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TITLE

Protocol of a cluster randomised controlled trial evaluating the effectiveness of an online parenting intervention for promoting oral health of young 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 lack the skills and confidence to help their children adopt these practices. This trial will evaluate the efficacy of *Healthy Habits Triple P,* a web-based online program, in improving children's oral health-related behaviours (tooth brushing, 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 of children aged 2-6 years. From the City of Gold Coast (Australia), eighteen childcare centres will be randomly selected, with equal numbers randomised into intervention and control arms. Intervention arm parents 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* intervention will be offered to parents in the control arm. The primary outcome of this trial is toothbrushing frequency, which will be assessed via Bluetooth supported smart toothbrushes and parent-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 foods, 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 (2020002839/2020/700). Findings will be submitted for publication in leading international peer-reviewed journals.

Trial registration number: ACTRN12621000566831, Australian New Zealand clinical trials registry.

STRENGTHS AND LIMITATIONS

- This simple, low-intensity online intervention is based on the principles underpinning the world-renowned Triple P-Positive Parenting Program.
- The intervention constitutes a primary preventive strategy in the true sense as it tackles early behavioural risk factors and promotes health behaviours which can be sustained throughout life.
- The intervention has the potential to reduce the burden of dental caries, which affects children's quality of life. Rather than relying on knowledge transfer through health education, this intervention will help parents improve their skills to promote positive oral health-related practices with their children.
- Limitations of the study could include non-participation bias, with those parents having the highest need (parents of children exhibiting poor oral health behaviour or with lower socioeconomic status) potentially facing more barriers to participation.

- Another limitation involves use of parent-report questionnaires to collect information related to dietary practices: this could be subject to recall or social desirability biases.

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 experienced 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 [3], and 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 tooth brushing and restricted sugar intake help in preventing dental caries [6]. In our meta-analysis, we found a significant association between tooth brushing 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 significantly 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 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 six 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 tooth brushing 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], and this 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 (e.g., 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, e.g., 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 benefiting 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]. The aims of this project are to test an online intervention for parents to promote tooth brushing and other oral health-related 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 randomised controlled trial of an online parenting intervention with four time-points for data collection, i.e., a 2 (online intervention vs. education only) X 4 (time: baseline, 6 weeks, 6-month and 12-month follow-up) design for questionnaire-based assessment and a 2 X 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 (tooth brushing, sugar consumption and dental visits), dental caries experienced, 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 to a control group.

Participants and recruitment

Recruitment of participants will be conducted over a period of six months (May 2021 – 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 disadvantage [29] 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 (e.g., smartphone, tablet, and 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.

Oral health promotion interventions in the past have been shown to improve tooth brushing habits in 25% of participants receiving intervention [30]. Assuming an increase in twice daily tooth brushing from 66% (national child oral health data demonstrate that only 66% of 5-6 year old Australian children brush twice daily [31]) to 91% in the intervention group with a type I error of 0.05 and 80% power, an intra cluster correlation coefficient of 0.03 [32], and consent rate of six children from each selected CCC, nine clusters per arm are required to detect a minimum difference of 24% in the primary outcome. This results in a sample size of 108 families (54 in each arm). Allowing for an overall attrition rate of 40%, 162 families (81 in each arm) and nine in each cluster will be recruited. We intend to allow for attrition of greater than the traditionally hypothesised 20% [33] 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 [34].

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 e-mail 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 and baseline questionnaires. Their child is examined for dental caries in the CCC. 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, parents receive: a Bluetooth supported smart toothbrush along with instructions (using the manufacturer provided manual) for setting up the mobile application, and monthly tooth brushing charts. All this information is provided to parents face-to-face when they come to collect their children from the CCC. Families receive a phone call after 2 days to check that they have successfully downloaded the Oral B app 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 data collection or recruitment: 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 is designed to improve parenting practices and confidence related to children's oral health-related behaviours (tooth brushing, 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 [35]. 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, lead to consistent discipline and promote routine. This program 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 tooth brushing, 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. Participants in the intervention group are encouraged to complete all the modules within two to four weeks of allocation. In between the 6 week and 18-month post-intervention assessments, parents receive monthly emails 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 Questionnaire [36]; 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 Lime survey 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.

Primary outcome (tooth brushing)

Mean daily tooth brushing frequency and mean time spent on tooth brushing 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 tooth brushing frequency and time spent at each session are remotely collected through the Oral-B app 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 app 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 three-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 tooth brushing problems are evaluated using the "Parent and Child Tooth-brushing Assessment" (PACTA); parents' knowledge, attitudes and self-efficacy is also assessed using this instrument. PACTA comprises four scales assessing: (i) tooth brushing 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 tooth brushing. We found PACTA to be valid and reliable [37].
- Tooth brushing and dental visiting habits (toothbrushing frequency of the parent respondent, family support with child's tooth brushing, dental visiting experience) are collected via self-report. Questions were adapted from a previous study testing a

community oral health promotion intervention [38] and a tooth brushing survey [39] 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 [38 40 41].
- Dental caries in children is assessed by a single examiner (ST) in the CCCs using the World Health Organisation criteria [42] 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 mirror and a blunt probe. The caries experience will be quantified as the sum of decayed, missing and filled surfaces.

Statistical analysis

All the data will be de-identified and SPSS (Version 24.0. Armonk, NY: 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 intent to treat (ITT) principle. Baseline differences in socio-demographic 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 tooth brushing frequency, time spent on tooth brushing and all other study outcomes 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 tooth brushing related behavioural problems in children, strategies parents use to promote toothbrushing in children, 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.

ETHICS AND DISSEMINATION

Ethical approval has been obtained from the Human Research Ethics Committees of Griffith University (2020/700) and the University of Queensland (2020002839/2020/700). 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.

CONTRIBUTORSHIP STATEMENT

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

COMPETING INTERESTS STATEMENT

The Parenting and Family Support Centre is partly funded by royalties stemming from published resources of the Triple P – Positive Parenting Program, which is developed and owned by The University of Queensland (UQ). Royalties are also distributed to the Faculty of Health and Behavioural Sciences at UQ and contributory authors of published Triple P resources. Triple P International (TPI) Pty Ltd is a private company licensed by Uniquest Pty Ltd on behalf of UQ, to publish and disseminate Triple P worldwide. The authors of this report have no share or ownership of TPI. A/Prof Morawska receives royalties from TPI.TPI had no involvement in the study design, collection, analysis or interpretation of data, or writing of this report. A/Prof Morawska is an employee and Dr Mitchell is affiliated with the University of Queensland.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	3	Date and version identifier	2
Funding	4	Sources and types of financial, material, and other support	9
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	9
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	NA

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	
	6b	Explanation for choice of comparators	
Objectives	7	Specific objectives or hypotheses	
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	

Methods: Assignment of interventions (for controlled trials)

Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
	31b	Authorship eligibility guidelines and any intended use of professional writers	
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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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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TITLE

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 program, in improving children's oral health-related behaviours (tooth brushing, 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), eighteen 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 foods, 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 (2020002839/2020/700). Findings will be submitted for publication in leading international peer-reviewed journals.

Trial registration number: ACTRN12621000566831, Australian New Zealand clinical trials registry.

STRENGTHS AND LIMITATIONS

- This is the first study conducted as a cluster randomised controlled trial testing a web-based parenting program 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, whilst 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 experienced 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 tooth brushing and restricted sugar intake help in preventing dental caries [6]. In our meta-analysis, we found a significant association between tooth brushing 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 significantly 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 six 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 tooth brushing 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], and this 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 (e.g., 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, e.g., 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 benefiting 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 health care 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 (e.g.,

plaque).[31] The aims of this project are to test an online intervention for parents to promote tooth brushing and other oral health-related 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, i.e., a 2 (online intervention vs. education only) X 4 (time: baseline, 6 weeks, 6-month and 12-month follow-up) design for questionnaire-based assessment and a 2 X 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 (tooth brushing, sugar consumption and dental visits), dental caries experienced, 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 to a control group.

Participants and recruitment

Recruitment of participants will be conducted over a period of six months (May 2021 – 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 disadvantage [32] 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 (e.g., smartphone, tablet, and 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 six 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 e-mail 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 (supplementary 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 tooth brushing charts. The research team helps the parents in setting up the mobile application on their smart phones. Families receive a phone call after 2 days to check that they have successfully downloaded the Oral B app 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 (tooth brushing, 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 program 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 tooth brushing, 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 two 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 Questionnaire [39]; 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 Lime survey 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 (tooth brushing)

Mean daily tooth brushing frequency and mean time spent on tooth brushing 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 tooth brushing frequency and time spent at each session are remotely collected through the Oral-B app 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 app 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 three-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 tooth brushing problems are evaluated using the "Parent and Child Tooth-brushing Assessment" (PACTA); parents' knowledge, attitudes and self-efficacy is also assessed using this instrument. PACTA comprises four scales assessing: (i) tooth brushing 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 tooth brushing. We found PACTA to be valid and reliable [40].

- Tooth brushing and dental visiting habits (toothbrushing frequency of the parent respondent, family support with child's tooth brushing, dental visiting experience) are collected via self-report. Questions were adapted from a previous study testing a community oral health promotion intervention [41] and a tooth brushing survey [42] 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 (ST) in the CCCs using the World Health Organisation criteria [45] 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 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 (Version 24.0. Armonk, NY: 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 intent to treat (ITT) principle. Baseline differences in socio-demographic 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 tooth brushing frequency, time spent on tooth brushing 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 tooth brushing related behavioural problems in children, strategies parents use to promote toothbrushing in children, 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 program (Microsoft Excel). The file comprising the 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 (2020002839/2020/700). Any modification to the protocol will be submitted as an amendment to the trial registry and 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.

CONTRIBUTORSHIP STATEMENT

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

COMPETING INTERESTS STATEMENT

The Parenting and Family Support Centre is partly funded by royalties stemming from published resources of the Triple P – Positive Parenting Program, which is developed and owned by The University of Queensland (UQ). Royalties are also distributed to the Faculty of Health and Behavioural Sciences at UQ and contributory authors of published Triple P resources. Triple P International (TPI) Pty Ltd is a private company licensed by Uniquest Pty Ltd on behalf of UQ, to publish and disseminate Triple P worldwide. The authors of this report have no share or ownership of TPI. A/Prof Morawska receives royalties from TPI.TPI had no involvement in the study design, collection, analysis or interpretation of data, or writing of this report. A/Prof Morawska is an employee and Dr Mitchell is affiliated with the University of Queensland. Oral-B (Procter & Gamble) has kindly provided the powered toothbrushes for this project but had no involvement in the study design, collection, analysis or interpretation of data, or writing of this report.

FUNDING

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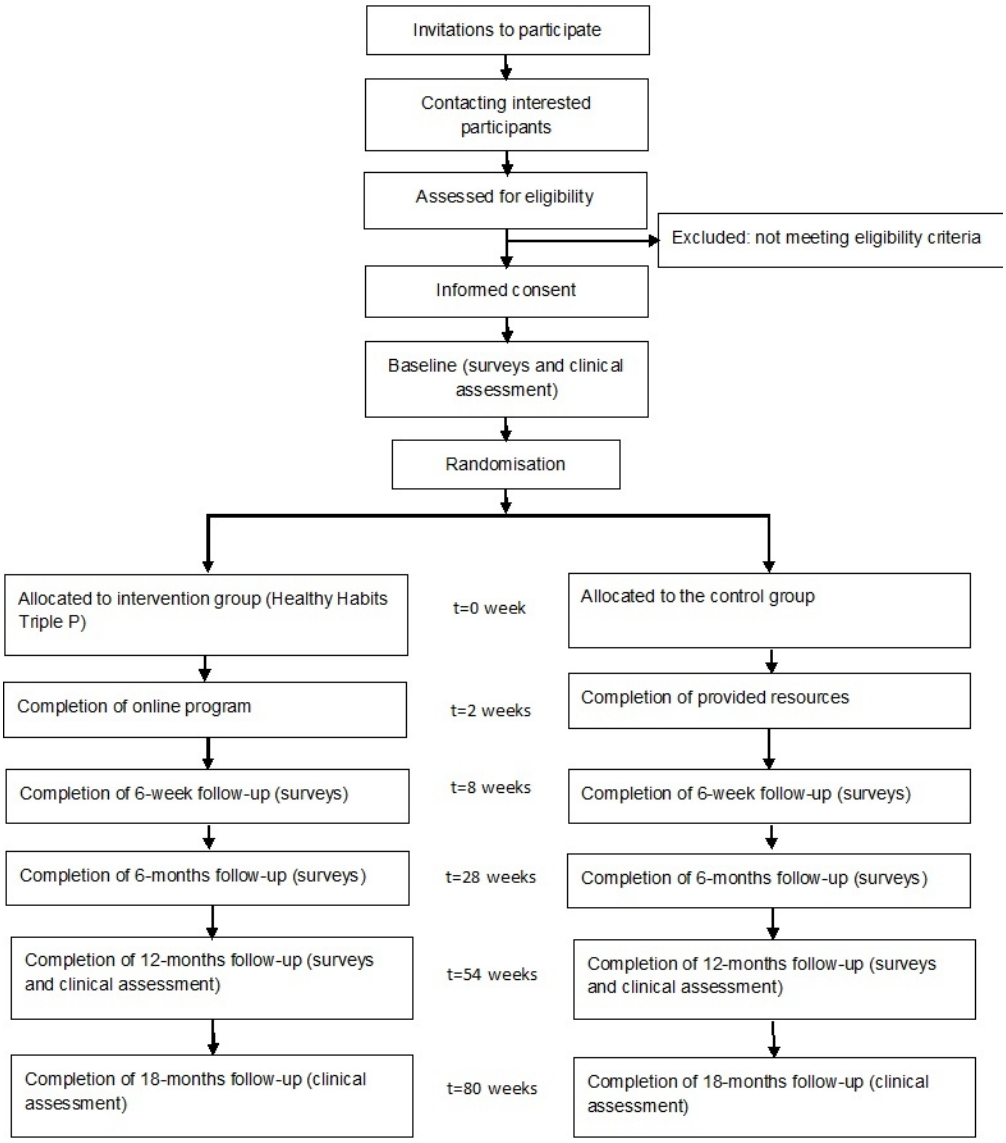
Figure 1: Flow diagram of the Healthy Habits Triple P - Oral health study



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

206x234mm (96 x 96 DPI)

Effectiveness of an interactive online parenting intervention for promoting oral hygiene practices and preventing dental caries in young children (GU ref no: 2020/700)
INFORMATION SHEET

Who is conducting the research

Dr Santosh Kumar Tadakamadla[1], Dr Vatsna Rathore[1], Prof Newell Johnson[1], Dr Amy Mitchell[2], A/Prof Alina Morawska[2]
[1]School of Dentistry and Oral Health, Griffith University, Gold Coast, Australia
[2]Parenting and Family Support Centre, School of Psychology, The University of Queensland, Brisbane, Australia
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Why is the research being conducted?

A team of researchers from Griffith University and the University of Queensland are undertaking this research to test a newly-developed internet-based online program designed to help parents to improve oral health-related practices and prevent the development of cavities ("dental caries") in their children's teeth.

What you will be asked to do

Your participation in this study will require a commitment from you and your child over a period of 18 months.

- First, a brief telephone screening interview with a member of the research team (taking approximately 5-10 minutes) will check that you are eligible to participate.
- If you consent to participate, you will be asked to complete a set of online questionnaires (taking approximately 30 minutes to complete).
- We will then invite you to attend your child's Childcare Centre or school to meet with a member of the research team. You will receive a Bluetooth supported powered toothbrush (and mobile app) free-of-charge for your child to keep and use during the study, along with monthly tooth brushing charts, information on how to use the toothbrush's app, and how to take pictures of your child's teeth with your smartphone camera. Your child's teeth will then be examined for tooth decay by the researcher who is a qualified dentist. Finally, you will be asked to take a set of photos of your child's teeth using your smartphone and share these with the research team. This visit should take approximately 20 minutes.
- If you are unable to attend your child's Childcare Centre or school during business hours, we can still assess your child's teeth (your attendance is welcome but not mandatory) and mail out the materials and equipment to your home address. This will be followed by a brief phone/Zoom call to explain how to use the toothbrush's app and take digital images. You will then be asked to take a set of photos of your child's teeth at home and send these to the research team.
- A week later, all families will be asked to send a screen shot of the "tooth brushing summary" from the app to the research team. We will then randomly assign your

child's Childcare Centre or school (50/50, like the toss of a coin) to an intervention ("Start Now") or to the control group ("Start Later").

- Families in the centres or schools allocated to Start Now will be given immediate access to the online program, and need to complete the four modules of the online program within the first four weeks. The program is interactive and includes video/audio clips, goal-setting activities and progress trackers. The program can be accessed via any device (e.g. smartphone, tablet, computer) with internet access, and you can work through the modules at your own pace.
- Families in a centre or school allocated to Start Later will receive links to the Queensland Health and Australian Dental Association providing information on how to maintain good oral hygiene in children, and will be provided with access to the online program after an 18-month waiting period.
- In addition to completing the questionnaires at the beginning of the study, you will be asked to complete the same simple questionnaires at 6-weeks, 6 and 12 months. You will receive a survey link by email to complete the survey online. The questionnaires will ask about your family background, tooth brushing difficulties with your child and methods you use to promote tooth brushing, your knowledge and attitudes towards tooth brushing, and your child's tooth brushing, sugar consumption and dental visiting practices. You will be asked about family background only once, at the start of the study.
- We will ask you to send a screenshot of the tooth brushing summary (from the toothbrush's mobile app) and a photo of the tooth brushing chart every month until 12 months. You will receive a survey link every month by email for uploading the screenshot and a picture of that month's tooth brushing chart.
- Your child will undergo simple examinations of his/her teeth by the same trained examiner (at their Childcare Centre or school) which will take 3-4 minutes again at 12 and 18 months. We will seek verbal assent from your child before examining their teeth every time. In the event of another lockdown due to COVID-19, we will ask you to take pictures of your child's teeth and send them to us through a survey link sent to you by email at 12 and 18 months.
- No treatment will be provided to children participating in this research. You will, however, be provided with a written report of each of your child's dental examinations free of charge, and you are free to follow up with your own family dentist if any treatment is recommended/required.

The basis by which participants will be selected or screened

You are eligible to participate if you have a child aged 2-6 years, are able to read and understand English, and have access to any device (e.g. smartphone, tablet, or computer) with internet access and a smartphone with camera.

The expected benefits of the research

We expect that completing the online program will lead to improvements in children's oral health practices and reduced incidence of tooth decay. All children, regardless of group allocation, will get to keep the powered toothbrush along with toothbrush heads that are sufficient for 18 months' use. Your participation will help us test a sustainable, low cost online oral health program for parents of young children that may benefit children's health and quality of life in the future. You will receive a written report following each of your

child's dental examinations.

Risks to you

We do not anticipate any particular risks to you or your child because of participation in this research. Some questions in the questionnaire ask about problems with tooth brushing with your child that might cause some discomfort to some parents. If you find any questions discomforting, you could choose not to answer those questions.

Your confidentiality

Data collected from you or your child will be de-identified, and any identifiable details, such as your or your child's name, will be removed and replaced by your participant ID. All records will be stored on secure password protected computer servers at Griffith University. At the end of the research project, we will delete all identifiable information, so your personal information could not be identified. You will not be personally identifiable in any report, presentation or publication. All the information collected on paper will be destroyed five years after study results are published.

Your participation is voluntary

Participation in this research is voluntary. If you or your child do not wish to participate, you are not obliged to participate. Also, if you decide to take part and later change your mind, you and your child are free to withdraw from the study at any time.

Questions / further information

You can contact Santosh Kumar Tadakamadla (santoshkumar.tadakamadla@griffithuni.edu.au, phone – (07) 5678 0153) or Vatsna Rathore (vatsna.rathore@griffithuni.edu.au) at any point in time for further information.

The ethical conduct of this research

This research project has received approval from the Griffith University Human Research Ethics Committee (GU ref no: 2020/700) and is conducted under the auspices of Griffith University in accordance with the *National Statement on Ethical Conduct in Human Research*. If you have any concerns or complaints about the ethical conduct of the research project you should contact the Manager, Research Ethics on (07) 3735 4375 or **research-ethics@griffith.edu.au**.

Feedback to you

We will send the results/outcomes of this study to you and to your child's early childhood education centre. We will ask the centre to share the findings to all the parents through their existing communication channels (e.g. newsletters, daily emails etc.).

Privacy Statement – non-disclosure

The conduct of this research involves the collection, access, storage and/or use of your identified personal information. The information collected is confidential and will not be disclosed to third parties without your consent, except to meet government, legal or other regulatory authority requirements. The Bluetooth toothbrushes given to you were provided by Oral B as in-kind support to the research team, they do not have any involvement in conception, conduct and dissemination of this research. A de-identified copy of this data may be used for other research purposes, including publishing openly (e.g. in an open access repository). Results of this research will be reported in an

academic thesis, and may also be disseminated via journal articles and / or conference presentations. However, your anonymity will at all times be safeguarded. For further information consult the University's Privacy Plan at http://www.griffith.edu.au/about-griffith/plans-publications/griffith-university-privacy-plan or telephone (07) 3735 4375.

Effectiveness of an interactive online parenting intervention for promoting oral hygiene practices and preventing dental caries in young children (GU ref no: 2020/700)

CONSENT FORM

Research Team

Dr Santosh Kumar Tadakamadla[1], Dr Vatsna Rathore[1], Prof Newell Johnson[1], Dr Amy Mitchell[2], A/Prof Alina Morawska[2]

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By signing below, I confirm that I have read and understood the information sheet and in particular have noted that:

- I understand that my participation may involve completion of the online program;
- I understand that my participation also involves completion of questionnaires;
- I understand that I will have to provide information about my child's tooth brushing every month;
- I understand that my child's involvement will include simple examinations of his/her mouth and teeth;
- I understand that I will have to take photos of my child's teeth at the start of the study and may be required to take photos again at 12 and 18 months if the researchers are unable to examine my child's teeth due to COVID-19 restrictions or other major disruptions;
- I understand that my child's and my participation in this project is voluntary;
- I understand the risks involved;
- I have had any questions answered to my satisfaction and understand that if I have any additional questions I can contact the research team and/or Chief Investigator;
- I understand that my child and I are free to withdraw at any time, without comment or penalty;
- I understand that I can contact the Manager, Research Ethics, at Griffith University Human Research Ethics Committee on 3735 4375 (or research-ethics@griffith.edu.au) if I have any concerns about the ethical conduct of the project.

Parent/Guardian First and Last Name	
Parent/Guardian Signature	
Date	

Please complete the following details about your child

Child's First Name	
Child's Last name	
Child's date of birth	

Griffith UNIVERSITY
Queensland, Australia

Child's sex (circle)	Male	Female

I agree for my child and myself to participate in this project (circle)	Yes	No

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Lines 1-3, page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Lines 47-48, page 2
	2b	All items from the World Health Organization Trial Registration Data Set	Available in registry
Protocol version	3	Date and version identifier	In the footnotes
Funding	4	Sources and types of financial, material, and other support	Lines 336-339, page 11
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Lines 317-321, page 11
	5b	Name and contact information for the trial sponsor	Page 1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Lines 323-334, page 11
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Not applicable

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Lines 63-124, Pages3-4
	6b	Explanation for choice of comparators	
Objectives	7	Specific objectives or hypotheses	Lines 124-126, page 5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Lines 129-133, page 5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Lines 139-146, page 5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Lines 147-155, page 5
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Lines 196-226, pages 7-8
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Lines 237-239, page 8
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Lines 186-187, page 6
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Lines 196-226, pages 7-8
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Lines 244-283, pages 8-9

Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Lines 156-163, page 5
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Lines 162-163, page 5
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Lines 189-193, page 7
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Lines 189-193, page 7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Lines 189-195, page 7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Lines 193-195, page 7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Lines 189-195, page 7
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Lines 228-283, page 8-9

	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Lines 220-221, page 7
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Lines 303-309, page 10
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Lines 285-293, page 10
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Lines 285-293, page 10
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Lines 290-292, page 10
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Lines 304,page 10
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Not applicable
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Not applicable
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Not applicable
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Lines 312-313, page 10

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Lines 313-315, page 10
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Lines 167-177, page 6
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Not applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Lines 304-310, page 10
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Lines 325-336, page 11
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Lines 309-310, page 10
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	Not applicable
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Lines 315-318, page10-11
	31b	Authorship eligibility guidelines and any intended use of professional writers	Lines 320-323, page 11
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Line 47, page 1
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary file
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.