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Impact of early caries intervention on dental treatment in Indigenous Australian children: a randomised controlled trial

Running title: Early caries intervention on dental treatment in Indigenous children

Dr. Xiangqun Ju, PhD^{a*,1}, Wendy Wai Sau Cheung, MPH^b, Prof. Lisa M Jamieson, PhD^{a,2}

^aAustralian Research Centre for Population Oral Health, Adelaide Dental School, the University of Adelaide, Adelaide, South Australia, Australia, 5005

^bAdelaide Dental School, University of Adelaide, Adelaide, South Australia, Australia, 5005

e-mail: xiangqun.ju@adelaide.edu.au

e-mail: wendy.cheung@adelaide.edu.au

e-mail: lisa.jamieson@adelaide.edu.au

*Corresponding author:

Dr. Xiangqun Ju

Australian Research Centre for Population Oral Health, Adelaide Dental School, the University of Adelaide, SA 5005, Level 4, 50 Rundle Mall Plaza, Adelaide, 5000, South Australia, Australia

Ph: +61 8 8313 7352,

e-mail: xiangqun.ju@adelaide.edu.au

Abstract

Objective

The study investigated the effects of an early childhood caries (ECC) intervention on the need for dental treatment in Indigenous Australian Children. We hypothesized that exposure to an early intervention program would reduce the need for dental treatment among Indigenous

¹ ORCID: <https://orcid.org/0000-0003-4759-3918>

² ORCID: <https://orcid.org/0000-0001-9839-9280>

children.

Methods

This randomized controlled trial allocated 448 pregnant women with an Aboriginal child to either an immediate (II) or delayed (DI) intervention group between January 2011 and May 2012. There were four components to the ECC intervention: 1) Dental care during pregnancy, 2) Anticipatory Guidance and 3) Motivational interviewing for mothers, and 4) Fluoride Varnish Application for children. The outcome was having dental treatment over five years. Bivariate log-Poisson regression models were used to estimate prevalence ratios (PRs) and 95% confidence interval (CI). Sensitivity analyses were performed to assess the strength of the ECC intervention in reducing dental treatment by using imputed data.

Results

Data were available for 181 in II and 186 in DI children aged 5 years. Children in the DI group had twice the prevalence (PR=2.00; 95% CI: 1.13–3.51) of having dental treatment compared to the II group. A higher prevalence of having dental treatment was positively associated with families residing in non-metropolitan areas, children with higher sweet food consumption and mothers with lower oral health literacy.

Conclusion

The study suggests that early intervention in infancy can decrease the need for dental treatment by age 5 years, potentially reducing the burden for children, families and Aboriginal communities.

Keywords: Early caries intervention, dental treatment, Indigenous children

Introduction

Despite dental caries being frequently described as a preventable disease, it is still one of the

most prevalent diseases worldwide.^{1, 2} Early childhood caries (ECC) is the presence of one or more decayed, missing, or filled primary teeth in children aged 71 months (5 years) or younger³. ECC has a major impact on children's health as well as costs to society⁴. Treatment of ECC in young children can require extensive restorative treatment and extraction of primary teeth. In cases where the child may be pre-cooperative for treatment in the dental chair, treatment under general anesthesia may be required. Other impacts from ECC include higher risk of new carious lesions, acute and chronic pain, hospitalisations and emergency room visits, reports of delays in growth and development, and diminished quality of life⁵. The physical, social, and psychological consequences of ECC on individual children can be significant⁶.

Aboriginal and Torres Strait Islander descent children (Indigenous Australian children here) represent 34% of the total Indigenous population and make up approximately 6% of the total child population in Australia⁷. Indigenous Australian children are disadvantaged in many health indicators compared to non-Indigenous Australian children, including oral health. The national child oral health survey 2012-14⁸ shown that Indigenous children had approximately three times more teeth with untreated decay (3.5 vs 1.2) and nearly two times more decayed, missing or filled tooth surfaces (dmfs) in primary dentition (2.9 vs 6.3) in children aged 5-10 years, compared with non-Indigenous children. Furthermore, Indigenous children had 1.6 times higher dental treatment (involving general anaesthesia) in children aged 0-4 years than their non-Indigenous counterparts⁹.

Preventing dental caries is complex because it is influenced by multiple interrelated factors that increase an individual's risk, such as parents' lower socioeconomic status (low education

level and household income)¹¹ and lifestyle (including maternal smoking and drink alcohol during pregnancy)¹², family residence in regional and remote areas¹², and parents low oral health literacy¹³ and children's birth condition (low birthweight¹² and preterm birth¹⁴), feeding and dietary habit (including not breast fed, consumption of free sugar and beverages)^{12, 15} and oral health related behaviors (brushing teeth less than twice daily)¹⁶ have been associated with ECC, finally lead to seeking dental treatment.

Motivational interviewing (MI) is a counselling approach aimed at strengthening individuals' motivation for change through four core principles: resisting the urge to correct, understanding personal motivations, listening empathetically, and empowering individuals. A recent systematic review and meta-analysis¹⁷ demonstrated that MI is effective in preventing early childhood caries (ECC) across all age groups, from infancy to childhood. The study also found that the number and length of MI sessions positively influenced ECC prevention. Additionally, Plutzer and Keirse¹⁸ reported a fivefold reduction in ECC prevalence at 20 months among first-time mothers who received preventive guidance. This benefit persisted over time, with fewer emergency dental visits and a lower proportion of children requiring treatment under sedation or general anaesthesia at a seven-year follow-up.

Previous study¹⁹ reported decayed teeth or decayed, missing, and filled teeth as the outcome, a proxy for the extent and impact of dental treatment needs. In young children, the most extreme end of the treatment spectrum would be the need to seek dental care in a hospital and/or clinical setting. This study aims to determine if an intervention program, which is introduced early, will reduce the prevalence of dental treatment among Indigenous children living in South Australia, Australia. We hypothesised that exposure to an early intervention program would reduce the need for dental treatment among Indigenous children.

Methods

Study design and sample size

Data were obtained from the Baby Teeth Talk, a single-blinded randomised controlled trial (Registration ID: ACTRN12611000111976). Participants were 448 pregnant women who were residing in South Australia expecting an Indigenous Australian baby or babies, or who had recently birthed an Indigenous Australian baby or babies less than six weeks of age. Recruitment was conducted using a computer-generated permuted block randomisation sequence, stratified by six sites: (1) Women's and Children's Hospital; (2) Flinders Medical Centre and Southern Metropolitan region; (3) Lyell McEwin and Northern Metropolitan region; (4) Whyalla and Port Pirie; (5) Port Augusta; and (6) non-metropolitan regions, including Murray Bridge, Mount Gambier, Port Lincoln, and Ceduna²⁰. Recruitment began on January 31, 2011, with the enrollment of the first pregnant mother, and continued until May 30th, 2012. The final child examination was completed on November 1, 2017. Participants represented two-thirds of those who were eligible during the recruitment period, adjusting by age, socio-economic status, and tobacco smoking status.²¹ A biostatistician at the Australian Research Centre for Population Oral Health (ARCPOH) generated the randomisation schedule on a 1:1 ratio. Participant numbers and their group allocations were enclosed in confidential envelopes. Envelopes were opened at the central office by an administrative staff, and the card inside revealed whether the participant was randomly assigned to the immediate intervention (II) or delayed intervention (DI), and this information was then given to the project team.^{22, 23}

ECC intervention

Study staff were trained in MI by a registered member of the Motivational Interviewing Network of Trainers. They attended a basic two-day MI training course, followed by an intense one-day follow-up course. Monthly one-day follow-up training was continued for six months, followed by bi-monthly one-day coaching, and occasional ad-hoc telephone coaching, for another year.²²

ECC intervention was conducted by MI-trained staff. The immediate intervention was provided at baseline and when the child was aged at 6-, 12-, and 18-months, which included:

- 1) Provision of dental care to mothers during pregnancy, which included extractions, restorations, and cleaning. Dentists providing the care were asked to focus on reducing bacterial load, such as filling or extracting teeth with frank carious lesions. Free transport was provided for the dental appointments through culturally sensitive transport providers.
- 2) Fluoride varnish was applied to children by trained staff in a setting convenient to participants, including their homes, at every follow-up point through 60 months.
- 3) Motivational interviewing (MI) using focused directives was provided by trained staff. Directives focused on encouraging participants to attend dental appointments at baseline; to learn more about the importance of non-cariogenic foods, education on the importance of fluoride in ECC prevention and encouraging participants to enrol their child for a dental check.
- 4) Anticipatory guidance: in our study, tailored oral health educational packages were compiled with dental-specific information relevant for mothers (focus on dental care provision, pregnancy gingivitis) and for children (focus on first solid foods, caring for infant teeth when they first erupt, tooth brushing and fluoride, avoiding sugar-containing foods and beverages, baby's first dental check-up, eruption of molar teeth).

For the delayed intervention group, mothers received standard oral health education and free dental care during pregnancy, and their children received the intervention at 24, 30, and 36 months. Subsequently, all children participated in a longitudinal follow-up study, during which fluoride varnish was applied at 60 months.

Data collection

Face-to-face interviews were conducted in by experienced researchers at baseline (pregnancy) and when children were aged 24, 36, and 60 months to collect self-report information. Information collected included carers' self-reported caries experience of their child, as well as carers' oral health knowledge, oral self-care, dental service utilisation for dental treatment, oral health-related self-efficacy and oral health literacy. Standardised oral examinations were conducted by two calibrated dental professionals at 24, 36, and 60 months. All participants were eligible to receive free dental care, including transportation services, fluoride varnish applications for their children's teeth, dental-related sample bags, and gift cards valued at \$50 as reimbursement for the time spent completing questionnaires at baseline, 24 months, and 36 months²⁰. (See Appendix)

Variables

The outcome variable was that the study children had at least one dental treatment due to dental decay, which included pain relief, teeth filled, and /or extraction over 5 years. It was a composite variable, which was carer-reported dental care with adjustment for filled teeth at 5 years follow-up:

- 1) Any dental care as reported at 2-, 3- or 5-year follow-up: 'Has your child ever had to go to the hospital for dental care?' and answered 'Yes', and/or
- 2) Filled teeth more than 1 from standardised oral examinations at 2-, 3- or 5-year.

The exposure variable was intervention status, which was identified as II or DI group.

Covariates

Covariates were baseline maternal characteristics, and children's birth, feeding/diet and oral health-related behaviours characteristics during 2-, 3- or 5-year follow-up:

- 1) Maternal characteristics included: maternal age was categorized into '14-24 years' or '25+ years'; education level was dichotomized into 'high school or less' or 'trade/technical or University'; residential location was dichotomized as 'non-metropolitan' or 'metropolitan'; household income was dichotomized into 'job' or 'Centrelink' (welfare/unemployed). Smoking and alcohol status as 'current', 'former/used' or 'never'. Health Literacy in Dentistry (HeLD)14 scores were dichotomised based on a median split: '<52 (lower) vs \geq 52 (Higher)'. HeLD14²⁴ was an instrument containing 14 items from 7 conceptual domains: communication, access, receptivity, understanding, utilisation, support and economic barriers. Each item is ranked on a 5-point Likert scale ranging from 1 to 5. After recording scores of 5 to 0, 4 to 1, 3 to 2, 2 to 3 and 1 to 4, summary scores ranged from 0-56. High scores indicate high oral health literacy.
- 2) Children's sex were classified into 'boy' or 'girl', gestation as 'preterm' or 'normal', baby birth rate as 'low or 'normal', breast feeding history of 'Yes' or 'No', free sugar consumption (% of total energy intake) at two years follow-up as ' \geq 5%' or '<5%', and tooth brushing frequency as 'less than two times per day' or 'two times or more per day'.

Statistical analysis

Data were analysed according to intention-to-treat principles, incorporating both descriptive and bivariate analyses.

Descriptive analysis began with the calculation of univariate statistics to summarise the frequency and percentage of covariates among participants with and without follow-up. Differences were assessed using a chi-squared test, with statistical significance set at $p < 0.05$. The prevalence of dental treatment, along with corresponding 95% confidence intervals (CIs), was reported by intervention status.

Bivariate analysis included bivariate logistic regression models with Poisson distribution estimation generation to calculate risk indicators. Unadjusted prevalence ratios (PRs) and their 95% CI were calculated for the prevalence of dental treatment.

Sensitivity analyses were performed to assess the strength of the ECC intervention in reducing dental treatment by using imputed data. Missing values were addressed through Multiple Imputation under the assumption that data were missing at random (MAR). The II and DI groups were imputed separately. The Fully Conditional Specification (FCS) method was applied, utilising logistic regression for categorical variables and linear regression for continuous variables. All missing data, including both outcome and explanatory variables, were imputed.

Data analyses were performed using SAS statistical software (SAS 9.4, SAS Institute Inc., Cary, NC, USA).

Results

Out of 448 participants recruited, 223 were randomly allocated to the immediate intervention (II) group and 225 to the delayed intervention (DI) group. Three hundred and sixty-seven

mothers (181/367 in the II and 186/367 in the DI group) had at least one dental treatment with a five-year follow-up (Figure 1).

The socio-demographic and dental behaviour characteristics of mother-child pairs are summarised in Table 1. A higher proportion of mothers were under 25 years of age, lived in non-metropolitan areas, had an education level of 12 years or less, scored ≥ 52 on the HelD14, received Centrelink support, and were current smokers. A greater proportion of children were boys, born at term with normal birth weight, had not been breastfed, consumed free sugars accounting for $\geq 5\%$ of total energy intake at age 2, and brushed their teeth less than twice per day. Both the II and DI groups showed similar patterns across all measured characteristics, with no statistically significant differences observed.

The overall prevalence of children reporting having dental treatment was 15.0 % (95% CI: 11.3% -18.7%). The DI groups had more than 2 times higher prevalence of dental treatment (19.9%, 95% CI: 14.3%-25.7%) than the II group (9.9%, 95% CI: 5.6%-14.3%).

Table 2 presents the association between intervention and dental treatment. Children in the DI group had twice the prevalence of dental treatment compared to those in the II group (PR = 2.00; 95% CI: 1.13–3.51). Additionally, children living in non-metropolitan areas (PR=1.87, 95% CI: 1.00-3.48), consuming higher amounts of free sugar (PR=1.67, 95% CI: 1.18-2.37), and brushing less than twice a day (PR=1.28, 1.03-1.59) had approximately 1.5 times higher prevalence of dental treatment than their counterparts. However, a lower prevalence of dental treatment was observed among children with low birth weight and those in the II group. Notable differences between the two groups were also identified: in the II group, higher dental treatment prevalence was associated with greater free sugar consumption, while in the

DI group, it was linked to living in non-metropolitan areas and brushing less than twice a day.

The sensitivity analysis (Table 3) revealed similar patterns, along with additional statistically significant findings. These included a higher prevalence of dental treatment among children whose mothers/carers had lower HeLD-14 scores across all participants and within both the II and DI groups, as well as among children who were not breastfed, particularly in the overall sample and the II group.

Discussion

Our findings support the hypothesis that exposure to an early intervention reduces the need for dental treatment among Indigenous children. This indicates that providing maternal dental care during pregnancy and implementing ECC interventions before the child turns two years old are more effective than initiating interventions after the age of two. In addition, key risk indicators for the need for dental treatment included residing in non-metropolitan areas, having mothers or caregivers with lower oral health literacy, higher free sugar consumption, lack of breastfeeding, and brushing teeth less than twice a day.

Comparison with existing literature

The prevalence ratio of the need for dental treatment of those residing in non-metropolitan areas is higher compared with those in metropolitan regions. This is not surprising as previously reported in both Australia and other countries.^{4,25} Children in rural communities face several issues that influence access to care and their oral health, including lack of water fluoridation (which was not accounted for in this study, but the location of residence can serve as a proxy), lack of dental professionals in their community and the need to travel outside their community for oral health care^{8,25}.

Free sugar intake and dental caries

This study showed that higher daily free sugar consumption is associated with a higher prevalence of needing dental treatment. This is not surprising as higher consumption of free sugars is associated with ECC. The majority (93%) of the study population consumed $\geq 5\%$ of total energy intake in free sugars despite the prevention intervention. A study that looked at dietary intake changes nested within Baby Teeth Talk reviewed no changes or differences in consumption of discretionary foods and beverages following immediate or delayed intervention in both groups²⁶. Results from this study reflected that despite not having a significant change in free sugar dietary intake, the clinical impact of reducing the need for dental treatment from a multifaceted early intervention program remains significant and justifies support of the early intervention program.

Maternal oral health literacy and children's dental caries and treatment

Our findings indicated that mothers with lower oral health literacy were associated with a higher prevalence of dental treatment. Oral health literacy reflects a person's ability to obtain, process or interpret and understand basic oral health information and services needed to make appropriate health decisions to improve oral health²⁷. Previous studies^{13, 28} have shown that mothers with lower literacy generally have less knowledge of children's oral health or preventive practices. As a result, the children had a high prevalence of dental caries and had to seek dental treatment.

Limitation

One limitation of this study is that it was nested within the Baby Teeth Talk trial.²¹

Information on whether children received dental care was based on self-reported responses

(‘yes’ or ‘no’) to the item ‘Dental care,’ without specifying whether the treatment was for dental caries or performed under general anesthesia. However, adjusting for filled teeth as an indicator may help reduce the potential for misclassification. Second, loss to follow-up was inevitable over the long-term follow-up period. However, the sensitivity analysis using multiple imputation data showed similar patterns, suggesting that potential biases were minimised and the effect of the early childhood caries intervention on reducing the need for dental treatment was adequately explored.

Another limitation is that this study was commenced before the now more widespread use of silver diamine fluoride (SDF) or silver fluoride (SF). SDF has been regarded as an efficient, affordable, and safe cariostatic agent, and effective in the management of ECC²⁹. The use of SDF or SF has been included in community programs and rural areas in both Australia and other countries²⁹. A previous study indicates that the non-invasive treatment can significantly reduce the number of children needing a general anaesthetic for caries treatment³⁰. The current randomised controlled trial has commenced with the use of SF on Indigenous children and youth aged between 2 and 18 years in Australia³¹. Further research, including SF use in earlier age groups within a multifaceted early intervention program such as Baby Teeth Talk, would be valuable to look into.

Conclusion

Our study suggests that early intervention commencing during pregnancy and early infancy, compared with introducing later in childhood, can decrease the need of dental treatment associated with ECC in long-term follow-up, potentially reducing the burden for individual children, their families, and the communities, and decreasing the social inequalities among Indigenous Australian children.

Statements

Author Contributions

Dr Xiangqun Ju contributed to conception, design, performed all statistical analyses, data acquisition and interpretation, and drafted and critically revised the manuscript.

Dr Wendy Wai Sau Cheung contributed to conception, design, interpretation, and critically revised the manuscript.

Prof Lisa Jamieson conceptualised and designed the study, coordinated and supervised data collection, interpretation, and critically revised the manuscript for important intellectual content.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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centres, domestic violence shelters, and primary and high schools.

Data Availability Statement

The datasets generated and/or analyzed during the current study are not publicly available due to privacy issues of the participants. Data are available from the corresponding author on reasonable request.

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Conflict of Interest Statement

The authors have no competing interests to declare.

Ethics statement

Ethics approval was obtained from the University of Adelaide Human Research Ethics Committee (H-057-2010), the Aboriginal Health Council of South Australia (04-09-362), the Government of South Australia and the Human Research Ethics Committees of the three participating South Australian birthing hospitals. The study additionally used the Ethical Conduct in Aboriginal and Torres Strait Islander Health Research guidelines to obtain consent.

Participants consent statement

All participants provided written informed consent at each phase of the study.

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Table legends

Table 1: Sample characteristics by intervention status

| | All | II | DI | P-values* |
|--|------------|------------|------------|-----------|
| | Number (%) | Number (%) | Number (%) | |
| Total | 367 (100) | 181 (49.3) | 186 (50.7) | 0.07 |
| MOTHERS' CHARACTERISTICS (BASELINE) | | | | |
| Maternal age | | | | |
| 14-24 | 197 (53.7) | 101 (55.8) | 96 (51.6) | 0.43 |
| 25+ | 170 (46.3) | 80 (44.2) | 90 (48.4) | |
| Missing | 0 (0.0) | 0 | 0 | |
| Residential location | | | | |
| Non-metropolitan | 230 (63.4) | 119 (66.1) | 111 (60.7) | 0.28 |
| Metropolitan | 133 (36.6) | 61 (33.9) | 72 (39.3) | |
| Missing | 1 | 1 | 0 | |
| Education | | | | |
| ≤12 years | 261 (71.5) | 128 (71.5) | 133 (71.5) | 1.00 |
| >12 years | 104 (28.5) | 51 (28.5) | 53 (28.5) | |
| Missing | 2 | 2 | 0 | |
| HeLD 14 score | | | | |
| <52 (Lower) | 120 (44.3) | 62 (44.3) | 58 (44.3) | 1.00 |
| ≥ 52 (Higher) | 151 (55.7) | 78 (55.7) | 73 (55.7) | |
| Missing | 92 | 41 | 51 | |
| Income | | | | |
| Centrelink [§] | 307 (84.6) | 149 (83.2) | 158 (85.9) | 0.49 |
| Job | 56 (15.4) | 30 (16.8) | 26 (14.1) | |
| Missing | 4 | 2 | 2 | |
| Smoking status | | | | |
| Current | 180 (51.9) | 85 (48.6) | 95 (55.2) | 0.36 |
| Former | 83 (23.9) | 47 (26.9) | 36 (20.9) | |
| Never | 84 (24.2) | 43 (24.6) | 41 (23.8) | |
| Missing | 20 | 6 | 14 | |
| CHILDREN'S CHARACTERISTICS | | | | |
| Sex | | | | |
| Boy | 184 (53.3) | 90 (52.9) | 94 (53.7) | 0.89 |
| Girl | 161 (46.7) | 80 (47.1) | 81 (46.3) | |
| Missing | 42 | 11 | 31 | |
| Gestation | | | | |

| | | | | |
|---|------------|------------|------------|------|
| Preterm (<37 weeks) | 22 (7.3) | 12 (8.2) | 10 (6.5) | 0.59 |
| Normal | 278 (92.7) | 135 (91.8) | 143 (93.5) | |
| Missing | 67 | 34 | 33 | |
| Baby birth weight | | | | |
| Low (<2500g) | 23 (8.7) | 14 (10.9) | 9 (6.6) | 0.21 |
| Normal | 241 (91.3) | 114 (89.1) | 127 (93.4) | |
| Missing | 103 | 53 | 50 | |
| Breast feeding | | | | |
| No | 190 (58.5) | 90 (56.3) | 100 (60.6) | 0.43 |
| Yes | 135 (41.5) | 70 (43.8) | 65 (39.4) | |
| Missing | 42 | 21 | 21 | |
| Free sugar consumption (% of total energy intake) at age 2 years | | | | |
| ≥ 5% | 241 (93.1) | 123 (92.5) | 118 (93.7) | 0.71 |
| < 5% | 18 (6.9) | 10 (7.5) | 8 (6.4) | |
| Missing | 108 | 48 | 60 | |
| Tooth brushing at age 3 years | | | | |
| <2/day | 245 (71.0) | 97 (64.7) | 100 (63.7) | 0.86 |
| ≥2/day | 100 (29.0) | 53 (35.3) | 57 (36.3) | |
| | 22 | 12 | 10 | |

Notes: II: immediate intervention; DI: delayed intervention

§: welfare/unemployed.

*Chi-squared test.

Table 2: Bivariate association between dental treatment and covariates under Intervention status among Indigenous Australian children

| | All | II | DI |
|--|--------------------------|------------------|-------------------------|
| | PR ^u (95% CI) | PR (95% CI) | PR (95% CI) |
| Intervention group | | | |
| DI ⁺ | 2.00 (1.13-3.51) | - | - |
| II [‡] | ref | - | - |
| MOTHERS' CHARACTERISTICS (BASELINE) | | | |
| Maternal age | | | |
| 14-24 | 1.29 (0.75-2.22) | 2.77 (0.91-8.41) | 0.99 (0.51-1.89) |
| 25+ | ref | ref | ref |
| Residential location | | | |
| Non-metropolitan | 1.87 (1.00-3.48) | 1.03 (0.38-2.73) | 2.78 (1.22-6.33) |
| Metropolitan | ref | ref | ref |
| Education | | | |
| ≤12 years | 1.16 (0.64-2.14) | 1.99 (0.58-6.88) | 00.94 (0.47-1.91) |
| >12 years | ref | ref | ref |
| HeLD[§] 14 score | | | |
| <52 (Lower) | 1.32 (0.73-2.40) | 1.68 (0.58-4.83) | 1.17 (0.57-2.43) |
| ≥ 52 (Higher) | ref | ref | ref |
| Income | | | |
| Centrelink [¶] | 1.07 (0.51-2.27) | 1.01 (0.29-3.48) | 1.05 (0.41-2.70) |
| Job | ref | ref | ref |
| Smoking status | | | |
| Current | 0.67 (0.37-1.23) | 0.67 (0.23-1.94) | 0.65 (0.31-1.34) |
| Former | 0.56 (0.26-1.22) | 0.61 (0.17-2.16) | 0.57 (0.21-1.52) |
| Never | ref | ref | ref |

| CHILDREN'S CHARACTERISTICS | | | |
|---|-------------------------|-------------------------|-------------------------|
| Sex | | | |
| Boy | 0.91 (0.53-1.58) | 0.53 (0.19-1.47) | 1.15 (0.58-2.24) |
| Girl | ref | ref | ref |
| Gestation | | | |
| Preterm (<37 weeks) | 1.66 (0.40-6.87) | 1.24 (0.16-9.46) | 1.96 (0.26-14.39) |
| Normal | ref | ref | ref |
| Baby birth weight | | | |
| Low (<2500g) | 0.64 (0.49-0.83) | 0.51 (0.32-0.79) | 0.79 (0.56-1.10) |
| Normal | ref | ref | ref |
| Breast feeding | | | |
| No | 1.20 (0.68-2.09) | 2.14 (0.78-5.90) | 0.95 (0.48-1.90) |
| Yes | ref | ref | ref |
| Free sugar consumption (% of total energy intake) at age 2 years | | | |
| ≥ 5% | 1.67 (1.18-2.37) | 2.67 (1.36-5.25) | 0.80 (0.53-1.20) |
| < 5% | ref | ref | ref |
| Tooth brushing at age 3 years | | | |
| <2/day | 1.28 (1.03-1.59) | 1.10 (0.78-1.55) | 1.37 (1.03-1.87) |
| ≥2/day | ref | ref | ref |

Notes: . +: delayed intervention

#: immediate intervention

§: Health Literacy in Dentistry

¶: welfare/unemployed

μ: Prevalence ratio.

Table 3. Bivariate Associations Between Dental Treatment and Covariates by Intervention Status Among Indigenous Australian Children (Sensitivity Analysis Using Multiple Imputation Data)

| | All | II | DI |
|--|--------------------------|-------------------------|-------------------------|
| | PR ^μ (95% CI) | PR (95% CI) | PR (95% CI) |
| Intervention group | | | |
| DI ⁺ | 1.68 (1.37-2.05) | - | - |
| II [#] | ref | - | - |
| MOTHERS' CHARACTERISTICS (BASELINE) | | | |
| Maternal age | | | |
| 14-24 | 1.01 (0.83-1.22) | 1.39 (0.99-1.93) | 0.87 (0.68-1.12) |
| 25+ | ref | ref | ref |
| Residential location | | | |
| Non-metropolitan | 1.48 (1.19-1.83) | 1.03 (0.74-1.44) | 1.91 (1.44-2.53) |
| Metropolitan | ref | ref | ref |
| Education | | | |
| ≤12 years | 1.05 (0.84-1.31) | 1.43 (0.96-2.12) | 0.91 (0.70-1.19) |
| >12 years | ref | ref | ref |
| HeLD[§] 14 score | | | |
| <52 (Lower) | 1.88 (1.55-2.29) | 2.17 (1.56-3.00) | 1.72 (1.34-2.20) |
| ≥ 52 (Higher) | ref | ref | ref |
| Income | | | |
| Centrelink [¶] | 1.18 (0.88-1.59) | 1.31 (0.80-2.14) | 1.07 (0.74-1.56) |
| Job | ref | ref | ref |
| Smoking status | | | |
| Current | 0.70 (0.56-1.08) | 0.83 (0.56-1.24) | 0.86 (0.50-1.07) |
| Former | 0.79 (0.61-1.03) | 0.98 (0.64-1.51) | 0.74 (0.53-1.04) |
| Never | ref | ref | ref |

CHILDREN'S CHARACTERISTICS

| | | | |
|---|-------------------------|-------------------------|-------------------------|
| Sex | | | |
| Boy | 0.92 (0.76-1.12) | 0.61 (0.44-1.85) | 1.17 (0.91-1.50) |
| Girl | ref | ref | ref |
| Gestation | | | |
| Preterm (<37 weeks) | 1.37 (1.05-1.78) | 1.38 (0.91-2.12) | 1.39 (1.00-1.94) |
| Normal | ref | ref | ref |
| Baby birth weight | | | |
| Low (<2500g) | 0.64 (0.49-0.83) | 0.51 (0.32-0.79) | 0.79 (0.56-1.10) |
| Normal | ref | ref | ref |
| Breast feeding | | | |
| No | 1.23 (1.01-1.50) | 1.57 (1.14-2.17) | 1.10 (0.85-1.41) |
| Yes | ref | ref | ref |
| Free sugar consumption (% of total energy intake) at age 2 years | | | |
| ≥ 5% | 1.67 (1.18-2.37) | 2.67 (1.36-5.25) | 0.80 (0.53-1.20) |
| < 5% | ref | ref | ref |
| Tooth brushing at age 3 years | | | |
| <2/day | 1.28 (1.03-1.59) | 1.10 (0.78-1.55) | 1.37 (1.03-1.87) |
| ≥2/day | ref | ref | ref |

Notes: . +: delayed intervention

≠: immediate intervention

§: Health Literacy in Dentistry

¶: welfare/unemployed

μ: Prevalence ratio.

Figure legends

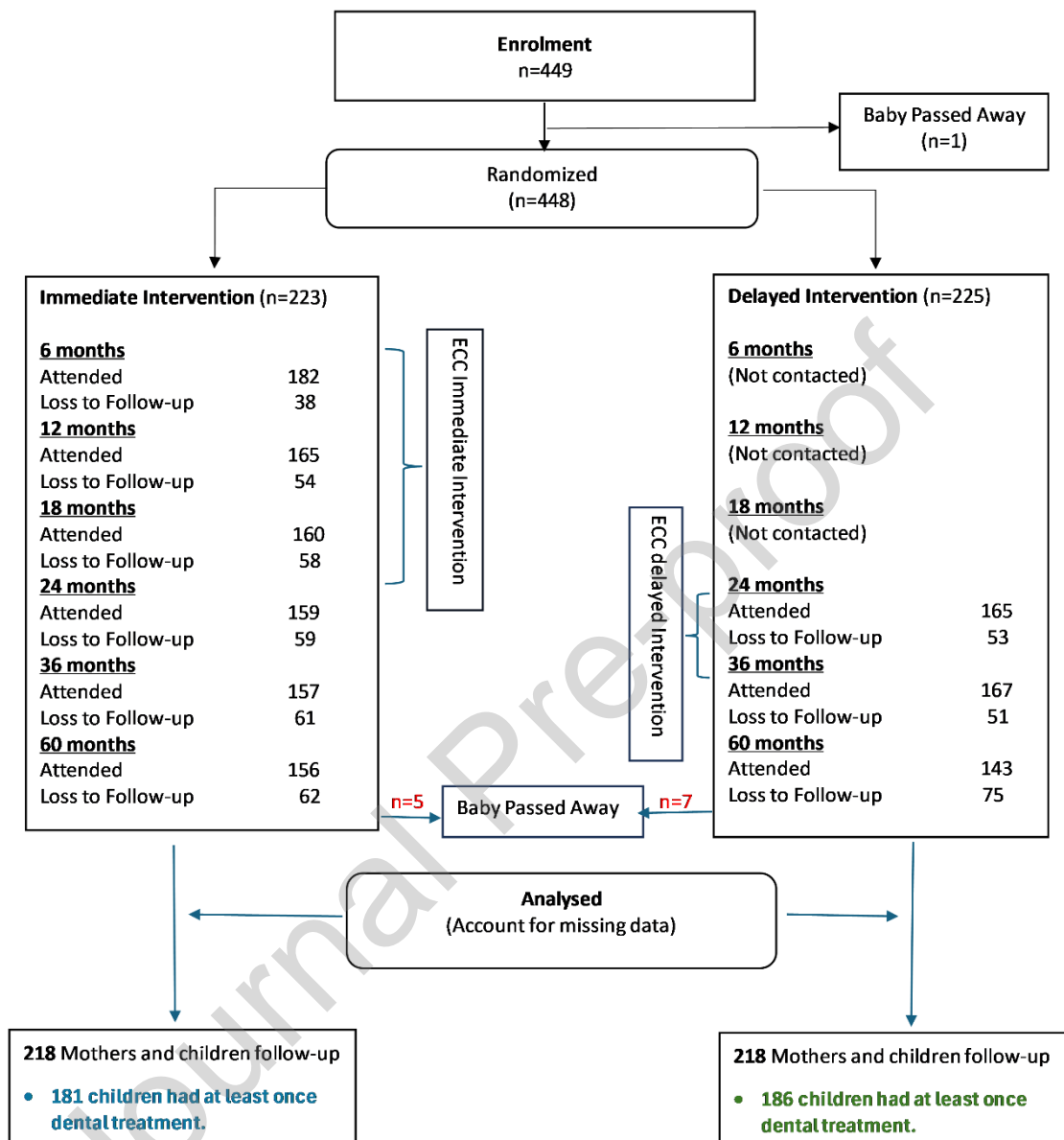


Figure 1: Flow diagram of participants through key stages of the randomised controlled trial

Immediate Intervention including: 1) Dental care during pregnancy (mother), 2) Anticipatory Guidance (mother), 3) Motivational interviewing (month), and 4) Fluoride Varnish Application (child).

Delayed Intervention including: 1) Anticipatory Guidance (mother), 2) Motivational

interviewing (month), and 3) Fluoride Varnish Application (child).

ECC: Early childhood caries

Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The authors have no competing interests to declare.

What's New

Our study suggests that early intervention commencing during pregnancy and early infancy can decrease the need for dental treatment, potentially reducing the burden for individual children, their families, and the communities, and decreasing the social inequalities among Indigenous Australian children.

Appendix

Appendix A: Consent Form

THE UNIVERSITY OF ADELAIDE HUMAN RESEARCH ETHICS COMMITTEE

STANDARD CONSENT FORM

FOR PEOPLE WHO ARE PARTICIPANTS IN A RESEARCH PROJECT

- | | | |
|----|---|----------------------------|
| 1. | I, | <i>(please print name)</i> |
| | consent to take part in the research project entitled: 'An Aboriginal early childhood caries intervention' | |
| 2. | I acknowledge that I have read the attached Information Sheet entitled: 'An Aboriginal early childhood caries intervention' | |
| 3. | I have had the project, so far as it affects me, fully explained to my satisfaction by the research worker. My consent is given freely. | |

4. Although I understand that the purpose of this research project is to improve the quality of medical care, it has also been explained that my involvement may not be of any benefit to me.
5. I have been given the opportunity to have a member of my family or a friend present while the project was explained to me.
6. I have been informed that, while information gained during the study may be published, I will not be identified and my personal results will not be divulged.
7. I understand that I am free to withdraw from the project at any time and that this will not affect medical advice in the management of my health, now or in the future.
8. I am aware that I should retain a copy of this Consent Form, when completed, and the attached Information Sheet.

.....

(signature)

(date)

WITNESS

I have described to *(name of subject)*

the nature of the research to be carried out. In my opinion she/he understood the explanation.

Status in Project:

Name:

.....

(signature)

(date)

Please provide your name and address if you would like a copy of the results sent to you.

Thank you very much for your participation. Your assistance is greatly appreciated

Appendix B: The instrument used to collect the parents' knowledge, self-care, utilisation, self-efficacy, and health literacy

| Q. Dental care and dental information: | | | | | | |
|---|--|---|--|---|---|---|
| Q1. Are you able to find the energy to manage your dental health? | Without any difficulty <input type="checkbox"/> 1 | Little difficulty <input type="checkbox"/> 2 | With some difficulty <input type="checkbox"/> 3 | Very difficult <input type="checkbox"/> 4 | Unable to do so <input type="checkbox"/> 5 | |
| Q2. Are you able to make time for things that are good for your dental health? | Without any difficulty <input type="checkbox"/> 1 | Little difficulty <input type="checkbox"/> 2 | With some difficulty <input type="checkbox"/> 3 | Very difficult <input type="checkbox"/> 4 | Unable to do so <input type="checkbox"/> 5 | |
| Q3. Are you able to change your lifestyle to improve your dental health? | Without any difficulty <input type="checkbox"/> 1 | Little difficulty <input type="checkbox"/> 2 | With some difficulty <input type="checkbox"/> 3 | Very difficult <input type="checkbox"/> 4 | Unable to do so <input type="checkbox"/> 5 | |
| Q4. Are you able to find dental health information in a language you understand? | Without any difficulty <input type="checkbox"/> 1 | Little difficulty <input type="checkbox"/> 2 | With some difficulty <input type="checkbox"/> 3 | Very difficult <input type="checkbox"/> 4 | Unable to do so <input type="checkbox"/> 5 | |
| Q5. Are you able to discuss your dental with people other than a dentist? | Without any difficulty <input type="checkbox"/> 1 | Little difficulty <input type="checkbox"/> 2 | With some difficulty <input type="checkbox"/> 3 | Very difficult <input type="checkbox"/> 4 | Unable to do so <input type="checkbox"/> 5 | |
| Q6. Are you able to take family or a friend with you to a dental appointment? | Without any difficulty <input type="checkbox"/> 1 | Little difficulty <input type="checkbox"/> 2 | With some difficulty <input type="checkbox"/> 3 | Very difficult <input type="checkbox"/> 4 | Unable to do so <input type="checkbox"/> 5 | I don't go to the dentist <input type="checkbox"/> 6 |
| Q7. Are you able to change your lifestyle to improve your dental health? | Without any difficulty <input type="checkbox"/> 1 | Little difficulty <input type="checkbox"/> 2 | With some difficulty <input type="checkbox"/> 3 | Very difficult <input type="checkbox"/> 4 | Unable to do so <input type="checkbox"/> 5 | |
| N. Knowledge of Children's Oral Hygiene: How much do you agree with the following statement? | | | | | | |
| N1. Holes in baby teeth don't matter much since baby teeth fall out anyway | Strongly agree <input type="checkbox"/> 1 | Somewhat agree <input type="checkbox"/> 2 | Neither agree nor disagree <input type="checkbox"/> 3 | Somewhat disagree <input type="checkbox"/> 4 | Strongly disagree <input type="checkbox"/> 5 | |
| N2. Keeping baby teeth clean is not very important because they fall out anyway | Strongly agree <input type="checkbox"/> 1 | Somewhat agree <input type="checkbox"/> 2 | Neither agree nor disagree <input type="checkbox"/> 3 | Somewhat disagree <input type="checkbox"/> 4 | Strongly disagree <input type="checkbox"/> 5 | |
| N3. There is not much I can do to stop my child from getting holes in their teeth | Strongly agree <input type="checkbox"/> 1 | Somewhat agree <input type="checkbox"/> 2 | Neither agree nor disagree <input type="checkbox"/> 3 | Somewhat disagree <input type="checkbox"/> 4 | Strongly disagree <input type="checkbox"/> 5 | |
| N4. There is not much I can do to help my child have healthy teeth | Strongly agree <input type="checkbox"/> 1 | Somewhat agree <input type="checkbox"/> 2 | Neither agree nor disagree <input type="checkbox"/> 3 | Somewhat disagree <input type="checkbox"/> 4 | Strongly disagree <input type="checkbox"/> 5 | |
| N5. Children don't need to brush every day until they get their adult teeth | Strongly agree <input type="checkbox"/> 1 | Somewhat agree <input type="checkbox"/> 2 | Neither agree nor disagree <input type="checkbox"/> 3 | Somewhat disagree <input type="checkbox"/> 4 | Strongly disagree <input type="checkbox"/> 5 | |
| N6. Children don't really need their own toothbrush until all their teeth come | Strongly agree <input type="checkbox"/> 1 | Somewhat agree <input type="checkbox"/> 2 | Neither agree nor disagree <input type="checkbox"/> 3 | Somewhat disagree <input type="checkbox"/> 4 | Strongly disagree <input type="checkbox"/> 5 | |

I. Oral health self-efficacy: How confident do you feel about your ability to brush your child's teeth at night when you are ...

| | | | | | |
|--|---|---|---|---|---|
| 11. Under a lot of stress | Very confident <input type="checkbox"/> ₁ | Somewhat confident <input type="checkbox"/> ₂ | Not very confident <input type="checkbox"/> ₃ | Not at all confident <input type="checkbox"/> ₄ | I never feel like this <input type="checkbox"/> ₅ |
| 12. Depressed | Very confident <input type="checkbox"/> ₁ | Somewhat confident <input type="checkbox"/> ₂ | Not very confident <input type="checkbox"/> ₃ | Not at all confident <input type="checkbox"/> ₄ | I never feel like this <input type="checkbox"/> ₅ |
| 13. Anxious | Very confident <input type="checkbox"/> ₁ | Somewhat confident <input type="checkbox"/> ₂ | Not very confident <input type="checkbox"/> ₃ | Not at all confident <input type="checkbox"/> ₄ | I never feel like this <input type="checkbox"/> ₅ |
| 14. Feeling like you do not have the time (too busy) | Very confident <input type="checkbox"/> ₁ | Somewhat confident <input type="checkbox"/> ₂ | Not very confident <input type="checkbox"/> ₃ | Not at all confident <input type="checkbox"/> ₄ | I never feel like this <input type="checkbox"/> ₅ |
| 15. Tired | Very confident <input type="checkbox"/> ₁ | Somewhat confident <input type="checkbox"/> ₂ | Not very confident <input type="checkbox"/> ₃ | Not at all confident <input type="checkbox"/> ₄ | I never feel like this <input type="checkbox"/> ₅ |
| 16. Worrying about other things in your life | Very confident <input type="checkbox"/> ₁ | Somewhat confident <input type="checkbox"/> ₂ | Not very confident <input type="checkbox"/> ₃ | Not at all confident <input type="checkbox"/> ₄ | I never feel like this <input type="checkbox"/> ₅ |
| 17. Bothered by your crying child | Very confident <input type="checkbox"/> ₁ | Somewhat confident <input type="checkbox"/> ₂ | Not very confident <input type="checkbox"/> ₃ | Not at all confident <input type="checkbox"/> ₄ | I never feel like this <input type="checkbox"/> ₅ |
| 18. Bothered because your child doesn't stay still when you want him or her to brush | Very confident <input type="checkbox"/> ₁ | Somewhat confident <input type="checkbox"/> ₂ | Not very confident <input type="checkbox"/> ₃ | Not at all confident <input type="checkbox"/> ₄ | I never feel like this <input type="checkbox"/> ₅ |
| 19. Told by your child that he or she does not feel like brushing right now | Very confident <input type="checkbox"/> ₁ | Somewhat confident <input type="checkbox"/> ₂ | Not very confident <input type="checkbox"/> ₃ | Not at all confident <input type="checkbox"/> ₄ | I never feel like this <input type="checkbox"/> ₅ |

N. HeLD-14. These questions are about your dental health ...

| | | | | | |
|--|---|--|---|---|---|
| N1. Are you able to get a second opinion about your dental health from a dental health professional? | Without any difficulty <input type="checkbox"/> ₁ | Little difficulty <input type="checkbox"/> ₂ | With some difficulty <input type="checkbox"/> ₃ | Very difficult <input type="checkbox"/> ₄ | Unable to do <input type="checkbox"/> ₅ |
| N2. Are you able to use information from a dentist to make decisions about your dental health? | Without any difficulty <input type="checkbox"/> ₁ | Little difficulty <input type="checkbox"/> ₂ | With some difficulty <input type="checkbox"/> ₃ | Very difficult <input type="checkbox"/> ₄ | Unable to do <input type="checkbox"/> ₅ |
| N3. Do you know where you can see a dentist? | Without any difficulty <input type="checkbox"/> ₁ | Little difficulty <input type="checkbox"/> ₂ | With some difficulty <input type="checkbox"/> ₃ | Very difficult <input type="checkbox"/> ₄ | Unable to do <input type="checkbox"/> ₅ |
| N4. Do you know what to do to get a dentist's appointment? | Without any difficulty <input type="checkbox"/> ₁ | Little difficulty <input type="checkbox"/> ₂ | With some difficulty <input type="checkbox"/> ₃ | Very difficult <input type="checkbox"/> ₄ | Unable to do <input type="checkbox"/> ₅ |
| N5. Are you able to pay attention to your dental or oral health needs? | Without any difficulty <input type="checkbox"/> ₁ | Little difficulty <input type="checkbox"/> ₂ | With some difficulty <input type="checkbox"/> ₃ | Very difficult <input type="checkbox"/> ₄ | Unable to do <input type="checkbox"/> ₅ |
| N6. Are you able to make time for things that are good for your dental or oral health? | Without any difficulty <input type="checkbox"/> ₁ | Little difficulty <input type="checkbox"/> ₂ | With some difficulty <input type="checkbox"/> ₃ | Very difficult <input type="checkbox"/> ₄ | Unable to do <input type="checkbox"/> ₅ |
| N7. Are you able to fill in dental forms, for example, enrolment forms at the dental clinic? | Without any difficulty <input type="checkbox"/> ₁ | Little difficulty <input type="checkbox"/> ₂ | With some difficulty <input type="checkbox"/> ₃ | Very difficult <input type="checkbox"/> ₄ | Unable to do <input type="checkbox"/> ₅ |
| N8. Are you able to read dental or oral health information brochures left in dental clinics and waiting rooms? | Without any difficulty <input type="checkbox"/> ₁ | Little difficulty <input type="checkbox"/> ₂ | With some difficulty <input type="checkbox"/> ₃ | Very difficult <input type="checkbox"/> ₄ | Unable to do <input type="checkbox"/> ₅ |
| N9. Are you able to follow instructions that a dentist gives you? | Without any difficulty <input type="checkbox"/> ₁ | Little difficulty <input type="checkbox"/> ₂ | With some difficulty <input type="checkbox"/> ₃ | Very difficult <input type="checkbox"/> ₄ | Unable to do <input type="checkbox"/> ₅ |
| N10. Are you able to use dentist advice to make dental health decisions? | Without any difficulty <input type="checkbox"/> ₁ | Little difficulty <input type="checkbox"/> ₂ | With some difficulty <input type="checkbox"/> ₃ | Very difficult <input type="checkbox"/> ₄ | Unable to do <input type="checkbox"/> ₅ |
| N11. Are you able to take family or a friend with you to a dental appointment? | Without any difficulty <input type="checkbox"/> ₁ | Little difficulty <input type="checkbox"/> ₂ | With some difficulty <input type="checkbox"/> ₃ | Very difficult <input type="checkbox"/> ₄ | Unable to do <input type="checkbox"/> ₅ |

| | | | | | |
|---|---|--|---|---|---|
| N12. Are you able to ask someone for help to understand dental information? | Without any difficulty <input type="checkbox"/> ₁ | Little difficulty <input type="checkbox"/> ₂ | With some difficulty <input type="checkbox"/> ₃ | Very difficult <input type="checkbox"/> ₄ | Unable to do <input type="checkbox"/> ₅ |
| N13. Are you able to pay to see a dentist? | Without any difficulty <input type="checkbox"/> ₁ | Little difficulty <input type="checkbox"/> ₂ | With some difficulty <input type="checkbox"/> ₃ | Very difficult <input type="checkbox"/> ₄ | Unable to do <input type="checkbox"/> ₅ |
| N14. Are you able to pay for medication to manage your dental or oral health? | Without any difficulty <input type="checkbox"/> ₁ | Little difficulty <input type="checkbox"/> ₂ | With some difficulty <input type="checkbox"/> ₃ | Very difficult <input type="checkbox"/> ₄ | Unable to do <input type="checkbox"/> ₅ |

Journal Pre-proof

Appendix C: Summary of Face-to-Face Interviews

Participants received information about the study either in person or over the phone from health service providers and study staff. With the participant's consent to meet, researchers provided a detailed explanation of the project and addressed any questions.

Those who agreed to participate were asked to complete and sign a consent form covering various aspects of the study, including participation, access to the child's dental and hospital records, and audio recording for the purpose of assessing researchers' proficiency in motivational interviewing.

All participants were informed that their participation was entirely voluntary and that they could decline or withdraw at any time without providing a reason. They were also given a form outlining how to discuss their rights as participants, raise concerns about the study, or make a complaint. Study results were shared with participants who expressed interest in receiving them.

Journal Pre-proof