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Protocol for the Let's Grow randomised controlled trial: examining efficacy, cost-effectiveness and scalability of a m-Health intervention for movement behaviours in toddlers

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ABSTRACT

Introduction Despite being an important period for the development of movement behaviours (physical activity, sedentary behaviour and sleep), few interventions commencing prior to preschool have been trialled. The primary aim of this trial is to assess the 12-month efficacy of the *Let's Grow* mHealth intervention, designed to improve the composition of movement behaviours in children from 2 years of age. *Let's Grow* is novel in considering composition of movement behaviours as the primary outcome, using non-linear dynamical approaches for intervention delivery, and incorporating planning for real-world implementation and scale-up from its inception.

Methods and analysis A randomised controlled trial will test the effects of the 12-month parental support mHealth intervention, *Let's Grow*, compared with a control group that will receive usual care plus electronic newsletters on unrelated topics for cohort retention. *Let's Grow* will be delivered via a purpose-designed mobile web application with linked SMS notifications. Intervention content includes general and movement-behaviour specific parenting advice and incorporates established behaviour change techniques. Intervention adherence will be monitored by app usage data. Data will be collected from participants using 24-hour monitoring of movement behaviours and parent report at baseline (T_0), mid-intervention (T_1; 6 months post baseline), at intervention conclusion (T_2; 12 months post baseline) and 1-year post intervention (T_3; 2 years post baseline). The trial aims to recruit 1100 families from across Australia during 2021. In addition to assessment of efficacy, an economic evaluation and prospective scalability evaluation will be conducted.

Ethics and dissemination The study was approved by the Deakin University Human Ethics Committee (2020-077). Study findings will be disseminated through publication in peer-reviewed journals, presentation at scientific and professional conferences, and via social and traditional media.

Trial registration number ACTRN12620001280998; U1111-1252-0599.

Strengths and limitations of this study

- This mHealth trial targets improvement in all movement behaviours with assessment of a single primary compositional outcome.
- Efficacy, economic and scale-up evaluations will each be conducted.
- A key strength is incorporation of stakeholder involvement and prospective evaluation and planning for implementation and scale-up at the efficacy testing stage.

INTRODUCTION

Life-course studies suggest interventions in early life, when children are undergoing rapid development, provide a window of opportunity to alter trajectories and have sustained effects on health.[1] Early childhood (0–5 years) is a key time to focus on crucial health behaviours that impact children's immediate and later outcomes.[2–4] From a young age, physical activity is associated with better motor skill development, fitness, cognitive development, cardiometabolic health, bone, skeletal and psychosocial health.[2] Longer sleep duration is positively associated with healthy growth and psychosocial health, lower adiposity and lower injury risk.[3 5] Sedentary behaviours (sitting or lying when awake with energy expenditure ≤1.5 metabolic equivalent) are unfavourably associated with adiposity, motor skill development, cognitive development and psychosocial health.[4] Yet only 9% of Australian 20 month olds[6] and 15% of 4 year olds[7] achieve nationally[8] and internationally recommended[9] levels of all three movement behaviours (physical activity, sedentary behaviour and sleep). This

is not a problem unique to Australia, similar adherence is observed internationally.[10–12] Thus, considerable potential exists to improve adherence to all three guidelines.

Although most intervention research has tended to consider these behaviours separately, it is increasingly recognised that a single integrated movement continuum exists,[6] from sleep (no conscious movement) through to high intensity physical activity. The composition of a day is understood as the proportion of time spent in each of the three movement behaviours where the proportion of time spent in one behaviour is considered relative to the other two. In practical terms, with only 24 hours in a day, the more time a child spends in one movement behaviour, the less time they have available for another. This provides enhanced opportunities to promote behaviour change by targeting both direct change, through impacting the target behaviour, and indirect change, by targeting other movement behaviours (ie, substitution).

Few early childhood health behaviour interventions have commenced prior to the preschool period (age 3–5 years), with the toddler period (age 1–2 years) particularly neglected.[13] Only one intervention including toddlers (but with a broad age range for commencement extending from 2 to 10 years old) has aimed to optimise all three movement behaviours.[14] It focused on community-based obesity prevention, also targeting diet, and showed impact on only one of the three movement behaviours, increased sleep duration.[14 15] Another study commencing in infancy and extending into the toddler period targeted all three movement behaviours as well as diet, observing little improvement in any movement behaviour with intervention.[16] Studies to date have conceptualised and analysed each movement behaviour individually. No studies have presented their findings using a compositional approach that takes into account the constrained nature of the data (the fact that there can only ever be 24 hours in a day). Further, the potential for future scale-up (delivery at scale within existing health systems) has not previously been assessed prospectively in early childhood behaviour interventions. Typically, hybrid effectiveness and implementation trials follow initial effectiveness trials,[17] although even this is rare.

Planning for real-world implementation and scale-up is essential for effective translation. For the purposes of this trial, we use the following definition of scalability: 'the ability of a health intervention shown to be efficacious on a small scale and/or under controlled conditions to be expanded under real world conditions to reach a greater proportion of the eligible population while retaining effectiveness'.[18] When efficacious interventions are scaled up and implemented in real-world settings, they can report lower effect sizes[19] and may be less likely to be sustained over time.[20 21] Increasing research into evaluations of effective interventions that are capable of sustainable practice translation is a public health priority.[22 23] A major challenge to practice translation is that intervention dissemination (spread of interventions) is often addressed later in the research process or is an afterthought in the evaluation process.[24] In addition, depictions of scale-up in the public health literature have tended to oversimplify the process[25] and have not adequately addressed the complexities involved.[26] Early engagement of stakeholders in the research process enhances research-practice translation of interventions,[27] can mitigate or reduce the impact of dissemination challenges,[27] and potentially increases the likelihood of successful scale-up.[28] Given the ongoing lack of evidence for the successful implementation and scale-up of efficacious interventions into practice,[22] interventions designed and evaluated with the 'end application' in mind may be more likely to achieve sustained population level impact. Nonetheless, the potential for intervention scale-up is rarely considered early in intervention design in this field.

There are numerous diverse challenges that impact successful scaling of interventions, many of which are outside the control of researchers (such as political climate) or may not be experienced until later in the scale-up process (such as contextual changes in the delivery setting). One aspect within the control of researchers is the design of interventions to ensure their delivery mode enhances widespread reach,[29] that they are closely aligned with intended delivery context,[30] and that implementation in practice does not exacerbate disparities in health.[31] Mobile health (mHealth) is one delivery mode that has the advantage of maximising reach across geographical and socioeconomic groups and has strong potential for scalability and cost-effectiveness.[32 33] Use of mHealth strategies (eg, applications (apps) accessed on a mobile phone) are well established in the field of behaviour change but have not been widely trialled in early childhood.[34] Systematic reviews of parenting programmes addressing a range of outcomes and delivered online, conclude that web-based delivery for both guided and self-guided interventions result in positive outcomes for parents and children.[35 36] A systematic review[37] of child and adolescent obesity prevention and treatment interventions using eHealth delivery (ie, mHealth or other electronic access such as via the internet or email) identified eight studies, all including physical activity or screen time targets, alongside diet. All targeted children older than 5 years. Only one study was solely eHealth, with the others also incorporating more traditional delivery modes such as telephone or face-to-face counselling, precluding conclusions on the benefit of eHealth.

A systematic review[38] of web-based interventions to change parent feeding practices for children up to 12 years of age identified seven studies that included children younger than 5 years, one targeting parents of infants, and the remainder focused on preschool children. Some of these studies had a broader focus (eg, obesity prevention) and hence also included one or more movement behaviours in their intervention. That review concluded that there was promise with this delivery mode, but current studies were predominantly of low quality with small sample sizes.[38] Given parents of young children often experience time and other logistical barriers

to participation in traditional intervention programmes, mHealth strategies offer the potential for good engagement. The few interventions in this population that have utilised mHealth delivery have shown high feasibility and acceptability for parents.[39 40]

AIMS

This paper presents the protocol for a trial, the primary aim of which is to assess the efficacy of the *Let's Grow* mHealth intervention, a purpose designed mobile web application for parents, to improve the composition of movement behaviours in 2-year-old children at conclusion of the 12-month intervention.

Secondary aims are to assess the:

- Maintenance of intervention effects 1-year post intervention.
- Cost-effectiveness of *Let's Grow* measured against current practice (ie, no intervention).
- Potential mechanisms of behavioural change via hypothesised mediating pathways (eg, parenting practices, parenting confidence).
- Potential translation and scalability of the intervention into real-world practice.

METHODS AND ANALYSIS

Trial design overview

A randomised controlled trial will test the effects of the 12-month parental support mHealth intervention, *Let's Grow* (figure 1). The control group will receive usual care plus electronic newsletters on unrelated topics for continued engagement. Data will be collected at baseline (T_0), mid-intervention (T_1; 6 months post baseline), at intervention conclusion (T_2; 12 months post baseline) and 1-year post intervention (T_3; 2 years post baseline). The trial will run from February 2021 to approximately December 2023. Consolidated Standards of Reporting Trials guidelines[41] will be followed.

Patient and public involvement

The intervention was designed and refined with end user (parent) input and piloting prior to commencement of the trial described in this protocol.

Theoretical framework

Intervention content was designed using Michie's Behaviour Change Wheel[42] which identifies sources of behaviour (ie, mediators) that the intervention will target across the COM-B domains of: (1) Capability—knowledge, tools, skills; (2) Opportunity—the things that make a behaviour possible and (3) Motivation—goals. Appropriate behaviour change techniques were identified from the CALO-RE taxonomy of behaviour change techniques[43] to target each mediator. Identification of target mediators was informed by Social Cognitive Theory-Family Perspective[44] and the Family Ecological Model.[45] These theories recognise the interplay of parent and child cognitions and behaviours within the family environment, and the multiple influences on child health behaviours: individual (eg, child age, temperament), family (eg, siblings, socioeconomic position), and community domains (eg, access to parks). They are centred around parenting influences (eg, modelling, shaping by rewards and rules, accessibility, knowledge, beliefs).

An important aspect of this intervention's design is that it mirrors real world complexity by using nonlinear dynamical approaches (chaos theory, complex dynamic systems).[46 47] These approaches operate on the premise that behaviour and behaviour change are nonlinear and unpredictable.[48] While health interventions are typically delivered in a predictable linear manner (eg, weekly sessions), the *Let's Grow* intervention will be delivered in

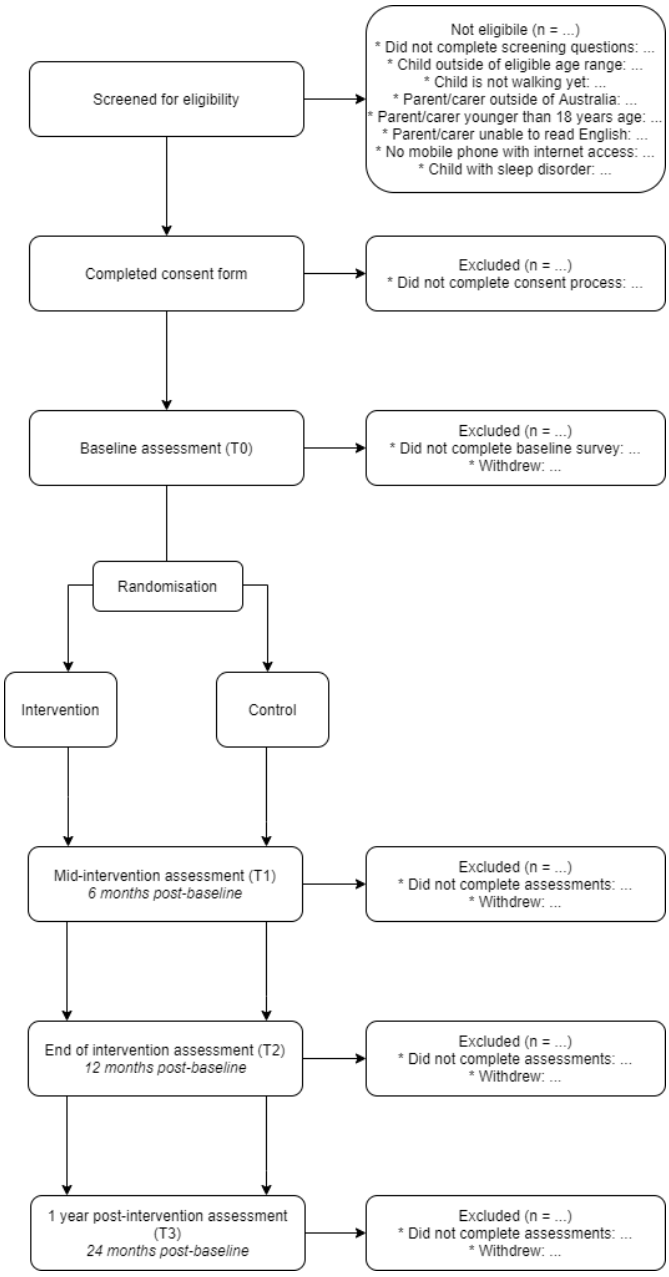

Figure 1 *Let's Grow* CONSORT flow chart. CONSORT, Consolidated Standards of Reporting Trials.

a dynamic fashion, responsive to individual family situations and parent choice. The aim is to maximise opportunities to target parents during periods when they are most receptive to behaviour change messages (teachable moments).

Intervention condition

The *Let's Grow* intervention will be delivered via a mobile web app with linked SMS notifications. Intervention content was developed based on the best available evidence, informed by the investigators' experience with behaviour change interventions in early childhood populations[16 34 40 49 50] and with input from end users on iterations of the app. It incorporates practical advice, established behaviour change techniques (eg, goal setting, self-monitoring), and tips and tools to assist parents to improve their child's physical activity, sleep and sedentary behaviour. This includes information about the behaviours, government guidelines, ideas for promoting each of the behaviours, parenting strategies, and tasks to put participant learning into action, for example, quizzes, goal setting, self-monitoring, creation of routines, strategy implementation, sharing ideas and successes. Information is presented with low literacy requirements using text, images, infographics, animations and live action videos.

After completing a short introduction module to give them an overview of the intervention and how to use the app, participants will work through eight modules in their own time over 12 months (table 1). They can choose the order and speed in which they undertake the modules. Once they commence a module, they will be unable to open another new module until it has been completed; however, completed modules remain accessible at all times, and key information is freely accessible via the toolkit (described below). This format is designed to allow the behaviour change activities, with linked SMS notifications, to be engaged in without the confusion that could arise by SMS notifications coming from multiple modules concurrently.

Within modules, the format is also non-linear with a range of tabs linking to information and activities that participants can undertake in the order of their choosing. Modules also provide an additional 'burst' of SMS notifications not linked to specific activities (up to three per module) while that module is active, providing tips and links to push participants back to module content. Once all modules are completed, 'refresher' notifications (one per week) push participants back to the app. SMS notifications will be personalised to include parent and child names and, where appropriate, personalised information related to their behaviour change activity (eg, the chosen goal in a goal setting activity). The app also contains a toolkit which stores all videos from completed modules and routines that parents have created, as well as additional information on play, screen time, sleep, parents' own health behaviours, parenting strategies, tantrums, behaviour change resources, ideas for active play and screen free activities. A social forum using randomly generated usernames (or parents can choose their own but are encouraged not to use real names) gives parents the opportunity to anonymously share ideas and connect with other participants should they wish to. The forum will be monitored by the research team to ensure appropriate use and moderated if necessary. Any moderation will be documented. A frequently asked questions section provides information on use of the app (eg, turning video captions on or off, changing password) and study information (eg, how to pause study involvement, how to wear monitors). A personal profile section allows participants to change their time zone and the preferred time of SMS notifications as well as add a secondary user (another carer) to have view-only access to the app (ie, second users can see information but not undertake the embedded behaviour change activities). Finally, a favourites section allows users to curate their own favourite information from the app by clicking a heart button that appears next to content. Selected content then concurrently appears in the favourites tab, automatically sorted into folders for different information types, for example, videos, activities, toolkit.

Intervention adherence will be monitored by app usage data. Automated notifications will be sent after predetermined periods of app inactivity (eg, after 2 and 3 weeks of inactivity an SMS will be sent; after 5 weeks of inactivity an email will be sent) to encourage participants to re-engage and complete the programme. If there is continued inactivity after the automated notifications, research staff will contact participants by phone to encourage continuation of the programme. Participants have the option to pause the programme during non-receptive times, for example, if they are going on holidays or dealing with personal issues.

Control condition

The control group will continue with any usual care (eg, key ages and stages visits with maternal, child and family health nurses) and will not have access to the *Let's Grow* app. They will receive eight electronic bulletins (Toddler Tips) on unrelated topics (eg, basic child first aid, language development, toilet training) delivered approximately every 6 weeks across the 12-month intervention period for cohort engagement. This method has been successful in ensuring high retention in a similar population.[51]

Inclusion criteria

Parents (aged 18+ years) with a child aged 22–35 months will be eligible. This is a key time, commencing when children are ambulant (walking) and encompassing a period of rapid physical and cognitive development. Other inclusion criteria are that the parent resides in Australia, has a mobile phone that can access the internet, can read English, and the child is walking independently.

Table 1 Intervention content

App component	Description	Key behaviour change techniques*
Topics		
Parents provide, kids decide	Division of responsibility in parenting	3.2 Social support (practical) 4.1 Instruction on how to perform a behaviour 8.1 Behavioural practice/ rehearsal 8.3 Habit formation
Switch off and play	Substituting screen time for active play	3.2 Social support (practical) 4.1 Instruction on how to perform a behaviour 5.1 Information about health consequences 5.6 Information about emotional consequences 8.2 Behaviour substitution
Avoid blue light to sleep tight	Reducing screen time to improve sleep; sleep hygiene	1.1 Goal setting (behaviour) 2.3 Self-monitoring of behaviour 4.2 Information about antecedents 5.1 Information about health consequences 5.6 Information about emotional consequences 7.1 Prompts/cues 8.2 Behaviour substitution
Play skills for life	Fundamental movement skills	4.1 Instruction on how to perform a behaviour 5.1 Information about health consequences 6.1 Demonstration of the behaviour 8.1 Behavioural practice/rehearsal
Play, sleep, repeat	Interaction of active play and sleep	1.1 Goal setting (behaviour) 2.3 Self-monitoring of behaviour 4.1 Instruction on how to perform the behaviour 5.1 Information about health consequences 5.6 Information about emotional consequences 7.1 Prompts/cues
Rocking routines	Parenting and family routines	2.3 Self-monitoring of behaviour 5.6 Information about emotional consequences 7.1 Prompts/cues
Build your best day	All three movement behaviours and achieving a good balance	4.1 Instruction on how to perform the behaviour 5.1 Information about health consequences 7.1 Prompts/cues 8.2 Behaviour substitution
Calm families	Parenting skills	1.2 Problem solving 5.4 Monitoring of emotional consequences 8.1 Behavioural practice/ rehearsal 11.2 Reduce negative emotions 12.1 Restructuring the physical environment 12.3 Avoidance/reducing exposure to cues for the behaviour 12.5 Adding objects to the environment 13.1 Identification of self as role model
Other sections		
Toolkit	Houses particular content from topics once completed for example, introduction and guide to the app, videos, infographics, created personal routines. Additional content on: ► Movement behaviour definitions and guidelines ► Active play and screen free ideas/activities ► Screen time considerations, for example, safety, monitoring, coviewing ► Parenting strategies ► Managing common sleep issues ► Managing difficult behaviour ► Parents' own movement behaviours ► Behaviour change tools that can be used offline (goal setting and monitoring chart; child reward chart)	4.1 Instruction on how to perform the behaviour 7.1 Prompts/cues 8.1 Behavioural practice/ rehearsal 9.1 Credible source 12.1 Restructuring the physical environment 13.1 Identification of self as role model

Continued

Table 1 Continued

App component	Description	Key behaviour change techniques*
Community	Social forum where users can interact with each other. Users can respond to *Let's Grow* posts with ideas and reflections (linked to activities within topics).	3.1 Social support (unspecified) 3.2 Social support (practical) 3.3 Social support (emotional)

*Linked to Michie *et al*'s Behaviour Change Taxonomy.[69]

Exclusion criteria

Child has been diagnosed with or is receiving treatment for a sleep disorder.

Recruitment

Participants will be recruited nationally, with recruitment open to all eligible parents residing anywhere in Australia. Recruitment strategies will include social media, for example, Facebook, Instagram, parenting blogs and snowball recruitment. These methods have been shown to result in equivalent participant demographics to traditional recruitment methods (eg, face to face) in this population.[32] Initial online screening prior to providing consent will ensure participants meet eligibility criteria. Recruitment commenced in February 2021.

Randomisation

Randomisation after baseline assessment will be on a 1:1 ratio stratified by geographical location (urban or outer/remote for each of the 8 Australian states/territories; 16 strata). The rationale for stratification is that background health services differ by location and are known to influence effectiveness of interventions.[52] The random allocation sequences were computer generated in advance and embedded in REDCap (Vanderbilt, USA), ensuring allocation concealment.

Measures

Participants will be assessed pre-randomisation (baseline; T_0), mid-way through the intervention (6 months post baseline; T_1), at completion of the 12-month intervention phase (T_2) and 1-year post intervention (T_3). The self-nominated main carer of the child will complete proxy reports on their child's behaviour as well as provide information on themselves and their family demographics. The partner of the main carer or other parent of the child will also be invited to participate (via the main carer) and provide information on their own behaviour. The measures included at each time point are outlined in online supplemental table.

Movement behaviour data (physical activity, sedentary behaviour and sleep)

The primary outcome is daily proportion of time spent in physical activity, sedentary behaviour and sleep at completion of the intervention (T_2). At T_0, T_2 and T_3 child movement behaviours will be concurrently assessed using ActiGraph GT3X+ (ActiGraph, Pensacola, USA) accelerometers, worn at the hip continuously for 24 hours across 8 days. Rewear will be requested where monitors are returned with less than 7.4 waking hours per day across a minimum of 4 days recorded. Accelerometers are the gold standard for assessing free living movement and have been validated with children as young as 16 months.[53] Hip worn accelerometers provide a valid measure of sleep duration in children.[54] Data will be recorded in 5 s epochs to capture the sporadic nature of young children's movement and 20 min of consecutive zero counts will be considered non-wear time and removed from analyses.[55] Sedentary behaviour[53] and different intensities of physical activity[56] will be estimated with age-specific movement count thresholds. Sleep duration will be estimated using a sleep-wake detection algorithm developed in MATLAB (MathWorks, Natick, Massachusetts, USA) that automatically finds and scores daytime naps and overnight sleep after age-appropriate approximations for evening sleep and morning wake times are entered into the MATLAB script. Some manual processing may be required for those with unpredictable times. The algorithm has been shown to have good agreement with parental sleep diaries.[55] Monitors will be initialised and posted to families with stickers identifying who should wear each monitor. Text messages or email will remind parents to ensure their child wears the monitor and to post it back at the end of the monitoring period. The monitors will be accompanied by a booklet providing instructions on how to fit the device, tips for wear and how to return the device. The booklet will also collect daily parent-reported data during monitor wear for non-parent care and single questions on child self-regulation and ease of parenting that day (covariates).

Additional contextual information on child movement behaviours will be collected by main carer parent report via REDCap (online supplemental table). This information will include parent report of the amount of time their child spends in a range of physical activities (eg, indoor and outdoor active play, high energy play), screen and non-screen based sedentary behaviours (eg, stroller/pram, watching shows, playing electronic games) and sleeping (eg, usual bedtime and wake time, night waking, sleep routines). Survey items are based on established measures where available. Purpose designed items will undergo reliability testing in a separate sample.

Potential mediators

Targeted mediators of the intervention including movement behaviour-related parent knowledge, efficacy/confidence, family rules and routines, co-participation and home environment, as well as child motor skills, general parenting and child behaviour will be assessed at all time points by parent report using existing reliable instruments (online supplemental table). Parent modelling of behaviours will be device assessed at T_0, T_2 and T_3 by parents wearing GT3X accelerometers concurrently with their child. In addition, parents will report on their own movement behaviours in relation to adult guidelines. This information will help identify possible pathways through which the intervention had an effect.

Demographic information and covariates

Standard demographic and socioeconomic information will be collected via parent report. In addition, data will be collected on potential covariates including child health conditions, temperament, dietary intake (food frequency questionnaire), birth weight and length, parent coping, concern with child movement behaviours, parent height and weight, and maternal pregnancy status (online supplemental table). Child height and weight data will also be collected through the online survey. Parents will be asked to upload a picture of their child's health record or copy the information into the survey if they have had measures recorded by their maternal child health nurse or another health professional recently. If they do not have recent measures, they will be asked to measure their child's height (against a wall) and weight (on bathroom scales) at home with instructions provided.

Secondary outcomes

Measures to be used for the economic evaluation include parent report of health service utilisation and cost,[57] and time spent seeking information online. In addition, a log of researcher time administering the intervention (eg, monitoring the social forum) and costs associated with this will be recorded by the research team (online supplemental table).

For the process evaluation, we will ask all participants to report how they heard about the study in the baseline parent survey. In addition, at T_1, T_2 and T_3 participants in the intervention group will be asked to provide feedback on their engagement, relevance and satisfaction with the intervention. Analytics will be collected directly from the app to provide information on individual participants' usage across the study (online supplemental table).

Sample size

The aim is to recruit 1100 families. Assuming 15% attrition rate at T_2, 25% attrition at T_3[52] and 75% of children providing valid accelerometer data at each time point, approximately 700 children at T_2 and 620 at T_3 will provide valid accelerometry data. Power calculations are based on Hotelling's T-squared test statistic, α=0.05, software PASS V.14.0.9 (NCSS). Accelerometry data for children 3.5 years and 5 years[16] were used to estimate time-use in the control group and the 2×2 variance-covariance matrix.

Primary outcome (daily proportion of time spent in physical activity, sedentary behaviour and sleep at T_2)

The target sample size of 700 (350 per group) will achieve 89% power to detect a 0.031 increase in physical activity and 0.038 decrease in sedentary time measured in the log-ratio scale (covariance matrix, $\sigma_1^2 = 0.087$, $\sigma_2^2 = 0.028$, $\sigma_{12}^2 = 0.007$). Thus, the study is powered to detect small changes translating to +9 min in physical activity, −13 min in sedentary time, and +4 min in sleep when the proportion of time spent in these behaviours in the control group is 16.9%, 28.1% and 55.0% respectively (as for 3.5 years in a prior study).[16]

Secondary outcome (daily proportion of time spent in physical activity, sedentary behaviour and sleep at T_3)

The target sample size of 620 children (310 per group) at T_3 would achieve 93% power to detect the same changes in movement behaviour minutes as for the primary outcome ($\sigma_1^2 = 0.070$, $\sigma_2^2 = 0.016$, $\sigma_{12}^2 = 0.005$) when the proportion of time spent in physical activity, sedentary behaviour and sleep in the control group is 16.4%, 29.2% and 54.4% respectively (as for 5 years in a previous study).[16] Of note, power is larger at T_3 for the same effects measured in minutes even with a smaller sample size due to the change in the distribution of time-use and the variability in the 5 years data compared with that of 3.5 years.

Statistical analysis

All analyses will be conducted on an intention-to-treat basis with the analyst blinded to allocation. Time-use data (primary outcome) are constrained to a total of 24 hours precluding the application of standard statistical techniques on the raw data. Compositional analysis will be undertaken to address the primary aim.[58] The fraction of daily time spent in physical activity (x_1), sedentary behaviour (x_2) and sleep (x_3) will be transformed to new variables $y1=\log(x_1/x_3)$ and $y_2=\log(x_1/x_3)$ using the proportion of time spent sleeping as the reference. This transformation translates the vector of proportions (x_1, x_2, x_3), which sum to 1, into a bidimensional vector (y_1, y_2) whose components are no longer constrained and can be analysed using standard multivariate methods.[59] The intervention effect on the log-ratio transformed data will be estimated using a multivariate linear mixed-effect model with trial arm as fixed effect and a 2×2 unstructured variance-covariance matrix to account for the correlation between components' proportions.[60] To facilitate interpretation, estimated mean log-ratios will be back transformed into proportion of time in each behaviour (minutes/day). To estimate the longitudinal effect of the intervention on the log-ratio transformed proportions, a multivariate linear mixed-effect model will be fitted with trial arm, time (T_0, T_2, T_3) and interaction arm×time as fixed effects, child as a random effect to account for the repeated measures, and a 2×2 unstructured

variance-covariance matrix. Classical and robust imputation algorithms for dealing with missing values in compositional data will be used.[61 62]

Intervention effects on parent reported time in various movement behaviours will be estimated using generalised estimating equation models with link and distribution selected according to the outcome. All models will include trial arm, time and arm×time effects. A causal mediation analysis, using a counterfactual framework, will explore whether the effects of the intervention on each individual time fraction (active, sedentary, sleep) is mediated by the targeted parenting practices and attitudes. The mediated (indirect) effect will be computed through G-estimation incorporating confounders of the mediator-outcome association.[63]

Economic evaluation

Incremental cost-effectiveness analysis will be undertaken to determine whether the intervention represents 'value for money' compared with current practice (ie, usual care with no access to the *Let's Grow* app). This will address technical efficiency (ie, 'how to do it') by analysing the net cost and net health benefit of the intervention, and will allow for determination of key intervention design features and their associated cost drivers through a trial-based economic evaluation. The cost-effectiveness analysis will be conducted from both a funder and a limited societal perspective, using detailed pathway analysis to specify all relevant intervention activities and costs. Resource use will be measured using unit costs drawn from trial data and published sources for the 2021 reference year. Cost data and trial outcomes data will be combined in a cost-consequence analysis, reporting a range of incremental cost-effectiveness ratios including cost per minute of screen-time saved, cost per additional unit of sleep and cost per metabolic equivalent task minute gained.

A modelled economic evaluation will also be undertaken for all movement behaviour outcomes together and separately by extending the target population, time horizon and decision context of the intervention. An existing multi-state Markov model[64] will be used to evaluate the intervention's cost-effectiveness (in terms of cost per health-adjusted life-year (HALY) saved), assuming it was delivered to the eligible Australian population and the observed intervention effect was extrapolated over the cohort's lifetime. In addition to incremental costs of the intervention (measured against the comparator), incremental cost offsets attributable to disease prevention over the life course will be reported. The commonly accepted reference threshold for cost-effectiveness of $A50 000 per HALY saved will be used.

Standard discounting will be applied to both costs and outcomes. Simulation modelling using the @RISK and Ersatz software packages will be used to calculate 95% uncertainty intervals (median, 2.5 and 97.5 percentiles) around the epidemiological probabilities and cost estimates. Sensitivity analyses will be undertaken, varying key input parameters into the economic evaluation and gauging overall impact on cost-effectiveness results.

Process evaluation

Web app analytics will provide information on frequency and duration of app access, pages visited, order of module completion and activities and modules completed to provide a measure of parent engagement and dose of intervention received by each participant. We will use an engagement index adapted from the Web Analytics Demystified visitor engagement index[65] that measures five subindices: click depth; loyalty; interaction; recency; and feedback. This information will be supplemented by quantitative data collected from all intervention group participants and qualitative data from interviews with a subsample of approximately 20 intervention participants on acceptability, satisfaction and relevance of the programme. Analysis of process evaluation data will occur prior to trial outcome data to minimise bias.[66]

Scalability evaluation

A novel addition to this study is inclusion of a prospective scalability evaluation. Our evaluation will be guided by the RE-AIM framework,[67] a global framework to evaluate the translation outcomes of health promotion programmes and the PRACTIS (PRACTical planning for Implementation and Scale-up) guide,[68] a framework for planning future implementation and scale-up with key stakeholders across multiple levels of the intended delivery system. Prospective scalability will be assessed based on: (1) parent acceptability and engagement with the intervention, (2) associations between intervention fidelity (participant adherence/level of engagement with the intervention as assessed by the engagement index) and impact on behavioural outcomes (effectiveness) and (3) parent and stakeholder (eg, government, family-facing organisations) perceptions of factors related to the future implementation and scale-up (such as individual and system level factors that may enhance or impede wider translation). These will be captured during interviews with approximately 20 participants and the *Let's Grow* Stakeholder Group and an online PRACTIS workshop with the Stakeholder Group.[68] Data will be transcribed verbatim and thematically analysed using NVivo V.12 software (QSR International, Melbourne, Australia).

DISCUSSION

This protocol addresses primary prevention of suboptimal movement behaviours, which impact young children's current and future health and well-being, as called for in the recent WHO Report on Ending Childhood Obesity.[1] The *Let's Grow* intervention incorporates a number of innovative features. It adopts a time-use epidemiology approach, which has recently been embodied in WHO and numerous national movement behaviour guidelines conceptualising the 24-hour day as consisting of time spent in physical activity, sedentary behaviour and

sleep,[10] and substitution as key to behaviour change strategies. It recognises that behaviour change does not occur in a linear manner, and thus is designed to be dynamic and non-linear, reacting to differing family situations and teachable moments. Furthermore, this tailored non-linear approach aligns with the dynamic way in which children develop motor skills and physical literacy over time through exposure to diverse physical activity opportunities,[47] thereby assisting children on their journey to lead an active life. Given the novel work with stakeholders to address implementation potential throughout the development and delivery of *Let's Grow,* if effective, it has the potential to be offered widely to parents of young children, to support them in promoting healthy movement behaviours from early in life.

Ethics and dissemination

The trial has received ethical approval from the Deakin University Human Ethics Committee (2020-077). After eligibility screening, the main carer will provide consent via an online form for their own and their child's participation in the study. Partners will provide consent for their own participation.

Trial findings will be disseminated via peer-reviewed publications, presentations at scientific and professional conferences, and via social and traditional media. In addition, findings will be disseminated directly to stakeholders involved in the scale-up evaluation.

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