Health Belief Model for Empowering Parental Toothbrushing and Sugar Intake Control in Reducing Early Childhood Caries Among Young Children – Study Protocol for A Cluster Randomized Controlled Trial

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Study protocol

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Abstract

Background: It has been recognized that oral health education for parents is critical for preventing early childhood caries (ECC). Few parents practiced caries prevention procedures for their children in daily life, though. A novel intervention scheme using mobile messages will be developed in this study under the framework of the Health Belief Model (HBM). The objective of the present randomized clinical trial (RCT) is to evaluate the effectiveness of the new scheme in promoting oral health of young children by reducing dental caries.

Methods: This RCT will involve 26-36 child care centers or kindergartens with nursery classes (clusters) located in Hong Kong. A total of 518-628 child-parent dyads (child age: 18-30 months) will be recruited and randomly allocated at the cluster level into the test or control group with a 1:1 ratio. For parents in the test group, the intervention will consist of a set of HBM-based text messages sent regularly in 48 weeks. A standard text message will be sent to the parents in the control group in the first week. The primary outcome will be dental caries measured by dmft/dmfs of the children after 2 years (around 4 years of age). The secondary outcomes will be toothbtushing and sugar intakes.

Discussion: HBM-based intervention via a low-cost text messaging vehicle may serves as a viable way to empower parents to establish proper oral health behaviors for their children and safeguard the oral health of children in Hong Kong.

Trial registration: This study has been registered on *ClinicalTrials.gov* (ID: NCT04665219).

Administrative Information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

Title {1}	**Health Belief Model for empowering parental toothbrushing and sugar intake control in reducing early childhood caries among young children - a cluster randomized controlled trial**
Trial registration {2a and 2b}.	The trial is registered on *clinical.gov* (NCT04665219)
Protocol version {3}	Version no.3, dated 2021.03.30
Funding {4}	Health and Medical Research Fund (Project no.: 17181971), Food and Health Bureau (FHB), Government of Hong Kong SAR, China
Author details {5a}	MCMW conceived of the study. MCMW, HMGL, PL, XG and SYSW initiated the study design and KW helped with implementation. MCMW, HMGL, PL, XG and SYSW are grant holders. MCMW provided statistical expertise in clinical trial design. All authors contributed to refinement of the study protocol and approved the final manuscript
Name and contact information for the trial sponsor {5b}	N/A
Role of sponsor {5c}	N/A

Introduction

Background and rationale {6a}

Dental caries is one of the most common chronic diseases during childhood. According to the Global Burden of Disease Study in 2017, more than 530 million children globally have dental caries of the primary teeth (1). The latest oral health survey in Hong Kong found that 51% of children aged five had dental caries (2), and another study reported that 31% of children aged three had dental caries already (3). Early childhood caries (ECC) is denoted as any form of caries occurring in the primary dentition of children aged 71 months or younger (4,5). ECC not only affects children's oral health function, but also puts these children at greater risk of developing caries in the permanent dentition and results in lifelong impacts (4,5). Therefore, preventing decay experience in primary teeth would enhance children's oral health-related quality of life and result in significant savings to dental service costs in the future.

Parents play an important role in shaping their children's oral hygiene practices and eating habits from a very young age (6), which were strong risk factors of dental caries (7). It has been recognized that oral health education for parents is critical for prevention of ECC (8,9). Unfortunately, although large quantities of oral health education campaigns have been launched, few parents are conducting ideal caries prevention practices for their children in daily life (10-12).

Limited amount of information, engagement, and support can be conveyed by traditional health education approaches such as conversations or brochures. Mobile technologies are therefore popularized for their informativeness and interactivity, among which sending text messages has been proved to be effective in health-related behavior intervention (13). Some studies indicated that sending text messages (SMS) was an effective method in oral health education among parents of preschool children (14,15). An ongoing trial is now evaluating the effectiveness of SMS as an adjuvant method for preventing ECC (16). However, the age of children engaged in these studies varies, some of which could have missed the best time for ECC prevention (17). Therefore, the present study targets younger children and aims to empower parents to establish proper oral health habits in their children.

Health Believe Model (HBM) is a social psychological model for health behavior change (18). HBM based intervention has been introduced to the field of dentistry to some degree. A recent systematic review indicated that HBM has a significant effect in improving the oral health of school children and adolescents (19). No reported trial is available on how HBM based intervention can be used among parents for promoting caries preventive behaviors on their infants. In this context, the effectiveness of HBM-based behavior intervention by text message is to be tested.

Objectives {7}

The objective of this study is to investigate the effectiveness of the HBM-based behavioral intervention using SMS to promote parental oral health care behaviors (toothbrushing and sugar intake control) and reduce early childhood caries compared to conventional oral health education.

Hypotheses to be tested:

i. The proposed HBM-based behavioral intervention via SMS will reduce early childhood caries at around age four compared to conventional oral health education,
ii. The proposed HBM-based behavioral intervention via SMS will promote parental oral health care behaviors (toothbrushing and sugar intake control) for their young children more than conventional oral health education.

Trial design {8}

This study will be a two-arm parallel design cluster-randomized controlled trial. Figure 1 demonstrates the whole study design. This RCT will be conducted according to the ICH-GCP and CONSORT checklist (20,21). The ethical approval is obtained from the Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster (IRB: UW 20–029).

Methods: Participants, Interventions And Outcomes

Study setting {9}

Child care centers and kindergartens with nursery classes, which formed the clusters of the trial, will be approached and invited to participate in the clinical trial. Each cluster will be considered as a unit for randomization and intervention.

Eligibility criteria {10}

The target population will be young children and their parents (or primary caregivers). Child-parent dyads will be recruited.

The inclusion criteria will be as follows: (i) child aged18-30 months, (ii) child not having any severe medical conditions complicating oral health and dental examination, (iii) parent having a mobile phone with certain Apps to receive the text messages in time (e.g., WhatsApp or WeChat), (iv) parent who can read Chinese.

Families that have been participating in other oral health promotion programs will be excluded.

Who will take informed consent? {26a}

Staff in those participating child care centers or kindergartens with nursery classes will help inviting parents of the children to participate in the study and distribut information sheet and consent form to the parents. All child-parent dyads who meet the inclusion criteria and not in any other oral health programs will be invited to participante. The informed consent signed by parent will be collected by researchers at baseline dental examination.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

N/A

Interventions

Explanation for the choice of comparators {6b}

The study adopts an active control group to verify the effectiveness of HBM framework in health promotion messages.

Parents in the control group will receive an oral health education pamphlet (in Chinese) produced by the Oral Health Education Division in the Department of Health, the Government of Hong Kong SAR (22), which is the standard dental care for young children in Hong Kong now. In order to maintain a double-blind design, the pamphlet will be distributed in an electronic form and sent via a mobile message. The selection of comparator is therefore justified.

Intervention description {11a}

The intervention in the test group will consist of a set of text messages developed based on the HBM to be sent to the parents regularly in 48 weeks.

According to the concept of HBM, parents are likely to adhere to recommended oral health care on children under a specific five sets of conditions (23). First, parents must have some minimal level of knowledge about early childhood caries and motivation towards keeping their childen caries free. Second, parents must perceive the high caries risk of young children without good oral health care, and they must also be convinced that caries is a serious oral health problem for children, which could affect the general health. Third, parents must also be convinced that regular toothbrushing and control of sugar intake for their children are effective in preventing caries. Fourth, internal or external stimulus, referred as “cue to action,” that triggers parental oral health care behavior in their children are present. Finally, parents’ self-efficacy to follow oral health care guidelines should be established and maintained during childhood.

The text messages to be sent will be designed and targeted on the six domains guided by HBM. We have gathered the questions, inquiries, comments and feedback from the parents in our two ongoing clinical trials for the development of the messages.

While the set of standardized messages can be sent to tackle several HBM domains (susceptibility, severity, benefit), “cues to action” and “barriers” are likely to vary across different parents and life scenarios and might emerge anytime in the behavioral change process. Taking the advantage of interactivity (two-way communication) of text messaging, parents will be encouraged to share their concerns/experiences/thoughts via texting us back, which will be responded/discussed/solved promptly. By doing this, continuous support can be provided to facilitate the enhancement of parental self-efficacy (another HBM domain), through which positive actions are likely to take place.

During the first 24 weeks, all parents will receive a text message (and feedback if deemed appropriate) each week. In the next 24 weeks, the parents will receive a text message every 4 weeks, altogether 30 messages will be sent to the parents. All messages will be sent to the parents individually through a free mobile App (e.g., WhatsApp or WeChat) by a research assistant. The RA (dentally trained) will seek consultation from the two dentists in our research team whenever necessary before responding to the parents.

Criteria for discontinuing or modifying allocated interventions {11b}

N/A

Strategies to improve adherence to interventions {11c}

Participation will be incentivized by offering participants a set of children’s oral health care products upon the completion of the assessment each time. Besides, a cash allowance of HK$100 will be offered to the parents to compensate for time spent, any inconvenience caused, and cover transportation costs or other expenses that may incur for each visit to the Prince Philip Dental Hospital.

Relevant concomitant care permitted or prohibited during the trial {11d}

During the research period, all the participants will not be prohibited from any dental visits for check-up or treatment. Information on their dental visits will be collected at each follow-up assessment.

Provisions for post-trial care {30}

N/A

Outcomes {12}

The primary outcome will be dental caries measured by dmft/dmfs (number of teeth/surfaces that are decayed, missing or filled due to caries) of the children at age around 4 years (42-54 months). The children will be examined at the Prince Philip Dental Hospital (PPDH) or child care centres or kindergartens at baseline, 1 year and 2 years follow-up.

The secondary outcomes will be

i. average frequency of parental toothbrushing per day (2 times as preferred)
ii. average frequency of intake of sugary snack/drink per day (2 times or less frequent as preferred)
iii. oral hygiene status using the Visible Plaque Index (VPI), the presence or absence of plaque on the buccal and lingual surfaces of all primary teeth.

Participant timeline {13}

The children will have oral examination while the parents will self-complete a questionnaire at baseline before receiving their allocated intervention. The participants will be followed up after 1 and 2 years.

Sample size {14}

Sample size has been calculated using G*Power software. From our ongoing clinical trial on family-centered oral health promotion for new parents and their infants, collected data show that the prevalence of early childhood caries for children at 3 years old is 15% in the control group and 7% in the intervention group (unpublished data). The reduction is 53%. In this study, we anticipate a smaller reduction, 40%, as the intervention will start when the young children are 18-30 months old instead of started when the mothers were pregnant in our ongoing clinical trial. Based on a previous study, the reported prevalence of dental caries of 4 years old children in Hong Kong was 36% (3). Assuming the prevalence of caries of children in our control group to be the same (i.e., 36%) and anticipating the prevalence of caries of children in the intervention group will be 22% (i.e., prevented fraction of 40%, cohen's h=0.31, a small to moderate effect size, considered to be of clinical significance), the required sample size will be 164 child-parent dyads in each group for the 2-sided test at 0.05 level of significance and 80% power. Considering a typical value of ICC = 0.03 in a cluster randomized clinical trial setting and if 15-25 children are to be recruited from each cluster, the design effect (or variance inflation factor) will be 1.42-1.72 (=1+(25-1)*0.03) (24). Assuming a 10% drop out rate at the 2 years follow-up, the sample size will be increased to 259-314 in each group, thus 518-628 child-parent dyads altogether. Then 26-36 clusters will be recruited.

[This sample size is considered to be feasible as our research team has recently completed a randomized controlled trial that successfully recruited 692 parent-child dyads from 27 kindergartens with a 2 year follow up rate of 91.3% (25)].

Recruitment {15}

The staff in child care centers or kindergartens with nursery classes will help to recruit dyads with children aged 18-30 months. Researchers will try to balance the clusters by geographical and socio-demographic factors at recruitment. Both verbal persuasion and recruitment posters will be used to recruit. Researchers will filter the dyads according to the eligibility criteria.

Assignment of interventions: allocation

Sequence generation {16a}

The study adopts randomization at the cluster level. All participants in the same study unit will be assigned to the same study group (test group or control group). The randomized sequence for each study unit will be generated by Microsoft Excel.

Concealment mechanism {16b}

All randomization will be done before the intervention by a statistician not involved in the data collection. The allocation concealment will be ensured, as the statistician will not release the randomization code until the baseline examination has been completed.

Implementation {16c}

The number of study units will be allocated at a 1:1 ratio. After the allocation, the research assistant who is in charge of sending text messages will be told the assignments of the study units. The oral examiners will not be told about the allocation until the end of the study.

Assignment of interventions: Blinding

Who will be blinded {17a}

The study will adopt a double-blind design. All parents will receive oral health education information via mobile messages so that they could be blinded. The oral examiners will be blinded to the assignment of the study units.

Procedure for unblinding if needed {17b}

N/A

Data collection and management

Plans for assessment and collection of outcomes {18a}

The data collection will involve oral examination and self-completed questionnaires. The children will have their oral examination at the PPDH or child care center/kindergarten (depending on the Covid-19 situation) at baseline, 1 year and 2 years follow-up carried out by trained, experienced, and calibrated examiners (dentists who are postgraduate students in Paediatric Dentistry/Dental Public Health under the supervision of an expert in Paediatric Dentistry in the research team). Methods, equipment, and indices as recommended by the World Health Organization (WHO) for conducting oral health surveys (WHO, 2013) will be employed. No x-ray will be taken. Dental behaviors during the examination will be observed and recorded.

The tooth status of the erupted primary teeth would be assessed by careful visual inspection. Dental caries assessment will be based on the merged ICDAS criteria (International Caries Detection and Assessment System), lesions will be recorded as non-cavitated (codes 1 and 2) or cavitated (codes 3-6) caries (26). Prior to the examination, the child's teeth would be cleaned and wet gauze would be used for the removal of food debris and dental plaque present on the tooth surfaces. No compressed air will be used in the examination because the children are too young to cooperate. The examiners would observe the occlusal, mesial, distal, buccal, and lingual surfaces of each tooth. Children in both case group and control group will be examined at the schools at baseline, 1-year and 2-year follow-up.

Self-completed questionnaires will be delivered to the parents at baseline, 1-year and 2-years follow-ups through the child care center/kindergarten or at PPDH. Information on the background of the parents, HBM Scale, self-reported average tooth brushing frequency, sugar intake habits and dental anxiety of their children will be collected.

Plans to promote participant retention and complete follow-up {18b}

Retention

Once a dyad is enrolled, the study investigators will make every reasonable effort to follow the dyad for the entire study period.

The study investigators will maintain interest of the parents in the study through text messages, incentivize parents by reminding them of a set of children’s oral health care products is to be received after the completion of the follow-up assessment and give parents some feedback on their children’s oral health after each examination.

Data management {19}

Intention-to-treat approach will be used for data analysis based on the random allocation regardless whether the intervention has been received or not.

Confidentiality {27}

All study-related information will be stored securely at the study site. All participant information will be stored in the computer with access only limited to the research team. All parents' phone numbers, WhatsApp and WeChat will only be used in the research.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

N/A

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

The effectiveness of HBM-based intervention will be evaluated by comparing the differences in the outcome variables between the intervention and control groups. Multilevel logistic regression adjusting for the effects of possible confounding factors for the clustered data will be performed to test the differences in the prevalence of dental caries (25), and proportions of children with parental tooth brushing twice daily and sugar intake twice or less frequent per day between the two groups. Multilevel linear regression will be performed for the difference in the extent of dental caries (mean dmft/dmfs) and visible plaque level (mean %) between the two groups adjusted by other confounding factors for the clustered data (25). The level of statistical significance for all tests will be set at 0.05. Two-level random-intercept models will be considered: children as level 1 and schools as level 2. All the analyses will be performed using the SPSS software package.

Interim analyses {21b}

N/A

Methods for additional analyses (e.g. subgroup analyses) {20b}

N/A

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Reasons for any non-adherence or withdrawal will be recorded for the subsequent analysis. Missing data will be checked and where appropriate, multiple imputation will be used and sensitivity analyses will be conducted.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

The protocol has been uploaded on *clinicaltrials.gov* (ID: NCT04665219). The participant level-data will be uploaded to the DataHub platform of The University of Hong Kong.

Oversight and monitoring

Composition of the coordinating center and trial steering committee {5d}

The principal investigator is responsible for the design of the study and the coordination of different departments. The research team comprises the trial steering committee responsible for the recruitment, dental check-up, message sending, and data analysis.

Composition of the data monitoring committee, its role and reporting structure {21a}

Adverse effects of oral health promotion as an intervention are not anticipated, thus, no data monitoring committee is needed in this study.

Adverse event reporting and harms {22}

Adverse effects of oral health promotion as an intervention are not anticipated. However, suppose any adverse effects are to have occurred, it will be reported to the Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster.

Frequency and plans for auditing trial conduct {23}

The trial steering committee will report the progress of the study to the Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster annually, and will report the findings at the end of the study.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

If there would be any further necessary protocol amendments, approvals will be sought from the research grant committee of the Health and Medical Research Fund, Food and Health Bureau (FHB), Government of Hong Kong SAR and the Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster. The trial participants will be notified as well.

Dissemination plans {31a}

The research findings will be published in international peer-reviewed journals. Besides the publications, we plan to communicate the research findings with the Chief Dental Officer and his team at the Department of Health in the government. We also plan to share the findings with local dental professional bodies (e.g., Hong Kong Dental Association, Hong Kong Society of Paediatric Dentistry, Hong Kong Paediatric Society, etc.), dental and medical practitioners, and dental hygienists and medical nurses working in child health care setting.

Discussion

With the rapid spread of mobile technology around the globe, mobile health (mHealth) has become increasingly popular in the past few years. According to the third global survey of the WHO Global

Observatory for eHealth, the use of mHealth has kept growing since 2010 (27). By offering care at a distance and mutual communication, mhealth service could reach remote populations, even those in underserved communities, enabling greater equity in universal health coverage (28,29).

There have been some mHealth practices in the field of oral healthcare field (30-32). Text messages, health care helplines, webpages and mobile apps were frequently used in these mHealth programs, among which the mobile information and communication technology was most adopted (27). The information can be conveyed via text, pictures or multimedia. Although most investigators claimed that their program could successfully promote a good oral health attitude and behavior among the targeted population, few were empirically validated to demonstrate their effectiveness. Tiffany et al. identified 19 available mobile apps for oral health promotion designed for Android or iOS in 2018, finding that the content of oral health care was unprofessional, and the design of most apps was not driven by sound behavioral theory (33).

In the present study, HBM is selected as the framework for text messages. HBM is recommended as a useful theoretical model to explain health behaviors, and it is also useful to plan behavioral interventions (18). HBM emphasizes individual characteristics and cognitive factors, giving less attention to social influences and emotional components of behavior (34). HBM suggests that health-promoting behaviors can be triggered by the presence of six domains: perceived susceptibility, perceived severity, perceived barriers, perceived benefit, cue to action and perceived self-efficacy (18). It is reported that psychological theories based on HBM effectively improve oral health behaviors (19). On the other hand, evidence also showed that HBM effectively improves adherence to oral health care instructions among adults and school children (35).

Previously, the emphasis of HBM based health behavior intervention would be laid on susceptibility, severity and benefits. The domain of ‘cue to action’ and ‘self-efficacy’ were less addressed (36), and barriers were not usually proactively expressed by subjects. In the present study, a set of standardized messages will be sent to address HBM domains of susceptibility, severity and benefit. Besides, parents will be encouraged to share their concerns/experiences/thoughts via texting us back, which will be responded/discussed/solved promptly. By these interactive messages, the barriers could be addressed in a timely manner. They could receive enough cues to action, so that continuous support can be provided to facilitate the enhancement of parental self-efficacy, through which positive actions are likely to occur.

Dental caries is a multifactor disease (37), whose risk factors are diverse and, like most noncommunicable diseases, related to social-economic factors (1). Therefore, parents’ oral health behavior is not the only causal factor of ECC. To eliminate the influence of the counfounding factors, we will collect information on possible confounding variables and include them in the multivariate analysis.

Caries prevention projects among children involving oral health education are often delivered through primary care, home visits, or kindergarten-based programs (38-40). However, most of these strategies have resulted in small, clinically insignificant effect in caries prevention. By HBM-based intervention via a

low-cost text messaging vehicle, the caries prevention scheme may help the parents establish proper oral health behaviors for their children and safeguard children's oral health.

Trial status

The protocol is version no. 3, dated 2021.03.30. The recruitment began on 2020.10.06 and it is still ongoing.

Abbreviations

HBM = Health Belief Model

SMS = Sending Text Messages

ECC = Early Childhood Caries

RCT = randomized controlled trial

mHealth = mobile health

ICC = intracluster correlation coefficient

CPI = community periodontal index

ICDAS = International Caries Detection and Assessment System

VPI = visible plaque index

Declarations

Acknowledgements

Authors' contributions {31b}

MCMW conceived of the study. MCMW, HMGL, PL, XG and SYSW initiated the study design and KW helped with implementation. MCMW, HMGL, PL, XG and SYSW are grant holders. MCMW provided statistical expertise in clinical trial design. All authors contributed to refinement of the study protocol and approved the final manuscript.

Funding {4}

The present study was funded by Health and Medical Research Fund (Project no.: 17181971), Food and Health Bureau (FHB), Government of Hong Kong SAR, China.

Availability of data and materials {29}

A completely de-identified data set will be uploaded to DataHub of The University of Hong Kong for sharing.

Ethics approval and consent to participate {24}

The study is approved by the Institutional Review Board of the University of Hong Kong/ Hospital Authority Hong Kong West Cluster (IRB: UW 20–029).

Consent for publication {32}

All authors have approved the publication of the present manuscript.

Competing interests {28}

The authors declare that they have no competing interests.

Authors' information (optional)

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Figures

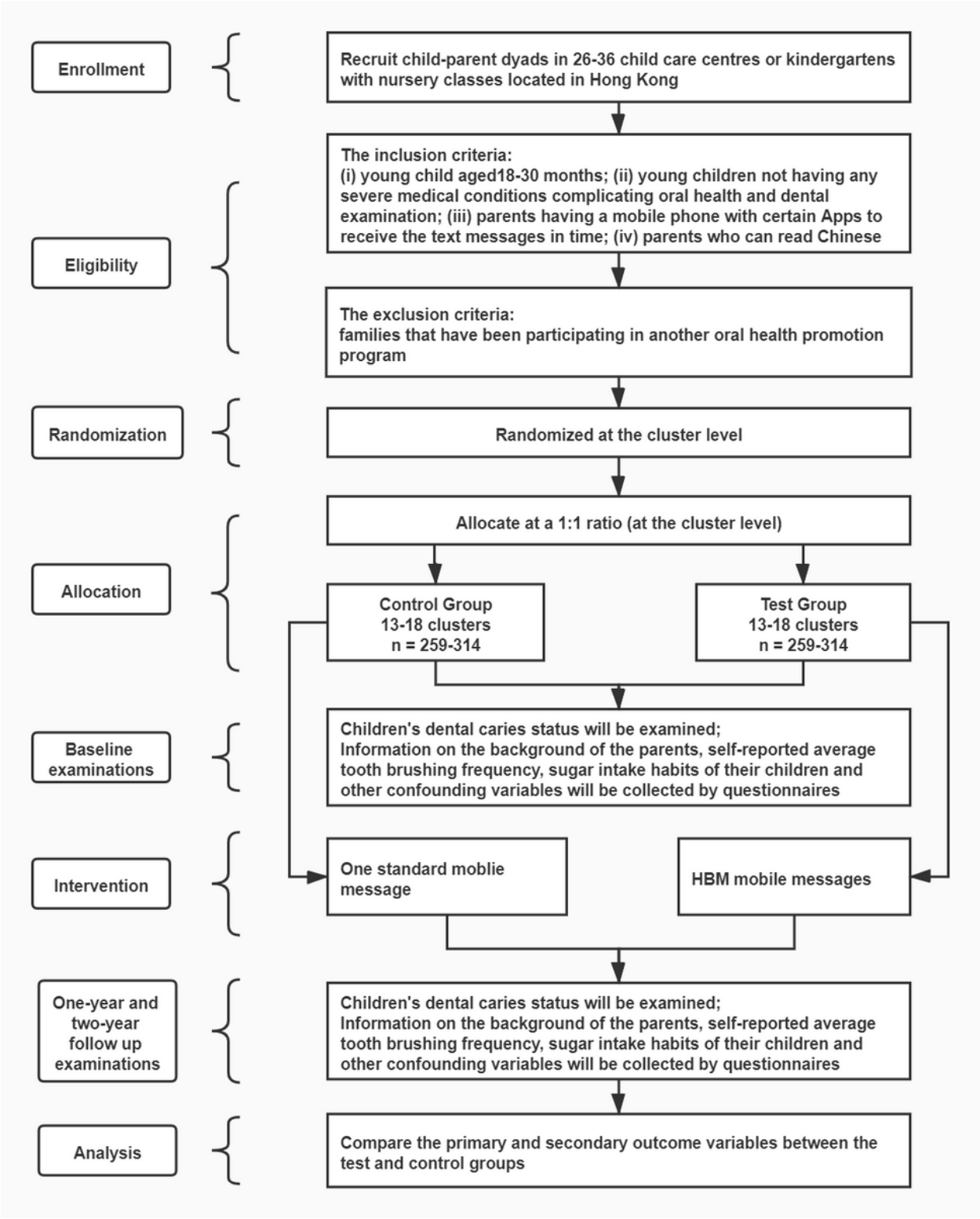

Figure 1

Study flowchart

Supplementary Files

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