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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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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 programme 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 GP. At the end of the c-RCT, a qualitative study using focus groups/interviews will evaluate parent and practitioner views of the WMG-I programme and inform national and state policy recommendations.

Ethics and dissemination The South Western Sydney Local Health District (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.

Trial registration number ANZCTR12621000680864.

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 programme 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.

INTRODUCTION

Early child development, including speech and language, motor and cognitive development, is an important predictor of health,

mental well-being 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 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[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 programmes 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 programmes in community health centres between 1 and 4 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 programme, 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-state 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, general practice (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 programme 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 programme 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 (1) increases the proportion of children receiving scheduled surveillance checks and (2) 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 Watch Me Grow (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 (1) 18 months of age and (2) from 18 months to 4 years of age compared with SaU.

Secondary aims

1. To determine if WMG-I increases test accuracy for identifying diagnostic global developmental delay and autism at 2 years of age compared with SaU.
2. To determine if WMG-I increases parent and clinician satisfaction with child surveillance and parent health literacy at 3 years of age compared with SaU.
3. To determine if WMG-I improves child behavioural outcomes and school readiness at 4 years of age compared with SaU.

4. To determine whether WMG-I is more cost effective compared with 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 c-RCT. GPs will be recruited across two locations: South Western Sydney Local Health District (SWSLHD) NSW and Brisbane South Primary Health Network (BSPHN) Queensland (20 per site) and randomly allocated into two groups: (1) SaU; 10 per site or (2) WMG-I; 10 per site.

Study locations reflect large healthcare service provision with almost 1 million people[24] in SWSLHD and 1.2 million people[25] in BSPHN. 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 1 year. All children and their parents/caregivers will be invited when presenting at participating GP practices for 18 months (range: 16–24 months) immunisation or other healthcare needs. For the qualitative study, parents/caregivers of children between 16 months and 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.

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 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 GPs per arm, with an average of 50 children per GP with a coefficient of variation=0.65 to account for unequal number of children recruited per GP, an intraclass correlation coefficient=0.3, statistical significance of 5% and a 10% lost to follow-up.

Randomisation

Randomisation will be conducted using minimisation across two factors, state and GP 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 GPs via newsletters, GP events and flyers sent or emailed to GPs with an expression of interest form, along with participant information statement and consent forms. Study coordinators/chief investigators will respond to GP responses and secure written informed consent. All parents/carers of children aged 16–24 months who present for their immunisation (or an opportunistic visit) will be invited to participate by the reception and practice staff in participating GPs. Participants will be recruited between May 2022 and June 2023. All families will receive the information statement prior to providing consent on the weblink (see online supplemental 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, for example, date of birth, sex, prematurity, birth weight; parent, for example, sex, country of birth, language spoken; family, for example, 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

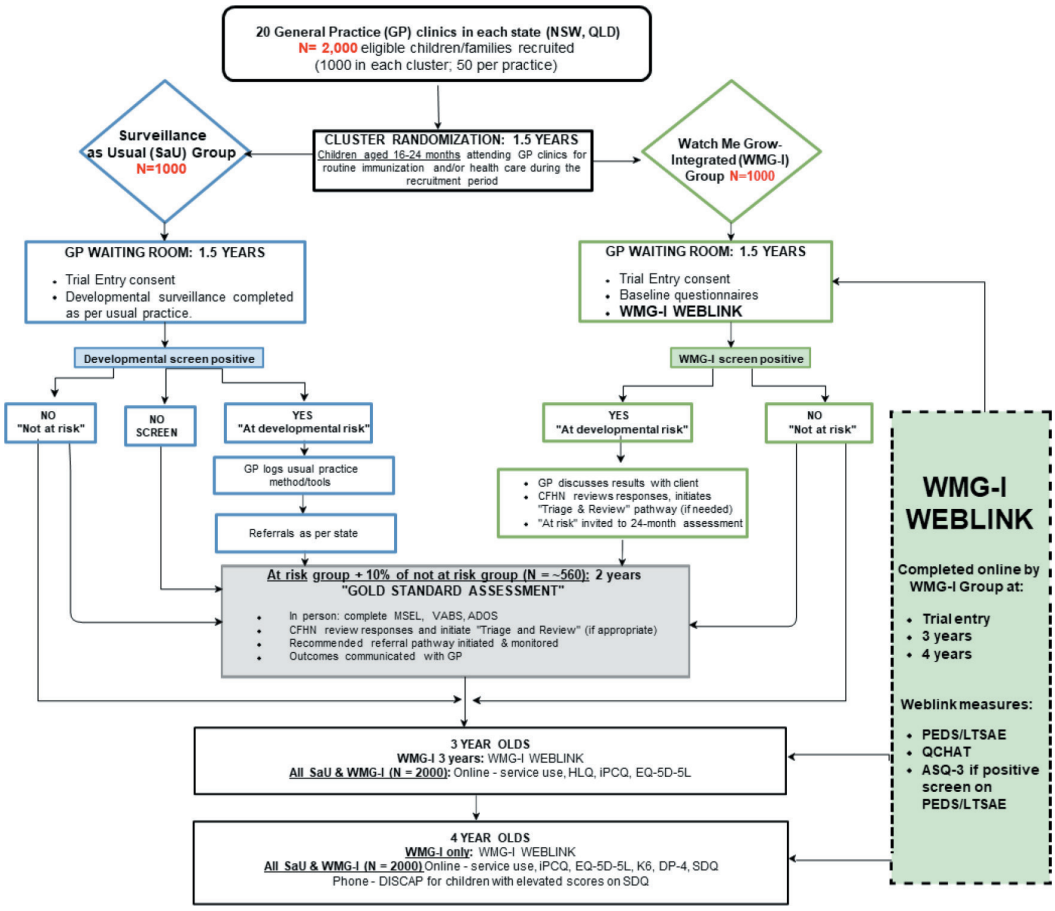

Figure 1 Study recruitment flow chart for the cluster RCT in New South Wales and Queensland. ADOS-2, Autism Diagnostic Observation Schedule Toddler Module; ASQ-3, Ages and Stages Questionnaire-Third Edition; DISCAP, Diagnostic Interview Schedule for Children, Adolescents and Parents; DP-4, Developmental Profile 4; EQ-5D-5L, EuroQol-5 Dimension; HLQ, Health Literacy Questionnaire; iPCQ, Institute for Medical Technology Productivity Cost Questionnaire; K6, Kessler Psychological Distress Scale; LTSAE, Learn the Signs Act Early; MSEL, Mullen Scale of Early Learning; PEDS, Parent Evaluation of Developmental Status; Q-CHAT-10, Quantitative Checklist for Autism in Toddlers, 10-item; RCT, randomised controlled trial; SDQ, Strengths and Difficulties Questionnaire; Vineland-3, Vineland Adaptive Behaviour Scales Third Edition; WMG-I, Watch Me Grow Integrated; GP, general practice; SAU, Surveillance as Usual.

anticipatory developmental guidance sent to the parent; and automated scoring sent to the GP) and (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 (two or more concerns) or path B (one 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 one 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 (ie, 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.

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 min (WMG-I) 5 min (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' and 10% no concern)	2 years	Research Site	1.5–2 hours	► 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 min	► WMG-I weblink	► WMG-I weblink		
Time three all participants		Online survey	10–20 min	► 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 min	► WMG-I weblink	► WMG-I weblink		
Time four all participants		Online survey	30 min	► 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 min	► DP-4 ► DISCAP	► DP-4 ► DISCAP	► DP-4 ► DISCAP	► DP-4 ► DISCAP

ADOS-2, Autism Diagnostic Observation Schedule Toddler Module; ASQ-3, Ages and Stages Questionnaire-Third Edition; DISCAP, Diagnostic Interview Schedule for Children, Adolescents and Parents; DP-4, Developmental Profile 4; EQ-5D-5L, EuroQol-5 Dimension; GP, general practice; HLQ, Health Literacy Questionnaire; iPCQ, Institute for Medical Technology Productivity Cost Questionnaire; K6, Kessler Psychological Distress Scale; LTSAE, Learn the Signs Act Early; MSEL, Mullen Scale of Early Learning; PEDS, Parent Evaluation of Developmental Status; Q-CHAT-10, Quantitative Checklist for Autism in Toddlers, 10-item; SAU, Surveillance as Usual; SDQ, Strengths and Difficulties Questionnaire; Vineland-3, Vineland Adaptive BBehaviour Scales Third Edition; WMG-I, Watch Me Grow Integrated.

- 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 Behaviour Scales Third Edition (Vineland-3)[33]: a standardised a parent report measure of the child's adaptive behaviour that supports the diagnosis of intellectual and developmental disabilities, autism and developmental delays.
- Autism Diagnostic Observation Schedule Toddler Module (ADOS-2)[34]: provides a semistructured 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[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 five 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,[40] a parent-reported semistructured interview for assessing psychiatric disorders in children.

Data analysis

Standard Protocol Items: Recommendations for Interventional Trials data will be collected from all GPs 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 deidentified. 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 three-level model will be used to compare developmental surveillance completion between the WMG-I and SaU groups from 18 months to 4 years. GP will be specified as level 3, with child nested within GP 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 GP size as level 3 fixed effects and a time point as level 1. Random intercepts of GP and child (nested in GP) 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 (eg, global development and autism) at 2 years. Children will be identified as at risk using the PEDS (QLD) or LTSAE (New South Wales), 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 standardised 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 (1) failing school readiness measures between SaU and WMG groups and (2) proportion of children at 4 years diagnosed with behavioural disorders between SaU and WMG group. Separate

two-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, while for behavioural disorders a logit link with a binomial distribution assumed. Predictor variables to be included are group, state and GP 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 healthcare 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 programme leading to a positive return on investment. Finally, uncertainty will be investigated using probability sensitivity analysis, and a 'value of information' analysis will assess the business case for the programme 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, programme 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 (six per site) and approximately 20 in-depth interviews (10 per site) will be conducted at the conclusion of the c-RCT. Parents of preschool-aged children will be recruited by invitations through early childhood education and care settings(ECEC), community health, GPs and local community groups (one group per site). Two parent focus group will be conducted with parents participating in WMG-I (one group per site) and SaU (one 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 (three groups per site), GPs, intervention service providers and policy-makers. 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 AND 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, policy-makers, 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 GP 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 (eg, 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 programmes

that provide early identification[17 32] and pathways to early intervention. There is, however, evidence that the current surveillance programmes 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 programmes.[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-and-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 programme 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 programmes 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 programme 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 utilisation and harmonise state and nationwide approaches to ensure equity for children and families while maximising resources and capacity—which together would result in cost-effective programmes and practices that would provide the best start in life for all children. Further study with vulnerable and remote populations are warranted.

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