BMJ Open Protocol of a cluster randomised controlled trial evaluating the effectiveness of an online parenting intervention for promoting oral health of 2–6 years old Australian children

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ABSTRACT

Introduction Dental decay is a major problem among Australian children. It can be prevented through good self-care and limiting sugar intake, but many parents/ caregivers lack the skills and confidence to help their children adopt these practices. This trial will evaluate the efficacy of *Healthy Habits Triple P - Oral health*, a web-based online programme, in improving children's oral health-related behaviours (toothbrushing, snacking practices and dental visits) and related parenting practices, thereby preventing dental caries.

Methods and analysis This is a cluster, parallel-group, single-blinded, randomised controlled trial of an online intervention for parents/caregivers of children aged 2-6 years. From the City of Gold Coast (Australia), 18 childcare centres will be randomly selected, with equal numbers randomised into intervention and control arms. Intervention arm parents/caregivers will receive access to a web-based parenting intervention while those in the control arm will be directed to oral health-related information published by Australian oral health agencies. After the completion of the study, the Healthy Habits Triple P - Oral health intervention will be offered to parents/caregivers in the control arm. The primary outcome of this trial is toothbrushing frequency, which will be assessed via Bluetooth supported smart toothbrushes and parent/caregiver report. Data on other outcomes: parenting practices and child behaviour during toothbrushing, consumption of sugar rich foods and parents' confidence in dealing with children's demands for sugar rich food, and dental visiting practices, will be collected through a self-administered questionnaire at baseline (before randomisation), and 6 weeks (primary endpoint). 6 months and 12 months after randomisation. Data on dental caries will be collected at baseline, 12 and 18 months post-randomisation.

Ethics and dissemination Ethical approval has been obtained from Human Research Ethics Committees of Griffith University (2020/700) and the University of Queensland (2020002839). Findings will be submitted for publication in leading international peer-reviewed journals.

Trial registration number ACTRN12621000566831.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is the first study conducted as a cluster randomised controlled trial testing a web-based parenting programme to improve oral health outcomes in children.
- ⇒ The secondary outcomes on parenting practices related to toothbrushing and snacking will help assess specific parenting practices related to risky oral health behaviours in children.
- ⇒ A comprehensive assessment of outcomes will provide extensive information on parental and child practices related to child oral health along with the burden of tooth decay.
- ⇒ The main limitation is the use of parent-reported questionnaires to collect information on dietary practices: this could be subject to recall or social desirability biases.
- ⇒ Longer follow-up to evaluate the efficacy of intervention in preventing dental caries, after 2 years or more, while desirable, was not possible.

BACKGROUND

Dental diseases are very common among Australian children, with caries being more than five times as prevalent as asthma.¹ Untreated dental caries in children can lead to significant pain and affect overall quality of life.² Although there has been a general decline in caries experience among children in higher-income countries in recent decades, the prevalence in children in Australia is still high. For instance, 40% of children aged 5-10 years have caries in their deciduous dentition with a mean caries experience of 3.1 tooth surfaces and 20% of children experienced 80% of the overall dental caries burden. Further, children from low-income families, especially those with an Indigenous background, living in rural or remote regions had higher prevalence and caries experience than their counterparts.³ Recent research indicates that Australia is among the top five countries in the world with the highest expenditure due to dental disease.⁴

Dental decay is the result of a complex interaction between fermentable dietary carbohydrates and acid producing bacteria.⁵ Regular toothbrushing and restricted sugar intake help in preventing dental caries.⁶ In our meta-analysis, we found a significant association between toothbrushing frequency and incidence of dental caries.⁷ The extent that tooth surfaces are cleaned and the time spent on brushing are also important for effective prevention of disease.⁸ However, national data reveal that half of Australian children brush less than twice every day with a fluoridated toothpaste,³ while the recommended frequency is at least twice a day.⁹ Most children also consume sugar-sweetened beverages every day.³ High caries rates in Australian children can be attributed to poor oral health-related practices.

Our previous research has shown that parents' child rearing practices could influence children's oral hygiene practices, levels of dental caries and overall quality of life.^{10 11} Findings from both observational and experimental research indicate that when parents (hereinafter, word 'parent/s' will be taken to include all caregivers for children) are more supportive of children's needs, children tend to develop more positive health behaviours, including oral hygiene behaviours.¹² In particular, children younger than 6 years require assistance and supervision from their parents in performing regular oral hygiene and making healthy food choices. Children in this age group are amenable to behaviour change, particularly when change is parent-led and consistently reinforced. Importantly, healthy practices adopted in childhood are more likely to continue into adolescence and adulthood.¹³

Although most parents are aware of their role in influencing children's self-care practices, they may lack motivation, planning, skills and confidence in executing those practices, including adoption of positive toothbrushing behaviours.¹⁴ For instance, a study found that many Australian children did not adhere to recommended behavioural practices in spite of their parents being aware of these,¹⁵ which might be due to a lack of skills and confidence among parents in promotion of healthy behaviours in their children. Parents' lack of competence in supporting children's oral health practices may arise from low levels of self-efficacy, viz: beliefs about their own abilities to perform a specific behaviour.¹⁶

There is abundant evidence that parenting interventions are helpful in improving both parental self-efficacy and child self-regulation with respect to child behaviour.¹⁷ Self-regulation constitutes the ability of an individual to regulate their own behaviours, cognitions and emotions with respect to external demands.¹⁸ Parents of young children are key to influencing children's health behaviours both distally by making healthy choices for them (eg, buying healthy foods) and also proximally through parenting practices that promote children's

self-regulation.¹⁸ Parenting interventions that promote positive, consistent and effective parenting behaviours have been widely evaluated and are the treatment of choice for child behaviour problems.¹⁹⁻²² While most of these interventions have focused on child emotional and behavioural problems,^{23 24} there is emerging evidence to suggest that such interventions can impact parenting practices related to children's health, for example, in the context of obesity, asthma, eczema and other chronic illnesses.^{25 26} Many of these interventions are lengthy and delivered face-to-face, and barriers that can prevent parents from attending and benefitting from these interventions include time constraints, caregiving demands, transport or other logistics.²⁴ More recently, online interventions have shown promising results in several domains of health.^{27 28} Such online or digital interventions for improving parenting practices related to oral health are rare. Many studies have been targeted to parents to improve parent supervised toothbrushing behaviour among children less than 8 years old. A systematic review found that among these interventions, most focused on parental knowledge, were intensive, delivered at home or in healthcare settings, and were not supported by a theoretical framework.²⁹ Only one study used a smartphone application to improve parental knowledge regarding children's oral health behaviours.³⁰ Literature indicates that health education interventions aimed at improving oral health outcomes in children have been found effective for limited clinical outcomes (eg, plaque).³¹ The aims of this project are to test an online intervention for parents to promote toothbrushing and other oral healthrelated practices and prevent dental caries in children aged 2-6 years through improving parental skills and self-efficacy.

METHODS AND ANALYSIS Design

This is a cluster, parallel-group, single-blinded, randomised controlled trial of an online parenting intervention with four time points for data collection, that is, a 2 (online intervention vs education only) \times 4 (time: baseline, 6 weeks, 6-month and 12-month follow-up) design for questionnaire-based assessment and a 2×3 (time: baseline, 12 and 18 months) for dental caries experience. This study will examine the effects of an online parenting intervention on children's oral health-related practices (toothbrushing, sugar consumption and dental visits), dental caries experience, parenting practices while brushing their child's teeth, strategies parents use to promote brushing and parents' self-efficacy, knowledge and attitudes in relation to oral health of children, compared with a control group.

Participants and recruitment

Recruitment of participants will be conducted over a period of 6 months (May 2021 to October 2021). Parents or caregivers and children aged 2–6 years are recruited

from randomly selected Child Care Centres (CCCs) of the Gold Coast. A list of CCCs in each tertile of socioeconomic disadvantage³² was created. CCCs are then randomly selected and invited via email or phone to participate, and recruitment continues until the required number of CCCs is achieved. Centre-based CCCs that deliver typical long day care are considered for inclusion while those providing home-based care or family-based care are excluded. CCCs in each arm are pair-matched based on their tertile of socioeconomic disadvantage.

Inclusion criteria for parents or caregivers are: having a child aged 2–6 years, being able to read and understand English, providing written informed consent and having access to a device (eg, smartphone, tablet or computer) with internet access. Only one parent and one child per family are eligible to participate. If a parent has more than one child in the eligible age range attending a selected CCC, they are asked to nominate the child whose oral health habits they are most concerned about. If they do not have concerns for one specific child, the youngest child is selected. Exclusion criteria are: child with a disability, child with behavioural difficulties for which parents are currently seeking professional help, and parents currently receiving psychological help or counselling for any reason.

A parent-focused intervention in the past found an absolute increase from 59% to 89% in the number of children brushing their teeth twice daily.³³ Therefore, assuming an effect size of 0.30 with a type I error of 0.05 and 80% power, an intra-cluster correlation coefficient of 0.03,34 and consent rate of six children from each selected CCC, six clusters per arm are required to detect a minimum difference of 29.6% in the primary outcome. This results in a sample size of 72 families (36 in each arm). Allowing for an overall attrition rate of 50%, 108 families (54 in each arm) and at least 6 in each cluster will be recruited. An additional CCC will be considered for each CCC that has a cluster size of less than six. We intend to allow for attrition of greater than the traditionally hypothesised $20\%^{35}$ due to the long assessment follow-up in a transient setting like a CCC: high attrition rates have been observed from past cluster randomised trials conducted in Australian CCC settings.³⁶

Parents of children aged 2–6 years in the consenting CCCs receive information about the study via a printed information sheet or a notice in their Centre's newsletter, or verbally from research staff attending the CCC during 'pick-up' hours. The notice in the newsletters directs parents to the study website where they can read the study information, register their interest in participating and consent to be contacted. Alternatively, parents can return a 'consent to be contacted' form to the CCC, or directly to the research team via email or text message, or via hardcopy returned to the researchers attending the CCC. Those providing 'consent to be contacted' are contacted by phone or email by a research staff member to assess their eligibility. Eligible parent participants are contacted again after a week to allow them time to discuss the

research project with family members. Interested parents are invited to complete online consent (online supplemental file 1) and baseline questionnaires. Their child is examined for dental caries in the CCC in the presence of a childhood educator or parent. Parents are invited to attend their child's caries examination appointment, but their presence is not mandatory. Verbal assent is obtained from children before conducting the oral examination at baseline and at each appointment by explaining their involvement in simple language. Appointments are postponed if a child appears distressed. After the baseline caries examination and completion of questionnaires, researchers meet parents' face-to-face when they come to collect their children from the CCC. During this consultation, parents receive: a Bluetooth supported smart toothbrush and monthly toothbrushing charts. The research team helps the parents in setting up the mobile application on their smartphones. Families receive a phone call after 2 days to check that they have successfully downloaded the Oral B application and that their child has started using the toothbrush.

Randomisation, allocation and blinding

After baseline surveys and caries assessments have been completed, each CCC is randomly allocated to the intervention or the control group in a 1:1 ratio using computer generated block randomisation by a member of the research team not involved in recruitment or data collection: this facilitates equal group allocation. Group allocation is stratified by the socioeconomic tertile (low, medium and high) of the location of the CCC. Participants in this study cannot be blinded to group allocation; however, the investigator responsible for caries outcome assessment is blinded to group allocation.

Intervention and control

Healthy Habits Triple P - Oral health is designed to improve parenting practices and confidence related to children's oral health-related behaviours (toothbrushing, snacking practices and dental visits), and thereby prevent dental caries in children. It is based on a social learning model to promote self-regulation in parents and children, which forms the theoretical basis of Triple P. Triple P is underpinned by five core principles of positive parenting: safe and engaging environment, positive learning environment, assertive discipline, realistic expectation and parental self-care.^{37 38} The focus of intervention delivery is on parents, not children, as children's behaviour is seen to be directly influenced by parent behaviour. The intervention aims to increase parental self-regulation and positive parenting practices to promote child cooperation, consistent discipline and routine related to oral health practices. This programme is easy to use and engaging, and includes interactive features like video/audio clips, goal-setting activities, reminders and progress trackers. It is compatible for use on a smartphone, tablet or computer and consists of two modules. Module one focuses on general parenting principles

and includes: strategies for encouraging healthy lifestyle behaviours; setting up and maintaining effective routines; preventing and dealing with children's resistance; planning for high risk situations that may disrupt routines; building children's independence in engaging in healthy lifestyle practices; coping with stressful situations; and finding appropriate evidence based information to support healthy lifestyles. The second module is oral health specific and focuses on the importance of starting oral health routines early, engaging in regular and effective toothbrushing, healthy approaches to snacking and drinks and strategies to ensure that visits to the dentist are regular and a positive experience for both parent and child. The online modules take 3-4 hours to complete but parents are encouraged to complete them at their own pace. Participants in the intervention group are encouraged to complete all the modules within 2 weeks of allocation. In between the 6-week and 18-month post-intervention assessments, parents receive monthly emails or phone call reminding them to follow their oral health-related habits plan.

The control group receives web links to Queensland Health (https://www.health.qld.gov.au/oralhealth/ healthy_smile/children) and the Australian Dental Association (https://www.ada.org.au/Your-Dental-Health/ Children-0-11/Kids) guidance for maintaining oral hygiene in children. Parents in the control group will have access to the intervention after completing their 18-month follow-up assessment.

Data collection

The parent questionnaires comprise questions assessing family socio-demographic characteristics, collected using the Family Background Questionnaire³⁹; child's age and sex, residential postcode, relationship of the respondent to the child, respondents' marital status, family structure, ethnicity, number of people living in the family home, level of education, work status and country of birth of the respondent and their partner and the family's ability to meet essential expenses. In addition, the respondents are asked about the ages at which their child first started brushing their teeth and had their first dental visit, and their own and their child's general and oral health status.

Questionnaires are administered online using the LimeSurvey platform, and the link to the survey is sent to the parent's email at each follow-up time point. Parents requesting paper questionnaires receive them through the post and are asked to return the completed questionnaires to the researchers using a postage paid return envelope. Reminders for completing the follow-up questionnaires are sent through emails/text messages at each follow-up time point. All data related to primary and secondary outcomes, except dental caries, are collected at baseline, 6-week, 6-month and 12-month follow-up time points. Dental caries assessment are done at baseline, 12-month and 18-month follow-up time points (figure 1).

Primary outcome (toothbrushing)

Mean daily toothbrushing frequency and mean time spent on toothbrushing at each session are the primary outcomes of the study. Two sources are used to collect these data: powered toothbrushes and parent report. Data on toothbrushing frequency and time spent at each session are remotely collected through the Oral-B application installed on parents' mobile devices, which stores the toothbrushing data transferred from Bluetooth-linked powered toothbrushes (Oral-B Genius 9000 electric toothbrushes). All the data collected through the Oral B application is stored on their self-built, secure cloud platform and complies with all standards and guidelines related to protecting customer data in Australia. Toothbrushing data along with the handle IDs (with no personally identifiable information) is provided to the research team on request, by Oral B researchers at each time point. Parent-reported toothbrushing information is collected every 3 months for a period of 12 months using a series of 3-month toothbrushing charts. Parents and/or children tick the chart after brushing in the morning and evening every day, and parents upload the image of the completed charts to the research team by scanning the QR code on the toothbrushing chart.

Secondary outcomes

- Parents' use of different parenting practices while brushing their children's teeth and the strategies that they use to overcome toothbrushing problems are evaluated using the 'Parent and Child Toothbrushing Assessment' (PACTA); parents' knowledge, attitudes and self-efficacy is also assessed using this instrument. PACTA comprises four scales assessing: (i) toothbrushing behaviour in children and parental self-efficacy with managing difficult child behaviours, (ii) parenting strategies used to promote brushing, and parents' (iii) attitudes and (iv) knowledge about toothbrushing. We found PACTA to be valid and reliable.⁴⁰
- ► toothbrushing and dental visiting habits (toothbrushing frequency of the parent respondent, family support with child's toothbrushing, dental visiting experience) are collected via self-report. Questions were adapted from a previous study testing a community oral health promotion intervention⁴¹ and a toothbrushing survey⁴² in Australia.
- Frequency of consumption of sugar rich foods and drinks among children and parents' confidence in dealing with children's demands for sugar rich foods is reported by parents. The questions were adapted from previous studies.^{41 43 44}
- Dental caries in children is assessed by a single calibrated examiner (SKT) in the CCCs using the World Health Organisation criteria⁴⁵ and the examiner remains blinded to the allocation status of the child. A lesion is considered as carious when it has a cavity, undermined enamel or a detectably softened floor or wall. Caries examinations will be done using a plane

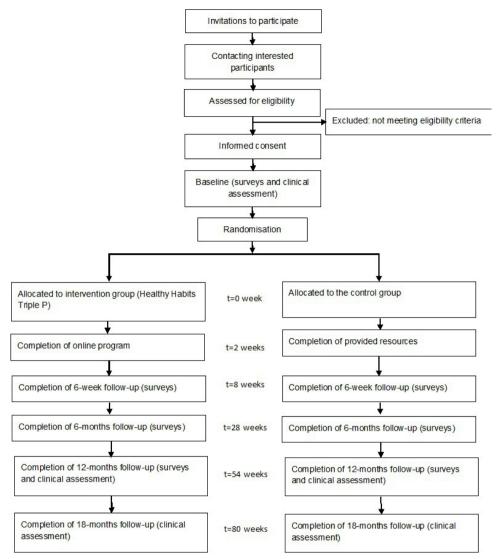


Figure 1 Flow diagram of the Healthy Habits Triple P - Oral health study.

mirror and a blunt probe. The caries experience will be quantified as the sum of decayed, missing and filled surfaces. Caries increment (number of surfaces developing new caries at subsequent time points) will be the outcome of interest.

Statistical analysis

All the data will be de-identified and SPSS (V.24.0. Armonk, New York, USA: IBM Corp) will be used to conduct data analyses. Data will be examined for outliers and missing values. All data will be analysed based on the intention-to-treat principle. Baseline differences in sociodemographic characteristics between the intervention and control groups will be presented using appropriate descriptive statistics. Individual participant will be unit of analysis and, to account for repeated measurements and clustering effects, linear mixed models will be used to evaluate the mean change in toothbrushing frequency, time spent on toothbrushing and all other study outcomes (including mean caries increment) across groups through the study period.

Patient and public involvement

In the first phase of this project, we conducted interviews with parents of young children and also liaised with experts in parenting interventions related to health, to develop a comprehensive measure that captures the toothbrushing-related behavioural problems in children, strategies parents use to promote toothbrushing in children, and attitudes and knowledge related to toothbrushing in parents. This information was used while developing the intervention proposed in this project. The design and outcomes measures for the study were first discussed with an early years coach working in the space of early childhood education locally. However, no other formal consultation with the public was undertaken for this study.

Data management and storage

VR and SKT will monitor the data regularly to ensure protocol compliance. All the data collected through paper and online resources will be entered into a computer programme (Microsoft Excel). The file comprising the

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information on participant ID, names and contact details will be separate from the other research data. All the print copies will be kept in a locked cabinet in locked personal office. Electronic data will be stored on a secured server of university computer network in a password protected folder. Data will only be accessible to the investigators.

ETHICS AND DISSEMINATION

Ethical approval has been obtained from the Human Research Ethics Committees of Griffith University (2020/700) and the University of Queensland (2020002839). Any modification to the protocol will be submitted as an amendment to the ethics committees for approval. Findings will be submitted for publication in leading international peer-reviewed journals. In addition, the results will be disseminated at national and international platforms through presentations at prominent conferences. The summary of findings from this research will be shared with the participating families and CCCs.

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Contributors SKT and AM conceptualised the study. SKT, AEM, AM and NJ contributed to the study design. VR and SKT are responsible for acquisition of data, analysis and interpretation. SKT and VR drafted the initial article. AEM, AM and NJ critically revised the article. All the authors agree to be accountable for all aspects of work.

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Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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