in a gold standard developmental assessment. For those children who are 24 months at the time of recruitment, the gold standard assessment will be delayed by 2 months to ensure that the child does not receive too many assessments at the one time, especially for those identified at risk for developmental concerns. The assessor (a clinical psychologist) will be blind to the participant group status and results of the screening measures at trial entry. The following diagnostic based tests will be administered:

- *Mullen Scale of Early Learning (MSEL)* (31, 32), a standardised measure of non-verbal and verbal development in children which assesses gross motor, fine motor, visual reception, receptive language and expressed language from birth to 68 months;
- *Vineland Adaptive Behavior Scales Third Edition (Vineland-3)* (33), a standardized a parent report measure of the child's adaptive behavior that supports the diagnosis of intellectual and developmental disabilities, autism, and developmental delays;
- *Autism Diagnostic Observation Schedule Toddler Module (ADOS-2)* (34), provides a semi-structured direct assessment of the child's social and communication skills and behaviour.

At 3 years, all participating parents from WMG-I group will be alerted to complete the next set of questionnaires using the WMG-I weblink. In addition, both the WMG-I and SaU groups will be asked to complete measures regarding health literacy, and a comprehensive cost questionnaire online (including costs for service usage and social/disability support):

- Health Literacy Questionnaire (HLQ) (35), a 44-question survey on how people find, understand and use health information, manage their health and interact with health systems/healthcare providers.
- Institute for Medical Technology Productivity Cost Questionnaire (iPCQ) (36), measures productivity losses due to 1) absenteeism, 2) presenteeism and 3) unpaid work.
- EuroQol-5 Dimension (EQ-5D-5L) (37), assesses 5 dimensions: mobility, selfcare, usual activities, pain/discomfort and anxiety/depression to generate a generic 'health-related quality of life'.
- A brief study-specific service uptake surveillance questionnaire capturing diagnosis of child developmental delays or disabilities, uptake on recommendations, service utilisation and parent satisfaction with services.

At 4 years, all participating parents from the WMG-I group will be alerted to complete the next set of questionnaires using the WMG-I weblink. All participants will be contacted to repeat the

comprehensive cost questionnaires and service uptake surveillance questionnaire (via email link as completed at 3 years), in addition to the:

- Developmental Profile 4 (DP-4) (38) measuring school readiness domains including: adaptive behaviour, social-emotional development, cognitive skills and communication.
- Strengths and Difficulties Questionnaire (SDQ) (39) measuring child emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems and prosocial behaviour.

Children with elevated scores ('abnormal' range) will be invited for further assessment using The Diagnostic Interview Schedule for Children, Adolescents and Parents (DISCAP) (40), a parent-report semi-structured interview for assessing psychiatric disorders in children.

Table 1. Summary of the measures administered in the WMG-I project

Time point	Child age	Method	Duration	Measures			
				WMG-I		**SaU**	
Baseline Time1	18 (16-24) months	Waiting room/ home (via online WMG web link)	10-20 mins (WMG-I) 5 mins (SaU)	• Consent • Trial entry questions • WMG weblink (PEDS/ LTSAE, QCHAT-10) • ASQ-3 (If screen positive on PEDS/LTSAE, Q-CHAT-10) • K6		• Consent • Trial entry questions • GP log: screens/concerns/referrals	
				Concerns	**No Concerns** **10% complete**	**Concerns**	**No Concerns** **10% complete**
Time 2 (All 'At-risk' & 10% no concern)	2 years	Research Site	1.5-2 hrs	• Surveillance Survey • MSEL • VABS • ADOS-2	• Surveillance Survey • MSEL • VABS • ADOS-2	• Surveillance Survey • MSEL • VABS • ADOS-2	• Surveillance Survey • MSEL • VABS • ADOS-2
				WMG-I		**SaU**	
Time 3 WMG-I Group	3 years	Online survey	5-10 mins	• WMG-I weblink	• WMG-I weblink		
Time 3 all participants		Online survey	10-20 mins	• Surveillance Survey • iPCQ • EQ5DL • HLQ	• Surveillance Survey • iPCQ • EQ5DL • HLQ	• Surveillance Survey • iPCQ • EQ5DL • HLQ	• Surveillance Survey • iPCQ • EQ5DL • HLQ
				WMG-I		**SaU**	
Time 4 WMG-I Group	4 years	Online survey	5-10 mins	• WMG-I weblink	• WMG-I weblink		
Time 4 all participants		Online survey	30 mins	• Surveillance Survey • K6 • iPCQ • EQ5D5L • SDQ	• Surveillance Survey • K6 • iPCQ • EQ5D5L • SDQ	• Surveillance Survey • K6 • iPCQ • EQ5D5L • SDQ	• Surveillance Survey • K6 • iPCQ • EQ5D5L • SDQ
		Telephone interview (if positive on SDQ)	40-60 mins	• DP-4 • DISCAP	• DP-4 • DISCAP	• DP-4 • DISCAP	• DP-4 • DISCAP

Note abbreviations: Parent Evaluation of Developmental Status (PEDS), Quantitative Checklist for Autism in Toddlers, 10-item (Q-CHAT-10), Learn the Signs Act Early (LTSAE), Ages and Stages Questionnaire-Third Edition (ASQ-3), Kessler Psychological Distress Scale (K6), Mullen Scale of Early Learning (MSEL), Vineland Adaptive Behavior Scales Third Edition (Vineland-3), Autism Diagnostic Observation Schedule Toddler Module (ADOS-2), Health Literacy Questionnaire (HLQ), Institute for Medical Technology Productivity Cost Questionnaire (iPCQ) , EuroQol-5 Dimension (EQ-5D-5L), Developmental Profile 4 (DP-4), Strengths and Difficulties Questionnaire (SDQ), Diagnostic Interview Schedule for Children, Adolescents and Parents (DISCAP).

Data analysis

Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) data will be collected from all general practices and include the number of eligible children attending practices during the study recruitment period. This service data will be obtained at a group level (WMG-I or SaU) and will be de-identified.

Primary aims will be assessed as follows:

1. Increase in developmental surveillance completion rates at 18 months and 4 years of age: A 3-level model will be used to compare developmental surveillance completion between the WMG-I and SaU groups from 18 months to 4 years. (Primary aim 1). General practice will be specified as level 3, with child nested within general practice as level 2 and each individual visit for the child as level 1. Logit link will be used with a binomial distribution. Predictor variables to be included are group, state and general practice size as level 3 fixed effects and a time point as level 1. Random intercepts of GP and child (nested in general practice) will be included. Random slope of time point (nested in child) will be considered. A cross level interaction of group and time point will be used to compare developmental surveillance between the groups over time. We will consider accounting for parents CALD background, child birth weight, gestation, presence of birth complications.

2. Increase in screening test accuracy for identifying diagnostic developmental problems (e.g., global development and autism) at 2 years: Children will be identified as at risk using the PEDS (QLD) or LTSAE (NSW), Q-CHAT-10, and ASQ-3 at baseline. Children identified as being at risk and 10% of no risk children will be invited to a standardized developmental assessment (MSEL, Vinelans-3, ADOS-2) at 2 years to calculate sensitivity and specificity and test the accuracy of diagnostic developmental problems.

3. *Increase in parent and clinician satisfaction with child surveillance, parent health literacy at 3 years*: This will be assessed qualitatively.

4. Improve child behavioural outcomes and school readiness at 4 years: Multilevel models will be used to compare children at 4 years of age i) failing school readiness measures between SaU and WMG groups and ii) proportion of children at 4 years diagnosed with behavioural disorders between SaU and WMG groups (Secondary aim 4). Separate 2-level multilevel models will be used to compare school readiness (DP-4) and behavioural disorders for each outcome between the groups. For school readiness a Gaussian distribution will be used, whilst for behavioural disorders a logit link with a binomial distribution assumed. Predictor variables to be included are group, state and general practice size.

We will also conduct an *exploratory economic evaluation* to assess cost effectiveness of introducing the integrated developmental surveillance and care pathway (Secondary aim 5)**.** A 'within trial' analysis will assess the cost effectiveness of introducing the integrated developmental surveillance and care pathway from the perspective of the health sector in three ways. First, the cost per additional yield will be estimated. Costs will include the time taken by the GPs/professionals to complete the assessment, and yield will be surveillance uptake and accurate positive diagnosis. Second, the cost per improvement in child outcome measures will be estimated. Costs collection will be widened to include additional service referrals/usage, and health care data as well as social/disability support (noting within the analysis that the latter are transfer payments, not traditionally including in economic evaluation), and will be sourced using a purpose-built cost questionnaire administered to parents. Third, a cost-utility analysis will focus on parents (carers) and responses to the EQ5D5L will be converted to health utilities using the bespoke algorithm, and the impact on adults' (carers) work productivity using the Institute for Medical Technology iPCQ. If substantial, the economic evaluation will be widened to include societal impacts, where productivity increases may exceed the investment cost of the program leading to a positive return on investment (ROI). Finally, uncertainty will be investigated using probability sensitivity analysis (PSA), and a 'value of information' (VOI) analysis will assess the business-case for the program to be implemented in routine practice.

Qualitative Study

Focus groups and in-depth interviews will be used to explore parents' and professionals' perceptions around the WMG web link, program uptake and referral pathways. They will also look at the findings of the c-RCT to inform the design of an integrated care model of developmental and behavioural surveillance, and the development of national policy recommendations for scale up and wider dissemination.

Method

Twelve focus groups (6 per site) and approximately 20 in-depth interviews (10 per site) will be conducted at the conclusion of the c-RCT. Parents of pre-school aged children will be recruited by invitations through early childhood education and care settings, community health, general practices and local community groups (1 group per site). Two parent focus group will be conducted with parents participating in WMG-I (1 group per site) and SaU (1 group per site), with parents recruited at the 3-year assessments. Focus groups with professionals will be conducted through partner organisations to include allied health, CFHNs, practice nurses (3 groups per site), GPs, intervention

service providers, and policy makers. Early Childhood Education and Care (ECEC) representatives who are unable to participate in focus groups will be offered in-depth interviews.

Data analysis

All focus groups/interviews will be audio-recorded with participant permission and fully transcribed. The Grounded Theory Method (41) will guide the interpretation and thematic analysis of this data. Identified themes will be compiled into a coding frame and, as new themes emerge, they will be compared against the initial coding frame, and either added as new themes, or used to expand and modify existing themes, until all data are accounted for. Data analysis will be undertaken using constant comparison methods and matrix displays will be used to explore similarities and differences across groups on key themes. Initial focus group and in-depth interview transcripts will be coded independently by two members of the research team to check the reliability of the coding frame.

ETHICS & DISSEMINATION

The SWSLHD Human Research Ethics Committee (2020/ETH01625), UNSW Sydney (2020/ETH01625) and University of Queensland (2021/HE000667) approved this study. Findings will be disseminated via peer-reviewed abstracts, conference presentations, published manuscripts and reports to funding bodies, policymakers, clinical staff and stakeholders in line with the National Health and Medical Research Council Australian Code for the Responsible Conduct of Research. Research participants can elect to receive a copy of the results at consent.

Participant safety

Potential risks to study participants will be mitigated by ensuring that recruitment is conducted after general practice staff have been trained in empathetic and informed consent. Data collection will be managed by appropriately trained research staff and securely stored/encrypted to maintain security and privacy. Any adverse or unintended effect will be reported to the relevant authorities and human ethics committees.

Management of the project/governance

A steering committee with representatives from the Chief Investigators and partner organisations, along with additional experts co-opted to the project and stakeholders including consumer representatives (e.g. parents) will meet quarterly to provide oversight/data monitoring/refine study protocols. Study investigators will meet monthly with project staff to oversee study operation. Source information may be audited by any of the approving ethics committees or government regulatory authorities.

DISCUSSION

The escalating burden of developmental and behavioural disorders in early childhood may be alleviated with effective developmental and behavioural surveillance programs that provide early identification (17, 32) and pathways to early intervention. There is, however, evidence that the current surveillance programs in Australia and internationally are failing to detect the majority of children who need additional help (42). This is coupled with the fact that there is a "silent period" during 2-4 years of age, especially in disadvantaged populations, which has flow-on effects on intervention commencement delay and consequent long-term disease burden (6-9). This provides a compelling argument for the need for integrated early childhood programs (43). Though it is known that the cost of inaction is a tragic loss to economic potential (44), knowledge about the true impact of social disadvantage on health outcomes particularly in the early developmental period is limited and this project will address this gap.

While cause-effect relationships between complex variables such as family factors, developmental problems, academic failure, peer difficulties and mental health consequences are difficult to untangle, there is clear evidence that such cumulative risks, especially when further compounded by social disadvantage, incur huge financial costs through impact on health, education and rehabilitation services (44). This project will support parents to engage with a Universal developmental surveillance program using a Proportionate Universalism framework (45) (integrated universal cover plus targeted services commensurate with needs) that will ensure participation of high-risk population groups who are currently not engaging optimally with health services. Given the high uptake of early childhood immunisation programs in Australia (46), providing a reliable and validated user-friendly web app for parents and professionals is expected to increase surveillance uptake during opportunistic immunisation contact. Consolidation of the program is expected to be sustainable and could be embedded into standard clinical service protocols within Australian health settings, with potential for dissemination internationally. Further, if appropriate pointers to risk can be identified as it relates to individual children or population groups, it will be possible to develop targeted interventions to address the individual child's needs, or to support disadvantaged groups in certain geographical locations through access to high quality ECEC or other early intervention efforts for these vulnerable children. Such an approach will be an important investment that will yield measurable long term benefits (47). This will prevent the cascade of a negative developmental trajectory with these difficulties becoming entrenched with secondary consequences such as academic failure, school absence, social dysfunction, and forensic involvement. However, despite the likely long-term benefits and cost-saving potential of early identification and intervention services,

short-term cost and knowledge barriers currently limit widespread implementation. Findings from this study will offer opportunities to address such barriers to service utilization and harmonise state and nation-wide approaches to ensure equity for children and families while maximising resources and capacity - which together would result in cost-effective programs and practices that would provide the best start in life for all children. Further study with vulnerable and remote populations are warranted.

Author contributions

Author VE along with SL, MP, RL, SW, BJ, AP, JK, JS, KL, HH, and PC conceptualised the study and obtained funding. CLC, EM, AD, DS, LC, K-LW, HA, DN, CM, AC, SS, MS, DS, KS, PG, VB, KR, PC CWMT provided expertise regarding the interface with service systems and assisted with the logistics and processes as it relates to the project work with the partner organisations. JD conducted sample size calculations and proposed statistical analyses. FK, AMD, SC, TW contributed to the revision of the manuscript. We thank the Lucy Tully for contributing to the development of the study protocol.

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Data Storage and Availability Statement

Parent personal information will be collected via the online survey tool REDcap on encrypted and password protected UNSW REDCap servers. Participants will be issued a unique ID number at the point of entry into the study and operational data will be limited to authorised trial personnel using password protected network drives. De-identified group data will be made available upon reasonable request.

Competing interests

None declared.

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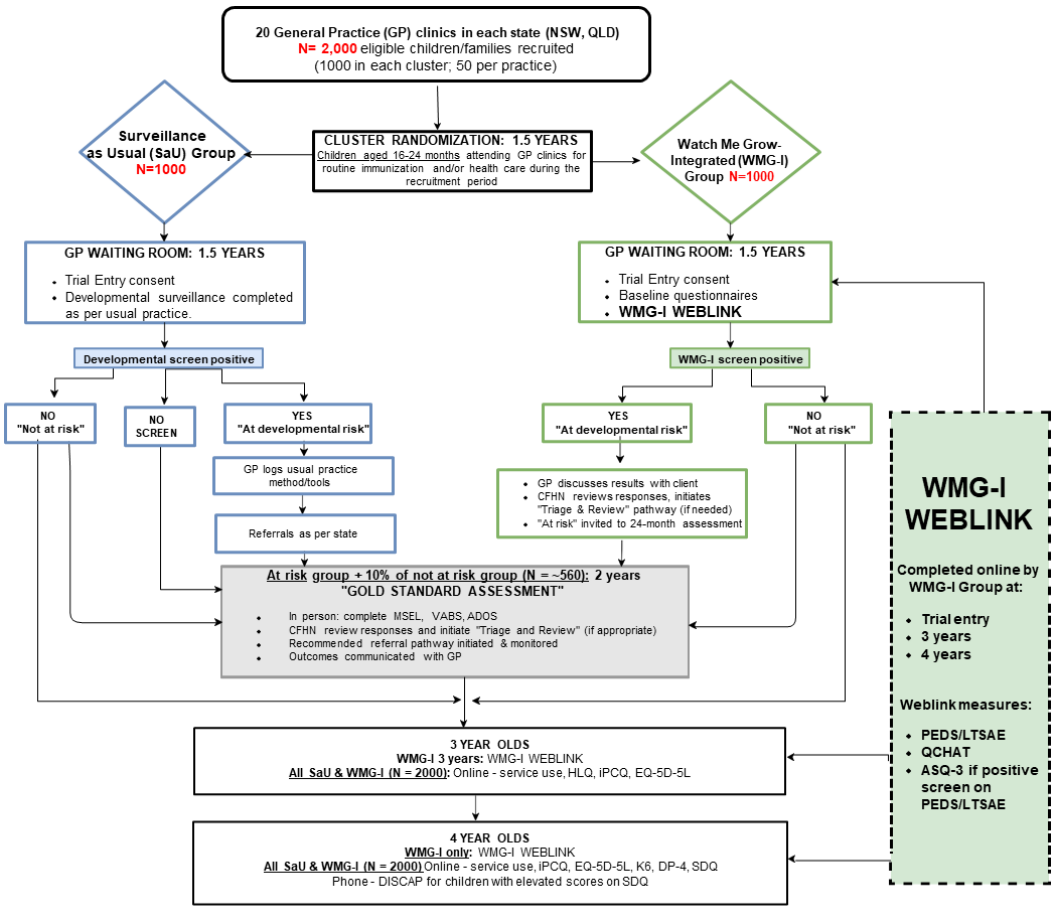
Figure 1. Study recruitment flow chart for the cluster RCT in New South Wales and Queensland.



***Note abbreviations**: Parent Evaluation of Developmental Status (PEDS), Quantitative Checklist for Autism in Toddlers 10-item (Q-CHAT-10), Learn the Signs Act Early (LTSAE), Ages and Stages Questionnaire Third Edition (ASQ-3), Kessler Psychological Distress Scale (K6), Mullen Scale of Early Learning (MSEL), Vineland Adaptive Behavior Scales Third Edition (Vineland-3), Autism Diagnostic Observation Schedule Toddler Module (ADOS-2), Health Literacy Questionnaire (HLQ), Institute for Medical Technology Productivity Cost Questionnaire (iPCQ), EuroQol-5 Dimension (EQ-5D-5L), Developmental Profile 4 (DP-4), Strengths and Difficulties Questionnaire (SDQ), Diagnostic Interview Schedule for Children, Adolescents and Parents (DISCAP).*

Completed SPIRIT 2013 Checklist for the manuscript entitled:
"Watch me Grow Integrated approach (WMG- I) study protocol: The effect of a web-based developmental surveillance approach on uptake of childhood screening and intervention in a primary care setting"

Section/page	Section/item	ItemNo	Description
	Administrative information		
Page 1	Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Page 3	Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
N/A		2b	All items from the World Health Organization Trial Registration Data Set
N/A	Protocol version	3	Date and version identifier
Page 17	Funding	4	Sources and types of financial, material, and other support
Page 1; Page 16	Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
p17		5b	Name and contact information for the trial sponsor
P16 author contributions		5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
p15		5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
	Introduction		

P4-6	Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
p5-7		6b	Explanation for choice of comparators
p5-6	Objectives	7	Specific objectives or hypotheses
p5-7	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
	Methods: Participants, interventions, and outcomes		
p6-7	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
p6-8	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
p5 & 8-12	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
N/A		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
N/A		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
N/A		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial

p5-11	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
see Figure 1	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
p8	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
p8	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
	Methods: Assignment of interventions (for controlled trials)		
	Allocation:		
p8	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
N/A	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
N/A	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions

P10, blinded assessors	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
N/A		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
	Methods: Data collection, management, and analysis		
p8-12	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
p8-12		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Study procedures p8-10 Analysis plan p12-15	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Analysis plan p12-15	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
p12-15		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
p12-15		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

	Methods: Monitoring		
p15	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
N/A		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
p15	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
p15	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
	Ethics and dissemination		
p3	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
p3	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
p8	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
N/A		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
P8-11 and 17	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial

p17	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
p17	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
N/A	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Availability of data and materials, p23	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
p17		31b	Authorship eligibility guidelines and any intended use of professional writers
p17		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
	Appendices		
N/A	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
N/A	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

BMJ Open

Watch me grow integrated (WMG-I): Protocol for a cluster randomised controlled trial of a web-based surveillance approach for developmental screening in primary care settings

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Watch me grow integrated (WMG-I): Protocol for a cluster randomised controlled trial of a web-based surveillance approach for developmental screening in primary care settings

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Word count: 4240 words excluding title page, abstract, references, figures, tables and acknowledgments

ARTICLE SUMMARY

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The Cluster Randomised Controlled Trial methodology provides sound reliability and validity
- A strength of the study is the systematic and inclusive approach to recruitment by inviting all children in the eligible age group attending the participating General Practices
- An economic analysis embedded in the study will elucidate the cost-effectiveness of the program for service and policy translation
- Retention of the study participants will be critical in the success of the study
- A potential weakness is the bias in the nature of General Practices that participate in the study who may have characteristics that enable developmental surveillance

ABSTRACT

Introduction

The increasing prevalence of developmental disorders in early childhood poses a significant global health burden. Early detection of developmental problems is vital to ensure timely access to early intervention, and universal developmental surveillance is recommended best practice for identifying issues. Despite this, there is currently considerable variation in developmental surveillance and screening between Australian states and territories and low rates of developmental screening uptake by parents. This study aims to evaluate an innovative web-based developmental surveillance program and a sustainable approach to referral and care pathways, linking primary care General Practice (GP) services that fall under Federal policy responsibility, and State Government funded child health services.

Methods and Analysis

The proposed study describes a longitudinal Cluster Randomised Controlled Trial (c-RCT) comparing a "Watch Me Grow Integrated" (WMG-I) approach for developmental screening, to Surveillance as Usual (SaU) in GPs. Forty practices will be recruited across New South Wales and Queensland, and randomly allocated into either the 1) WMG-I or 2) SaU group. A cohort of 2000 children will be recruited during their 18-month vaccination visit or opportunistic visit to General Practices. At the end of the c-RCT, a qualitative study using focus groups/interviews will evaluate parent and practitioner views of the WMG-I program and inform national and state policy recommendations.

Ethics and Dissemination

The SWSLHD (2020/ETH01625), UNSW Sydney (2020/ETH01625) and University of Queensland (2021/HE000667) Human Research Ethics Committees independently reviewed and approved this study. Findings will be reported to the funding bodies, study institutes and partners; families and peer-reviewed conferences/publications. The trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR12621000680864).

INTRODUCTION

Early child development, including speech and language, motor, and cognitive development, is an important predictor of health, mental wellbeing, and school attainment. Globally, the prevalence of developmental disorders in the early childhood period is increasing, posing a significant global health burden (1, 2) with an estimated 200 million children worldwide not reaching their developmental potential (3, 4). Data from the Australian Early Development Census (AEDC) indicate that around one in five children starting their first year of school are developmentally vulnerable (5) but that the detection of developmental problems is often delayed. In this regard, previous research has found the period from 12 months to 5 years of age to be a crucial "silent" period for assessing developmental issues including speech and language problems and Autism Spectrum Disorder (ASD) (6-9); resulting in missed opportunities for early intervention during a critical window of brain plasticity in the preschool years. Early intervention in the first few years of life is the most promising avenue to improve child development and mental health, and lower family stress and dysfunction. The last three decades have seen significant research data indicating that programs beginning in infancy and toddler years have the potential to affect key developmental outcomes (10, 11) and the earlier the intervention, the better the outcome (12).

Given the benefits of early identification, universal developmental surveillance is recommended best practice (13-17). Developmental surveillance is a continuous and cumulative process whereby knowledgeable healthcare professionals identify children who may have developmental problems (18, 19). There is, however, a significant gap between policy recommendations regarding developmental surveillance and clinical practice with the uptake being only 20% for the current Australian state-based surveillance programs in community health centres between one and four years of age (20). Variation in care of these children is also an issue, with evidence indicating that children from higher socioeconomic groups with developmental difficulties are more likely to be identified and to receive an appropriate referral, in contrast to those children from lower socioeconomic groups (21). In fact, there is evidence of an 'inverse care law' whereby those at highest risk (including mothers born overseas and of lower educational and income levels) are least likely to engage with health services and access the surveillance program, thereby exacerbating health inequalities (6, 9).

In addition, reviews of current practice in primary care have demonstrated that detection of developmental and behavioural disorders is occurring in an opportunistic, unstandardised fashion, rather than a systematic, proactive way (22). In Australia, developmental surveillance varies

considerably among states and territories, in terms of the surveillance and screening tools used, time points at which screening occurs and professionals providing the screening and surveillance (6). There are also substantial between- and within-state differences regarding pathways to diagnostic assessment following identification of children at developmental risk. In NSW, for example, the type of assessment that a child receives depends on the pathway that has been developed in his or her local health district and this can include referral to a paediatrician, GP or a local developmental clinic (6).

There is an urgent need to develop a contemporary standardised model of early childhood developmental screening and surveillance that engages parents, addresses existing inequalities and improves universal developmental surveillance in the preschool years. Delays in detection of developmental problems prevent access to early intervention. Consequently, this leads to adverse long-term outcomes. The current project will test a new web-based integrated-service approach to child developmental screening. The program is designed to address the current inequity in uptake of developmental surveillance and provide a system that is both parent-friendly and supports practitioners to use routine contact with preschool children as an opportunity for surveillance, rather than as a 'one-off' screen. This new integrated service approach will achieve these things by incorporating the screening program with vaccination visits at GP clinics, which has an uptake of over 90% (23). This project will also include an evaluation of an integrated care pathway achieved via a *'Triage and Review Team'* funded by the project and embedded in the state health system. The Triage and Review Team will receive referrals from the GPs following identification of developmental concerns and carry out further assessments and referral to appropriate services including early childhood education, early intervention and disability services. We will compare the new integrated service to surveillance as is usually provided by GPs to examine whether it (i) increases the proportion of children receiving scheduled surveillance checks; and (ii) improves child outcomes up to school age.

Aims

Cluster Randomised Control Trial

First, in a Cluster Randomised Controlled Trial (c-RCT) we aim to compare WMG Integrated (WMG-I), a web-based integrated-service approach to child developmental screening and surveillance, with Surveillance as Usual (SaU) in primary care GPs:

Primary Aim

1. To determine if WMG-I increases scheduled developmental screening completion rates at (a) 18 months of age and (b) from 18 months to 4 years of age compared to SaU.

Secondary Aims

2. To determine if WMG-I increases test accuracy for identifying diagnostic global developmental delay and autism at 2 years of age compared to SaU.

3. To determine if WMG-I increases parent and clinician satisfaction with child surveillance and parent health literacy at 3 years of age compared to SaU.

4. To determine if WMG-I improves child behavioural outcomes and school readiness at 4 years of age compared to SaU.

5. To determine whether WMG-I is more cost effective compared to SaU.

Qualitative evaluation

Second, a qualitative study using focus groups and in-depth interviews will examine parent and practitioner views around the results of the c-RCT, and about child surveillance and referral pathways more broadly. This qualitative study will inform the development of national policy recommendations regarding developmental surveillance for scaling up and wider dissemination.

METHODS AND ANALYSIS

Study design and setting

This study is a prospective, longitudinal cluster randomised controlled trial (c-RCT). General practices will be recruited across two locations: SWSLHD NSW and Brisbane South Primary Health Network (BSPHN) Queensland (20 per site) and randomly allocated into two groups: (1) SaU; 10per site, or (2) WMG-I; 10 per site.

Study locations reflect large health care service provision with almost 1 million people (24) in South Western Sydney Local Health District (SWSLHD) and 1.2 million people (25) in Brisbane South Primary Health Network. Both comprise a large Indigenous and culturally and linguistically diverse (CALD) community, with 43% of the SWSLHD and 30% of Brisbane South population born overseas, and almost one-third of the population (32%) of SWSLHD speaking a language other than English at home (24) and 19% born in a non-English speaking country from Brisbane South (25). Study locations are characterised as having high unemployment, and the accompanying health and psychosocial concerns of disadvantaged populations (24) (25).

Inclusion criteria

Practices located within the trial sites that offer child immunisation and have the capacity to recruit approximately 50 children in one year. All children and their parents/caregivers will be invited when presenting at participating GP practices for 18-month (range: 16 to 24 months) immunisation or other health care needs. For the qualitative study, parents/caregivers of children between 16 months to 5 years of age, clinicians, and policy administrators involved in any aspect of child developmental surveillance will be eligible for inclusion. Figure 1 illustrates the recruitment process and measures.

INSERT FIGURE 1 AROUND HERE

Figure 1. Study recruitment flow chart for the cluster RCT in New South Wales and Queensland.

Measures and Methods

Patient and public involvement

The acceptability and utility of the WMG-I weblink was developed and assessed with parents and health practitioners in a previous study (17).

Sample size

Based on our previous work (6, 17) we estimate that uptake of developmental screening in the WMG-I and SaU groups will be 100% vs 50% at 18 months, 80% vs 30% at 3 years and 60% vs 10% at 4 years, respectively (Aim 1). A sample size of 2000 children comprised of 1000 children in each

group is sufficient to detect a 30% improvement with minimum 80% power in complete developmental screening at 18 months and at 4 years assuming the SaU group completion rate is 50% and 10% respectively. There will be 20 general practices per arm, with an average of 50 children per general practice with a coefficient of variation= 0.65 to account for unequal number of children recruited per general practice, an intraclass correlation coefficient (ICC) = 0.3, statistical significance of 5%, and a 10% loss to follow up.

Randomisation

Randomisation will be conducted using minimisation across 2 factors, state and general practice size. This will be conducted in the statistical software R using the 'Minirand' package.

Recruitment and promotion

Forty practices will be recruited across two sites, SWSLHD NSW and BSPHN Queensland (20 per site). The study will be promoted to general practices via newsletters, GP events and flyers sent or emailed to general practices with an expression of interest form, along with Participant Information Statement and Consent Forms. Study Coordinators/Chief Investigators will respond to general practice responses and secure written informed consent. All parents/carers of children aged 16 to 24 months who present for their immunisation (or an opportunistic visit) will be invited to participate by the reception and practice staff in participating general practices. Participants will be recruited between May 2022 to June 2023. All families will receive the information statement prior to providing consent on the weblink (See Appendix 1). Participants can withdraw consent at any time, without reason, by completing the withdrawal form at the end of the consent form and returning it to the research team.

Assessment procedure

All parents who consent to participate in the study will complete the following trial entry information using an iPad/smartphone before their appointment. Sociodemographic information about the *child* e.g., date of birth, sex, prematurity, birthweight; *parent* e.g., sex, country of birth, language spoken; *family* e.g., income, mental health of self/partner, substance use of self/partner, learning problems of self/partner; and *service use* (developmental checks, facility attended and satisfaction). Arabic, Vietnamese and Simplified Chinese language formats are available on the weblink.

After completion of the trial entry information, a parent/child attending a practice in the SaU group will be assessed by their GP according to their usual standard of care. The GP will complete a short online questionnaire noting any screens used, developmental risk identified, and referrals/recommendations provided. Alternatively, a parent/child attending a practice in the WMG-I group will 1) complete the trial entry information and standardised developmental screens via the

WMG-I web link (with automated feedback and anticipatory developmental guidance sent to the parent; and automated scoring sent to the GP); (2) receive a GP consultation and discuss the screening results and management options (if concerns were detected). Those who screen positive for developmental/behavioural concerns will be referred to the research Child and Family Health Nurse who will coordinate a 'Triage and Review Team' to recommend, implement and follow-up referral pathways with GPs and parents. The CFHN will record via an online case report form any referrals/recommendations provided to the family.

The primary screening measures used in the WMG-I web link are the:

- *Parent Evaluation of Developmental Status (PEDS)* (26), screens for global/cognitive, expressive language and articulation, receptive language, fine and gross motor, behaviour, self-help, socialisation and academic concerns. Scoring Path A (2 or more concerns) or Path B (1 predictive concern) indicate "at-risk" status and further screening is required.
- *Quantitative Checklist for Autism in Toddlers, 10-item (Q-CHAT-10)* (27), screens for behaviours/symptoms known to be typical in children with autistic disorder. Identification of 3 or more concerns indicates "at-risk" status and further screening is required.
- *Learn the Signs Act Early (LTSAE)* (28) seeks to identify social/emotional, language/communication; cognitive and movement/physical development concerns; Scoring 1 or more concerns indicate "at-risk" status and screening is required.
- Parents of children in WMG-I group who are identified "at-risk" of developmental concerns on the primary screens or tools (i.e., PEDS, Q-CHAT-10 and LTSAE) will also complete *a secondary screen* the *Ages and Stages Questionnaire-Third Edition (ASQ-3)* via the web link. The ASQ-3 screens for the child's Communication, Gross Motor, Fine Motor, Problem Solving, and Personal-Social skills. Standardised cut-off scores will be applied.
- Kessler Psychological Distress Scale (K6) (29, 30), a global measure of anxiety and depressive symptoms experienced by the parent.

From the time of the initial developmental screens (at child age 18 months) until the child is aged 4-years, automated emails/text-messages will be sent to parents to invite them to complete the recommended developmental tools (outlined in their child's Personal Health Record) via a web link and steps (1) and (2) above are repeated. Table 1 provides a summary of measures.

At the 2 year assessment, all children in WMG-I and SaU who screen positive for developmental risk (at 16-24 months) plus a random sample of 10% not at risk, will be invited to participate in a gold standard developmental assessment. For those children who are 24 months at the time of recruitment, the gold standard assessment will be delayed by 2 months to ensure that the child does

not receive too many assessments at the one time, especially for those identified at risk for developmental concerns. The assessor (a clinical psychologist) will be blind to the participant group status and results of the screening measures at trial entry. The following diagnostic based tests will be administered:

- *Mullen Scale of Early Learning (MSEL)* (31, 32), a standardised measure of non-verbal and verbal development in children which assesses gross motor, fine motor, visual reception, receptive language and expressed language from birth to 68 months;
- *Vineland Adaptive Behavior Scales Third Edition (Vineland-3)* (33), a standardized a parent report measure of the child's adaptive behavior that supports the diagnosis of intellectual and developmental disabilities, autism, and developmental delays;
- *Autism Diagnostic Observation Schedule Toddler Module (ADOS-2)* (34), provides a semi-structured direct assessment of the child's social and communication skills and behaviour.

At 3 years, all participating parents from WMG-I group will be alerted to complete the next set of questionnaires using the WMG-I weblink. In addition, both the WMG-I and SaU groups will be asked to complete measures regarding health literacy, and a comprehensive cost questionnaire online (including costs for service usage and social/disability support):

- Health Literacy Questionnaire (HLQ) (35), a 44-question survey on how people find, understand and use health information, manage their health and interact with health systems/healthcare providers.
- Institute for Medical Technology Productivity Cost Questionnaire (iPCQ) (36), measures productivity losses due to 1) absenteeism, 2) presenteeism and 3) unpaid work.
- EuroQol-5 Dimension (EQ-5D-5L) (37), assesses 5 dimensions: mobility, selfcare, usual activities, pain/discomfort and anxiety/depression to generate a generic 'health-related quality of life'.
- A brief study-specific service uptake surveillance questionnaire capturing diagnosis of child developmental delays or disabilities, uptake on recommendations, service utilisation and parent satisfaction with services.

At 4 years, all participating parents from the WMG-I group will be alerted to complete the next set of questionnaires using the WMG-I weblink. All participants will be contacted to repeat the comprehensive cost questionnaires and service uptake surveillance questionnaire (via email link as completed at 3 years), in addition to the:

- Developmental Profile 4 (DP-4) (38) measuring school readiness domains including: adaptive behaviour, social-emotional development, cognitive skills and communication.
- Strengths and Difficulties Questionnaire (SDQ) (39) measuring child emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems and prosocial behaviour.

Children with elevated scores ('abnormal' range) will be invited for further assessment using The Diagnostic Interview Schedule for Children, Adolescents and Parents (DISCAP) (40), a parent-report semi-structured interview for assessing psychiatric disorders in children.

Table 1. Summary of the measures administered in the WMG-I project

Time point	Child age	Method	Duration	Measures			
				WMG-I		**SaU**	
Baseline Time1	18 (16-24) months	Waiting room/ home (via online WMG web link)	10-20 mins (WMG-I) 5 mins (SaU)	• Consent • Trial entry questions • WMG weblink (PEDS/ LTSAE, QCHAT-10) • ASQ-3 (If screen positive on PEDS/LTSAE, Q-CHAT-10) • K6		• Consent • Trial entry questions • GP log: screens/concerns/referrals	
				Concerns	**No Concerns** **10% complete**	**Concerns**	**No Concerns** **10% complete**
Time 2 (All 'At-risk' & 10% no concern)	2 years	Research Site	1.5-2 hrs	• Surveillance Survey • MSEL • VABS • ADOS-2	• Surveillance Survey • MSEL • VABS • ADOS-2	• Surveillance Survey • MSEL • VABS • ADOS-2	• Surveillance Survey • MSEL • VABS • ADOS-2
				WMG-I		**SaU**	
Time 3 WMG-I Group	3 years	Online survey	5-10 mins	• WMG-I weblink	• WMG-I weblink		
Time 3 all participants		Online survey	10-20 mins	• Surveillance Survey • iPCQ • EQ5DL • HLQ	• Surveillance Survey • iPCQ • EQ5DL • HLQ	• Surveillance Survey • iPCQ • EQ5DL • HLQ	• Surveillance Survey • iPCQ • EQ5DL • HLQ
				WMG-I		**SaU**	
Time 4 WMG-I Group	4 years	Online survey	5-10 mins	• WMG-I weblink	• WMG-I weblink		
Time 4 all participants		Online survey	30 mins	• Surveillance Survey • K6 • iPCQ • EQ5D5L • SDQ	• Surveillance Survey • K6 • iPCQ • EQ5D5L • SDQ	• Surveillance Survey • K6 • iPCQ • EQ5D5L • SDQ	• Surveillance Survey • K6 • iPCQ • EQ5D5L • SDQ
		Telephone interview (if positive on SDQ)	40-60 mins	• DP-4 • DISCAP	• DP-4 • DISCAP	• DP-4 • DISCAP	• DP-4 • DISCAP

Note abbreviations: Parent Evaluation of Developmental Status (PEDS), Quantitative Checklist for Autism in Toddlers, 10-item (Q-CHAT-10), Learn the Signs Act Early (LTSAE), Ages and Stages Questionnaire-Third Edition (ASQ-3), Kessler Psychological Distress Scale (K6), Mullen Scale of Early Learning (MSEL), Vineland Adaptive Behavior Scales Third Edition (Vineland-3), Autism Diagnostic Observation Schedule Toddler Module (ADOS-2), Health Literacy Questionnaire (HLQ), Institute for Medical Technology Productivity Cost Questionnaire (iPCQ) , EuroQol-5 Dimension (EQ-5D-5L), Developmental Profile 4 (DP-4), Strengths and Difficulties Questionnaire (SDQ), Diagnostic Interview Schedule for Children, Adolescents and Parents (DISCAP).

Data analysis

Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) data will be collected from all general practices and include the number of eligible children attending practices during the study recruitment period. This service data will be obtained at a group level (WMG-I or SaU) and will be de-identified. Outcomes will be assessed as follows:

Primary outcome*:*

Increase in developmental surveillance completion rates at 1) 18 months, and 2) at 3 and 4 years of age. A 3-level model will be used to compare developmental surveillance completion between the WMG-I and SaU groups from 18 months to 4 years. General practice will be specified as level 3, with child nested within general practice as level 2 and each individual visit for the child as level 1. Logit link will be used with a binomial distribution. Predictor variables to be included are group, state and general practice size as level 3 fixed effects and a time point as level 1. Random intercepts of GP and child (nested in general practice) will be included. Random slope of time point (nested in child) will be considered. A cross level interaction of group and time point will be used to compare developmental surveillance between the groups over time. We will consider accounting for parents CALD background, child birth weight, gestation, presence of birth complications.

Secondary outcomes:

1. Increase in screening test accuracy for identifying diagnostic developmental problems (e.g., global development and autism) at 2 years. Children will be identified as at risk using the PEDS (QLD) or LTSAE (NSW), Q-CHAT-10, and ASQ-3 at baseline. Children identified as being at risk and 10% of no risk children will be invited to a standardized developmental assessment (MSEL, Vinelans-3, ADOS-2) at 2 years to calculate sensitivity and specificity and test the accuracy of diagnostic developmental problems.

2. *Increase in parent satisfaction with child surveillance at 4 years.* This will be assessed qualitatively.

3. Increase in parent health literacy at 4 years. This will be assessed qualitatively.

4. Increase in clinician satisfaction with child surveillance uptake at 4 years. This will be assessed qualitatively.

5. Increase in school readiness and the proportion of children diagnosed with behavioural disorders at 4 years: Multilevel models will be used to compare children at 4 years of age i) failing school readiness measures between SaU and WMG groups and ii) proportion of children at 4 years diagnosed with behavioural disorders between SaU and WMG group. Separate 2-level multilevel models will be used to compare school readiness (DP-4) and behavioural disorders for each outcome

between the groups. For school readiness a Gaussian distribution will be used, whilst for behavioural disorders a logit link with a binomial distribution assumed. Predictor variables to be included are group, state and general practice size.

6. Cost effectiveness of introducing the integrated developmental surveillance and care pathway. A 'within trial' exploratory economic analysis will assess the cost effectiveness of introducing the integrated developmental surveillance and care pathway from the perspective of the health sector in three ways. First, the cost per additional yield will be estimated. Costs will include the time taken by the GPs/professionals to complete the assessment, and yield will be surveillance uptake and accurate positive diagnosis. Second, the cost per improvement in child outcome measures will be estimated. Costs collection will be widened to include additional service referrals/usage, and health care data as well as social/disability support (noting within the analysis that the latter are transfer payments, not traditionally including in economic evaluation), and will be sourced using a purpose-built cost questionnaire administered to parents. Third, a cost-utility analysis will focus on parents (carers) and responses to the EQ5D5L will be converted to health utilities using the bespoke algorithm, and the impact on adults' (carers) work productivity using the Institute for Medical Technology iPCQ. If substantial, the economic evaluation will be widened to include societal impacts, where productivity increases may exceed the investment cost of the program leading to a positive return on investment (ROI). Finally, uncertainty will be investigated using probability sensitivity analysis (PSA), and a 'value of information' (VOI) analysis will assess the business-case for the program to be implemented in routine practice.

Qualitative Study

Focus groups and in-depth interviews will be used to explore parents' and professionals' perceptions around the WMG web link, program uptake and referral pathways. They will also look at the findings of the c-RCT to inform the design of an integrated care model of developmental and behavioural surveillance, and the development of national policy recommendations for scale up and wider dissemination.

Method

Twelve focus groups (6 per site) and approximately 20 in-depth interviews (10 per site) will be conducted at the conclusion of the c-RCT. Parents of pre-school aged children will be recruited by invitations through early childhood education and care settings, community health, general practices and local community groups (1 group per site). Two parent focus group will be conducted with parents participating in WMG-I (1 group per site) and SaU (1 group per site), with parents recruited at the 3-year assessments. Focus groups with professionals will be conducted through partner

organisations to include allied health, CFHNs, practice nurses (3 groups per site), GPs, intervention service providers, and policy makers. Early Childhood Education and Care (ECEC) representatives who are unable to participate in focus groups will be offered in-depth interviews.

Data analysis

All focus groups/interviews will be audio-recorded with participant permission and fully transcribed. The Grounded Theory Method (41) will guide the interpretation and thematic analysis of this data. Identified themes will be compiled into a coding frame and, as new themes emerge, they will be compared against the initial coding frame, and either added as new themes, or used to expand and modify existing themes, until all data are accounted for. Data analysis will be undertaken using constant comparison methods and matrix displays will be used to explore similarities and differences across groups on key themes. Initial focus group and in-depth interview transcripts will be coded independently by two members of the research team to check the reliability of the coding frame.

ETHICS & DISSEMINATION

The SWSLHD Human Research Ethics Committee, UNSW Sydney and University of Queensland approved this study. Findings will be disseminated via peer-reviewed abstracts, conference presentations, published manuscripts and reports to funding bodies, policymakers, clinical staff and stakeholders in line with the National Health and Medical Research Council Australian Code for the Responsible Conduct of Research. Research participants can elect to receive a copy of the results at consent.

Participant safety

Potential risks to study participants will be mitigated by ensuring that recruitment is conducted after general practice staff have been trained in empathetic and informed consent. Data collection will be managed by appropriately trained research staff and securely stored/encrypted to maintain security and privacy. Any adverse or unintended effect will be reported to the relevant authorities and human ethics committees.

Management of the project/governance

A steering committee with representatives from the Chief Investigators and partner organisations, along with additional experts co-opted to the project and stakeholders including consumer representatives (e.g. parents) will meet quarterly to provide oversight/data monitoring/refine study protocols. Study investigators will meet monthly with project staff to oversee study operation. Source information may be audited by any of the approving ethics committees or government regulatory authorities.

DISCUSSION

The escalating burden of developmental and behavioural disorders in early childhood may be alleviated with effective developmental and behavioural surveillance programs that provide early identification (17, 32) and pathways to early intervention. There is, however, evidence that the current surveillance programs in Australia and internationally are failing to detect the majority of children who need additional help (42). This is coupled with the fact that there is a "silent period" during 2-4 years of age, especially in disadvantaged populations, which has flow-on effects on intervention commencement delay and consequent long-term disease burden (6-9). This provides a compelling argument for the need for integrated early childhood programs (43). Though it is known that the cost of inaction is a tragic loss to economic potential (44), knowledge about the true impact of social disadvantage on health outcomes particularly in the early developmental period is limited and this project will address this gap.

While cause-effect relationships between complex variables such as family factors, developmental problems, academic failure, peer difficulties and mental health consequences are difficult to untangle, there is clear evidence that such cumulative risks, especially when further compounded by social disadvantage, incur huge financial costs through impact on health, education and rehabilitation services (44). This project will support parents to engage with a Universal developmental surveillance program using a Proportionate Universalism framework (45) (integrated universal cover plus targeted services commensurate with needs) that will ensure participation of high-risk population groups who are currently not engaging optimally with health services. Given the high uptake of early childhood immunisation programs in Australia (46), providing a reliable and validated user-friendly web app for parents and professionals is expected to increase surveillance uptake during opportunistic immunisation contact. Consolidation of the program is expected to be sustainable and could be embedded into standard clinical service protocols within Australian health settings, with potential for dissemination internationally. Further, if appropriate pointers to risk can be identified as it relates to individual children or population groups, it will be possible to develop targeted interventions to address the individual child's needs, or to support disadvantaged groups in certain geographical locations through access to high quality ECEC or other early intervention efforts for these vulnerable children. Such an approach will be an important investment that will yield measurable long term benefits (47). This will prevent the cascade of a negative developmental trajectory with these difficulties becoming entrenched with secondary consequences such as academic failure, school absence, social dysfunction, and forensic involvement. However, despite the likely long-term benefits and cost-saving potential of early identification and intervention services,

short-term cost and knowledge barriers currently limit widespread implementation. Findings from this study will offer opportunities to address such barriers to service utilization and harmonise state and nation-wide approaches to ensure equity for children and families while maximising resources and capacity - which together would result in cost-effective programs and practices that would provide the best start in life for all children. Further study with vulnerable and remote populations are warranted.

Author contributions

Author VE along with SL, MP, RL, SW, BJ, AP, JK, JS, KL, HH, and PC conceptualised the study and obtained funding. CLC, LK, NO, RL, EM, AD, LC, K-LW, HA, DA, RB, CT, CM, AC, SS, MS, DS, KS, PG, VB, KR, PC, CWMT provided expertise regarding the interface with service systems and assisted with the logistics and processes as it relates to the project work with the partner organisations. JD conducted sample size calculations and proposed statistical analyses. FK, AMD, SC, TW contributed to the revision of the manuscript.

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Data Storage and Availability Statement

Parent personal information will be collected via the online survey tool REDcap on encrypted and password protected UNSW REDCap servers. Participants will be issued a unique ID number at the point of entry into the study and operational data will be limited to authorised trial personnel using password protected network drives. De-identified group data will be made available upon reasonable request.

Competing interests

None declared.

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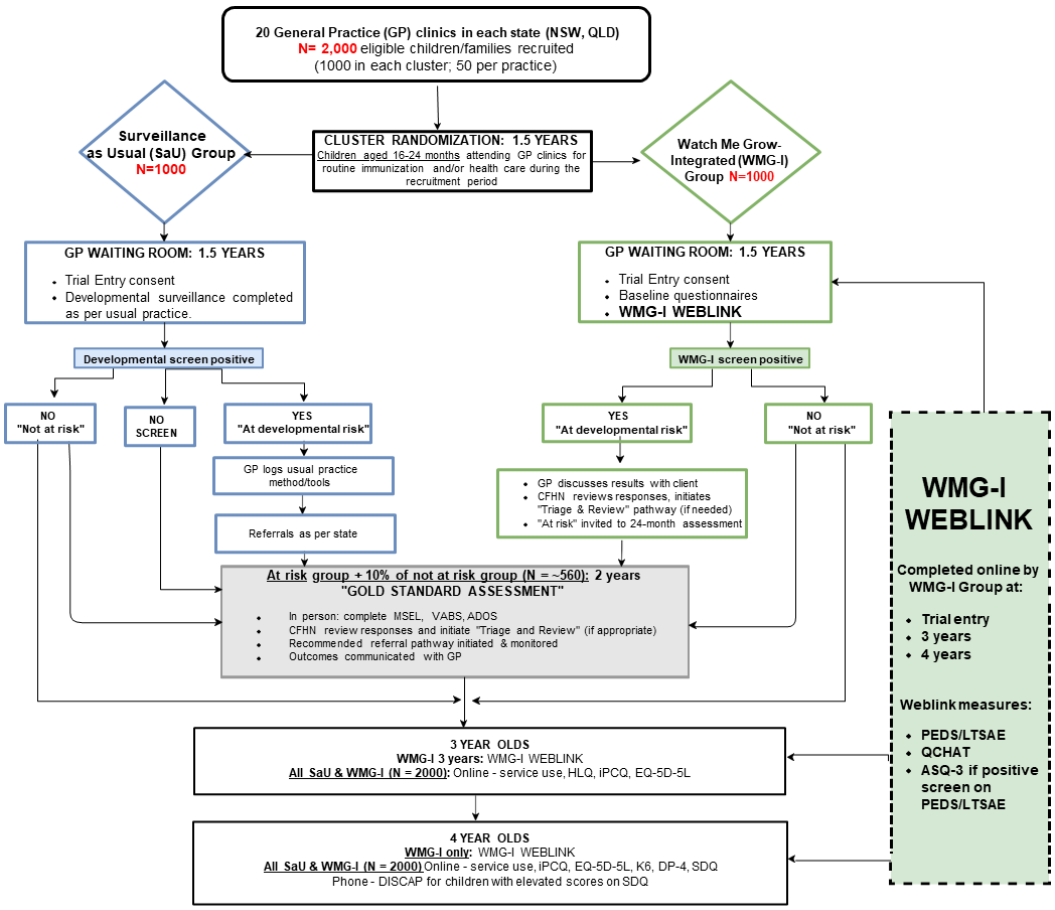
Figure 1. Study recruitment flow chart for the cluster RCT in New South Wales and Queensland.



***Note abbreviations**: Parent Evaluation of Developmental Status (PEDS), Quantitative Checklist for Autism in Toddlers 10-item (Q-CHAT-10), Learn the Signs Act Early (LTSAE), Ages and Stages Questionnaire Third Edition (ASQ-3), Kessler Psychological Distress Scale (K6), Mullen Scale of Early Learning (MSEL), Vineland Adaptive Behavior Scales Third Edition (Vineland-3), Autism Diagnostic Observation Schedule Toddler Module (ADOS-2), Health Literacy Questionnaire (HLQ), Institute for Medical Technology Productivity Cost Questionnaire (iPCQ), EuroQol-5 Dimension (EQ-5D-5L), Developmental Profile 4 (DP-4), Strengths and Difficulties Questionnaire (SDQ), Diagnostic Interview Schedule for Children, Adolescents and Parents (DISCAP).*

Health
South Western Sydney
Local Health District

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

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

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

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

Completed SPIRIT 2013 Checklist for the manuscript entitled:
"Watch me Grow Integrated approach (WMG- I) study protocol: The effect of a web-based developmental surveillance approach on uptake of childhood screening and intervention in a primary care setting"

Section/page	Section/item	ItemNo	Description
	Administrative information		
Page 1	Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Page 3	Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
N/A		2b	All items from the World Health Organization Trial Registration Data Set
N/A	Protocol version	3	Date and version identifier
Page 17	Funding	4	Sources and types of financial, material, and other support
Page 1; Page 16	Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
p17		5b	Name and contact information for the trial sponsor
P16 author contributions		5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
p15		5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
	Introduction		

P4-6	Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
p5-7		6b	Explanation for choice of comparators
p5-6	Objectives	7	Specific objectives or hypotheses
p5-7	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
	Methods: Participants, interventions, and outcomes		
p6-7	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
p6-8	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
p5 & 8-12	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
N/A		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
N/A		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
N/A		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial

p5-11	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
see Figure 1	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
p8	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
p8	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
	Methods: Assignment of interventions (for controlled trials)		
	Allocation:		
p8	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
N/A	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
N/A	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions

P10, blinded assessors	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
N/A		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
	Methods: Data collection, management, and analysis		
p8-12	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
p8-12		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Study procedures p8-10 Analysis plan p12-15	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Analysis plan p12-15	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
p12-15		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
p12-15		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

	Methods: Monitoring		
p15	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
N/A		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
p15	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
p15	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
	Ethics and dissemination		
p3	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
p3	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
p8	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
N/A		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
P8-11 and 17	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial

p17	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
p17	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
N/A	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Availability of data and materials, p23	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
p17		31b	Authorship eligibility guidelines and any intended use of professional writers
p17		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
	Appendices		
Supplemental material	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
N/A	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable