Implementation and Evaluation of Fluorosis Educational program in Tamil Nadu, India

Master of Public Health Integrating Experience Project

Community Service Grant Proposal Framework

By

Janani Ramasamy Kali, MD (c), MPH (c)

Advising team:

Vahe Khachadourian, MD, MPH, PhD candidate

Aida Giloyan, MPH

Varduhi Petrosyan, MS, PhD

School of Public Health,

American University of Armenia,

Yerevan, Armenia, 2016

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Acknowledgements

I would like to express my sincere gratitude to my advising team for their continuous support and feedback throughout this project. I am grateful to Dr. Vahe Khachadourian for his quick feedback and practical solutions provided throughout the project. I am grateful to Dr. Varduhi Petrosyan, for her constant support and advice that helped me frame the project in a much better format. I am thankful to Aida Giloyan, for her swift responses to my questions and doubts regarding the project.

In addition, I would like to thank Dr. Kristina Akopyan, for her advice in framing the consent and assent forms.

Last but not the least, I take this opportunity to thank my mother, who encouraged and supported me throughout this project, and for her regular updates regarding the problem and also for the help rendered with the Tamil translation of the questionnaire.

Executive summary

Fluorosis is caused by consuming excess amount of fluoride, and it is considered to be endemic in 25 countries. It mostly affects the teeth and bones and is characterized by pitting and staining of teeth. Long term consumption of excess amount of fluoride can lead to skeletal deformities and impaired movement. Groundwater is the main source of fluoride, besides vegetation that is cultivated using the groundwater. Other sources of fluoride include artificial dental products like toothpastes, gels and dietary fluoride supplements. It is proven that optimal level of fluoride is essential for healthy dentition, however, higher levels can cause multisystem damage. These systemic damages have negative impact on the quality of life. The situation of fluorosis is worse in India, where most of the population rely on ground water for day to day activities. Studies conducted in Tamil Nadu, a state in southern part of India, showed that fluorosis is a serious problem in many districts (sub-divisions of a state). Lack of knowledge on fluorosis and its effects, and lack of knowledge about strategies to defluoridate water are among the factors contributing to the high prevalence of fluorosis in Tamil Nadu. Although the state government has implemented a fluoride mitigation project in two districts, the remaining 30 districts remain ignorant of the impact of excess amount of fluoride on health. This project aims to implement and evaluate an educational program on fluorosis and its effects in 10 randomly selected districts of Tamil Nadu. The proposed program is a Randomized Field Trial, in which there will be random assignment of 5 districts to the intervention group and the other 5 districts to the control group using block randomization with two districts in each block (an intervention district and a control district) by which a total of five blocks will be obtained. From the five blocks, one block at a time will be chosen randomly from which the schools and students are selected using multistage clustered random sampling for evaluating the program. The same method for

selecting schools and students will be used in all five blocks selected. Since children of age 10 to 16 years are more vulnerable to fluorosis, the current project will target students from rural schools who are in this age group. The project will last 2 years starting from January 2017 and will be completed by December 2018. The intervention includes seminars and lectures that are conducted in school premises during working hours excluding weekends, holidays and vacations. The implementation of the program and its evaluation in each block will be completed in two months. The materials used for the intervention contains detailed information about causes and symptoms of fluorosis, effective preventive measures, dietary and food regulations that should be followed, methods for testing skeletal fluorosis, and various pictures depicting these information. This educational program aims to improve knowledge of children regarding fluorosis, and various defluoridation methods available. In order to evaluate the change in knowledge, a pretest and posttest will be conducted among the selected students in the 10 districts. A 20% absolute increase in mean knowledge percent score is expected in the intervention group after the education program. For evaluation, 10 schools from each block are selected (5 schools from intervention district and 5 schools from control district), and from each school a total number of 26 students are selected and administered a questionnaire on two different occasions (pretest and posttest) with an interval of 2 months. The change in knowledge score of these students in the intervention and control district is used to evaluate the program. The program implementation and evaluation in those 5 blocks will be completed by August 2018, followed by the analysis and final report which will be completed by December 2018. Based on the results obtained from the evaluation, a state wide implementation of the education program will be done.

Introduction

According to the World Health Organization (WHO), fluorosis is defined as a condition caused by ingestion of excess amount of fluoride. Naturally rich in fluoride ground water is the most common source of excess fluoride[1] and it can have negative impact on teeth and bones.[2] The fluorine found in water is of geological origin. This water is usually found at the foot of high mountains and lands where the sea has made geological deposits of minerals and salts. There are two types of fluorosis: dental and skeletal. The dental effects of fluorosis are manifested earlier, and they usually precede the skeletal effects. Clinical dental fluorosis is a condition characterized by staining and pitting of the teeth.[2] Severe cases of dental fluorosis may cause enamel damage resulting in dentition problems in children.[2] Maternal intake of water with high concentration of fluorine during pregnancy can cause mottled discoloration and pitting of the enamel of the secondary and primary dentition in their children. However, similar symptoms may also arise when there is malnutrition or deficiency of specific vitamins such as vitamin D.[2]

Skeletal fluorosis is defined as skeletal changes due to long term ingestion of excessive fluoride; they may include hyperostosis, osteopetrosis, and osteoporosis.[3] Individuals with skeletal fluorosis may have stiffness and pain in the joints. In severe cases of skeletal fluorosis, the structure of the bone can change, and the ligaments may undergo calcification leading to musculoskeletal impairments.[2] Usually both skeletal fluorosis and vitamin D deficiency cause pain in joints, and since radiological findings are not always evident, and skeletal changes take a long time to appear, the differential diagnosis of fluorosis from vitamin D deficiency symptoms becomes challenging for physicians. Physicians often measure the amount of 25-hydroxyvitamin D concentration in blood to identify whether the pain is due to deficiency of vitamin D or fluorosis.[4] Nonetheless, misdiagnosis of fluorosis remains a common error among

medical professionals. Severe chronic fluorine poisoning leads to osteosclerosis and other pathological bone and joint changes in adults.[3] The severe form of skeletal fluorosis is crippling, in which the person finds it difficult to move his/her limbs, this condition is caused due to the partial fusion of vertebrae, which leaves the person crippled for the rest of their life. Skeletal fluorosis also has several neurological manifestations. Sclerosed vertebral column and ossified ligaments (osteophytosis) lead to mechanical compression of the nerve roots and the spinal cord, a condition known as radiculo-myeopathy.[5] Non-skeletal manifestations of fluoride include cardiotoxicity, neurotoxicity, endocrine dysfunction, hepatotoxicity, and nephrotoxicity.[6]

According to the American Dental Association (ADA), children begin to develop teeth by the age of 6 months.[7] The risk of dental fluorosis usually is confined to children of age 6 months to 8 years, as this is the period when growth of permanent teeth takes place under the gums.[8,9] Dental fluorosis cannot develop after the formation of permanent teeth, thus adult cases of dental fluorosis have had their exposure to excess amount of fluoride during their childhood (i.e. during their teeth formation age).[8]

The WHO 1984 guidelines on quality of drinking water suggested that countries with warm climatic conditions should have the optimal fluoride concentration below 1.0ppm/l in drinking water. The current recommended standard for artificial fluoridation in the United States (US) in community water systems should be 0.7ppm/l. This level prevents the risk of tooth decay and dental fluorosis.[10] However, these values vary across countries. Acceptable levels depend on the climate, volumes of water intake, and other sources of fluoride intake.[11] In India, the level of fluoride in drinking water is considered acceptable if it is below 1.5ppm/l with the benefit range for preventing dental fluorosis ranging from 0.8 ppm/l to 1.2ppm/l.[11,12]

Fluoride in safe amounts is proven to prevent and control dental cavities, both in children and adults.[8] Research have shown that there is a decrease in caries rate among school children in the US, and this can be attributed to the consumption of community fluoridated water.[13,14] The mechanism of fluoride in protecting the teeth from dental caries is that it inhibits the enzymes produced by oral bacteria that erode tooth enamel.[12] So consuming fluoride in optimal level is necessary to develop healthy dentition.

Naturally or artificially fluoridated drinking water is the main source of fluoride. Beverages and foods prepared with fluoridated water and dietary prescription supplements with fluoride (fluorical tablets, chewable fluoride drops) are also sources of noticeable amounts of fluoride.[8] Ingestion of fluorine containing toothpaste by children over a long period of time can also cause dental fluorosis. Professional products used in dentistry such as mouth rinses, gels, and foams are other potential sources of fluoride.[8] Fluoride is also found in infant formulas, which can cause fluorosis in infants.[15] Another source of fluoride exposure in India is the consumption of locally available foods such as rice, millets, pulses, sorghum, vegetables, milk, fish, chicken, eggs, meat, betel vine, tea, and sea salt.[16]

Situation worldwide

Many countries have water containing fluoride naturally. Those are Syria, Jordan, Egypt, Algeria, Turkey, Sudan, Libya, Kenya, Iraq, Iran, Afghanistan, Thailand, China, Japan, and the United States.[2] According to the US Centers for Disease Control and Prevention (CDC) data, 74.6% of the US population or a total of 210,655,401 people, had access to fluoridated water in 2012. Other countries that have artificial fluoridation of drinking water are Australia (80%[i]),

[i] The numbers in brackets denote the percentage of population consuming artificially fluoridated water in the respective countries.

Brunei (95%), Chile (70%), Guyana (62%), Hong Kong (100%), the Irish Republic (73%), Israel (70%), Malaysia (75%), New Zealand (62%), Singapore (100%) and the United States (64%). Globally, 377,655,000 million people drink water that is artificially fluoridated, this forms 5% of the world's total population.[17] A study reported that 22.6% of the adolescents in the United States ranging from the age 12-15 years were identified with dental fluorosis in 1986-1987.[18] During 1999-2004, the percentage increased, and about 40.7% of adolescents in the US in the same age group had dental fluorosis.[18]

According to the UNICEF, fluorosis is endemic in at least 25 countries.[12] Although the exact number of people affected is not known, it is expected to be in the tens of millions worldwide.[12] Tea also contains fluoride. Hence, consumption of tea during infancy is known to cause dental fluorosis. A national longitudinal study of children in Ireland during 2010 reported that 8% of infants were given tea during nine months of age.[6] Fluoride can pass the placenta, therefore, excess fluoride during pregnancy can accumulate in the fetal brain and causes neurogenic disorders.[6] The Nuclear Regulatory Commission (NRC) reported that even in the absence of fluoride consumption from other sources, consuming water with fluoride level of 1.0 ppm/l, fluoride deposits in the bone can reach about 2500mg/kg in two years and in long term consumption can reach a level of about 3000 to 4000 mg/kg.[6] Owing to the effects caused by high fluoride consumption, artificial fluoridation of water is not accepted in many countries including Austria, Belgium, China, Czech Republic, Denmark, Finland, France, Germany, Hungary, India, Israel, Japan, Luxembourg, Netherland, Northern Ireland, Norway, Scotland, Sweden, and Switzerland.[19] There has been no study investigating the economic losses due to fluorosis.[20] However, some studies conducted among children have shown that fluorosis can cause embarrassment for school aged children if left untreated. It can also cause psychological

stress, damage self-esteem and affect the quality of life significantly.[21] Crippling disease affects the working force and this is an indicator for considerable economic loss.[20]

Appraisal of different strategies: Methods of treating fluoride in drinking water

Defluoridation and provision of alternate drinking water through pipelines are among currently employed strategies for treating the fluoride content in drinking water.[22] There has been a significant reduction of fluorosis incidence in China and the United States following the provision of alternate water source.[23,24] Bone-meal and bone-char methods were used in the Ethiopian region, and efficient reduction of fluoride concentration from 6ppm/l to 0.1ppm/l was noted. However, these methods were not accepted as the treated water had an unpleasant taste, moreover, religious consideration has been another factor restricting use of this method.[22] Flocculation is a defluoridation method used widely in which the water is mixed with few coagulant chemicals thoroughly stirred, after a maximum of two hours, the flocs which are heavier than water sediments in the base of the container, a tap which is fixed above a level of 5 centimeters, is then used to drain water from the container and stored separately, which is later used for drinking and cooking purpose.[12] Filters containing several herbal plants have been proved to be an inexpensive defluoridation method, the percentage of fluoride removal increases with the adsorbent dosage, but the fluoride removal efficiency decreases with increasing initial fluoride ion concentration.[25]

Adsorption is another very common method for defluoridate. In the adsorption method, a filter is used which absorbs fluoride, and makes the water safe for drinking. The adsorption method can be used to treat both community and household water. However, since the used filter

columns contain a high concentration of absorbed fluoride, a careful disposal of these filters is crucial.[12] Fluoride adsorbing clay filters are also effective for treating water fluoride content.[20] Rain water harvesting method should also be encouraged as it dilutes the content of fluoride present in the soil.[9]

Situation in India

The earth's crust has a total fluorine deposit of 85 million tons, out of which 12 million is found in India.[26] Fluorosis is considered to be endemic in 17 states of India.[27] It is estimated that about 62 million people in India are at risk of developing fluorosis from drinking high fluoride containing water. About six million children below the age of 14 years are affected.[28] Reliance of a majority of the population on surface water for consumption and their day to day activity is an important factor contributing to the disease burden. In many places of India, the ground water has high fluorine content.[29] A study conducted in India showed that risk of dental fluorosis is high in areas where the water has high fluoride content.[30]

Flocculation and adsorption methods have been used in various states of India including Nalgonda and Andhra Pradesh, where fluoride level in water is above the permissible levels.[12] In this method, the groundwater collected for usage is treated with alum (hydrate aluminium salts), which flocculates the fluoride ions that are present in the water.[12] Also check dams used in the state of Andhra Pradesh proved to be effective in diluting fluoride concentration in ground water.[31] These check dams were structures designed to harvest rain water, which provided and alternate source of drinking water.[32]

Situation in Tamil Nadu

Tamil Nadu, located in the southern region of India, is bordered by the Indian Ocean in the south, and Bay of Bengal in the east. It is the eleventh largest state in the country, with a population of 72 million (2011). Agriculture is considered to be one of the main occupations till date, with 43% relying on rain fed cultivation and the remaining 57% depending on irrigation (Tamil Nadu Agriculture and Animal Husbandry). According to the 2011 census, Tamil Nadu has 32 districts.[33]

A study conducted in the Southern state of India, Tamil Nadu identified the correlation between daily intake of fluoride and dental fluorosis[9] through examining every possible source of fluoride that was consumed by the local people including drinking water, staple food grains, green leafy vegetables, cow milk samples, and cooked rice[9]. This study identified that the age group 10 to 18 years were exposed to high amount of fluorosis through consuming various dietary sources rich in fluoride.[9] These sources included drinking water, cow's milk, grains, greens, and rice.[9] The level of fluoride obtained from these samples tested were found to be higher than the permissible level (1.5ppm/l) determined by Institute of Medicine, Washington, DC.[9] Among the drinking water samples tested for fluoride, 14% of them showed to have levels above 3ppm/l and 86% had fluoride levels above 1.5ppm/l, which were higher than the permissible levels. Based on a study conducted in KanyaKumari district of Tamil Nadu, lack of knowledge about the effects of fluorosis, negligence, careless attitude and lack of good quality drinking water along with the geological conditions of the areas aggravates the sitaution.[34] Educating the population about the adverse effects of high fluoride exposure can reduce the risk of fluorosis. With the aim to tackle this situation, the Government of India has initiated the National Program for Prevention and Control of Fluorosis, with educating people as its main

goal.[35] Other than educating, and providing knowledge, steps planned should be executed by the Tamil Nadu State Government to address this situation. Fluorosis education programs are being conducted in two districts of the state.[36] Although there are other districts affected by high concentrations of fluoride in drinking water, they are not included in any education program. According to a water analysis report, there are 10 districts in Tamil Nadu with 0% fluoride contamination, 20 districts with <5% contamination, and one district with 5% to 10% of fluoride in sources collected from drinking water.[36] At the time of the report the Tamil Nadu state had 31 districts.

The water quality analysis report of two districts in Tamil Nadu (Dharmapuri and Krishnagiri) shows the concentration of fluoride in ground water in many parts of these districts to be in the range of 1.5mg/l to 12.4mg/l.[37] Due to the consumption of fluoride contaminated water over a prolonged period, people living in these districts are suffering from skeletal fluorosis, dental fluorosis, non-skeletal manifestation or combination of the above.[37] To overcome this situation the Government of Tamil Nadu has started the Hogenakkal Water Supply and Water Mitigation Project in 2008, which includes a water treatment plant, water supply, and fluorosis awareness programmes conducted in two districts.[37]

A recent study[9] conducted in Dindigul district, an administrative region in the southern part of Tamil Nadu, found that the water samples collected from 22 villages had fluoride concentration of more than 1.5mg/l in drinking water.[9] Among these 22 villages, Akkarakaranpatti, Silukuvarpatti and Thoppinayakkanpatti had water samples with more than 3.0ppm/l of fluoride. Fourteen percent of the water samples tested from these villages contained more than 3.0mg/l of fluoride and the remaining 86% showed to have more than 1.5mg/l of fluoride.[9] The highest

level of dental fluorosis was identified among adult population in both Akkarakaranpatti (82.4%) and Thoppinayakanpatti (81.8%).[9]

Project's aims and objectives

Since there is lack of knowledge about fluorosis, it is essential to educate children about the effects of dental and skeletal fluorosis. The main concern here is to enlighten the children about the mechanism of fluorosis, how it affects the teeth and also the bones so that future cases of fluorosis will reduce significantly. They should know that long term exposure to excess amounts of fluoride from different sources will cause life-long impairment of bones and will finally result in deformities. Although Tamil Nadu Water Supply and Drainage Board report shows that there is 0% fluoride content in 10 districts[36], a cross sectional study conducted in Kancheepuram district of Tamil Nadu, a region considered non endemic for fluorosis, showed the prevalence of dental fluorosis to be 19.2% among the 348 school children included in the study.[38] After excluding the two districts where an education program by the Tamil Nadu government is already being conducted, 10 randomly selected districts from the remaining 30 districts will be included in the proposed program.

The proposed program has the following objectives:

- Educating children (10 to 16 years old) about fluorosis and its effects in 5 districts of Tamil Nadu, with the other 5 districts as the control group.
- To increase the mean knowledge percent score about fluorosis by 20% (absolute increase) from the baseline by the end of the education program in the intervention group.

Evaluation of the education program after its implementation in both intervention and control districts using pre-intervention and post-intervention surveys.

Methodology

Program Implementation Plan

In order to implement the education program 10 randomly selected districts out of the 30 districts will be randomly assigned to intervention or control groups using block randomization with two districts in each block. In order to evaluate the program, a block will randomly chose at a time. In each selected block a sample of students from intervention and control group will receive the pretest, after which the intervention district will alone receive the education program for 2 months. Finally, the posttest will be provided to the students in both district (intervention and control districts within each selected block). The education program will be conducted in the respective school lecture halls or classrooms, after obtaining permission from the school administration. Students who provide assent will be included in the program, and consent will be obtained from their parents. Students will be provided subject id according to their attendance order obtained from the school register. This will make the identification of participant during posttest much easier. The education program will be conducted as sessions, which will last up to two hours, and will be conducted only during allowed weekdays.

The timeline for the program was framed after considering examination periods and holidays. The materials used for education include details on causes and prevention of fluorosis, its effects on human body, and also dietary regulations that should be followed. Booklets with the above mentioned information will be provided to children in the intervention group after the education session. As many factors such as consumption of water with fluoride, using toothpastes with

high fluorine content, improper brushing of teeth, and malnutrition can lead to dental fluorosis, and consuming high fluoridated water for long period can result in skeletal fluorosis it is necessary to educate children about regulating their diet and oral hygiene.

After the implementation and evaluation of the program in the selected bock, the same process is repeated in the next randomly selected block, until all blocks are covered. After the completion of the 5 blocks the collected data will be analyzed and summarized, and if significant results are obtained, a state wide education program will be recommended.

Since the target population is children from 10 to 16 years old, schools with primary (classes 1 to 5th) upper primary (classes 6th to 8th), secondary (classes 9th and 10th) and higher secondary education (classes 11th and 12th)[39] will be selected. The number of children based on census of 2011, for age group 10 to 14 is 6,177,547 (rural – 3,325,160) and 15 to 19 is 6,253,792 (rural – 3,373,098).[40] These students are recruited in government, private aided, and private unaided schools.[41] Since children from rural areas are more susceptible to develop fluorosis only students from rural schools will be included in the proposed program.

Inclusion criteria will be:

- Schools in rural areas of the districts
- Schools willing to participate in the program, students and parents who provide consent for participation
- Schools with primary, upper primary, secondary and higher secondary education (with students 10 to 16 years).

In each block the pretest and posttest along with the education program (only in the intervention district) will end by 2 months.

Program Evaluation Plan

We will sample from the selected 10 districts (5 blocks) to evaluate the program, (5 districts from intervention group and 5 from control group). The sampling method used for the evaluation of the education program is multistage clustered random sampling, with the schools being the sampling unit within the districts and students being the sampling unit within the schools. The program will start in January 2017 and end by December 2018. From January 2017 to April 2017 is the planning phase, where officials and schools administrations are contacted, meetings are conducted in schools for parents to obtain their consents, and training of trainers and their recruitment is done. From June 2017 to August 2018 the implementation and evaluation of the program among 5 blocks will be done.

A validated pre-post-test interviewer administered questionnaire will be used among the children aged 10 to 16 years to assess the mean percent knowledge. Completion of the questionnaires will take about 20 minutes. In the 5 intervention districts the pretest will be followed by the education program, and at the end of two months a posttest will be conducted among the initially selected sample of students who participated in the pretest. Within each block, each control district will have the pretest and posttest at the same time as administered in the intervention district.

Evaluation question: After the implementation of a fluorosis education program in the intervention group, will there be a 20% absolute increase from the baseline in mean knowledge percent in the intervention group when compared to the control group?

Hypothesis: There is an increase of mean knowledge percent by absolute 20% from the baseline (June, 2017) in the intervention group after the implementation of fluorosis education program.

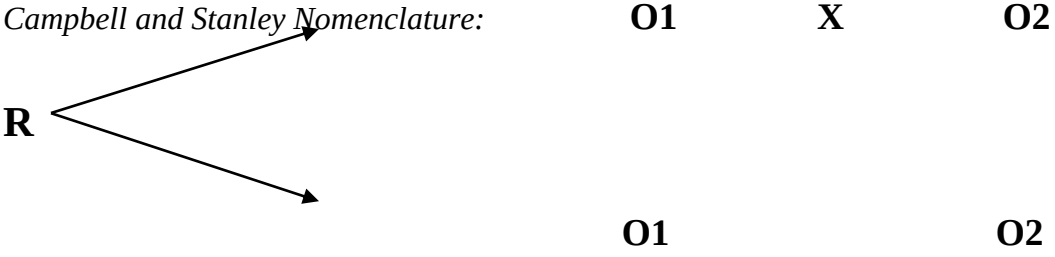
Null hypothesis: There is no increase in mean knowledge percent between the intervention and control group students.

Independent variable: Presence of fluorosis education program.

Dependent variables: Mean knowledge percent of fluorosis.

Evaluation design: The design more appropriate for this study will be multistage clustered random sampling using pre-post-test. Because fluorosis is present in almost all districts of Tamil Nadu it is necessary to have a control group to assess if the knowledge increase in the intervention group is due to the fluorosis education program.

Campbell and Stanley Nomenclature:



Where,

O_1 is the pretest conducted in both intervention and control groups.

O_2 is the posttest conducted in both intervention and control groups.

R is the randomization (random assignment to the intervention or control groups).

X is the intervention (fluorosis education program) conducted in the intervention group alone among the 5 blocks.

Sampling method: We will use multistage clustered random sampling to evaluate the education program. In the first stage of sampling, the schools from the 10 districts will be randomly selected, followed by the second stage where random selection of students from the previously

selected schools will be done. In the first stage, the schools are the sampling unit and in the second stage students are the sampling units. The data source used will be the list of schools obtained from the directorate of education board, the schools which did not participate in the education program will be excluded from the list. Among the selected 10 districts 5 schools from each district will be chosen randomly to evaluate the education program. After considering design effect and attrition a sample size of 1272 was obtained.

Sample size: The sample size for evaluating the program is calculated using the reference obtained from previous study for comparison of two sample means.

The formula used to calculate the sample size is,

$$N= (Z_{\alpha/2} +Z_{\beta})^2 \text{ x } 2 \text{ x } \sigma^2 / d^2$$

Where, $Z_{\alpha/2} =1.96$

$Z_{\beta} = 0.84$

$\sigma = 3.4$ and

$d = 0.20$ (20%).

The calculated sample size for evaluation $N_1= 884$

The final sample size after design effect and attrition $N_2= 1272$.

So from each district we need a sample of 128 children. A total of 5 schools within each districts will be selected with further 26 students elected within each of the schools to obtain a sample of 128 students within each district.

Threats to internal validity:

History: This is considered a threat since there might be other interventions taking place during the same time of fluorosis education program.

Maturation: Since the study population is the student population, normal changes that occur during the education program can affect the results, hence maturation is also considered as a threat. However, given the information obtained through the control group, such a threat can be identified and controlled.

Testing: Testing is a threat which can be controlled, but not avoided. Since the pre and posttest questionnaires are the same, the changes may be seen in control group, but this can be controlled.

Experimental mortality: As this study is a voluntary one, subjects are free to exclude themselves from the education program, which makes this a threat to internal validity.

Selection interactions: Since students are from different schools, there might be chances to interact among themselves during vacations, as children travel to native regions during vacations which can cause a change in knowledge assessed. Hence it is considered a threat.

Threats to external validity:

Reactive effects of experimental arrangements: This is considered a threat as students might try to improve their knowledge in different ways, just because they know they are evaluated but can be controlled as it would be the same among both groups.

Testing/Intervention interaction: The change in knowledge mean score may be due pretest and intervention and not the education program alone. There might be an interaction between the education program and the tests, hence, this can be a potential threat to the program's generalizability in the absence of the evaluation/testing.

Questionnaire

The questionnaire will contain questions adapted from previous studies and contains questions to assess information on demographics (age, sex, educational qualification, employment status, resident district) questions about oral hygiene and questions on knowledge of fluorosis, alternate sources of water, methods of defluoridation are present in the questionnaire[42,43]. The questionnaire will be interviewer administered.

Budget

Considering the vast geographical area, population, time duration for which the education program will be conducted, the budget has been framed accordingly. The budget is framed based on personnel and operational costs. Nationwide program is used for reference while framing the budget approximately for the salaries of staffs.[35]The personnel costs will include salary for the project coordinators, dentists, supporting staff (interviewers, data analysts, transport staff (drivers). The operational cost includes office room rent, office supplies, communication costs (landline phones and internet) paper costs and printing costs. The total amount quoted for personnel cost is 18,050,000Indian Rupees (INR), and 128,202,519 Armenian Drams (AMD). The amount quoted for operational cost is 2,848,000 INR, and 19,994,912AMD. Except for the first four months which has only planning phase, the salary for the staff are calculated on monthly and weekly bases. Since the population in each district has huge variations, the materials to be printed will be obtained after acquiring details from the Education board of Tamil Nadu.

Ethical considerations

The evaluation plan satisfies the Institutional Review Board requirements of the American University of Armenia. Participation in the program evaluation is voluntary. Confidentiality will be respected and oral assent will be obtained from the students, and consent from the parents. Participants will be informed about voluntary involvement in the program and their rights to withdraw at any moment after informing the coordinator of the program. Students will be informed that participation in the program evaluation will not affect their grades or classes. Consent from parents and assent from children will be obtained. Since this is a project based on education all willing members will be included in the project, favorable time for students to participate will be decided after discussions. After the completion of the program, since it is not ethical to leave the control group uneducated, education will be conducted for the control group.

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Appendix:

Appendix 1:

Survey Questionnaire:

Questionnaire: English version

Subject ID:

DD MM YY:

Instructions: Please read the questions and check the most appropriate option with a (✓) mark.

Demographic data:

1. Gender a) Male b) Female.

2. Date of birth: ----------

A. Oral hygiene practices:

1. Have you suffered from any teeth or mouth problems in the last one year?
    a. No (if no, please go to q.no.3)
    b. Yes
    c. Don't know.

2. If yes, what were or was the problem?
    a. Dental decay
    b. Gum diseases

c. Foul breath

d. Trauma

e. Abscess

f. Crooked teeth

g. Ulcer

h. Others_____

3. What is the source of water that you and your family uses for drinking?

a. Bore well or hand pump water

b. Can water

c. Corporation water or tap water

d. Water from river, lakes or ponds.

e. Others_____

B. Knowledge of fluorosis:

4. Does water contain minerals and salts needed for the formation of healthy teeth and bones?

a. Yes b. No c. Don't know

5. Does long term consumption of water with high amount of minerals and salts causes health effects.

a. Yes b. No c. Don't know.

6. Do you think fluoride cleans the teeth?

a. Yes b. No c. Never noticed.

7. Do you think fluoride makes tooth enamel more resistant to decay?

a. Yes b. No c. Don't know.

8. Do you think high fluoride in drinking water can also cause discoloration of teeth when consumed over years.

a. Yes b. No c. Don't know.

9. Does drinking water with high fluoride content can damage your bones and cause mobility disorders?

a. Yes b. No c. Don't know.

10. Does anyone else in your family have discolored or stained teeth?

a. Yes b. No c. Don't know.

11. Do you think fluoride is an essential nutrient for bones and teeth?

a. Yes b. No c. Don't know.

12. Do you think changing your water source will improve your oral health?

a. Yes b. No c. Don't know.

13. Is water treatment (chlorination) done periodically in your water source?

a. Yes b. No c. Don't know.

14. Do you know any defluoridation methods that are available?

a. Yes (if yes, please mention) b. No c. Don't know.

Appendix 2:

Survey Questionnaire

Questionnaire: Tamil version தமிழ் வினாதொடர்:

அடையாள எண் :

தேதி:

வழிமுறைகள்: கேள்விகளை படித்தப்பின் விடையினை (✓) கொண்டு குறிக்கவும்.

1.பாலினம்: ஆண் பெண்

2.பிறந்த தேதி: ----------

அ) பல் மற்றும் வாய் சுகாதாரம் :

1. கடந்த ஒரு வருடத்தில் ஏதேனும் பல் அல்லது வாய் சமந்தப்பட்ட பிரச்சனைகள் ஏற்பட்டுள்ளதா?

அ. இல்லை ஆ. ஆம் இ. தெரியவில்லை

2. ஆம் என்றால் என்ன பிரச்சனை?

அ. பற்சொத்தை

ஆ. ஈறுகளில் பிரச்சனை

இ. வாய் துர்நாற்றம்

ஈ பல் அல்லது வாயில் காயம்

உ. வாயில் கட்டி அல்லது சீழ் வடிதல்

ஊ. சீரற்ற பற்வரிசை

எ. வாய்புண்

ஏ. மற்றவை----------

3. நீங்கள் மற்றும் உங்கள் குடும்பத்தார் பயன்படுத்தும் குடிநீரின்

ஆரம்ப நிலை அல்லது உற்பத்தி ஸ்தானம் எது?

அ. குழாய்க்கிணறு / ஆழ்துளை கிணறு

ஆ. பதப்படுத்தபட்டு வழங்கப்படும் குடிநீர்

இ. வடிகுழாய் நீர் / நகராட்சி வழங்கும் குடிநீர்.

ஈ. ஆறு / நதி / குளம்.

உ. மற்றவை.

ஆ. ப்லுஒரொஸிஸ் சார்ந்த கேள்விகள்:4. ஆரோக்கியமான எலும்புகள் பற்கள் உருவாக தேவையான தாது கனிமங்கள் மற்றும் தாது உப்புகள் தண்ணீரில் உண்டா?

அ. ஆம் ஆ. இல்லை இ. தெரியவில்லை.

5. அதிக அளவு தாது கனிமங்கள் மற்றும் தாது உப்புகள் உள்ள குடிநீரை நெடுங்காலம் உட்கொள்வது உடலுக்கு கேடு விளைவிக்கும்.

அ. ஆம் ஆ. இல்லை இ. தெரியவில்லை.

6. புளோரைட் உப்பு பற்களை சுத்தம் செய்யுமா?

அ. ஆம் ஆ. இல்லை இ. தெரியவில்லை.

7. புளோரைட் உப்பு பல் எனாமலை சிதைவில் இருந்து பாதுகாக்கிறதா?

அ. ஆம் ஆ. இல்லை

8. அதிக அளவிலான புளோரைட் உப்பு உள்ள குடிநீரை பல ஆண்டுகள் குடிப்பதால் பற்களில் நிறமாற்றம் ஏற்படும்.

அ. ஆம் ஆ. இல்லை இ. தெரியவில்லை

9. அதிக அளவிலான புளோரைட் உப்பு உள்ள குடிநீரை குடிப்பதினால் எலும்புகளுக்கு சேதம் மற்றும் உடல் இயக்கம் சீர்கேடு ஏற்படும்.

அ. ஆம் ஆ. இல்லை இ. தெரியவில்லை

10. தங்கள் குடும்பத்தில் வேறு யாருக்கேனும் பற்களில் நிறமாற்றம் உள்ளதா?

அ. ஆம் ஆ. இல்லை இ. தெரியவில்லை

11. வலுவான பற்கள் மற்றும் எலும்புகள் உருவாக புளோரைட் சத்துஅத்தியாவசியமானதா?அ. ஆம் ஆ. இல்லை இ. தெரியவில்லை

12. தங்கள் குடிநீரை மாற்றினால் பல் மற்றும் வாய் ஆரோக்கியம் கூடும் என்று கருதுகின்றீர்களா?

அ. ஆம் ஆ. இல்லை இ. தெரியவில்லை.

13. தங்கள் குடிநீரில் அவ்வப்போது குளோரின் உப்பு சேர்க்கப்படுகின்றதா? அவ்வப்போதது நீர் ஆராயப்படுகின்றதா?

அ. ஆம் ஆ. இல்லை இ. தெரியவில்லை.

14. குடிநீரில் உள்ள புளோரைட் அளவை குறைக்க பல்வேறு முறைகள் உள்ளதா?

அ. ஆம் (என்றால் குறிப்பிடவும்) ஆ. இல்லை இ. தெரியவில்லை

Appendix 3:

Education materials

Outline:

1. Causes of Fluorosis, symptoms and preventive measures[35]
2. Food/Dietary recommendations[35]
3. Methods for testing skeletal fluorosis.[35]
4. Pictures differentiating dental fluorosis and other dental diseases.[35]

Appendix 4:

Time line:

Year/Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
2017	Planning				-	*	*	*	-	*	*	-
2018	*	*	-	-	-	*	*	*	Analysis and final report			

*	Pretest and Posttest in intervention and control sample districts, with education program only in intervention districts
-	Examination period and vacations

Appendix 5:

Program Team Members:

• Program coordinator:	Conduct training session for the interviewers in administering questionnaires, and data collection and entry using relevant education materials.
	Conduct meetings in schools with teachers and school headmasters/mistress to obtain consent for the program implementation. Select suitable time and place for conducting education program in schools. Maintain reports of the data collected in each visit to the site.
• Trainers (Dentists):	Educate the fieldworkers using the materials provided. Provide suggestions to the field workers and clarify doubts if any.
• Team workers/staffs (Dental college students, medical staffs, volunteers with at least 2 years undergraduate degree in any field, Non-Governmental Organization workers)	Educate the students with the materials provided. Administer pre and posttest questionnaires. Receive baseline data from students and send it to program head office.
• Data entry staff:	Receive data from the program leader. Check data for any mistakes in the data submitted. Careful entry of data, and maintain it. Regular updates of data entered to be made to the program coordinator.

Appendix 6:

Budget:

Personnel fee:

Budget item	**Type of appointment**	**Number of units**	**Amount (INR)**	**Total (INR), (AMD)**
Project coordinator *	Fixed monthly	a.5 (Intervention) b.5 (Control)	a.60000 per month b.30,000 per month	a.1,800,000 INR & 12,785,147 AMD b. 300,000 INR & 2,130,857 AMD
Dentist ◊ (*Trainers of program*)	Fixed for each training session	5 (Dentists)	5000 /session per dentist(5 sessions)	50,000 INR & 351,047 AMD
Supporting staffs• (*Interviewers, field workers, paramedics, dental students*)	Fixed monthly	a.150 (per intervention district) b.26 (total for all control districts)	a.40,000 per month, per intervention district. For 2 months= 80,000 per person. b.30,000 per person for one control district covered.	a.12,000,000 INR & 85,234,316 AMD b.3,900,000 INR & 27,701,152 AMD

				Total: 15,900,000 INR & 112,935,469 AMD
Supporting staff ◙ (*Data entry and data cleaning, data analysts*)	a. Fixed hourly b. Fixed monthly	a.10 (data entry) b.2 (data analysts)	a. 2500 per person for each district b. 20,000 per person	a.2,50,000 INR & 1,775,714 AMD b. 80,000 INR & 568,228 AMD Total: 330,000 INR & 2,346,298 AMD
Supporting staff □ (*Transport compensation for conducting survey*)	Fixed monthly	a.5 (intervention district) b.1 (control district)	a.20,000 per month. For 2 months = 40,000 INR b.15,000 per month. (5 control districts)	a.1,000,000 INR & 701,413 AMD b.75,000 INR & 532,714 AMD Total: 3075000 INR & 21,841,293 AMD
			Total	18,050,000 INR 265,995 USD 128,202,519AMD

*=

a. Intervention group

5 coordinators (1 for each intervention district)

1 district = 2 months

1 month salary = 60,000 INR

So, for 5 staffs for 2 month each = 5* 120,000 = 1,800,000 INR

b. Control group

5 coordinators (1 for each district)

1 district = 2 months

1 month salary = 30,000 INR

So, for 5 staffs for 2 month each = 5*60,000 = 300,000 INR.

◊=

1 session = 5000 INR, for each dentist, total dentists = 5

5 sessions = 5*10,000 = 50,000 INR

●=

a. Interviewers (Intervention group)

150 per district (5 districts)

For 2 months = 80,000 INR per staff

For 150 staff, = 12,000,000 INR

b. Interviewers (Control group)

26 staffs (for all 5 districts, same interviewers)

5 districts (control group)

For 1 district covered during pretest and posttest = 30,000 INR

For, 5 districts = 5*26*30,000 = 3,900,000 INR

◙ =

a. Data entry staff = 10 nos.

1 district = 130 questionnaires collected.

1 staff = 13 questionnaires to complete

1 district covered = 25,000 INR per staff

For 10 staffs, 5*25,000 = 250,000 INR

b. Data analysts = 2 nos.

1 month = 20,000 INR

Total analysis period = 2 months

So, total = 2months* 2 staffs* 20,000 INR = 80,000 INR

□=

a. Intervention districts (5)

Transport staffs = 5 nos.

Per month per staff = 20,000 INR

Total period of transport for 1 district = 2 months

So, for all 5 districts = 5*5*20,000*2 months = 1,000,000 INR

b. Control districts (5)

Transport staff = 1 no.

Per month = 15,000 INR

For 5 districts = 5*15,000 = 75,000 INR

Administrative costs:

Budget item	**Type of appointment**	**Number of units**	**Amount (INR)**	**Total (INR)**
Office room rent[Δ]	Monthly (full time)	10 rooms(5 intervention & 5 control) one per district	12,000 per month (total 18 months)	2,160,000 INR & 15,164,687 AMD
Office supplies	NA	NA	NA	400,000 INR & 2,808,196 AMD
Communication costs[❖] (Landline phone, Internet)	Monthly (full time)	20 (5 intervention & 5 control)	6000 per month (10 months for program and 8 months for planning and reporting)	108,000 INR & 758,258AMD
Paper cost and Printing cost.	NA	NA	NA	180,000 INR& 1,263,771AMD
			Total	2,848,000INR 41,938USD 19,994,912AMD

Δ =

Total months = 12 months

Per month per room = 12,000 INR

Total = 10*12*12000 = 2,160,000 INR

❖ =

Per month = 6000 INR

Total months = 18 months

Total = 60,000 (6000*18 months)

= 108,000 INR

Appendix 7:

Evaluation sample: