King Faisal University

Al-Ahsa, Kingdom of Saudi Arabia

College of Dentistry

Study protocol

Title: Oral Health Education Effect on Children's Oral Hygiene and Mothers' Oral Hygiene Knowledge, Attitudes, and Practices: A Randomized Controlled Trial.

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Contents

Introduction:

Oral health is a vital component of overall health and an important part of a child's well-being (Sharma, Saxena et al. 2021). According to World Health Organization (WHO), oral health is the state of the mouth, teeth and orofacial structures that enables individuals to perform essential functions such as eating, breathing and speaking (WHO 2023). It has been accurately declared that there is no health without good oral health (FDI 2017). The maintenance of oral health plays a crucial role in enabling people to actively engage in societal activities and fulfill their own capacities (WHO 2023). A fundamental aspect of preserving good oral health is recognizing the importance of adhering to appropriate oral hygiene practices (Malik, Sabharwal et al. 2017). To maintain optimal oral health, the Centers for Disease Control and Prevention (CDC) advise fluoridated water, fluoride toothpaste, twice-daily brushing, regular flossing, and yearly dental examinations (CDC 2023). It is well acknowledged that developing good oral hygiene practices from an early age is essential to achieving favorable long-term results (K, Deshpande et al. 2022). Despite significant progress in the field of oral and dental health across several nations, the prevalence of oral health issues remains a persistent worldwide concern (Hashemi, Khorsandi et al. 2021).). Oral disease encompasses a wide variety of conditions, such as dental caries, periodontal disease, oral cancers, dental erosion, and dental fluorosis. Among these several oral diseases, dental caries and gingival disease are the most prevalent chronic oral conditions in children (CDC 2022) (de Silva, Hegde et al. 2016). Hence, dental caries is a worldwide health issue (Mallineni, Alassaf et al. 2023). It is a relatively common global condition that affects over 621 million children worldwide (Alayadi, Alsiwat et al. 2023). Besides, it has a significant effect on both health and the economy around the world (Innes, Clarkson et al. 2020, Mallineni, Alassaf et al. 2023). Dental caries is a microbiological disease that affects teeth through the process of demineralization and destruction of the inorganic and organic components of dental hard tissue (Mallineni, Alassaf et al. 2023). It may occur in teeth at an early age, and if left untreated, it might lead to potentially serious complications (Gerreth, Ari et al. 2020). Children who have dental caries can experience pain that may negatively impact an individual's ability to eat and maintain proper nutrition, speak clearly, sleep soundly, concentrate effectively, and learn efficiently (Alayadi, Alsiwat et al. 2023). The overall well-being and quality of life of children may also be impacted by dental caries, potentially affecting their school attendance and their performance in the classroom (Alayadi, Alsiwat et al. 2023). It was reported that over 51 million hours of school are

missed per year as a consequence of dental-related illnesses (Kashyap, Reddy et al. 2022). Dental caries influenced by a variety of factors, including biological, behavioral, psychosocial, and environmental factors (Machiulskiene, Campus et al. 2020). Consequently, dietary and hygiene practices, bacterial flora, saliva composition and flow rate, oral health care access, and socioeconomic level all play important role in caries development (Gerreth, Ari et al. 2020). Despite the preventability of dental caries, its prevalence remains significantly high (Adam, Al-Sharif et al. 2022). As stated by WHO, globally 514 million children suffer from caries of primary teeth. This means that the average rate of cases is expected to be 43% (WHO, Global oral health status report 2022). Furthermore, the rate of dental caries among the Arab population ranges from 77% in Jordan to 99.4% in the United Arab Emirates (Al Suwyed, Al Zoman et al. 2021). However, the Saudi Ministry of Health reported that the percentage of tooth decay among children in Saudi Arabia reached 96% (MOH, 2021). Unfortunately, the treatment of dental caries typically involves surgical procedures and restorative therapy, which may induce stress for a child and incur financial burden on the family (Gerreth, Ari et al. 2020). The burden of oral illness keeps rising, and it is particularly serious in low- and middle-income nations. In most high-income countries, oral diseases rank as the fourth most expensive condition to treat. Moreover, the expense of providing curative therapy for dental caries alone in children would reach the overall healthcare budget in most low-income nations (de Silva, Hegde et al. 2016). This might imply that society faces a significant expense as a consequence of a lack of awareness about prevention and an inadequate care supply (Wang, Liu et al. 2022). Therefore, prevention of dental caries in children is widely recognized as a crucial objective since it is usually more cost-effective in comparison to treatment (Wang, Petersen et al. 2018). While it is possible to prevent oral diseases in the initial stages, there is a lack of awareness among many children and their guardians, such as parents and teachers, about the effectiveness of simple self-administered oral hygiene practices in preventing these diseases. Furthermore, policymakers may also overlook this issue. Therefore, the prevention has established as a fundamental principle in current dental healthcare (Gurav, Shetty et al. 2022). Prevention of caries need a comprehensive and collaborative strategy that includes several factors and involves multiple agencies. This approach requires providing health education and promoting the development of life skills (Aljafari, Gallagher et al. 2017). The World Health Organization's (WHO) Ottawa Charter commands the integration of health education into health promotion activities, as the acquisition of knowledge remains a critical component for encouraging behavioral

changes (Aljafari, ElKarmi et al. 2022). Health promotion is provided to help individuals manage and enhance their health. Besides, Oral Health Education (OHE) is an important element of oral health promotion and a necessary component of oral health care. Through educational approaches, information is given to increase oral health awareness in order to adopt a healthy lifestyle, improved attitudes, and desired behaviors (Gurav, Shetty et al. 2022). However, waiting to educate children about oral health until they seek dental care is occasionally too late, especially in nations and communities where people only visit the dentist when experiencing pain. Accordingly, it is important to provide oral health education in nonclinical settings (Aljafari, ElKarmi et al. 2022). Oral health education encompasses several strategies, such as public awareness campaigns, informative presentations in primary schools, the use of oral health films, and establishing a complete and reinforced course that is incorporated into the school curriculum (Gurav, Shetty et al. 2022). The implementation of OHE programs in schools is critical for achieving adaptive changes and improving oral wellbeing. School plays an important part in a child's development, enabling them to proceed towards becoming successful (K, Deshpande et al. 2022). Additionally, school years are a child's physical and mental formative years, shaping them into potential adults. The health behaviors that are developed during this phase will persist until adulthood, old age, and maybe into the next generation (Malik, Sabharwal et al. 2017). Also, children have a rapid capacity for assimilating new information. Furthermore, the acquisition of habits at an earlier stage has a more enduring influence (Sharma, Saxena et al. 2021, Gurav, Shetty et al. 2022). Fortunately, school is one of the most accessible avenues for reaching out to children and their families and considered an ideal platform for providing OHE. They may reach over one billion children worldwide, which supply an excellent opportunity for supporting children to improve their health-related behaviors (PEREIRA and MATHEW 2020, Gurav, Shetty et al. 2022). Dental health education in schools is conducted through a variety of methods, from simple educational presentations to technology-enabled multimedia programs that include strategies designed to support behavioral and psychological changes. The efficacy of oral health education in schools is based on the extent to which the acquired health behaviors are retained. In order to have a long-lasting effect, it is essential to use repetition and reinforcement approaches in health education (PEREIRA and MATHEW 2020). Studies show that the use of conventional OHE alone does not provide sufficient outcomes for modifying oral health behavior and attitude (K, Deshpande et al. 2022). Furthermore, research has revealed that these particular programs have little impact on oral

hygiene practices and minimal effect on the overall oral health status of children (Malik, Sabharwal et al. 2017, Sharma, Saxena et al. 2021). Nevertheless, conventional methods of education for schoolchildren are still in use (PEREIRA and MATHEW 2020). Education is a three-part process that involves the transmission of knowledge, the development of skills and interests, and the establishment of attitudes and life values (K, Deshpande et al. 2022). It should be delivered in a manner that stimulates the recipient's thoughts rather than just filling their minds with information. Hence, the integration of entertainment with education provides an enjoyable learning experience (K, Deshpande et al. 2022). Moreover, employing interesting approaches to oral health education in schools might help in improvement of children's oral health (Kashyap, Reddy et al. 2022). The use of interactive learning methods offers several benefits, including enhanced attention span, improved memory recall, increased visual alertness, and support for memory strategies and reasoning skills (Sharma, Saxena et al. 2021). Implementation of games as a way of learning has emerged as an interactive learning strategy that has shown promising outcomes. This strategy emphasizes experiential learning as a method of obtaining knowledge (Kashyap, Reddy et al. 2022). Moreover, game-based approach is an effective teaching method that strengthens and expands a child's knowledge base in an attractive and dynamic setting (Sharma, Saxena et al. 2021). Additionally, it has been estimated that children spend nine and a half hour a week playing games. The use of games in education have the capability to activate pre-existing information and act as a motivator for individuals to alter their behavior (Aljafari, Gallagher et al. 2017). While playing games, children happily get valuable experiences and proactively pick up new information without feeling any pressure (Hashemi, Khorsandi et al. 2021). Furthermore, gaming is quite popular, especially among the younger generation (Aljafari, Rice et al. 2015). Currently, such innovative and creative prevention techniques are now being developed in response to the urgent need to tackle the nation's rising prevalence of oral health issues (Kashyap, Reddy et al. 2022). However, the previously stated evaluations have shown that, although these games have the potential to enhance health outcomes, the vast majority of research are of low quality. As a consequence, more comprehensive randomized controlled trials in this field are urgently needed (Aljafari, Rice et al. 2015).

Study aim and objectives:

Aim:

-To evaluate the effect of conventional versus non-conventional oral health education on the oral hygiene status of preschool children and on mothers' oral hygiene knowledge, attitudes, and practices towards their children in Al-Ahsa region.

Objectives:

-To measure the oral hygiene status of preschool children using simplified oral hygiene index.

-To assess mothers' oral hygiene knowledge, attitudes, and practices towards their children using an online questionnaire.

-To measure the impact of conventional oral health education on the oral hygiene status of preschool children and mothers' knowledge, attitudes and practices.

-To measure the impact of non-conventional oral health education on the oral hygiene status of preschool children and mothers' knowledge, attitudes and practices.

-To compare the effect of conventional versus non-conventional oral health education on the oral hygiene status of preschool children and on mothers' oral hygiene knowledge, attitudes, and practices towards their children.

Hypothesis

Non-conventional oral health education can improve the oral hygiene status of preschool children, and mothers' oral hygiene knowledge, attitudes, and practices towards their children more than the conventional programs.

Null Hypothesis

There is no difference between conventional and non-conventional oral health education on oral hygiene status of preschool children, and on mothers' oral hygiene knowledge, attitude, and practices towards their children.

Materials and methods:

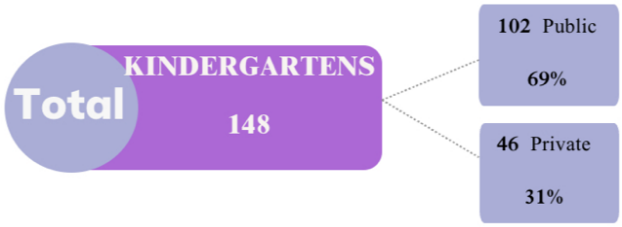
Type of study:

The study will be carried out as a double arm single-blinded randomized controlled trial.

Study area:

The study will be conducted in public and private kindergartens (KG) in Al-Ahsa region, Saudi Arabia, during the period from October 2024 to August 2025.

There are 154 kindergartens distributed among three educational offices: Al-Mubarraz, Al-Hofuf, and Villages Education Offices. This study sampling population will only cover 148 kindergartens since six of schools are excluded as they serve children with special needs.



Study population:

The study will include children attending kindergartens who are aged 5–6 years old and their mothers.

There are 13,583 children enrolled in Al-Ahsa kindergarten schools, the exclusion of special needs schools results in the elimination of 53 children from the study population. Therefore, only 13,530 children will be included.

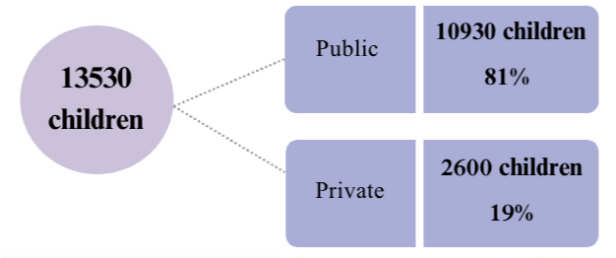
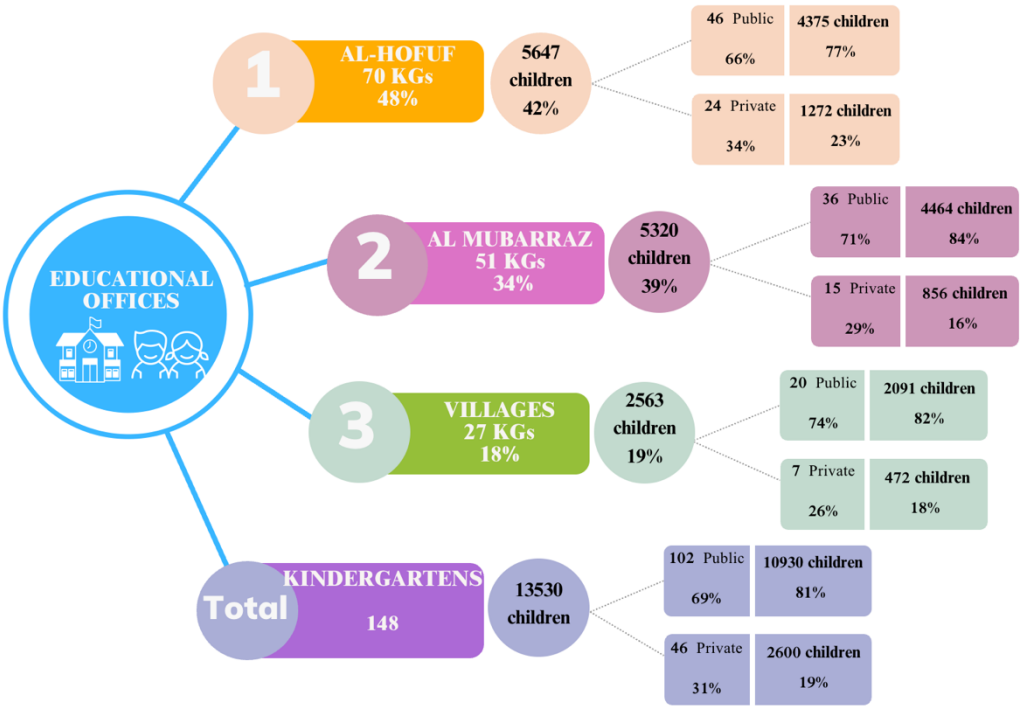


Figure 1. The distribution of kindergartens and children in the Al-Ahsa region based on the relevant educational offices.



Study sample:
Mother-child pair.

Inclusion criteria:
-Children aged 5-6 years who are registered in the respective academic year at kindergarten schools in Al-Ahsa.

-Mothers of preschool children who agree to participate and provide consent.

-Children and mothers who can attend all educational sessions.

Exclusion criteria:
-Special needs kindergartens.

-Illiterate mothers.

-Children with dental anomalies.

-Children with orthodontics appliance.

-Children with systemic diseases (Diabetes mellitus, Hemophilia, Cancer, Craniofacial anomalies and syndromes).

To avoid deprivation of learning, all children will get oral health education, but they will not be counted in the study sample. Exclusion will occur during the data analysis process.

Sample size:

The calculation of the sample size for this study was conducted using the OpenEpi (openepi.com). The expected sample size will be 788 mother-child pair at a power of 0.80 and an alpha error of 0.05. To increase the statistical power and account for dropout during the follow-up period, the sample size will be raised by 10%, resulting in an additional 78 mother-child pair. Thus, the total sample size of this study will be 866 mother-child pair. These participants will be divided equally into two groups conventional group and non-conventional group. Each group will consist of 433.

Sampling technique:

In this study we will use a multi-stage stratified random sampling technique.

-At the educational offices level: All three educational offices will be included.

-At kindergarten level: Cluster sampling using stratified proportional sampling technique. This study will include ten kindergartens. The number of kindergartens was determined based on a comprehensive assessment, taking into consideration each educational office's weight and the extent of its children enrollment. This method will ensure that the sample size from each office is distributed proportionally by accounting for the public and private strata.

To select kindergartens from each education office, we will use the Simple Random Sampling (SRS) technique. The names of kindergartens will be listed, assigning a number to each KG. A computer random numbers generator will be used to randomly select KGs to be invited to take part in the study.

1-Al-Hofuf Education office:

Public kindergartens:

A list of all 46 public kindergartens in Al-Hofuf was obtained. A computer random number generator will be used to randomly select five kindergartens in the following manner:
1- The number of children in each kindergarten varies from 10 to 212; thus, Al-Hofuf kindergartens will be divided into three groups based on the number of children enrolled.
2-Each group will consist of approximately 15-16 kindergartens.
3-One kindergarten will be randomly selected from each group using a computer random number generator.

Private kindergartens:

A list of all 24 private kindergartens in Al-Hofuf was obtained. A computer random number generator will be used to randomly select two kindergartens in the following manner:
1- The number of children in each kindergarten varies from 5 to 128; thus, Al-Hofuf kindergartens will be divided into two groups based on the number of children enrolled.
2-Each group will consist of 12 kindergartens.
3-One kindergarten will be randomly selected from each group using a computer random number generator.

This procedure for KGs selection will be applied in all educational offices.

Sampling fraction= 14/149 = 0.09. The probability of each KG to be selected is 9%.

Study weight= 149/14 = 11. Each KG will represent 11 KGs.

-Classroom and children level:

The selection of classes from each KG will be conducted in the following manner:

-The total number of classes in each KG will be determined.

-The number of children enrolled in each class will be determined.

*If the number of classes and/or children fulfills the sample size, all of them will be included.

*If the number of classes and/or students exceeds the required sample size, simple random sampling techniques will be used.

-At the classroom level:

Using a lottery.

-At the children level:

Using a computerized random number generator.

Classes will be randomly allocated into the two study groups (conventional and non-conventional) using a a coin toss.

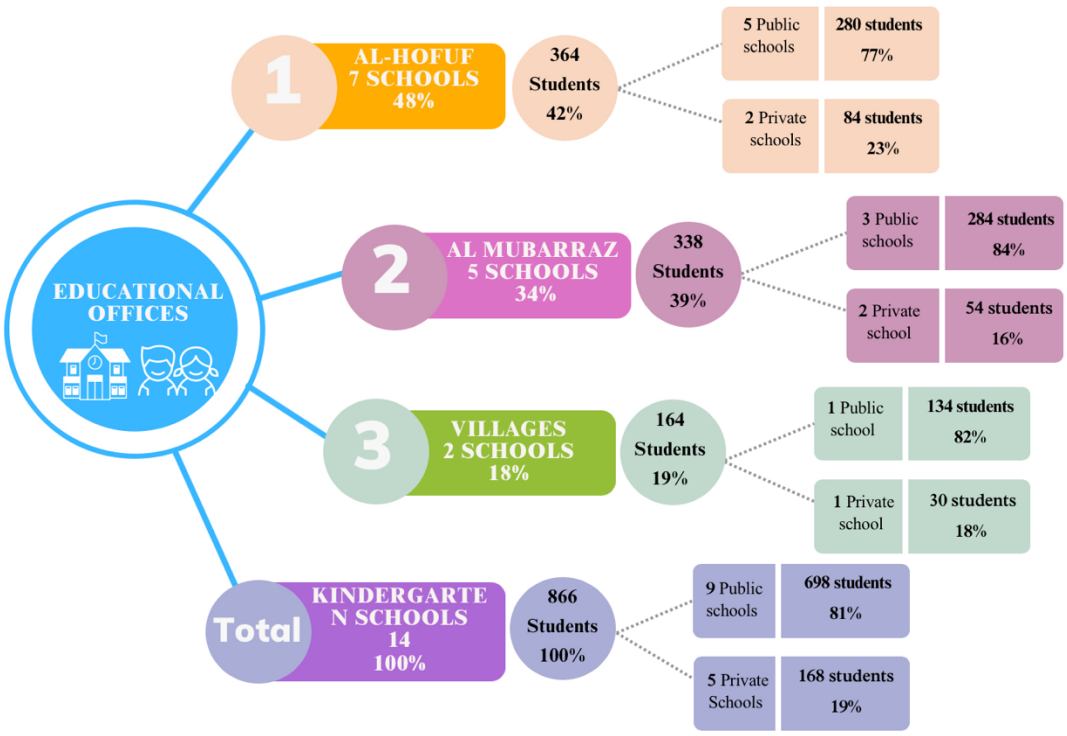
Children will be recruited proportionately between the three educational offices.

Sampling fraction= 866/13530= 0.064. The probability of each child to be selected is 6.4%

Study weight= 13530/866= 16. Each child will represent 16 children.

Kindergartens and children sampling

Figure 2. Recruited kindergartens and children from each educational office based on public and



Data collection

Oral health education will cover:

-Mouth component.

-Dental plaque.

-Consequences of plaque accumulation.

-Dental caries.

-Consequences of dental caries.

-Optimal oral hygiene practices.

-Role of preventive measures such as fissure sealant, fluoride, and importance of regular dental visits.

The oral health education program will be delivered by:

Specialized kindergarten teachers.

Teachers will undergo through a special, well-structured program for preparation, training and calibration.

For children, they will receive the program during regular school hours on weekdays.

For mothers, depending on what they prefer, the lecture will either be arranged in person or virtually via the Zoom online platform.

In conventional group:

1- A power point presentation will be provided to the children. (One visit)

In non-conventional group:

1- Children will be subjected to an interactive learning approach that includes: (Four visits)

-Brain-based learning strategies using storytelling and hands-on activities.

-An online game-based learning platform (Kahoot).

(It can be accessed via a web browser or the Kahoot app).

2-Mothers will be subjected to an oral health education lecture.

Non-conventional Oral Health Education

1.First Visit: Introduction to the importance of oral hygiene through visual storytelling, depicting a child who experiences dental pain due to poor oral hygiene. And game-based session using puzzle and Kahoot app for question-and-answer activities related to oral hygiene.

2.Second Visit: Explanation of the process of plaque accumulation and hands-on activity where children practice brushing plaque off a paper character to simulate good oral hygiene practices. And game-based session using Kahoot for question-and-answer activities related to plaque accumulation

3.Third Visit: Explanation of the importance and components of the mouth and the right way for brushing teeth including activity on a jaw model to apply the correct brushing technique. And game-based session using Kahoot for question-and-answer activities related to importance and components of the mouth.

4.Fourth Visit: Oral hygiene instruction, how to keep our teeth healthy and reinforcement of preventive measures such as dental visits. And game-based session using memory matching game and Kahoot app for question-and-answer activities related to healthy mouth.

Then, over a period of 3 months, this game will be played online from home in a competitive and group setting once a week.

Measurements:

1- Children's plaque index will be measured using simplified oral hygiene index (S-OHI). The plaque scores will be recorded according to the (S-OHI) to assess oral hygiene status for children. The oral examination will be performed using a sterilized disposable examination kit, including a mouth mirror and explorer, in a separate classroom with each student seated on a chair under optimum artificial light.

The examiners will perform an oral examination for children in both groups and record their plaque score before the intervention and after 3 months of intervention.
Oral examination will be conducted in the morning hours before the school meal.
Children will not be informed about the day of examination to prevent **Hawthorne effect**.
Hawthorne Effect: It is a psychological phenomenon that occurs when individuals modify their behavior or performance in response to the awareness of being observed.

2-Mothers' oral hygiene knowledge, attitudes, and practices towards their children, using a questionnaire. Paper questionnaire will be submitted before the intervention and after 3 months of intervention.

3-Demographic information, parents' socioeconomic condition, dietary habits and oral hygiene performance to reduce confounding factors, using a self-administered questionnaire to complete at home and return to the researchers before conducting the study.
(Accounting for the cultural sensitivity self-administered parental questionnaire will be used. Before conducting the study, the validity and practicality of the questionnaire will be tested.)

Evaluations of children's oral hygiene status and mothers' knowledge, attitude and practices toward their children will be recorded before the intervention and after 3 months of intervention for the two groups.

By the end of implementing oral health education, we will compare:

The children's oral hygiene status and mothers' knowledge, attitude and practice toward their children between the conventional and non-conventional group.

Data collector:

Two dentists will perform the oral examinations. Prior to the commencement of the trial, dentists will be trained and calibrated. Inter-examiner reliability will be measured by repeated examinations in a sample of ten children to assess the inter-examiner agreement of plaque score using Cohen's Kappa statistics.

Coding

During data collection, the coding procedure will be carried out. Each child will have a specific code.

Data analysis

Descriptive statistics will be used to summarize baseline characteristics. Inferential statistics, including t-tests for continuous variables and Chi-squared tests for categorical variables, will be used to compare outcomes between the two groups. A significance level of $p < 0.05$ will be used for all analyses.

Children's oral hygiene status, mothers' knowledge, attitudes, and practices will be the dependent variables in this study. **Conventional and non-conventional oral health education** will be the independent variables.

Methodological issues:

Random errors: Eliminating random error completely is unattainable, as the study is restricted to a sample from the population, not the entire population.

Systematic errors

Loss of follow-up

This is the main issue because it is a follow-up study.

Minimize by:

In design level: Sample size will be raised by 10% to account for any participant loss during the follow-up period.

In conducting level: Maintaining good communication and offer incentives.

Ascertainment and Observer bias

This can effect the validity of the study and lead to inaccurate conclusions about a intervention efficacy

Minimize by:

In design level: Blinding of examiners, training for examiners, and applying a stringent protocols.

Responder bias

This bias can impact the validity and reliability of study results.

Minimize by:

In conducting level:

-Ensure participant's anonymity and confidentiality.

-Establish a trusting environment to encourage honest responses from participants.

Measurements errors

This can reduce the precision of study findings.

Minimize by:

In conducting level:

-Clear explanation to the examiners about the measurement methods that will be used in the study.

-Using disclosing agent help to make individual measurements as precise as possible.

Confounding factors

There are variables that are not the main focus of the study but can potentially affect the study's outcome, leading to erroneous or misleading conclusions. The expected confounding factors for this study include but are not limited to parents' demographic information, socioeconomic condition, dietary habits and oral hygiene performance.

Minimize by:

In design level:

-Randomization, using probability sampling techniques.

-Restriction, by applying exclusion criteria.

In conducting level:

-Stratification, by applying public and private strata.

-Standardization, by applying stringent protocols, and by training and calibration of examiners.

-Check and measure the expected confounding factors.

Ethical considerations

This study will obtain approvals from:

-Internal Research Board (IRB) Approval from internal department of college of dentistry.

-Deanship of Scientific Research Approval from King Faisal University (KFU).

-Formal Approval from Ministry of Education (MOE).

-Formal Approval from each kindergarten (KG) administration.

-Informed consent from each child’s guardian.

Participant's confidentiality will be protected. Research data will be preserved by using participant codes in all data and will be stored securely.

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