EFFECT OF TWO COMMERCIALLY AVAILABLE FLUORIDATED DENTIFRICES ON THE RISK FACTORS OF DENTAL CARIES AMONG INSTITUTIONALIZED GERIATRIC POPULATION IN CHENNAI CITY – AN INTERVENTIONAL STUDY

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MASTER OF DENTAL SURGERY

BRANCH VII

PUBLIC HEALTH DENTISTRY

MAY 2018

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Dr. P. D. Madan Kumar, MDS, aged 39 years, working as Professor and Head of the Department of Public Health Dentistry at the college, having address at Department of Public health dentistry, Ragas Dental college and hospital, (herein after referred to as the 'Researcher and Principal investigator')

And

Dr.B.Arthi, aged 34 years, currently studying as Post Graduate student in the Department of Public Health Dentistry (herein after referred to as the 'PG/Research student and Co- investigator').

Whereas the 'PG/Research student as part of his curriculum undertakes to research on the study titled **"Effect of two commercially available fluoridated dentifrices on the risk factors of dental caries among institutionalized geriatric population – An interventional study"** for which purpose the Researcher and Principal investigator shall act as Principal investigator and the College shall provide the requisite infrastructure based on availability and also provide facility to the PG/Research student as to the extent possible as a Co-investigator

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Truly,

B. Arthi

Dr.B.Arthi

INTRODUCTION

Ageing is a natural process. Old age should be regarded as a normal, inevitable biological phenomenon.[1] A demographic revolution is happening throughout the world. Since the beginning of recorded history, young children have outnumbered their elderly. However, in about five years' time, it is projected that the number of people aged 65 years or older will outnumber children under age 5 years. Globally the number of people aged 65 years or older is projected to grow from an estimated 524 million in 2010 to nearly 1.5 billion in 2050, with most of the increase in developing countries.[2] Currently, India is the second largest country in the world next to China, sharing a significant proportion of this growing elderly population with 100 million aged people. The absolute number of the elderly population in India which was around 77 million in 2001 is projected to increase around 137 million by 2021.[3] When the percentage of working people in the total population is high it indicates that more people have the productivity potential and contribute to economic growth of the country, which is termed as demographic dividend. Since it was projected that the number of the elderly population (dependent) in India will increase by 2021, there may be a decrease in demographic dividend in near future.[3]

The ages of elderly population is nearing or surpassing the average life span of human beings. Government of India has adopted "National Policy on Older Persons" in January, 1999. The policy defines "senior citizen" or "elderly" as a person who are of age 60 years or above.[4] A few unique facts regarding the elderly population in India include the following,

1. The rate of growth of the elderly population is faster than that of the general population
2. There is a larger proportion of women among the elderly (52% of the >60 years and >55% of the >80 years age groups)
3. Eighty per cent of the elderly population resides in rural areas
4. Nine per cent of the elderly live alone or with persons other than their immediate family members
5. Nearly 75% of the elderly are economically dependent, with little difference between the urban and rural elderly
6. Three-fourths of the dependent elderly population are supported by their own family members

7. Thirty per cent of the elderly are below the poverty line. Only 53.5% of the urban elderly and 37% of the rural elderly possess some kind of financial assets

8. Only 28% of the elderly population are literate (lower when compared with the national average).[5]

Decrease in the mortality rate and increase in the average lifespan of the elderly population in most parts of the world is because of discoveries in medical science and improving social conditions. This is called "graying of the society or global graying."[6] The global increase in the older age group population has led to increase in the number of old age homes or residential homes for geriatrics. Old age homes or residential homes are geriatric long care facilities which provide supervision and assistance in activities of daily living with medical and nursing services when required.[7]

Of many issues concerning the welfare of elderly, health is one of the major concerns. This demographic change will have a major impact on the delivery of health care, as well as on the providers of these services especially on general and oral health. Some older adults have physical and/or psychological conditions that require special attention on the delivery of health care. The study of the physical and psychological changes which is incident to

old age is called gerontology and care of aged is called clinical gerontology or geriatrics.[8]

The most common diseases seen in elderly are cardiovascular diseases, diabetes, respiratory diseases, blood dyscrasias, nutritional deficiencies, physical and mental disabilities and other systemic diseases. The presence of these systemic diseases not only influences the patient's ability to maintain oral hygiene and promotion of oral health, but can actually be related to the occurrence of certain oral diseases. Oral health in the elderly contributes significantly towards the quality of life. Poor oral health, including dental caries, periodontal disease, and loss of teeth can adversely affect the dietary intake and nutritional status and thereby compromise general health.[9]

There are about three segments of elderly population such as 1) People aged 65-74 years are the new or young elderly who tend to be relatively healthy and active; 2) People aged 75-84 years are the old or mid-old, who vary from those being healthy and active to those managing an array of chronic diseases; 3) People 85 years and older are the oldest-old, who tend to be physically frailer. This last group is the fastest-growing segment of the older adult population which has to be taken into account when planning treatment for senior persons.

Thus, a complete understanding of the chronic diseases the elderly lives daily is needed, as this play a critical role in the acceptance and success of the treatment plans.[10]

Oral health is vital to the general health and well-being of humans. The mouth reflects a person's health and well-being throughout life. Oral and general diseases share common risk factors, thus it is important to examine the interplay of general diseases with oral disease, and their combined impact on overall health among older adults as the risk of chronic conditions increases with age.[11] A cross-sectional survey of 5,061 elderly residents in urban Nagpur, India revealed that 43.2% of the study participants aged 60 years and above had dental caries, 34.8% had periodontal disease, 24.2% had dento-facial anomaly, 18.7% had enamel disorders, and 7.1% had oral mucosal lesions.[12] A National Oral Health Survey among 18,233 elderly subjects in 19 states of the rural and urban parts of the country reported a prevalence of 85% and 80% among the 65–74 years old for dental caries and periodontal disease respectively.[13] A survey conducted among all the institutionalized elderly in urban Delhi, found that 39.2% of the elderly were edentulous, 44.9% had decayed teeth and 57.9% had deep periodontal pockets, as high as 78.5% required dentures and 38.3% required either extraction or pulpal care.[14] Thus, the available data suggests that the Indian geriatric population has poor oral health with dental caries and periodontal disease being prevalent oral diseases,

following prosthetic status with high unmet needs, increasing the geriatric oral health challenges in India. Hence, there is a need for a special emphasis towards reducing geriatric oral health burden and improving the oral health-related quality of life of the elderly by integrating National oral health policy with National general health policy[15] and with focus on preventive oral health strategies which can be customized to geriatric population.

Various preventive measures to reduce the oral health burden of geriatrics includes use of fluoride toothpastes, fluoride mouth rinses, professional fluoride gel applications, dietary sugar substitutes, saliva substitutes and regular care of dentures.[16,17] Despite various preventive strategies available, fluoride toothpaste, which are readily available and accessible has been found to be cost-effective to prevent dental caries. Fluoride toothpaste with 1000 ppm specification containing inorganic fluoride has been effective in reducing dental caries among geriatrics by its remineralizing effect.[18] Organic fluoride (amine fluoride) based toothpaste has also showed a reduction of 45% in dental caries prevalence compatible to the most commonly used fluoride dentifrice compounds.[19] Experimental studies had shown reduced caries incidence, plaque index and gingival index with use of amine fluoride toothpaste and amine fluoride mouth rinse compared to other fluoride containing toothpaste and mouth rinse.[21] Studies based on organic fluoride (amine fluoride tooth paste) showed more than 90% of dead biofilm organisms

compared to 25% dead biofilm organisms in untreated pellicle, thus showing its anti-bacterial effect.[20] Amine fluoride tooth paste containing 1400 ppm fluoride increased structurally bound fluoride in dentine compared to the placebo tooth paste, thereby enhancing remineralization effect.[21] The rationale behind the use of amine fluoride is due to rapid distribution and formation of a homogenous film on all oral surfaces, increased fluoride absorption and formation of a fluoride depot on the enamel, superior acid resistance for longer time periods, enhanced remineralization of initial caries lesions, antibacterial and antiglycolytic efficacy of organic fluoride.[22] The unique property of organic fluoride is its amphilic nature represented by hydrophilic and hydrophobic parts within one molecule thus reducing the surface tension of the liquid.[23] Oral health is integral to general health and essential for well-being.1

Though there are numerous studies conducted globally to compare the effectiveness of various concentration of fluoride containing toothpaste on prevention of dental caries in the elderly, literature search shows little evidence of studies related to effectiveness of organic fluoride containing tooth paste on the risk factors of dental caries in the elderly. Hence, the present study was contemplated to compare the effect of two commercially available fluoridated dentifrices (organic and inorganic fluoride) on risk factors of dental caries based on cariogram model among institutionalized geriatric population in Chennai city.

HYPOTHESIS

RESEARCH QUESTION:

Does organic fluoride based dentifrice (Amflor, Group pharmaceuticals limited) and inorganic fluoride based dentifrice (Colgate Total, Advanced Health, Colgate – Palmolive Ltd) have the same effect on the risk factor of dental caries among institutionalized geriatric population in Chennai city.

RESEARCH HYPOTHESIS:

There is difference on the risk factor of dental caries, after use of organic fluoride based dentifrice (Amflor, Group pharmaceuticals limited) compared to inorganic fluoride based dentifrice (Colgate Total, Advanced Health, Colgate – Palmolive Ltd) among institutionalized geriatric population in Chennai city.

NULL HYPOTHESIS:

There is no difference on the risk factor of dental caries, after use of organic fluoride based dentifrice (Amflor, Group pharmaceuticals limited) compared to inorganic fluoride based dentifrice (Colgate Total, Advanced Health, Colgate – Palmolive Ltd) among institutionalized geriatric population in Chennai city.

AIM AND OBJECTIVES

AIM:

To compare organic fluoride based dentifrice (Amflor, Group pharmaceuticals limited) with inorganic fluoride based dentifrice (Colgate total, Advanced Health, Colgate – Palmolive Ltd) on risk factors of dental caries among institutionalized geriatric population in Chennai city

OBJECTIVES:

1. To assess the dental caries risk factors among institutionalized geriatric population in Chennai using Cariogram model (Brathall D, 1997).
2. To determine the effect of organic fluoride based dentifrice (Amflor, Group pharmaceuticals limited) and inorganic fluoride based dentifrice (Colgate total, Advanced Health, Colgate – Palmolive Ltd) on risk factors of dental caries among institutionalized geriatric population in Chennai city.
3. To compare the effect of organic fluoride based dentifrice (Amflor, Group pharmaceuticals limited) with inorganic fluoride based dentifrice (Colgate total, Advanced Health, Colgate – Palmolive Ltd) on the risk factors of dental caries among institutionalized geriatric population in Chennai city.

REVIEW OF LITERATURE

Franke W et al (1976)[24] tested clinically and radiographically the caries-inhibiting efficiency of topically applied amine fluoride in defined group in a 3 year, 4 year and 5 year studies among children of age 4-5 years. The defined groups were fluoride group with Elmex (amine fluoride) fluid and Elmex (amine fluoride) tooth-paste for unsupervised dental and oral hygiene at home, placebo group and control group. After the fifth study year, the caries increment in the children who were 11 years of age at this time had decreased by 30.6% (DMF/T index) and 32.1% (DMF/S index). Thus, amine fluoride has caries-inhibiting efficacy compared to other groups.

Nemes J et al (1992)[25] conducted a double blind study to assess the remineralizing effect of an amine fluoride $(AmF)^-$ and stannous fluoride $(SnF2)^-$ containing toothpaste and mouthrinse on exposed root surfaces. A total of 44 adults participated in the 20-week study, were grouped as follows: (1) 20 participants (mean age 45.7 years) used an AmF/SnF2 experimental toothpaste plus AmF/SnF2 (Meridol) mouthwash, and (2) 24 participants (mean age 48.8 years) used an NaF-containing toothpaste and mouthrinse. Root surface score and root caries index (RCI) were determined by a modified method of Katz (J Dent Res, 1984). RCI mean values decreased of approximately 47% in the AmF/SnF2

group, and 10% in the NaF group. There was a statistically significant ($p < 0.05$) decrease in the number of persons with decreased softened (non-carious) surfaces between the baseline and control examinations in the AmF/SnF2 group but no significance in the NaF group. Thus, there is a possible remineralizing effect of topically applied AmF/SnF2 on softened root caries surfaces.

Pakhomov GN et al (1997)[19] investigated the caries-reducing effect of amine fluoride toothpaste when used under real-life conditions in a community preventive program. Approximately 12,500 children 3-12 years of age were provided with toothpaste (four tubes or 360 grams annually during three years) to be used in kindergartens or schools and once a day at home. The teachers supervised daily tooth brushing sessions. Random samples of children in each of the ages 3, 6, 9, and 12 years were selected from the intervention and the reference communities at both the start of the study and after three years, and examined for dental caries experience. Amine fluoride dentifrice seemed to provide a reduction of 45% in dental caries prevalence compatible to the most commonly used fluoride dentifrice compounds. The implemented fluoride toothpaste program is a feasible and practical method of improving the oral health status of children.

Baysan A (2001)[26] compared the effectiveness of two sodium fluoride dentifrices, one containing 5,000 ppm fluoride (Prevident 5000 Plus) and the

other 1,100 ppm fluoride (Winterfresh Gel), to reverse primary root caries lesions (PRCLs). A total of 201 subjects, all more than 18 years of age, who had at least 10 natural teeth, with at least one PRCL each entered the study and were allocated randomly to use one of the dentifrices. After 6 months, the statistical analyses were done for 186 subjects. At baseline and after 3 and 6 months, the lesions were clinically assessed and their electrical resistance measured using an electrical caries monitor. The results of subjects with mean age was 58.9±13.0 years, with a range of 27–90 years had shown, between baseline and 3 months, the log10 mean ± SD resistance values of lesions for subjects in the 1,100 ppm F^- group had decreased by 0.06 ± 0.55, whereas those in the 5,000 ppm F^- group had increased by 0.40 ± 0.64 ($p<0.001$), between baseline and 6 months, the log10 mean ± SD resistance values of lesions for subjects in the 1,100 ppm F^- group decreased by 0.004 ± 0.70, whereas in the 5,000 ppm F^- group, they increased by 0.56 B 0.76 ($p<0.001$). After 3 and 6 months, the distance from the apical border of the root caries lesions to the gingival margin increased significantly in the 5,000 ppm F group (from 0.7 to 1.4) when compared with the 1,100 ppm F– group (1.0 to 1.1). The plaque index in the 5,000 ppm F group (from 1.6 to 0.4) was also significantly reduced when compared with the 1,100 ppm F group (from 1.0 to 0.6). It was concluded that the dentifrice containing 5,000 ppm F was significantly better at remineralising PRCLs than the one containing 1,100 ppm F.

Madlena M et al (2002)[27] conducted a longitudinal study to establish a preventive program with combined use of amine fluoride toothpaste and gel in groups of adolescents. The study population consisted of 586 secondary school pupils aged 14-16 years from two Hungarian cities. The fluoride content of drinking water was 0.01 and 0.03 ppm respectively. They were divided into 3 groups: 1 control and 2 test groups. Control group continued usual oral habits. One of the test group received amine fluoride toothpaste and the other group received amine fluoride and placebo gel. Caries (DMFT and DMFS) and oral hygiene (visible plaque index) examinations were performed at baseline and after two years. The combined use of amine F and gel provided a significant reduction in DMFS mean values (8.4 ± 7.0 - 38% including white spot lesions, 34% not including white spot lesions with a $p<0.05$) and in visible plaque index (32.2 ± 31.4) compared to control group DMFS (10.8 ± 8.3) and visible plaque index (44.1 ± 31.8) after two years.

Twetman S et al (2003)[18] conducted a systematic review to report the findings concerning the preventive effect of fluoride toothpastes in various age groups, with special emphasis on fluoride concentration and supervised versus non-supervised brushing. A systematic search in electronic databases for articles published between 1966 and April 2003 was conducted with inclusion criteria of a randomized or controlled clinical trial, at least 2 years follow-up and caries increment in the permanent (DMFS/T) or primary (dmfs/t) dentition as end point.

Out of 905 articles identified, 54 met the inclusion criteria. These studies were assessed by two reviewers and measure of effect was the prevented fraction (PF) expressed as percent. The results revealed strong evidence for the caries preventive effect of daily use of fluoride toothpaste compared to placebo in the young permanent dentition (PF 24.9%), the toothpastes with 1,500 ppm of fluoride had a superior preventive effect compared to standard dentifrices with 1,000 ppm F in the young permanent dentition (PF 9.7%), higher caries reductions were recorded in studies with supervised toothbrushing compared with non-supervised (PF 23.3%). This review insisted the importanced of daily toothbrushing with fluoridated toothpastes for prevention of dental caries.

Galuscan A et al (2003)[28] conducted an experimental study to find the decreasing of caries index by using toothpaste based on amine fluoride. A total of 45 participants of age ranging from 8 -30 years were divided into four groups were involved in the study. Group 1 had been given placebo toothpaste and mouth rinse, containing the same ingredient as amine fluoride toothpaste. Group 2 was provided with amine fluoride toothpaste and mouth rinse (Meridol – 1400 ppm F). Group 3 was given Meridol with instructions how to use toothpaste and mouth rinse. Group 4 used placebo toothpaste and Meridol mouth rinse. All participants were instructed to brush their teeth twice daily and after that to wash their mouth with 10 ml of Meridol for one minute. DMFT index, PI index and gingival bleeding index were assessed at baseline, 6, 9, 12, 15, 18 months. The third group

had less DMFT, plaque index and gingival index compared to other groups in all time periods. Not only the tensioactive property of amine fluoride are responsible for this reduction but also the technical skills obtained by the group 3 participants to use amine fluoride toothpaste and mouth rinse also had contributed.

Ogaard B et al (2006)[29] conducted a prospective, randomized clinical study on the effects of an amine fluoride/stannous fluoride toothpaste/mouthrinse on the development of white spot lesions, plaque, and gingivitis on maxillary anterior teeth in orthodontic patients. 115 orthodontic patients (42 males and 73 females, average age 14.4 years) were divided into two groups and Group A (50) brushed twice daily with an AmF/SnF 2 toothpaste (1400 ppm F) and rinsed every evening with an AmF/SnF 2 solution (250 ppm F). Group B (47) brushed twice daily with a sodium fluoride (NaF) toothpaste (1400 ppm F) and rinsed every evening with a NaF solution (250 ppm F). Visible plaque index (VPI), gingival bleeding index (GBI) and white spot lesion index (WSL) was recorded on the six maxillary anterior teeth at bonding and after debonding. In group A no significant differences between bonding and debonding were recorded for WSL, VPI and GBI whereas statistically significant differences were found in group B between bonding and debonding for WSL (1.00 ± 0.02 versus 1.08 ± 0.17, P = 0.01), VPI (0.06 ± 0.13 versus 0.17 ± 0.25, P = 0.01) and GBI (0.06 ± 0.12 versus 0.16 ± 0.21, P = 0.01). The increase in lesions on the upper anterior teeth was 4.3 per cent in group A and 7.2 per cent in group B. It was concluded that the combined

use of an AmF/SnF2 toothpaste/mouthrinse had a slightly more inhibitory effect on white spot lesion development, plaque and gingivitis on maxillary anterior teeth during fixed orthodontic treatment compared with NaF.

Patil et al (2007)[30] conducted an in-vivo study, to assess the anti-microbial effect of two commercially available toothpastes, to compare and evaluate the effect of the two toothpastes on Streptococcus mutans count level in 4 - 6 years age children with dmft 0. 100 student participants in the age group of 4-6 years with dmf = 0 were selected. Streptococcus mutans colonies were counted from the salivary sample. The 100 participants were randomly divided into two groups with 50 participants in each group. Group I was provided with Himalaya Herbals Dental cream containing Neem, Group II was provided with 458 ppm containing fluoride toothpaste Cheerio gel. The toothpastes, toothbrush and instructions were provided over a period of 5 months for home care use. The saliva sample was then collected and streptococcus mutans estimated in 4 phases, 1) 15 days 2) 30 days 3) 90 days 4) 150 days. Results had shown there was a steady decrease in the bacterial count over a period of 5 months; the overall percentage decrease in Group I being 90.69%and Group II being 89.69%. However, there was no statistically significant difference ($p>0.05$) in the bacterial count between the toothpastes and both were efficacious in reducing the bacterial count. Thus, toothpastes form a major part of the home care prevention measure

in combating dental caries with a good antimicrobial effect on caries producing salivary streptococcus mutans bacteria.

Van der Mei HC (2008)[31] conducted an in-vitro study to determine changes in pellicle and bacterial cell surface properties of the strains Actinomyces naeslundii HM1, Streptococcus mutans NS, S. mutans ATCC 700610, S. sobrinus HG1025 and S. oralis HM1 upon adsorption of this AmF and accompanying effects on bacterial adhesion and biofilm growth. The pellicles of in-vitro samples had a zeta potential of –12 mV that became less negative upon adsorption of AmF. The chemical functionalities in which carbon and oxygen were involved changed after AmF adsorption and AmF-treated pellicles had a greater surface roughness than untreated pellicles. The water contact angles decreased from 56 to 45° on AmF treatment in the in-vitro samples, which corresponded to the water contact angles (44°) measured on the incisors intra-orally of volunteers immediately after using an AmF-containing toothpaste. Biofilms on untreated pellicles contained on average about 25% dead organisms, while after AmF treatment more than 90% of all biofilm organisms were dead, regardless of the strain involved. There was a significant reduction in the Streptococcus mutans strain adhesion and growth to salivary pellicles and biofilm after AmF treatment, but not of A. naeslundii or S. oralis. Thus, the electrostatic interaction between cationic AmF and negatively charged bacterial cell surfaces was pivotal in

establishing reduced biofilm formation by AmF through a combination of effects on initial adhesion and killing.

Van Loveren C et al (2009)[32] conducted a randomized crossover examiner-blind controlled trial to evaluate the effect of different oral hygiene protocols on the bacterial composition of dental plaque. About 30 volunteers (22 women, 8 men; mean age: 26.8 ± 7.3 years) were enrolled. After using fluoride-free toothpaste for 2 weeks , participants followed three 1-week experimental protocols, each followed by 2-week fluoride-free washout periods. The 1-week experimental protocols comprised the use of AmF/SnF 2 toothpaste twice daily, after which participants either (1) rinsed with tap water, (2) did not rinse but only spat out the toothpaste, or (3) rinsed with an AmF/SnF2 mouthwash. The participants brushed their teeth with fluoride-free toothpaste in the washout peroids without further instructions. Six hours after the last brushing (8 rinsing) of each period, buccal plaque samples in the upper molar region were taken. The microbiota composition of the plaque samples was analyzed by checkerboard DNA: DNA hybridization. A statistically significant reduction was found in the total amount of DNA of the 39 major plaque species measured, and in the proportions of some acid-producing bacterial strains after the period having used the AmF/SnF2 toothpaste + AmF/SnF2 mouthrinsing. The results indicate that using the AmF/SnF 2 toothpaste and rinse combination could result in plaque of lower cariogenicity.

Laheij A.M.G.A (2010)[33] conducted a double-blind, randomized, cross-over in situ experiment to compare the effect on lesion progression of 2 versus 3 fluoride moments a day. Sixteen participants wore an enamel and a dentine specimen with a preformed lesion placed buccally in their partial prosthesis. The participants brushed twice a day with 1,400 ppm F (amine fluoride) toothpaste and rinsed once a day with either 250 ppm F (amine F/NaF) or a placebo rinse. The experiment comprised 2 in situ periods of 3 weeks with a washout period of 3 weeks in between. At the end of the experiment the specimens were retrieved for fluoride analysis and the assessment of integrated mineral loss with transversal microradiography. The fluoride analysis showed a statistically significant increase in structurally bound fluoride in dentine (119.8 ± 63.8 µg F-/cm²) than the placebo mouthrinse group (82.2 ± 45.9 µg F-/cm²) ($p = 0.049$) but not in enamel. In dentine IML gain was significantly ($p<0.05$) higher for the fluoride mouthrinse group (1,357 ± 731 vol% min µm) than for the placebo mouthrinse group (779 ± 629 vol% min µm). For dentine a third fluoride moment may be beneficial in enhancing remineralisation, even under the remineralising conditions as in this study.

Tan H.P et al (2010)[34] compared the effectiveness of four methods in preventing new root caries in institutionalized elderly by conducting a clinical trial. From 21 residential homes, 306 generally healthy elders having at least 5 teeth with exposed sound root surfaces were randomly allocated into one of four

groups: .1 individualized oral hygiene instruction (OHI), 2. OHI and applications of 1% chlorhexidine varnish every 3 months, 3. OHI and applications of 5% sodium fluoride varnish every 3months and 4. OHI and annual applications of 38% silver diamine fluoride (SDF) solution. About two thirds (203/306) of the elders were followed for 3 years. Mean numbers of new root caries surfaces in the four groups were 2.5, 1.1, 0.9, and 0.7, respectively ($p < 0.001$). The relative risk of developing new root caries for OHI + chlorhexidine vs. OHI was 0.27, OHI + sodium fluoride vs. OHI was 0.26, OHI + SDF vs. OHI was 0.19. Thus SDF solution, sodium fluoride varnish and chlorhexidine varnish were more effective in preventing new root caries than giving OHI alone.

Schiller A et al (2012)[35] aimed to determine the antimicrobial effect of various gel formulations on plaque formation; different tooth gels were compared to a toothpaste containing comparable anti-microbial ingredients with regard to its microbiocidal activity. Ledermix® fluoride gel as commercially available with preservative, and without preservative and perfume oils, Elmex® gel, and Meridol® toothpaste were tested in a standardized in-vitro test modification of the quantitative suspension test EN 1040. The respective product was placed on a contaminated sterile stainless steel disk without adding any bio-burden. 50% egg yolk in Aqua dest was used as a neutralizer. Within 1 min, Elmex® gelée showed a RF >5 log10 against S. pyogenes and S. sanguinis. Against S. mutans, a log10 RF of ≥5 was achieved after 2 min, against C. albicans after 5 min, and against P.

aeruginosa after 10 min S. aureus was the most difficult organisms to be reduced. After an application time of 10 min, only a log10 RF of 2.4 was achieved. Ledermix exceeded the antimicrobial efficacy of Elmex® gel against S. mutans and C. albicans, but did not show the same antimicrobial efficacy as Elmex® gel against P. aeruginosa. A reduction of >5 log10 for antimicrobials was not achieved against S. aureus in Ledermix fluoride gel similar to Elmex® gel. Ledermix fluoride gel without preservatives and perfume oil did not show the antimicrobial efficacy of the standard Ledermix® fluoride gel formulation, indicating that the observed antimicrobial efficacy is chiefly based on the preservative, and possibly the perfume oil. Meridol® toothpaste was less effective and reached any antimicrobial effect >5 log10 only against S. sanguinis after 10 min compared to other gels. The results indicate that the antimicrobial efficacy of gels is determined by their formulation. For the prevention of plaque formation a sustained antimicrobial effect may be of greater importance compared to the combination of mechanical removal and antimicrobial activity.

Lopez RM et al (2013)[36] conducted a pilot study to compare the efficacy of amine fluoride toothpaste and gel with chlorhexidine spray in an institutionalized elderly population. Twenty-six people over 65 years old who had at least four teeth and living in a nursing home were assigned to three groups: A: amine fluoride toothpaste and once a week amine fluoride gel (Elmex®), B: 0.12% spray-chlorhexidine once a day (Perio-Aid®) and C: brush teeth without

toothpaste. The plaque and gingival index of Silness and Loe, General Oral Health Assessment Index, McLeran and Pfeiffer index were recorded, and the number of colonies of Streptoccocus mutans and Lactobacillus and the remineralisation of caries were evaluated using Diagnodent®. Measurements were taken at the beginning of the study and after 6 months. Out of twenty two complete the study, the results had shown no group showed a statistical difference in the plaque or gingival index, but there was a tendency to show improvement in the amine fluoride group. There was also no difference between the number of colonies of either S. mutans or Lactobacillus. There was a significant difference between the plaque and gingival index and the cognitive status ($p = 0.0054$), along with their requirement for assistance to perform good oral hygiene ($p = 0.0001$). Both products remineralised the carious lesions in this period similar to the control group ($p = 0.0151$). Thus the plaque and gingival indices did not improve during the study, but both products remineralised the previous caries lesions.

Ekstrand KR (2013)[37] aimed to compare the effectiveness of tooth brushing with 5,000 versus 1,450 ppm of fluoridated toothpaste (F-toothpaste) for controlling root caries in disabled elderly nursing home residents. Inclusion criteria were: residents who were not able to brush their teeth themselves; residents who would allow the nursing staff to brush their teeth; residents who had 5 or more natural teeth; residents with ≥ 1 root caries lesion, and residents

who were not bedridden. They were randomly assigned to use one of the two toothpastes. Both groups had their teeth brushed twice a day by the nursing staff. A total of 125 residents completed the study. Baseline and follow-up clinical examinations were performed by one calibrated examiner. The mean numbers of active root caries lesions at the follow-up examination were 1.05 (2.76) versus 2.55 (1.91) and mean numbers of arrested caries lesions were 2.13 (1.68) versus 0.61 (1.76) in the 5,000 and the 1,450 ppm fluoride groups, respectively ($p < 0.001$). To conclude, 5,000 ppm F-toothpaste is significantly more effective for controlling root caries lesion progression and promoting remineralization compared to 1,450 ppm F-toothpaste.

Madlena M (2013)[38] carried out a review to report the clinical experiences with amine fluoride containing products in the management of dental hard tissue lesions based on Hungarian studies. All Hungarian studies done using amine fluoride products from 1968 to 1989 on subjects with age from 6 to 20 years were included in the review. The review of 5 studies in favor of amine fluoride toothpaste and 6 studies in favor of amine fluoride gel has showed 25% and 45% caries reduction (DMFT and DMFS). Thus, regular use of different oral hygienic products containing an AmF and AmF combination contributes to the prevention of plaque accumulation and consequently to the prevention of dental diseases.

Petersson L.G (2013)[39] conducted a systematic review to bring light on fluoride to control dentin hypersensitivity (DHS) and prevent root caries. Search strategy included papers mainly published in PubMed, Medline from October 2000 to October 2011. The results had shown that fluoride toothpaste shows a fair effect on sensitive teeth when combined with dentin fluid-obstructing agents such as different metal ions, potassium, and oxalates. Prevention of root caries is favored by toothpaste with 5,000 ppm F and by fluoride rinsing with 0.025–0.1 % F solutions, as the application of fluoride gel or fluoride varnish three to four times a year. Thus, fluoride is an effective agent to control DHS and to prevent root caries particularly when used in higher concentrations.

Priyadharshini SH et al (2013)[40] conducted an in-vitro study to compare the enamel surface micro hardness after topical application of sodium fluoride (NaF) and amine fluoride (AmF) solutions. Twenty fresh samples of sound human enamel were treated with demineralizing solution for 72 hours and divided into group A (treated with NaF) and group B (treated with AmF) solutions for 3 min twice daily for 7 days. In between treatment, the samples were stored in artificial saliva. The enamel hardness was measured with Vickers hardness test at baseline, post-demineralization, and post-treatment with two different fluoride solutions. There was a statistically significant ($p<0.01$) difference, with increased mean micro hardness after treatment with AmF application when compared to the mean

hardness after treatment with NaF. Thus, AmF compounds result in a marked increase in enamel micro hardness when compared to NaF.

Mannaa A et al (2014)[41] assessed the caries risk following 6 weeks' use of 5000 ppm F toothpaste using 'Cariogram' software. A total of 34 participants, 17 mothers and their teenage children, were enrolled in a 6-week clinical trial in which they were given 5000 ppm F toothpaste. They were followed consecutively for 6 weeks with visits that were 2 weeks apart (four in total). A clinical examination was done at baseline and salivary chair-side tests to record the buffer capacity and mutans streptococci (MS) and lactobacilli (LB) counts were performed at each visit. Based on these data, seven caries-related variables were collected and inserted into the Cariogram software to calculate the actual chance of avoiding caries. Results have shown that the use of 5000 ppm F toothpaste resulted in a statistically significant modification of the caries-risk profile, increasing the actual chance of avoiding caries in the future among the mothers and teenagers from 28.0 at baseline to 53.7 at 6 weeks for the mothers and from 31.0 to 55.8 for the teenage children at each visit following baseline ($p < 0.01$). The changes essentially related to the salivary parameters (buffer capacity, MS and LB counts). A statistically significant linear trend was observed for MS counts ($p < 0.01$) and the number of subjects with a salivary concentration of MS < 103 increased at each visit. The same trend was also observed for LB and buffer capacity scores ($p = 0.04$ and $p = 0.03$, respectively). It has been concluded that

short-term use of 5000 ppm F toothpaste is able to reduce the caries risk, which can be clearly demonstrated using 'Cariogram' software.

Wyatt C.C.L (2014)[42] conducted a two year follow-up study to evaluate the incidence and reversal of caries on coronal and root surfaces in a sample of caries-susceptible, community-dwelling older adults who were using fluoride toothpaste and to examine associations with risk factors for caries. Subjects included in the study were community-dwelling adults 65 years of age or older with more than half (> 14) of their natural teeth. Coronal and root surfaces were scored with the International Caries Detection and Assessment System (ICDAS) at baseline and at 6, 12, 18 and 24 months. Participants were given instruction to use fluoride toothpaste to brush their teeth twice daily for 2 minutes. Percent incidence and progression or reversal of carious surfaces was measured (in relation to number of surfaces per participant), and relationships with diet, age, sex, medications and systemic conditions were determined. The results had shown that mean coronal caries incidence was 1.8% (SD 3.0%) for noncavitated carious surfaces and 0.3% (SD 0.8%) for cavitated carious surfaces. Mean root caries incidence was 2.0% (SD 4.1%) for noncavitated carious surfaces and 1.4% (SD 3.2%) for cavitated carious surfaces. Reversal of caries for noncavitated carious surfaces was greater for root surfaces than for coronal surfaces (2.9% (SD 4.4%) vs. 0.5% (SD 1.5%)). Number of medical conditions and greater age would have increased the incidence of root caries. Therefore, among community-dwelling

elderly people using fluoride toothpaste, rates of progression and reversal of coronal and root carious surfaces were low.

Shah SG (2014)[43] compared the efficacy of silver diamine fluoride (SDF) as a topical fluoride agent in vivo with Fluoride Varnish and Acidulated phosphate fluoride (APF) Gel. A total of 123 children of age 6 -9 years comprised of 82 boys and 41 girls were included in the study for a period of 18 months. Children were divided into three different groups - Group 1: SDF; Group 2: Fluoride Varnish; Group 3: APF Gel. All Subjects were evaluated through decayed, missing, and filled surface (dmfs) + DMFS index at 6th, 12th and 18th months as well as fluoride content in enamel at 6th month of follow-up. Significant increase in mean fluoride content of enamel was found in Group 1 (5663.08) when compared with Group 2 (4903.81) and 3 (4698.31), whereas no significant difference was found between Group 2 and 3. Reduction in dental caries found in all groups but inter group comparison shows no significant difference ($p>0.05$). Thus, in vivo application of SDF on enamel significantly increases fluoride content in enamel as compared to Fluoride Varnish and APF Gel and can be used effectively as topical fluoride agent.

Srinivasan M et al (2014)[44] conducted a single-blind, multicenter, parallel, randomized controlled trial with an allocation ratio of 1:1 to evaluate the effectiveness of the application of high-fluoride toothpaste on root caries in

adults. About 130 adults of age group 18-75 years diagnosed with root caries were randomly allocated to intervention with toothpaste containing high-fluoride of 1.1% sodium fluoride (5000 ppm) in a silica substrate and control group were allotted with standard regular fluoride toothpaste (with 1350 ppm). The packets were identical and consisted of 3-4 tubes of toothpastes along with two standard soft bristled adult toothbrushes. Clinical examinations and surface hardness scoring of carious lesions (Pre-validated clinical surface texture grading scale was adopted for the evaluation of root caries surface hardness) were performed at baseline, 3 months and 6 months after intervention. The mean surface hardness was calculated for each subject by dividing the sum of individual scores by the number of surfaces scores. The results had shown that overall surface hardness at 3, 6 months after intervention was better for the test group (2.9 ± 0.67) (2.4 ± 0.81) than for the control group (3.1± 0.75) (2.8 ± 0.79) with a p value of 0.0001. The surface hardness of untreated root caries improve with twice daily application of high fluoride containing toothpaste (5000 ppm) when compared with regular fluoride containing toothpaste (1350 ppm)

Ekstrand KR (2015)[45] analyzed whole-saliva fluoride levels and mineral saturation indices during different fluoride toothpaste regimens using standard elctrodes in home-living elderly. Inclusion criteria were: (i) 65 years or more with good general health living in their own homes, (ii) natural teeth in maxilla as well as in the mandible (partial dentures were accepted), and (iii) no cognitive

impairment. Whole saliva was collected from 27 subjects (7 males and 20 females, mean age 73.5±6.1 years) at ten time points covering the whole day during five 2-week periods. During the first period, participants used their normal toothpaste without instructions (baseline). This was followed by TP1: 1,450-ppm NaF toothpaste; TP2: 1,450-ppm monofluorophosphate (MFP) toothpaste with addition of calcium; TP3: 5,000-ppm NaF toothpaste, and TP4: the same toothpaste with additional 'smearing' of toothpaste on the teeth, twice daily. During TP1-TP4, the participants were instructed to brush 3 times per day using 1.5 g of toothpaste without rinsing. Salivary fluoride levels increased with toothpaste fluoride content ($p<0.001$), although major interindividual and intraindividual variations were observed. The highest fluoride values appeared in the morning and at night ($p<0.001$). Saturation indices for calcium fluoride were affected by the fluoride content in pastes ($p<0.05$). Concerning hydroxyapatite and fluorapatite, indices were highest with the MFP toothpaste and extra calcium (NS to $p<0.05$). Use of a high-fluoride toothpaste resulted in significantly increased fluoride levels in whole saliva and mineral saturation indices were indeed influenced by choice of toothpaste.

An estimation and comparison of pH of saliva before and after brushing and mouth rinsing with fluoridated toothpaste and mouthwash was done by **Soham B et al (2015)**[46]. 40 study subjects were divided into two groups, Group A (combination of toothpaste and mouthrinse) and Group B (Toothpaste) with 20

children each of age 6 – 12 years were instructed to perform oral hygiene practice and salivary pH estimation was done before and after brushing and mouthrinsing on day 1, 1st week, 2nd week, 3rd week and 4th week. The salivary pH was directly estimated using the digital pH meter calibrated using buffers of pH 4, 7 and 9. The Mean difference in pH in Group –A was found to be 0.2, 0.25, 0.33 and 0.4, Group –B was found to be 0.09, 0.13, 0.19 and 0.23 at 1st week, 2nd week, 3rd week and 4th week respectively. There is a rise in pH as the duration increases and pH increase is more in Group-A than that of Group-B and the difference between the groups found to be statistically not significant (p-value = 0.06). The pH of saliva increases more after brushing and rinsing with fluoridated toothpaste and mouth rinse rather than toothpaste alone.

A review by **Ekstrand KR (2016)**[47] to present the available evidence that toothpaste containing >1,500 ppm (2,500–2,800 and 5000 ppm F) provide an additional caries-preventive effect compared to traditional F containing toothpaste (1000-1500 ppm F) on root caries lesions. A total of 11 articles with crossover trials and longitudinal studies from 2009 to 2015 were included in this review. The outcome of clinical trials was preventive fraction and risk ratio for longitudinal studies. The overall risk ratio was 0.49 (95% CI, 0.42 – 0.57), thus risk can thus be halved by exchanging traditional F- containing toothpaste for toothpaste containing 5,000 ppm F. The available data from the studies suggest that high-concentration fluoridated toothpaste provides better caries prevention on

root caries lesions in the elderly population by enhancing F concentration in both saliva and plaque, by forming significant amount of calcium fluoride.

Marinho VC et al (2016)[48] conducted a systematic review and meta-analysis which was an update of the Cochrane review of fluoride mouthrinses for preventing dental caries in children and adolescents, first published in 2003. The primary objective is to determine the effectiveness and safety of fluoride mouthrinses in preventing dental caries in the child and adolescent population. The secondary objective is to examine whether initial level of caries severity influences the effect of fluoride rinses, background exposure to fluoride in water (or salt), toothpastes or reported fluoride sources other than the study option(s) or fluoride concentration (ppm F) or frequency of use (times per year). Searched studies on electronic databases 1986 to 22 April 2016 with inclusion criteria of Randomized or quasi-randomized controlled trials where blind outcome assessment was stated or indicated, comparing fluoride mouthrinse with placebo or no treatment in children up to 16 years of age. Study duration had to be at least one year. The caries increment was primary outcome measured by the change in decayed, missing and filled tooth surfaces in permanent teeth (D(M)FS). The primary measure of effect was the prevented fraction (PF), that is, the difference in mean caries increments between treatment and control groups expressed as a percentage of the mean increment in the control group, calculated by random-effects meta-analyses where data could be pooled. All trials tested supervised use

of fluoride mouthrinse in schools, with two studies also including home use. Almost all children received a fluoride rinse formulated with sodium fluoride (NaF), mostly on either a daily or weekly/fortnightly basis and at two main strengths, 230 or 900 ppm F, respectively. The D(M)FS pooled PF was 27% and the pooled estimate of D(M)FT PF was 23%. Thus, supervised regular use of fluoride mouthrinse by children and adolescents is associated with a large reduction in caries increment in permanent teeth.

The salivary fluoride levels were compared following tooth brushing with three different fluoride concentrations of amine fluoride toothpastes and to evaluate the effect of rinsing with water on the oral fluoride levels up to 90 min by **Nazzal H et al (2016)**[49]. A double blind randomized six arm crossover study was conducted with 32 child of age 5-6 years' participants. Depending on their caries experience the participants were divided into two groups with caries free group (n=17, mean age = 72.9 months) and caries prone group (n =15, mean age = 69.6 months). Participants brushed their teeth with a smear of dentifrice containing (250 ppm, 500 ppm, 1250 ppm toothpastes) for 60 seconds. The participants were instructed neither to rinse with water nor did not rinse at all after spitting the dentifrice/saliva slurry. Samples of whole mixed unstimulated saliva were collected at baseline, 1, 15, 30, 45, 60, 90 mins post-brushing/rinsing. Salivary F were analyzed immediately using an Orion F ion-specific electrode. It was found that caries was not a significant variable (p = 0.567) after completing

the study on residual F concentration. The three-way interaction between time, toothpaste F concentration and water rinsing had significant effects ($p<0.001$). In general, higher residual salivary F concentrations were found with increased F concentration in toothpastes and when no rinsing was performed after brushing. The residual salivary F concentration remained over 0.06 ppm salivary F threshold for caries prevention up to 90 min with 1250 ppm F toothpaste regardless of rinsing. The same pattern was observed for toothpastes containing 500 ppm F with no rinsing. The 250 ppm F containing toothpaste with rinsing dropped under the threshold after 30 min. For any given toothpaste, the residual salivary fluoride levels were lower after rinsing with water. Thus, toothpastes with >1000 ppm F concentration in children with an increased caries risk in addition to spitting excess toothpaste with no rinsing flowing brushing was recommended by this study.

The effectiveness of different preventive programs in young adults at high caries risk using cariogram software was accessed by **KarabekiroLlu S and Unlu N (2017)**[50]. Sixty-six young adults (22 per group) of age 18 – 25 with high caries risk were evaluated. Dental caries risk for all subjects was determined according to WHO criteria. Subjects were divided into three different preventive groups (control: OH (1450 ppm fluoride toothpaste), fluoride varnish: FV, and chlorhexidine varnish: CV). They were followed for 12 weeks (baseline: T0, 1 week: T1, 4 weeks: T2, and 12 weeks: T3). Clinical examination to record plaque

index, an interview to record diet frequency, and salivary chair side tests (to record the flow rate, buffer capacity, and Streptococcus mutans and Lactobacillus counts) were performed at each visit. The predicted chance of avoiding new caries for each subject was calculated after entering data on ten caries related variables in the cariogram software. The results had shown that the chance of avoiding caries increased significantly ($p < 0.001$) during the study for all subjects in the three groups separately: from 46.55 at T0 to 59.0 at T3 for the OH group, from 42.55 to 67.59 for the FV group, and from 42.09 to 60.27 for the CV group, respectively. The cariogram software clearly demonstrated the effectiveness of one visit application of fluoride, regular and effective short-term (three months) use of 1450 ppm fluoridated toothpaste, and chlorhexidine varnishes for reducing caries risk in young adults.

Shetty KP et al (2017)[51] did an in-vitro study to compare and evaluate the micro hardness of enamel surface after application of organic fluoride and inorganic fluoride dentifrices. Twenty freshly extracted premolars were collected and decoronation of all teeth was done at cemento-enamel junction. The crowns were sectioned mesio-distally into two halves and kept in 1% citric acid for demineralization and divided into group A (inorganic sodium fluoride dentifrice) and group B (organic amine fluoride dentifrice). They were treated for 3 minutes twice daily for 7 days. Samples were preserved in artificial saliva in between

treatment. Enamel surface micro hardness was evaluated using Vickers hardness at baseline, after demineralization and after remineralization. The samples treated with sodium fluoride could not restore the mean micro hardness after treatment to that of preoperative level whereas amine fluoride treated samples showed a statistically significant increase in mean surface micro hardness from baseline. Thus, amine fluoride remineralization was more effective in restoring enamel micro hardness than inorganic fluoride remineralization.

Baeshen H (2017)[52] conducted a single-blind, randomized, crossover study from February 2010 to January 2011. Fifteen healthy subjects of age 18 - 35 participated in this study. The participants were instructed to use the following: (1) 0.5% NaF-impregnated miswak, (2) nonfluoridated miswak, (3) toothbrush with nonfluoride toothpaste, and (4) toothbrush with 1450 ppm fluoride toothpaste. Each method was used twice a day for 1 week after which plaque amount and fluoride concentration in resting saliva were measured. There was a 1-week washout period between each method. The results had shown no significant difference between miswak and tooth-brushing was found regarding plaque removal on buccal and lingual surfaces ($p>0.05$). A somewhat higher fluoride concentration in resting saliva was found after using impregnated miswak when compared with toothbrushing with fluoride toothpaste ($p < 0.05$). The plaque removing effect on buccal and lingual surfaces was found to be same for miswak and toothbrushing. Miswak impregnated with 0.5% NaF resulted in a

higher concentration of fluoride in saliva than brushing with 1450 ppm fluoride toothpaste.

MATERIALS AND METHODS

Study Design: An intervention study

Study Setting: Old aged homes in Chennai (East Chennai)

Study Duration: 6 months (From December 2016 to June 2017)

Study Population: Institutionalized geriatric population above 60 years

ETHICAL CLEARANCE:

A detailed protocol of the study was prepared and submitted to the Institutional Review Board of Ragas Dental College and Hospital, Chennai. The intervention study was started after obtaining ethical clearance from the Institutional review board (Annexure – I) and registering in the Clinical Trials Registry – India (CTRI) hosted at the ICMR's National Institute of Medical Statistics (http://nims-icmr.nic.in) (Annexure – II) (Reference no: REF/2017/11/015967)

PERMISSION FROM AUTHORITIES:

Permission to conduct the study was obtained from the

1. Principal, Ragas Dental College and Hospital, Chennai

2. The Secretary, Vishranthi Home for Aged Destitute Women, Palavakkam, Chennai. (Annexure – III)
3. The Secretary, Sir John De Britto Old Age Home for Women, Kovalam, Chennai. (Annexure – IV)
4. Informed consent (bilingual) was obtained from the study participants in the vernacular language (Tamil) and English. (Annexure – V and VI)

STUDY DESIGN:

This interventional study was designed to compare the effect of organic fluoride based dentifrice (Amflor, Group pharmaceuticals limited) with inorganic fluoride based dentifrice (Colgate total, Advanced Health, Colgate – Palmolive Ltd) on risk factors of dental caries among institutionalized geriatric population in Chennai city. The study participants were divided into two groups based on their baseline characteristics as: Group I who were given organic fluoride based dentifrice (Amflor, Group Pharmaceuticals Limited) as intervention and Group II, who were given inorganic fluoride based dentifrice (Colgate Total, Advanced Health) as intervention. Cariogram model (Bratthall D, 1997) was used to assess the risk factors for dental caries in individuals of each group at baseline and after 6 months of intervention. The study was conducted for 6 months from December 2016 to June 2017.

ELIBILITY CRITERIA:

INCLUSION CRITERIA:

1. Participants above 60 years of age and who gave consent to participate in the study
2. Participants who had been living in an institutional set up for at least 1 year before the commencement of this study
3. Participants who proposed to stay in the institution for at least 1 year after the commencement of study
4. Participants who had minimum 10 or more natural teeth
5. Participants who had not participated in any clinical trial at least 6 months prior to this trial

EXCLUSION CRITERIA:

1. Participants who were not willing to participate in the study
2. Participants who were lacking manual dexterity to perform tooth brushing
3. Participants who had developed any acute dental problems during the study period which require emergency dental care
4. Participants who avail any dental services during the study period

SAMPLE SIZE ESTIMATION:

The sample size for each group was calculated using the G power statistical software. The mean change in the surface hardness score of carious lesion from baseline to six months after intervention in the test group (Duraphat 5000 ppm F; Colgate–Palmol1ive Company, Hamburg, Germany) and in the control group (Odol-med 3, 1350 ppm F; GlaxoSmithKline, Bruhl, Germany) from a previous study conducted by Srinivasan M et al, 2014 was considered for estimating the sample size.[51]

The mean change in the surface hardness in test group was reported to be 1.0 and control group was reported to be 0.6.51 Sample size was calculated using the formula

$$n = [(Z\alpha/2 + Z\beta)^2 \times (S.D)^2]/ (\mu1 - \mu2)^2$$

Where Zα/2 is the value of the normal distribution which cuts off an upper tail probability of α/2 (if α = 0.05 (probability of type II error), then Zα/2 = 1.96).

Where Zβ is the value of the Normal distribution which cuts off an upper tail probability of β (if β = 0.2 (probability of type I error), then Zβ = 0.84).

S.D = Standard deviation of outcome (0.73).

On substituting the values to the formula

$$n = [(1.96 + 0.84)^2 \times (0.73)^2] / (0.4)^2$$

$$= 7.84 \times 0.53/0.16$$

$$= 4.15/0.16$$

$$= 25.97$$

We obtained a sample size of 26 for each group, a total of 52 samples. Since this was a clinical trial design with institutionalized geriatric population forming clusters, the sample size was multiplied by design effect of 1.5, thus 52 x 1.5 = 78. With 5% loss of follow up, 78 + 3 = 81, this was approximated to 40 in each group. Hence, for the present study we included 40 individuals in each group. Thus, a total of 80 participants were included in the study.

RECRUITMENT OF THE STUDY SUBJECTS:

There were about 39 old ages homes in Chennai city. Five free old age homes in Chennai city (West, East and Central part) which had enough number of inmates were approached to obtain permission to carry out the intervention study. The nature and purpose of the study, was explained in detail to the old age home authorities. Among the five old age homes approached only two old age homes granted permission [Vishranthi Home for Aged Destitute Women, Palavakkam, Chennai] and [Sir John De Britto Home for Aged Women, Kovalam, Chennai] to carry out the study in their premises.

A total of 80 participants were included in the study. The participants were divided randomly into two groups with 40 in each group: 40 participants received organic fluoride based dentifrice, Amflor toothpaste, Group pharmaceuticals limited were included in Group I and 40 participants received inorganic fluoride based dentifrice, Colgate total, Advanced Health, Colgate – Palmolive Ltd were included in Group II.

Recruitment of participants who received Amflor dentifrice (Group I):

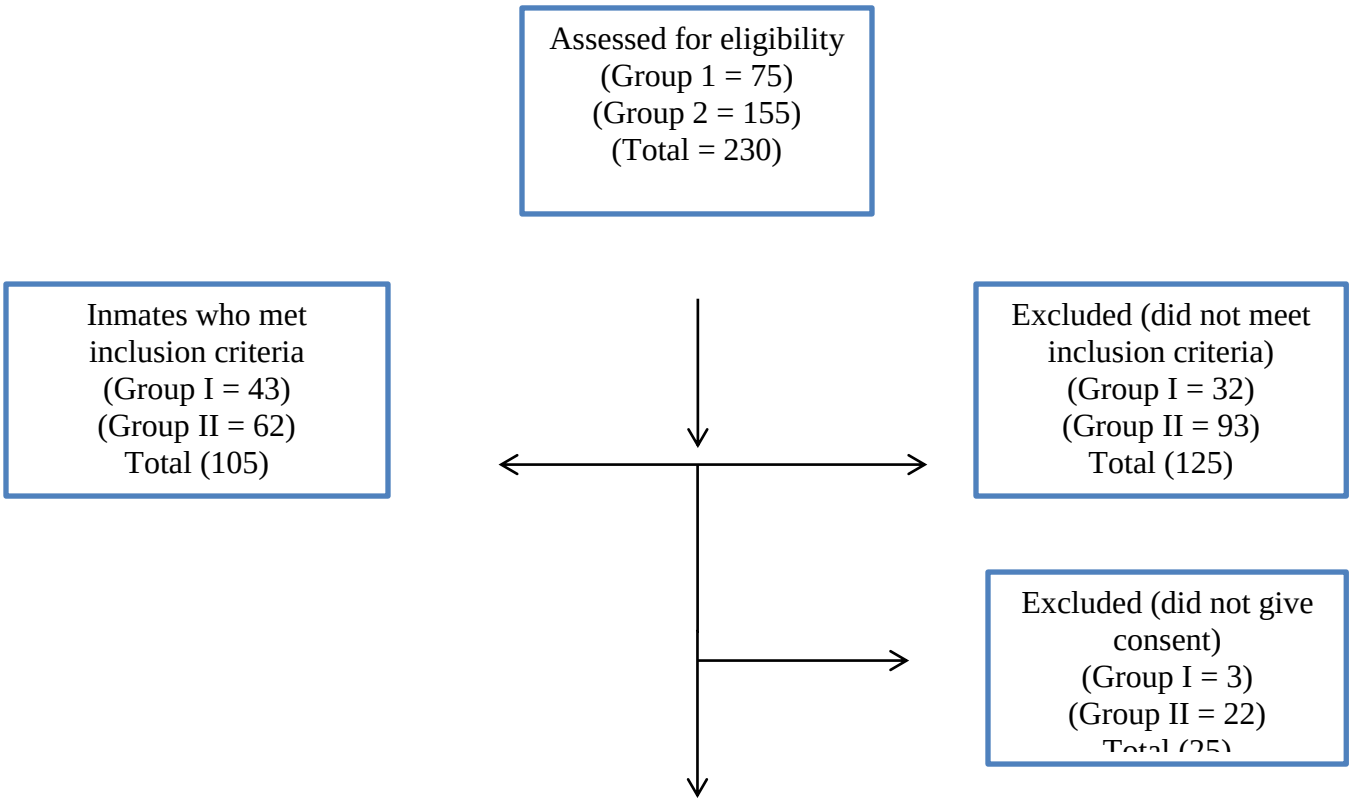
A total of 75 inmates of Sir John De Britto Home for Aged Women, Kovalam, Chennai were approached, out of which only 43 inmates met the inclusion criteria. The nature and purpose of the study were explained in detail to the 43 inmates and their queries were cleared. All the selected inmates were given informed consent form, which was to be filled, and signed by them. Only those individuals who were willing to participate and returned the consent form were selected. Among the 43 participants, 3 did not give consent; finally around 40 geriatric participants were included in the study.

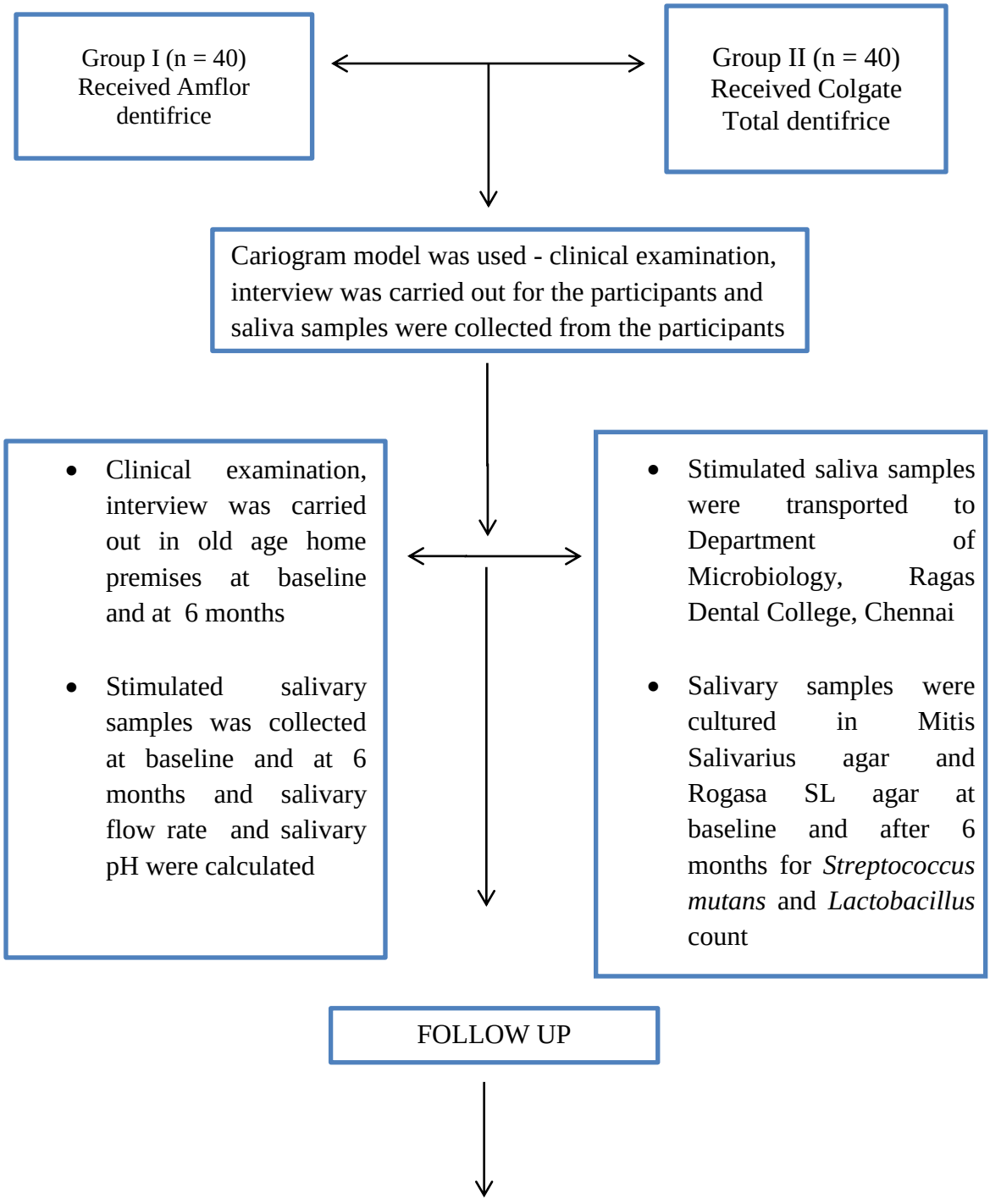
Recruitment of participants who received Colgate Total dentifrice (Group II):

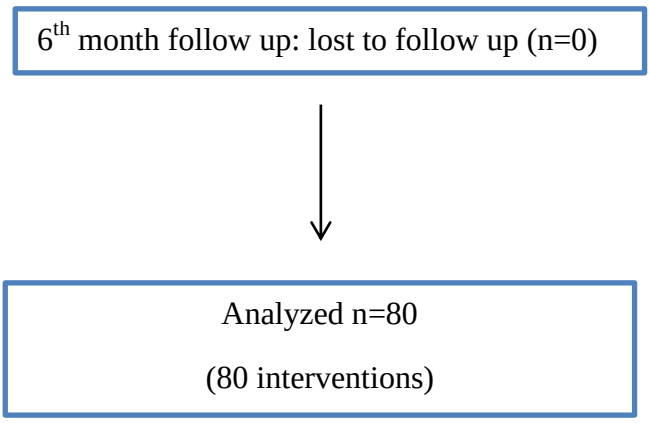
A total of 155 inmates of Vishranthi Home for Aged Destitute Women, Palavakkam, Chennai were approached out of which 62 inmates met the inclusion

criteria. The nature and purpose of the study were explained in detail to the 62 inmates and their queries were cleared. All the selected inmates were given informed consent form, which was to be filled, and signed by them. Only those individuals who were willing to participate and returned the consent form were selected. Among 62 participants, 22 did not give consent; finally around 40 geriatric participants were included in the study.

FLOWCHART ILLUSTRATING THE METHODOLOGY OF THE STUDY




Group I (n = 40)
Received Amflor dentifrice
Group II (n = 40)
Received Colgate Total dentifrice
Cariogram model was used - clinical examination, interview was carried out for the participants and saliva samples were collected from the participants
Clinical examination, interview was carried out in old age home premises at baseline and at 6 months
Stimulated salivary samples was collected at baseline and at 6 months and salivary flow rate and salivary pH were calculated
Stimulated saliva samples were transported to Department of Microbiology, Ragas Dental College, Chennai
Salivary samples were cultured in Mitis Salivarius agar and Rogasa SL agar at baseline and after 6 months for Streptococcus mutans and Lactobacillus count
FOLLOW UP



CALIBRATION OF THE EXAMINER:

The investigator was adequately trained and calibrated to assess Cariogram Caries related programs and to use Cariogram software in the Department of Public Health Dentistry, Ragas Dental College and Hospital, Chennai, under the supervision of the Head of the Department. A single calibrated investigator assessed the caries related programs and used Cariogram software to provide chance of avoiding caries for the study participants.

DATA COLLECTION AT BASELINE:

DEMOGRAPHIC PROFILE:

Questionnaires were provided to all participants who gave consent for the study. Data pertaining to age and education were recorded prior to the clinical

examination. The demographic data was collected for all participants in Group I and Group II on a week day during their leisure time (10.00 am – 12.00 pm).

CARIES RISK ASSESSMENT USING CARIOGRAM:

Cariogram illustrates the interaction between caries related factors and act as a guide to estimate the caries risk. The main purpose is to demonstrate the caries risk graphically, expressed as the "Chance to avoid new caries" in the near future and also encourage preventive measures.[53] Cariogram, a pie circle-diagram is divided into five sectors, in the following colours: green, dark blue, red, light blue and yellow indicating the different groups of factors related to dental caries. There are about 10 caries related factors according to cariogram,

S.NO	CARIES RELATED FACTORS
1.	Caries experience
2.	Related general diseases
3.	Diet content
4.	Diet frequency
5.	Plaque amount
6.	*Streptococcus mutans* count
7.	Fluoride programme
8.	Saliva secretion

9.	Saliva buffer capacity
10.	Clinical judgement

ASSESSMENT OF CARIES EXPERIENCE: (Photograph 1 and 2)

A clinical examination was carried out to record Decayed – Missing – Filled Teeth index (Henry T. Klein, Carrole E. Palmer, and Knutson J.W, 1938). The clinical examination was carried out in the dental chair at the old age home premises. The time taken for clinical examination of each participant was 5 – 8 minutes. Clinical examination was done using type III examination

1. Plain mouth mirror
2. Dental explorer
3. Cotton

The assessed DMFT index score were entered into the cariogram software according to the codes given in the cariogram manual.

INTERVIEW FOR RELATED GENERAL DISEASE: (Photograph 3)

An interview was carried out on all participants of Group I and Group II regarding presence of any related general diseases and any medications which increase the risk for caries were recorded and verified with the medical records in

the general clinic present in the old age home premises. The collected data was entered in the cariogram software using the codes in the manual.

ASSESSMENT OF DIET CONTENT: (Photograph 4 and 5)

Estimates of cariogenicity of the food were done by counting Lactobacillus colonies using standard bacteriological culture methods. The saliva from all the participants was collected from Group I and Group II on a different day of clinical examination and interview. After taking the breakfast at 9.00 am, the participants were asked to rinse their mouth with water for three times. Two hours later they were then given a piece of paraffin wax to chew. The participants were instructed to spit out the first pooled saliva and the saliva pooled in next 5 minutes was collected in a sterile container given to them. The armamentarium used for saliva collection, was as follows

1. Sterile collection tubs – 80 + 80 = 160 (Baseline and at 6 months)

2. Chewable paraffin wax – 80 + 80 = 160 (Baseline and at 6 months)

3. Thermacoal Ice box – 2 nos

The collected saliva was then transferred to the sample collection box containing ice packs and transported to the Department of Microbiology, Ragas Dental College and Hospital, Chennai. The samples were then cultured in the selective media (Rogosa SL agar) culture plates which were prepared freshly.

Culture procedure:

Spread Plate Technique[54]: (photograph 6, 7, 8 and 9)

1. A dilution series from the samples were prepared aseptically up to fifth dilution using sterile test tubes.
2. 0.1 ml of the pipetted sample from the dilution series was applied onto the center surface of an agar plate, using a L-shaped glass spreader which was sterilized by dipping it into alcohol and by flaming over the Bunsen burner, the sample was then spreaded evenly by carefully rotating the petri plate underneath at the same time.
3. The agar plates were incubated at 37^{o}C for 96 hours anaerobically using anaerobic candle jar.

After 96 hours of incubation anaerobically, the Lactobacillus colonies were counted manually using magnifying lens. The counted colonies were recorded and substituted in the colony forming units (CFU) formula to give CFU/ml.

$$\text{CFU/mL} = \frac{\text{Number of Colonies X dilution factor}}{\text{Volume of the sample}}$$

The colony forming units were then entered into the cariogram software using the codes given in the cariogram manual.

INTERVIEW FOR DIET FREQUENCY: (Photograph 10)

An interview was carried out on all participants of Group I and Group II regarding 24 hours dietary recall to estimate the number of meals and snacks consumed per day. The collected data was recorded using the codes given in the cariogram manual for diet frequency.

ASSESSMENT OF PLAQUE AMOUNT: (Photograph 11 and 12)

A clinical examination was carried out to record Silness and Loe plaque index 1964. The clinical examination was carried out in the dental chair at the old age home premises. Time taken to record plaque index for each participant was 5 – 8 minutes. Clinical examination was done using

1. Plain mouth mirror
2. Explorer
3. Chip blower

The assessed full mouth plaque index score were coded and entered into the cariogram software given in the cariogram manual.

STERPTOCOCCUS MUTANS COUNT: (Photograph 13, 14, 15 and 16)

Streptococcus mutans colony count was done using standard bacteriological culture methods. The stimulated saliva collected in the early mentioned fashion from the participants of Group I and Group II. The collected saliva was cultured in the freshly prepared selective media (Mitis Salivarius agar) petri plates. Spread plate technique was followed to culture the Streptococcus mutans as mentioned earlier. The agar plates were then incubated at 37^{o}C for 48 hours aerobically. After 48 hours of incubation the colonies were isolated and incubated at 37^{o}C for 24 hours in the sugar fermentation broth containing sterilized peptone water, Raffinose sugar and Bromothymol blue. This sugar fermentation test was done for the confirmation of streptococcus mutans colony. A change in color of the broth from green to yellow indicated positive sugar fermentation test confirming presence of Streptococcus mutans colony. The colonies of Streptococcus mutans were then counted and colony forming unit was calculated using the CFU/ml formula. The colony forming units were then entered into the cariogram software using the codes given in the cariogram manual.

INTERVIEW FOR FLUORIDE PROGRAM:

An interview was carried out on all participants of group I and group II regarding any previous and present fluoride programs and any additional fluoride

programs were recorded. The collected data was recorded and entered in the software using the codes given in the cariogram manual for fluoride program.

ASSESSMENT OF SALIVARY SECRETION AMOUNT: (Photograph 17)

Salivary flow rate was assessed by collecting the stimulated saliva from all the participants of group I and group II in the similar manner. The stimulated saliva was collected in the measuring jar so that the amount of saliva collected for 5 minutes was divided by 5 to give the amount of salivary secretion rate for 1 minute in milliliter. The salivary secretion rate was entered into the software using the codes given in the manual.

ASSESSMENT OF SALIVARY BUFFER CAPACITY: (Photograph 18)

Salivary buffer capacity was assessed by measuring the pH of saliva using digital pH meter. The armamentarium used for measuring the pH of saliva was as follows

1. Digital pH meter (pHep® HI 98107 Pocket-sized pH Meter, Hanna Instruments)
2. Disposable Syringe (2 ml)
3. Tissue paper

The measured salivary buffer capacity was entered into the software using the codes given in the manual.

CLINICAL JUDGEMENT:

Clinical judgement was the opinion of the dental examiner. It was the examiners own clinical and personal score for the individual patient. In the cariogram software, clinical judgement factor was a preset score of 1 which comes automatically.

ORAL PROPHYLAXIS:

A complete oral prophylaxis was done for all the participants in Group I and Group II to make the plaque score equal among them. Oral prophylaxis was done for 10 participants daily and the approximate time taken for each participant was 15 minutes. The toothpaste and the toothbrush were given to the participants after completing oral prophylaxis and they were instructed not to use any other oral hygiene aids during the study period.

DISPENSING OF DENTIFRICE:

The participants in Group I and Group II were distributed randomly with their assigned fluoride toothpaste.

INGREDIENTS OF AMFLOR TOOTHPASTE:

S.NO	INGREDIENTS
1.	Sorbitol
2.	Purified water
3.	Propylene Glycol
4.	Silica
5.	Amine Fluoride
6.	Cocamidopropyl betaine
7.	Titanium Dioxide
8.	Hydroxyethyl cellulose
9.	Flavor
10.	Sodium Saccharin

The maximum available fluoride content in the toothpaste was 1000ppm. The organic fluoride (amine fluoride) containing toothpaste with net quantity of 70g was given to all the participants of Group I along with Colgate soft toothbrush.

The participants were instructed to brush their teeth twice daily using the given toothbrush and toothpaste. They were asked to dispense pea nut sized toothpaste on to the toothbrush and to use brushing technique which they were practicing earlier.

INGREDIENTS OF COLGATE TOTAL TOOTHPASTE:

S.NO	**INGREDIENTS**
1.	Sorbitol
2.	Water
3.	Polyethylene Glycol 12
4.	Hydrated Silica
5.	Cellulose Gum
6.	Sodium Lauryl Sulfate
7.	Flavor
8.	Sodium Sacchrine
9.	Titanium Dioxide

10.	Dye
11.	Sodium Fluoride

The maximum available fluoride content in the toothpaste was 1100ppm. The inorganic fluoride (sodium fluoride) containing toothpaste with net quantity of 70g was given to all the participants of Group II along with Colgate soft toothbrush. The participants were instructed to brush their teeth twice daily using the given toothbrush and toothpaste. They were asked to dispense pea nut sized toothpaste on to the toothbrush and to use the brushing technique which, they were practicing earlier.

REPLENISHMENT OF TOOTHPASTE:

The toothpaste was restored to all the participants in Group I and Group II, every 45 days once for 6 months. So a total of 4 numbers of toothpaste were distributed to each participant. The toothbrush was restored for every 60 days. A total of 3 numbers of toothbrushes were distributed to each participant during the study period.

CHECKING FOR THE COMPLIANCE:

A monitoring sheet containing 31 days calendar with morning and night columns for each day was given to all the participants and they were instructed to put a tick mark after brushing their teeth each day on the respective columns which was supervised by the nurse assistant who reside in the old age home. This sheet was checked by the examiner for each participant by making a visit to the study places every week. Any non-compliance with tooth brushing in the participants was instructed strongly to brush their teeth twice daily by the examiner.

DATA COLLECTION AT SIX MONTHS:

CLINICAL EXAMINATION:

The clinical examination to record the DMFT scores and plaque scores was done in the same method carried out at the baseline assessment. The index scores were entered into the cariogram software according to the codes given in the manual.

INTERVIEW:

An interview regarding the general diseases, medications, diet frequency and fluoride program was carried out in the same method followed at the baseline

assessment. The collected data were then entered into the software in correspondence with the codes given in the manual to each factor.

ASSESSMENT OF LACTOBACILLUS AND STREPTOCOCCUS MUTANS COUNT:

The stimulated saliva from each participant was collected in the similar manner done at the baseline assessment. The collected saliva was transferred to the laboratory carefully in the thermacoal box containing ice packs. The salivary samples were then cultured in the petri plates containing the respective selective medium which was freshly prepared. The petri plate containing Mitis salivarius agar was cultured for 48 hours at 37^{o}C aerobically and Rogosa SL agar was cultured for 96 hours at 37^{o}C anaerobically in the anaerobic candle jar. The colonies formed were counted in the similar manner and substituted to the colony forming units' formula to calculated CFU/ml. This CFU/ml was entered into the software using the codes given in the manual.

ASSESSMENT OF SALIVARY SECRETION RATE AND BUFFER CAPACITY:

The stimulated salivary secretion rate and salivary buffer capacity was measured in the similar fashion done at the baseline using measuring jar and

digital pH meter. The measurements were then entered into the cariogram software using the codes given in the manual.

STATISTICAL ANALYSIS:

The following procedures were carried out:-

1. Data compilation and presentation

2. Statistical analysis

1. Data compilation and presentation:

Data obtained were compiled systematically in Microsoft Excel spreadsheet. The dataset was subdivided and distributed meaningfully and presented as graphs and tables.

2. Statistical analysis:

Statistical analyses were performed using Statistical package for Social Sciences software (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp). Normality test was done using Kolmogorov-Smirnov test and Shapiro-Wilk numerical test and it was found that all variables were normally distributed. Depending upon the nature of the data, appropriate parametric statistical tests were chosen. p value of < 0.05 was considered to be significant.

Student's unpaired t- Test was used to compare the age, salivary flow rate, salivary buffer capacity, mean green sector, red sector, yellow sector, light blue sector and dark blue sector, Streptococcus mutans count, Lactobacillus count, Plaque index score, DMFT scores among two groups at baseline and after 6 months. Student's paired t-Test was used to compare the variables in each group at baseline and after 6 months.

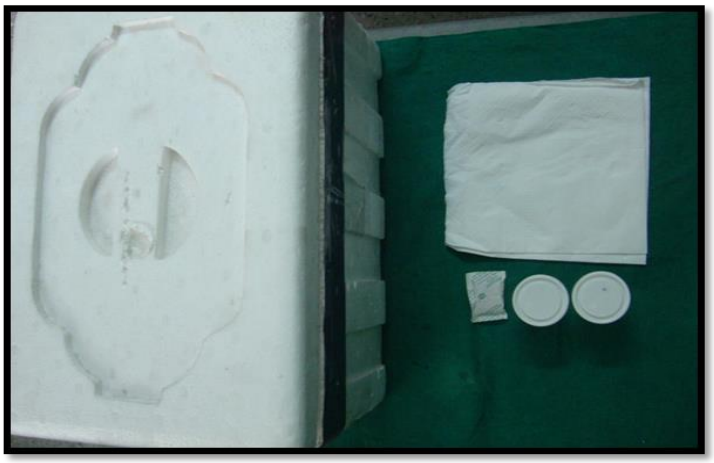
PHOTOGRAPHS

PHOTOGRAPH 1: ARMAMENTARIUM USED FOR ASSESSMENT OF CARIES EXPERIENCE

PHOTOGRAPH 2: ASSESSMENT OF CARIES EXPERIENCE USING DECAYED – MISSING FILLED TEETH

PHOTOGRAPH 3: INTERVIEW FOR RELATED GENERAL DISEASE IN STUDY PARTICIPANTS

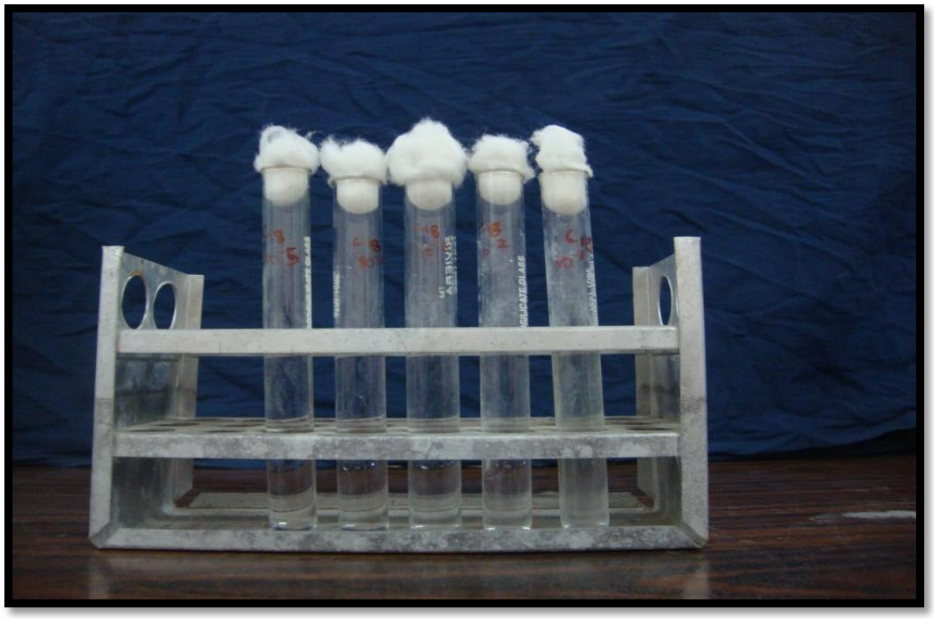
PHOTOGRAPH 4: ARMAMENTARIUM USED FOR COLLECTION OF STIMULATED SALIVA



PHOTOGRAPH 5: COLLECTION OF STIMULATED SALIVA FROM STUDY PARTICIPANTS

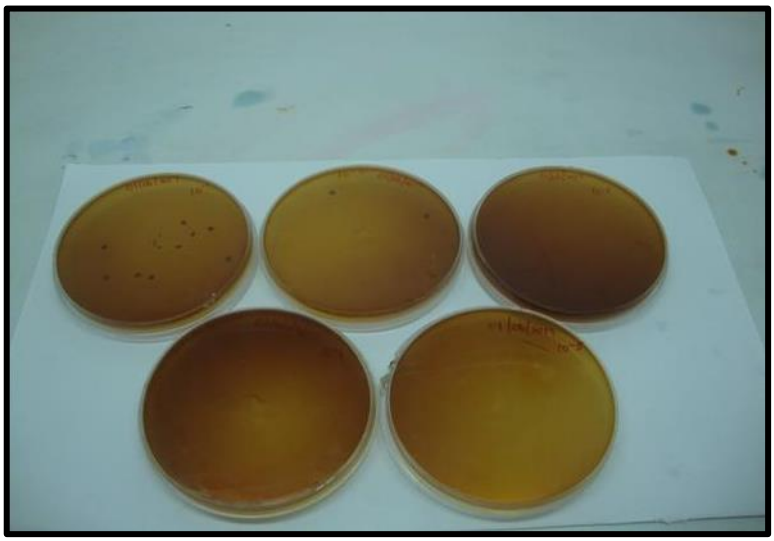
PHOTOGRAPH 6: ROGOSA SL AGAR MEDIA PREPARATION AND MEDIA POURED IN CULTURE PLATE

PHOTOGRAPH 7: SERIAL DILUTION OF STIMULATED SALIVA SAMPLES



PHOTOGRAPH 8: SPREAD PLATE TECHNIQUE TO CULTURE *LACTOBACILLUS*

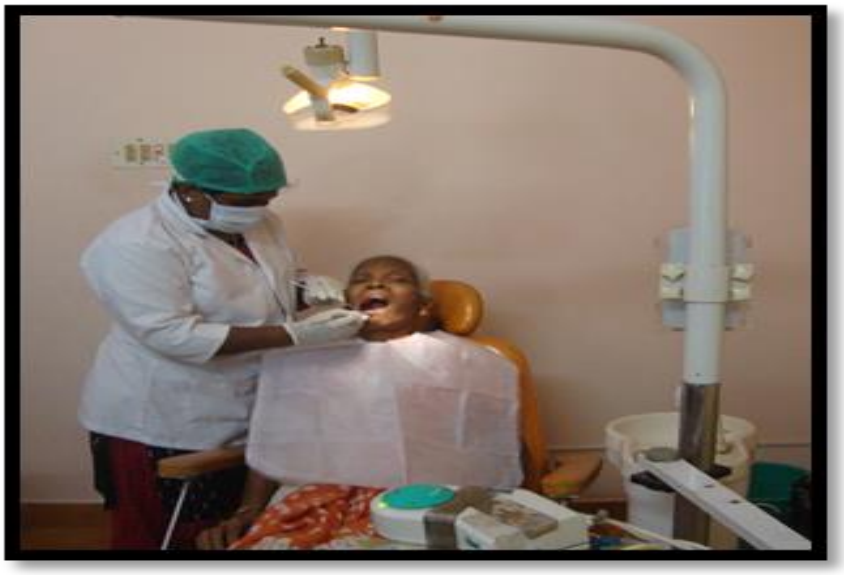
PHOTOGRAPH 9: LACTOBACILLUS COLONY FORMATION AFTER 96 HOURS INCUBATION



PHOTOGRAPH 10: INTERVIEW FOR DIET FREQUENCY AND FLUORIDE PROGRAM

PHOTOGRAPH 11: ARMAMENTARIUM USED FOR ASSESSMENT OF PLAQUE AMOUNT

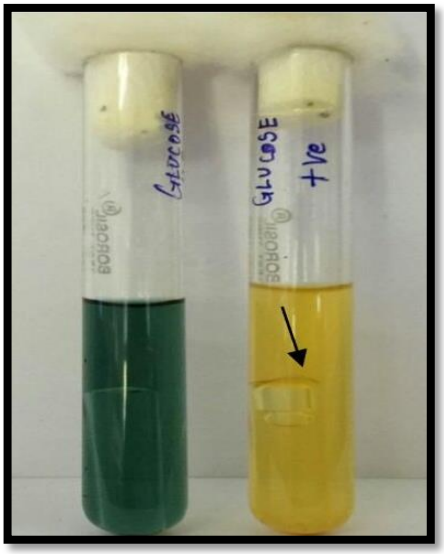
PHOTOGRAPH 12: ASSESSMENT OF PLAQUE AMOUNT USING SILNESS AND LOE PLAQUE INDEX



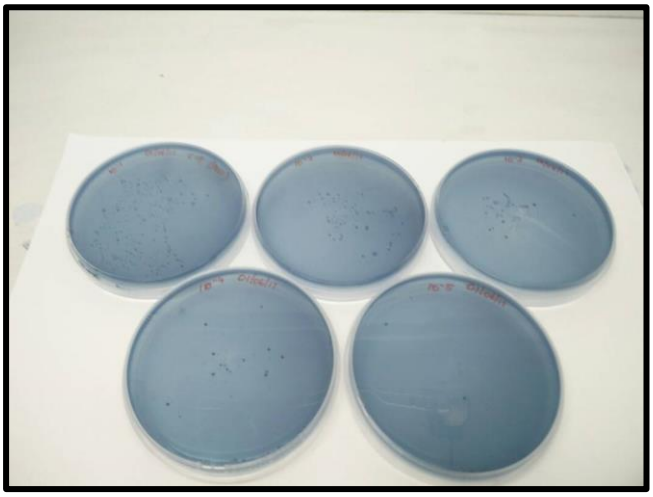
PHOTOGRAPH 13: MITIS SALIVARIUS AGAR PREPARATION AND MEDIA POURED IN CULTURE PLATE

PHOTOGRAPH 14: SPREAD PLATE TECHNIQUE TO CULTURE STREPTOCOCCUS MUTANS

PHOTOGRAPH 15: SUGAR TEST TO IDENTIFY *STREPTOCOCUS MUTANS*



PHOTOGRAPH 16: *STREPTOCOCCUS MUTANS* COLONY FORMATION AFTER 48 HOURS INCUBATION



PHOTOGRAPH 17: ASSESSMENT OF STIMULATED SALIVA SECRETION RATE

PHOTOGRAPH 18: ASSESSMENT OF STIMULATED SALIVA PH

RESULTS

The present study was conducted to compare the effect of two commercially available fluoridated dentifrices on the risk factors of dental caries among institutionalized geriatric population in Chennai city. This study was done among 80 subjects divided into two groups with 40 participants in each group. Inmates of one old age home were included in Group I (organic fluoride toothpaste) and inmates of other old age home were included in Group II (Inorganic fluoride toothpaste). The study was conducted over a period of 6 months.

Figure 1: Distribution based on mean age of study population

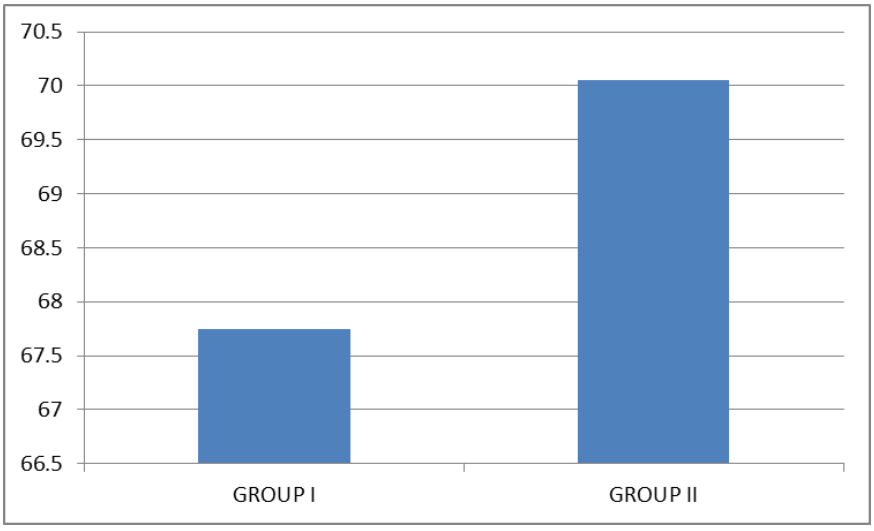


Table 1: Distribution based on mean age of study population

Variable	Group I		Group II		t Value	P Value
	n	Mean (±SD)	n	Mean (±SD)		
Age	40	67.75 (±4.1)	40	70.05 (±7.4)	0.846	0.093

*Unpaired t – Test

Table 1 shows the mean age distribution of the study population in Group I and Group II. The mean age of the participants in Group I was 67.75 (±4.1) and in Group II was 70.05 (±7.4). There was no statistically significant difference in mean age between the study participants of two groups.

Figure 2: Distribution based on educational qualification among study population

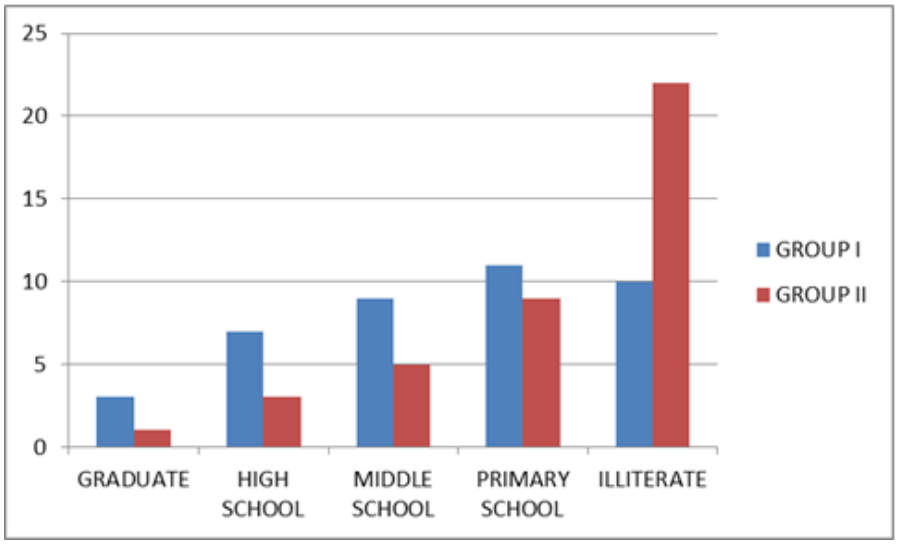


Table 2: Distribution based on educational qualification among study population

Variable	Group I n (%)	Group II n (%)	χ2Value	p Value
Graduate	3 (7.5%)	1 (2.5%)		
High School	7 (17.5%)	3 (7.5%)		
Middle School	9 (22.5%)	5 (12.5%)	5.420	0.000*
Primary School	11 (27.5%)	9 (22.5%)		
Illiterate	10 (25%)	22 (55%)		

*Chi-square test

Table 2 shows the distribution based on educational qualification of the study population in Group I and Group II. Among 40 participants in Group I, 3 participants were graduates, 7 participants had high school education, 9 participants had middle school education, 11 participants had primary school education and 10 participants were illiterate. Among 40 study participants in Group II, 1 participant was graduated, 3 participants had high school education, 5 participants had middle school education, 9 participants had primary school education, and 22 participants were illiterate. There was a statistical significant difference in the educational qualification between Group I and Group II participants.

Figure 3: Distribution based on mean chance of avoiding caries sector (Green) at baseline and at 6 months among study population

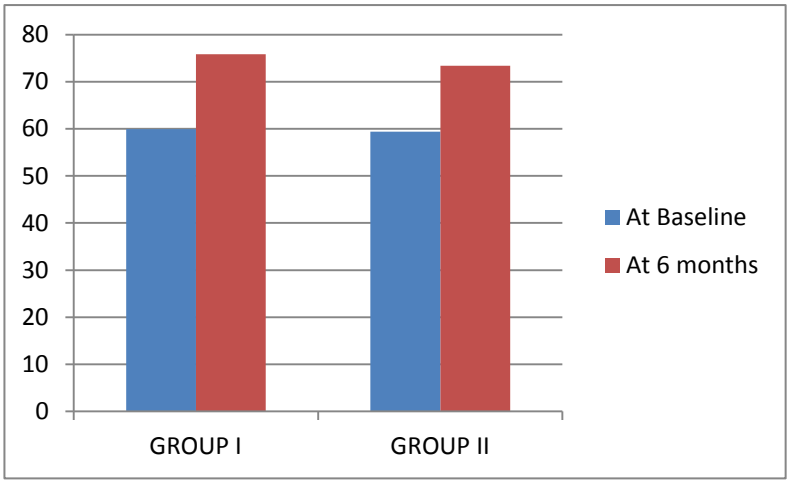


Table 3: Distribution based on mean chance of avoiding caries sector (Green) at baseline and at 6 months among study population

Variable	Group I		Group II		t value	p value
Chance of avoiding caries	n	Mean (±SD)	n	Mean (±SD)		
At baseline	40	59.93 (±11.1)	40	59.38 (±15.7)	0.180	0.852*
At 6 months	40	75.85 (±8.28)	40	73.40 (±15.6)	0.875	0.384*
t value		-19.78		-17.85		
p Value		0.000#		0.000#		

Table 3 shows the mean distribution of green sector of the study population in Group I and Group II. The mean chance of avoiding caries at

baseline in Group I and Group II was 59.93 (±11.1) and 59.38 (±15.7) respectively with no statistical significant difference in their mean value between two groups. The mean chance of avoiding caries at 6 months after intervention between Group I and Group II was found to be 75.85 (±8.28) and 73.40 (±15.6) respectively with no statistical significance in their mean green sector between two groups. However there was a statistical significant difference in the mean chance of avoiding caries at baseline and at 6 months within Group I and Group II.

Figure 4: Distribution based on mean circumstances sector (Yellow) at baseline and at 6 months among study population

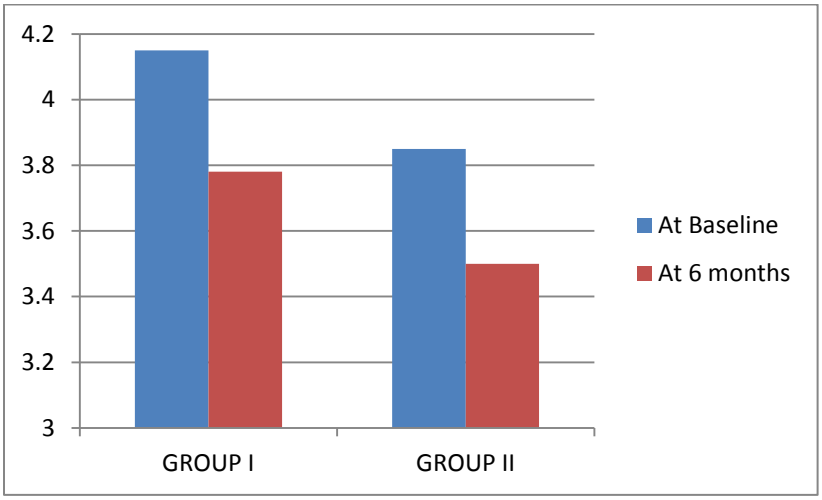


Table 4: Distribution based on mean circumstances sector (Yellow) at baseline and at 6 months among study population

Variable	Group I		Group II		t value	p Value
Circumstances	n	Mean (±SD)	n	Mean (±SD)		
At Baseline	40	4.15 (±1.51)	40	3.85 (±1.49)	0.893	0.300*
At 6 months	40	3.78 (±1.38)	40	3.50 (±1.41)	0.878	0.275*
t Value		3.553		2.655		
p Value		0.001#		0.011#		

*Unpaired t – Test
Paired t – Test

Table 4 shows the distribution of yellow sector at baseline among Group I and Group II. The mean value of yellow sector among study participants in Group I and Group II at baseline was 4.15 (±1.51) and 3.85 (±1.49) respectively. Similarly there was no statistical difference in the yellow sector at 6 months after invention among Group I and Group II with a mean value of 3.78 (±1.38) and 3.50 (±1.41) respectively. There was a statistical significant difference in the mean value of yellow sector at baseline and at 6 months within Group I and Group II participants.

Figure 5: Distribution based on mean susceptibility sector (Light blue) based on at baseline and at 6 months among study population

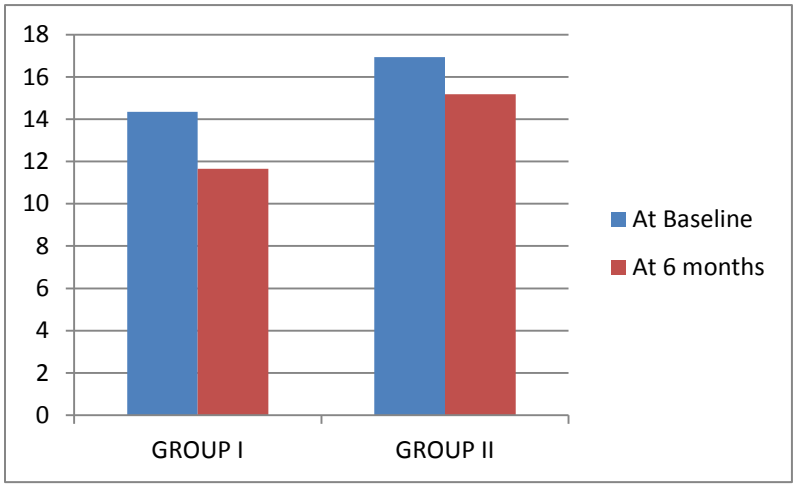


Table 5: Distribution based on mean susceptibility sector (Light blue) at baseline and at 6 months among study population

Variable	Group I		Group II		t value	p Value
Susceptibility	n	Mean (±SD)	n	Mean (±SD)		
At Baseline	40	14.35 (±9.71)	40	16.93 (±16.4)	-0.853	0.396*
At 6 months	40	11.65 (±4.11)	40	15.18 (±14.2)	-1.501	0.137*
t Value		2.253		2.420		
p Value		0.030#		0.020#		

*Unpaired t – Test
Paired t – Test

Table 5 shows the mean distribution of susceptibility of caries sector of the study population. The mean value of combination of fluoride program, saliva secretion rate and salivary buffer capacity at baseline and at 6 months among Group I and Group II was 14.35 (±9.71); 16.93 (±16.4) and 11.65 (±4.11); 15.18 (±14.2) respectively. It was found that there was no statistical difference in the mean value of light blue sector between Group I and Group II at baseline and at 6 months. There was a statistically significant difference at baseline and after 6 months among Group I and Group II in their fluoride program, saliva secretion rate and salivary buffer capacity with a p value of 0.002 and 0.020. Reduction of mean light blue sector was more in the Group I (from 14.35 to 11.65) compared with Group II (from 16.93 to 15.18).

Figure 6: Distribution based on combination of mean amount of plaque and *Streptococcus mutans* count sector (Red) at baseline and at 6 months among study population

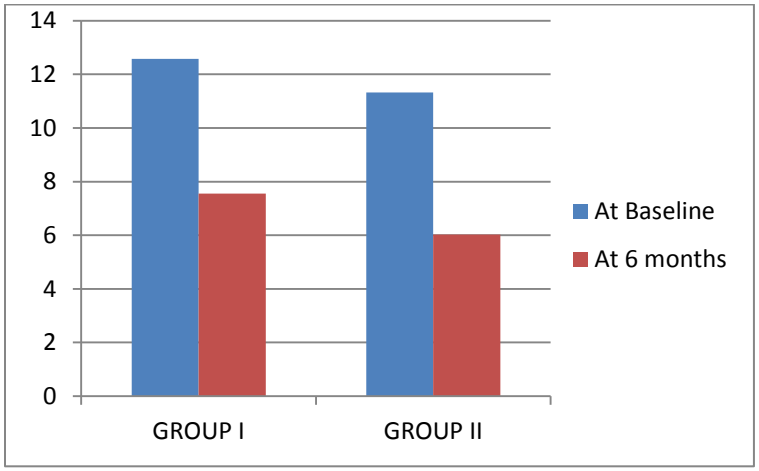


Table 6: Distribution based on combination of mean amount of plaque and *Streptococcus mutans* count sector (Red) at baseline and at 6 months among study population

Variable	Group I		Group II		t value	p Value
Bacteria	n	Mean (±SD)	n	Mean (±SD)		
At Baseline	40	7.55 (±4.42)	40	11.33 (±4.82)	1.207	0.231*
At 6 months	40	4.15 (±4.81)	40	6.03 (±4.34)	1.487	0.141*
t Value		16.78		14.67		
P Value		0.000#		0.000#		

*Unpaired t – Test
Paired t – Test

Table 6 shows the distribution of Group I and Group II study participants based on combination of amount of plaque and *Streptococcus mutans* count. The mean value of red sector among Group I and Group II was 7.55 (±4.42) and 11.33 (±4.82) with no statistical significance between the two groups at baseline. The mean value of red sector among group I and group II at 6 months was 4.15 (±4.81) and 6.03 (±4.34) with no statistical significance in their mean red sector value between the two groups. There was a statistically significant difference in the mean red sector values at baseline and at 6 months within Group I and Group II participants.

Figure 7: Distribution based on the mean diet contents and diet frequency sector (Dark blue) at baseline and at 6 months among study population

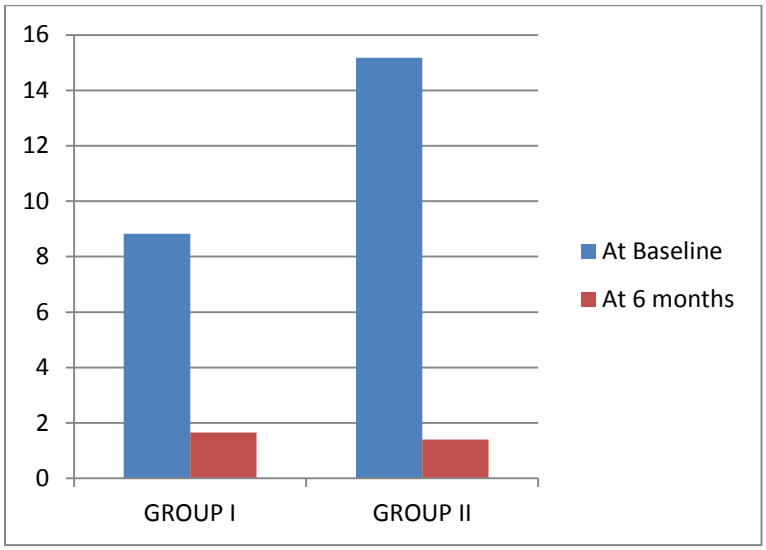


Table 7: Distribution based on mean diet contents and diet frequency sector (Dark blue) at baseline and at 6 months among study population

Variable	Group I		Group II		t value	p Value
Diet	n	Mean (±SD)	n	Mean (±SD)		
At Baseline	40	8.83 (±1.10)	40	15.18 (±1.23)	1.427	0.157*
At 6 months	40	1.65 (±1.70)	40	1.40 (±0.98)	0.804	0.424*
t Value		34.80		36.79		
p Value		0.000#		0.000#		

*Unpaired t – Test
Paired t – Test

Table 7 shows the mean distribution of diet sector (Dark blue) of the study participants. The diet sector was based on the combination of diet contents (*Lactobacillus count*) and diet frequency. The mean scores for dark blue sector at baseline for group I and group II was 8.83 (±1.10) and 15.18 (±1.23) respectively with no statistical significant difference in their values. The mean value of dark blue sector at 6 months in Group I and Group II was 1.65 (±1.70) and 1.40 (±0.98) respectively with no statistical difference between the two groups. There was a high statistical significant difference in their diet contents and diet frequency at baseline and at 6 months within Group I and Group II participants.

There was no change in the mean DMFT value in Group I (4.0) at baseline over 6 months and in Group II (4.5) at baseline over 6 months. There found to be no statistical significant difference in the mean DMFT between the Group I and Group II study participants.

Figure 8: Distribution based on the presence of general related diseases at baseline among study population

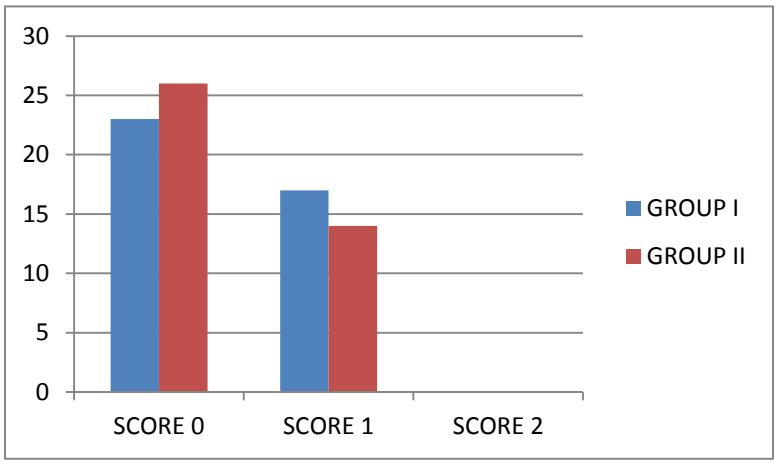


Table 8: Distribution based on the presence of general related diseases at baseline among study population

Variable	Group I n (%)	Group II n (%)	χ^2 Value	p value
Score 0	23 (57.5%)	26 (65%)		
Score 1	17 (42.5%)	14 (35%)	4.050	0.044*
Score 2	0	0		

*Chi-square test

Table 8 shows the distribution based on the presence of general related disease at baseline among the study participants. In Group I, 23 participants had no disease and 17 participants had mild degree of disease. Similarly in Group II, 26 participants had no disease and 14 participants had mild degree of disease. There was a statistical significant difference between the two groups based on the distribution of general related disease.

Table 9: Distribution based on mean *Lactobacillus* colony forming unit (CFU)/ml at baseline and after 6 months among study population

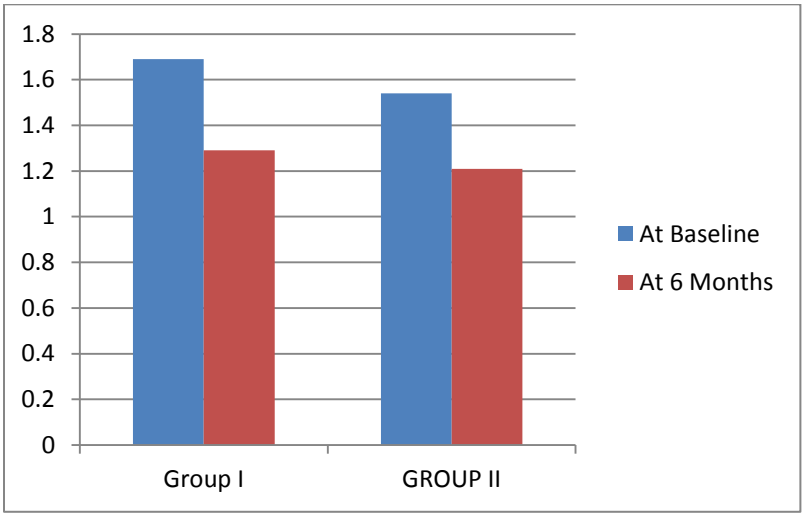
Variable	Group I		Group II		t Value	p Value
***Lactobacillus* count**	n	Mean CFU/ml (±SD)	n	Mean CFU/ml (±SD)		
At Baseline	40	$2.4x10^5(\pm 2x10^5)$	40	$3.6x10^5(\pm 2.2x10^5)$	-2.807	0.000*
At 6 months	40	$7.4x10^2$ $(\pm 1x10^2)$	40	$2.5x10^3(\pm 1.4x10^3)$	-5.694	0.000*
t Value		14.87		13.45		
p Value		0.000#		0.000#		

*Unpaired t – Test
Paired t – Test

Table 9 shows the mean CFU/ml of *Lactobacillus* colony count of the study population in Group I and Group II. The mean colony forming unit per ml

of *Lactobacillus* at baseline and at 6 months among Group I study participants was $2.4x10^5$ CFU/ml and $7.4x10^2$ CFU/ml respectively with a statistical significant p value of 0.000. The mean colony forming unit per ml of *Lactobacillus* in Group II at baseline and at 6 months was $7.4x10^2$ CFU/ml and $2.5x10^3$ CFU/ml respectively. There was a statistical significant difference in the mean colony forming unit (CFU) per ml of *Lactobacillus* at baseline and at 6 months within Group I (p=0.000) and Group II (p=0.000) study participants. Also there was a high reduction in CFU/ml of *Lactobacillus* in Group I participants compared to that of Group II participants.

Figure 9: Distribution based on mean plaque score at baseline and at 6 months among study population



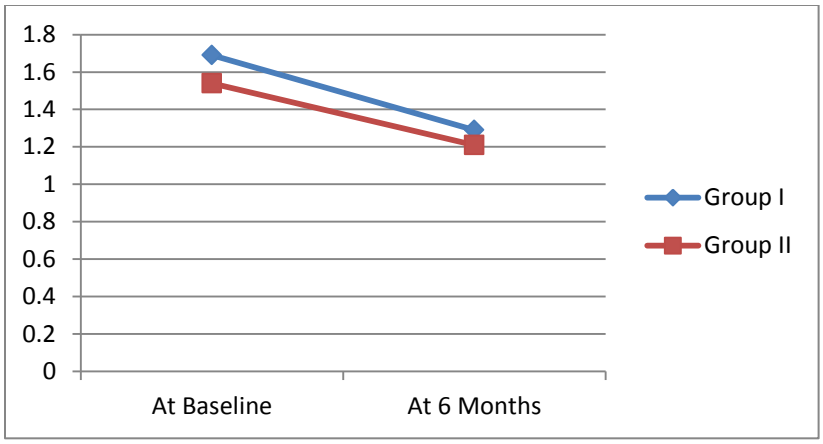


Table 10: Distribution based on mean plaque score at baseline and at 6 months among study population

Variable	Group I		Group II		t Value	p Value
Plaque score	n	Mean (±SD)	n	Mean (±SD)		
At Baseline	40	1.69 (±0.85)	40	1.54 (±0.97)	0.693	0.491*
At 6 months	40	1.29 (±0.74)	40	1.21 (±0.78)	1.435	0.155*
t Value		6.211		4.373		
p Value		0.000#		0.000#		

*Unpaired t – Test
Paired t – Test

Table 10 shows the mean plaque score of the study population at baseline and at 6 months. The mean plaque score using Silness and Loe plaque index in

Group I and GroupII at baseline was 1.69 (±0.85) and 1.54 (±0.97) respectively. There was no statistical difference in the mean plaque score between Group I and Group II at baseline. The mean plaque score of Group I and II at 6 months after intervention reduced to 1.39 (±0.74) and 1.15 (±0.78) respectively. Though there was no statistical difference in their mean value between two groups, there existed a statistical significant reduction in the mean plaque score from baseline to 6 months within Group I and Group II.

Table 11: Distribution based on mean *Streptococcus mutans* colony forming unit (CFU)/ml at baseline and at 6 months among study population

Variable	Group I		Group II		t Value	p Value
S. mutans	n	Mean CFU/ml (±SD)	n	Mean CFU/ml (±SD)		
At Baseline	40	$9.3x10^5(\pm3.7x10^5)$	40	$5.5x10^5$ $(\pm2.6x10^5)$	5.265	0.000*
At 6 months	40	$1.2x10^3$ $(\pm0.5x10^3)$	40	$3.1x10^3(\pm1.4x10^3)$	-5.504	0.000*
t Value		34.56		29.78		
p Value		0.000#		0.000#		

*Unpaired t – Test
Paired t – Test

Table 11 shows the mean CFU/ml count of *Streptococcus mutans* of the study participants in Group I and Group II. The mean CFU/ml count of *Streptococcus mutans* in Group I at baseline and at 6 months was $9.3x10^5$ CFU/ml and $1.2x10^3$ CFU/ml respectively with a statistical significant difference in their mean CFU/ml values. The mean CFU/ml count of *Streptococcus mutans* in Group II at 6 months after intervention was $5.5x10^5$ CFU/ml and $3.1x10^3$ CFU/ml respectively. There was a statistical significant difference in the CFU/ml of *Streptococcus mutans* at baseline and at 6 months within Group I (p=0.000) and Group II (p=0.000) study participants. Though there was reduction CFU/ml of *Streptococcus mutans* in both the groups over 6 months, Group I participants had high reduction of CFU/ml compared to Group II participants.

Figure 10: Distribution based on mean saliva secretion rate (ml/minute) at baseline and at 6 months among study population

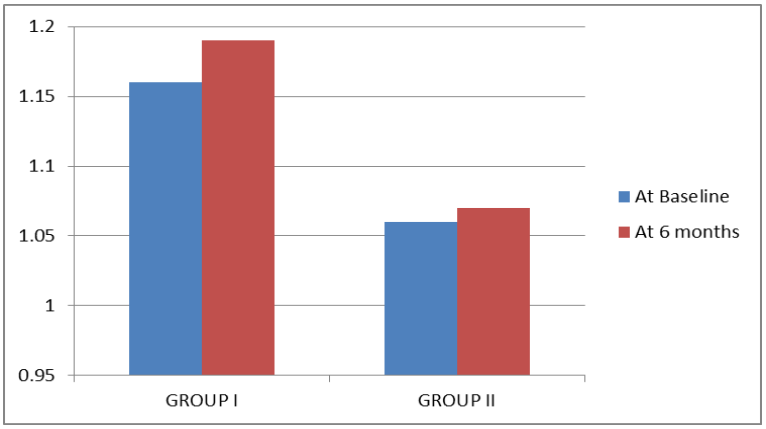


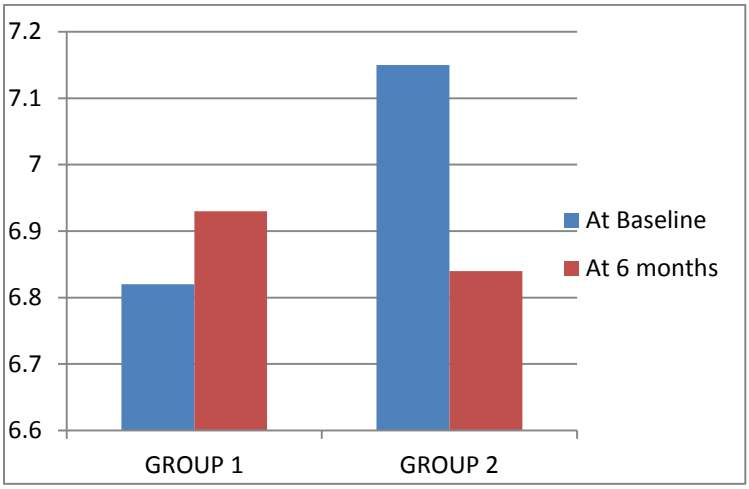
Table 12: Distribution based on mean saliva secretion rate (ml/minute) at baseline and at 6 months among study population

Variable	Group I		Group II		t Value	p Value
Salivary secretion	n	Mean ml/min (±SD)	n	Mean ml/min (±SD)	1.146	0.255*
At Baseline	40	1.16 (±0.44)	40	1.06 (±0.37)	1.425	0.158*
At 6 months	40	1.19 (±0.35)	40	1.07 (±0.42)		
t Value		-1.030		-0.264		
p Value		0.309#		0.793#		

*Unpaired t – Test
Paired t – Test

Table 12 shows the mean saliva secretion rate ml/minute of Group I and Group II study population. The mean saliva secretion rate of Group I and Group II study participants at baseline was 1.16(±0.44) ml/min and 1.06(±0.37) ml/min with no statistical difference in their mean value. Similarly the mean saliva secretion rate of Group I and Group II study participants at 6 months was 1.19(±0.35) ml/min and 1.07(±0.42) ml/min respectively with no statistical significant difference in their mean value. There was no statistically significant difference in the mean saliva secretion rate at baseline and at 6 months within Group I and Group II also.

Figure 11: Distribution based on mean salivary buffer capacity of study population at baseline and at 6 months



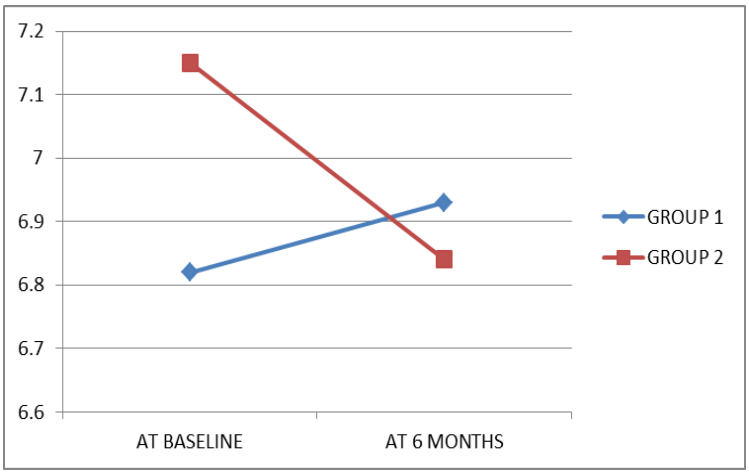


Table 13: Distribution based on mean salivary buffer capacity at baseline and at 6 months among study population

Variable	Group I		Group II		t Value	p Value
Salivary buffer capacity	n	Mean (±SD)	n	Mean (±SD)		
At Baseline	40	6.82 (±0.31)	40	7.15 (±0.48)	-3.602	0.001*
At 6 months	40	6.93 (±0.27)	40	6.84 (±0.38)	1.163	0.248*
t Value		-2.490		3.847		
p Value		0.017#		0.000#		

*Unpaired t – Test
Paired t – Test

Table 13 shows the mean salivary buffer capacity of Group I and Group II study population. The mean salivary buffer capacity of Group I and Group II study participants at baseline was 6.82 (±0.31) and 7.15 (±0.48) respectively with a statistical significant difference. The mean salivary buffer capacity at 6 months after intervention among Group I and Group II was 6.93 (±0.27) and 6.84 (±0.38) respectively with no statistical significant difference in their mean buffer capacity. There was a statistical significant difference in the mean buffer capacity at baseline and at 6 months within Group I and Group II

DISCUSSION

The present study was conducted to evaluate the effectiveness of two commercially available fluoridated dentifrices on the risk factors of dental caries among institutionalized geriatric population. Interventional study design was considered to be an appropriate design since the effectiveness of two commercially available fluoridated dentifrices on the risk factors of dental caries could be better compared by them rather than any other study design. There is a demographic revolution happening globally with increased number of people aged 65 or older. India being the second largest country with 103 million elderly populations in the year 2016, faces challenges concerning the health welfare of the geriatrics[3]. Since oral health, is an integral part of general health and well-being of humans, efforts should be directed to maintain adequate oral health and hygiene. Among the most common oral diseases leading to tooth loss in the elderly population, dental caries is considered to be the most prevalent entity next to periodontal disease. Moreover, the prevalence of dental caries among the geriatrics in India was found to be 85% in 2012.[55] Studies also have reported that dental caries contributes to 63% of the tooth loss in the elderly population.[56, 57] In recent times, substantial body of evidence shows alarming levels of increase in the prevalence of dental caries in the geriatric institutions of urban areas in Tamil Nadu state. The high prevalence of dental caries among the geriatric population,

and the associated tooth loss can be attributed to lack of awareness among them about oral diseases, lack of proper oral hygiene practices, lack of preventive measures and lack of access to dental services.[58] Many elderly still hold the opinion that tooth loss is a normal part of the aging process and hence not preventable; further they are also not introduced to the concept of preventive dentistry at younger age. In addition due to the increased dependency of institutionalized geriatrics on the caregivers in making their dental visits and maintaining their oral hygiene, there is a need for preventive measures to reduce the risk of dental caries among the geriatrics. Hence, the present study was aimed to assess the effectiveness of two preventive fluoride based program on the risk factors of dental caries among institutionalized geriatrics.

Centuries ago, only surgical approach for management of dental caries was being practiced with no other valid alternative. Present advances in field of caries research has not only led to improved understanding of disease process, but also emphasized on early detection of initial carious lesion and preventive measures to control dental caries. The discovery of the anti-cariogenic properties of fluorides is one of the most important landmarks in the history of dentistry. The cariostatic effect of fluoride is primarily due to its ability to decrease the rate of demineralization by forming fluorohydroxyapatite crystals and enhancing the remineralization of incipient carious lesions. Fluoride incorporated post-eruptively during the caries challenge plays an important role in caries prevention.

The most effective caries preventive fluoride regimen is provided by the daily application of topical fluoride in the form of dentifrices and mouth-rinses. There are about two types of topical fluorides used in dentistry, such as inorganic fluoride and organic fluoride which are made available in various forms such as toothpaste, mouth rinse, gels/foams, varnish, lozenges and chewable tablets. The anti-cariogenic action of topical fluorides depends on the solubility of the fluoride containing compound and its adhesion to the tooth surface.[40]

Systematic reviews and meta-analysis have been conducted to compare the effectiveness of various topical inorganic fluoride (sodium fluoride, calcium fluoride, stannous fluoride and sodium mono-fluoro phosphate) therapies for the prevention of dental caries in primary and permanent dentition.[59] These studies confirmed the properties of inorganic fluorides in prevention of dental caries such as decrease in enamel solubility, enhanced remineralization and anti-enzymatic property by formation of Fluor apatite crystals, improving the crystal growth, stabilizing the crystal structure, affecting the enzymatic glycolytic pathway, sugar transport and intracellular pH homeostasis of bacteria respectively.

Though prevention of dental caries by use of topical inorganic fluoride agent had been evidenced since 1970s, the experiment by Wainriht in 1954 on high permeability of enamel to organic molecules like urea, made him to recommend the use of organic molecule as a carrier of fluoride. Muhleman et al in

1957 found that organic fluoride like amino fluoride compounds were superior to inorganic fluorides in reducing the solubility of the enamel in his in-vitro study.[60] The superiority of organic fluoride in preventing dental decay compared to inorganic fluoride was demonstrated by Muhlman in 1967. He also observed that amine fluoride had a pronounced affinity towards enamel, thus raising the quantity of fluoride in the enamel in addition to its antienzyme effect on the microbial activity of dental plaque. He also concluded that even in low concentration amino fluorides produced the most powerful enrichment in fluoride by its unique amphilic nature with hydrophilic and hydrophobic parts within one molecule. The carious preventive action of organic fluoride is due to fluoride on one side and the anti-enzyme effect of the organic fraction on the other side, arresting the formation of dental plaque, as a result of the tension-active properties.[28] Hence, organic fluoride (amine fluoride) was made available commercially as gels, fluids, dentifrices and mouth rinses. Numerous animal studies, in-vitro and in-situ human studies comparing the effect of organic fluoride and inorganic fluoride agents in prevention of dental caries had been conducted till date demonstrating the superiority of organic fluoride with its enhanced remineralization and anti-enzymatic property. However, only a few human clinical trials have been conducted recently comparing organic and inorganic fluoride agents in prevention of dental caries in primary and permanent dentition. Hence, the present study was designed to compare the effectiveness of a

commercially available organic fluoride dentifrice (amine fluoride, Amflor) and an inorganic fluoride dentifrice (sodium fluoride, Colgate Total) on the risk factors of dental caries among the institutionalized geriatric population.

The study participants were divided into two groups: Group I (received organic fluoride toothpaste) and Group II (received inorganic fluoride toothpaste). Caries related risk factors using cariogram model was used to evaluate the effectiveness of two commercially available fluoridated dentifrices. Clinical examination was done in both the groups to assess the caries experience using Decayed – Missing – Filled Teeth index (Henry T. Klein, Carrole E. Palmer, and Knutson J.W, 1938) and plaque amount using Silness and Loe plaque index (1964). An interview was carried out to record general health related diseases, diet frequency and fluoride programme of cariogram caries related factors. Saliva samples were collected from the participants of both the groups to estimate saliva secretion rate, saliva buffer capacity, *Streptococcus mutans* count, and diet content (*Lactobacillus count*). This interventional study was conducted over a period of 6 months.

INORGANIC FLUORIDE VERSUS ORGANIC FLUORIDE:

A prospective, randomized, double-blind study with 115 orthodontic patients conducted by Oogard B et al, examined the effect of combined use of a toothpaste/mouthrinse containing amine fluoride/stannous fluoride (AmF/SnF_2;

meridol®) and sodium fluoride (NaF) toothpaste/mouthrinse on the development of white spot lesions, plaque, and gingivitis on maxillary anterior teeth. The subjects were followed up longitudinally during the orthodontic treatment (average approximately 1.5 years). On brushing twice daily and rinsing every evening with their respective allotted tooth paste and mouth rinse showed no significant difference in the visible plaque index (VPI), gingival bleeding index (GBI) and white spot lesion index (WSL) at bonding and after debonding in the AmF/SnF_2 group but showed a significant increase in the indices among the participants of NaF group. The number of new lesions that developed on the upper anterior teeth in the AmF/SnF_2 group was 13 on a total of 297 teeth or 4.3 per cent compared with 20 new lesions on a total of 282 teeth or 7.2 per cent in the NaF group. Thus it was concluded that combined use of an AmF/SnF_2 toothpaste/mouthrinse had a slightly more inhibitory effect on white spot lesion development, plaque and gingivitis compared with NaF.[29] A review done by Madlena M on the clinical experiences of amine fluoride containing products in the management of dental hard tissue lesions on children and adults showed a 30% decrease in the mean plaque index score and reduction in caries increment of 35% - 70%.[38]

A clinical trial conducted by Poureslami HR et al, with 100 children divided into five groups, treated with amine fluoride solution, professional prophylactic paste, chewing gum containing xylitol and fluoride, chlorhexidine

solution and sodium fluoride gel resulted in significant high reduction in the mean stimulated salivary CFU/ml of *Streptococcus mutans* from 10^5 to 10^3 CFU/ml and significant high reduction in the mean stimulated salivary CFU/ml of *Lactobacillus* from 10^5 to 10^4 over a period of 2 months with amine fluoride solution group compared to sodium fluoride gel group from 10^5 to 10^4 CFU/ml.[61]

The results of the present study were also comparable with the findings of above mentioned studies where a significant reduction in mean CFU/ml of *Streptococcus mutans* and *Lactobacillus* were observed in organic (amine) fluoride group compared to inorganic (sodium) fluoride group.

Caries Experience (Caries prevalence):

The mean DMFT obtained by calculating the number of decayed, missing and filled teeth illustrates the balance between resistance factors and caries inducing factors in the past, or at the present. Participants of both the groups in the present study showed no difference in the caries prevalence at baseline and at 6 months after intervention. Though previous studies have demonstrated higher caries increments on use of inorganic fluoride (sodium fluoride) toothpaste compared to the use of organic fluoride (amine fluoride) toothpaste, the present study demonstrated no difference in caries increment among the participants. This difference could be attributed to the lower follow up time for the subjects of the present study. The results of the present study could have been more valid if the

participants were followed for a longer duration to demonstrate the difference in the caries increments between inorganic fluoride (sodium fluoride) and organic fluoride (amine fluoride) dentifrices.

Related general diseases:

Several general diseases or conditions can directly or indirectly influence the caries risk, either through factors affecting saliva formation and composition, their dietary pattern or through medications. The present study results showed no difference in the general disease related factors among the study population.

Diet Content:

Diet plays a key role in the development of dental caries, and a correlation between consumption of fermentable carbohydrates and caries had been demonstrated in several studies, especially where an effective preventive fluoride program is absent. Fermentable carbohydrates include dietary sugars (mainly sucrose, glucose, and fructose) and cooked starches, which can be broken down rapidly by salivary amylase to fermentable sugars (glucose, maltose and maltotriose). Thus most frequent eating occasions are potentially cariogenic.[53] A good indicator for an effective diet counseling is the use of saliva tests, like the *Lactobacillus* test. A high *Lactobacillus* colony count may indicate high carbohydrate consumption. The mean colony forming unit of *Lactobacillus* in the

present study showed a significant reduction on use of organic fluoride (amine fluoride) and inorganic fluoride (sodium fluoride) dentifrices over a period of 6 months. The diet sector of cariogram pie-circle diagram showed a reduction of *Lactobacillus* count from baseline over 6 months on use of both inorganic fluoride and organic fluoride dentifrice. The present study was in agreement with the previous studies, demonstrating a higher reduction of mean *Lactobacillus* count in the organic fluoride (amine fluoride) group [from $9.3x10^5$ at baseline to $1.2x10^3$ at 6 months] compared to the inorganic fluoride (sodium fluoride) group [from $5.5x10^5$ at baseline to $3.1x10^3$ at 6 months]. The enhanced anti-enzymatic and anti-glycolytic effect of amine fluoride could be the possible reason for the reduction in mean *Lactobacillus* count.

Diet frequency:

Frequency of intake of fermentable carbohydrates is one of the key factors in the estimation of caries risk. An interview regarding the 24 hours dietary recall, which estimated the number of meals and snacks consumed per day among all the participants of both organic fluoride and inorganic fluoride groups revealed no statistical difference between the groups.

Dental plaque accumulation:

Dental plaque is the direct and an important risk factor for dental caries. The mean plaque score estimated using Silness and Loe plaque index in the present study demonstrated a statistical significant reduction from baseline over 6 months among the participants in both the groups. Although numerous studies had demonstrated that amine fluoride were more effective in preventing dental plaque and bacterial adherence compared to sodium fluoride, the present study could not perceive any difference[29,31,32]. In the present study dental plaque was assessed Silness and Loe method which estimated plaque accumulation on visual basis rather than by using disclosing agents.

Mutans Streptococci:

Mutans streptococci refers to a group of bacteria, mainly *Streptococcus mutans* and *Streptococcus sobrinus*, considered to play a particular active role in the development of dental caries, especially in the early stages of the lesion formation. They are both acidogenic and aciduric and grow on solid surfaces in the mouth, including teeth, crowns, bridges and dentures. The saliva culture test indicates a rough estimate of the tooth surfaces that are colonized. In the present study there existed a significant reduction in the mean *S.mutans* count from the baseline over 6 months in both the groups. The bacteria sector of cariogram pie-circle diagram in the present study showed a reduction of *S.mutans* count from the

baseline over 6 months on both inorganic fluoride (sodium fluoride) dentifrice and organic fluoride (amine fluoride) dentifrice. The present study, in agreement with the previous studies showed a significant reduction in the mean colony forming unit of *S.mutans* among the participants of organic fluoride group compared to inorganic fluoride group. Thus, amine fluoride dentifrice was more effective with its improved anti-bacterial and anti-glycolytic effect compared to sodium fluoride dentifrice.

Fluoride program:

Fluoride is a very strong factor inducing resistance to caries and of importance for remineralisation of early caries lesions. Since, there was no simple test available to estimate the fluorides in the mouth; an interview was carried out among the participants of both the groups regarding their fluoride exposure. This interview demonstrated no significant difference in this variable among the study population.

Saliva Secretion amount:

The saliva has several important protective functions, both for teeth and for oral mucosal surface and in particular, it clears food debris, sugars and acids from the oral cavity and prevents dental caries occurrence. This study demonstrated no significant difference in the mean stimulated saliva secretion rate

over 6 months use of organic fluoride (amine fluoride) and inorganic fluoride (sodium fluoride) dentifrices. Though there was no significant difference in the mean saliva secretion rate among the participants of both the groups, there was a substantial reduction of susceptibility sector of the cariogram model among organic fluoride group when compared to the inorganic fluoride group. A six week clinical trial conducted by Alina C et al among 34 healthy young adults showed a reduction in the salivary secretion rate on use with organic fluoride (amine fluoride) toothpaste.[62]

Salivary buffer capacity:

Though several buffer systems tries to keep pH close to neutral in the oral cavity exhibiting caries protection, the saliva buffer capacity is one that can be measured. The measured pH of stimulated saliva in the present study demonstrated a significant increase in the pH from the baseline over 6 months of use of organic fluoride (amine fluoride) dentifrice among the participants when compared to inorganic fluoride (sodium fluoride) dentifrice. This contributed to reduction in susceptibility sector of cariogram model in the organic fluoride group. This study results were similar to the study conducted by Alina C et al, who showed a significant increase in the salivary buffer capacity on use of organic fluoride (amine fluoride) toothpaste in a six week clinical trial.[62]

Actual chance of avoiding new cavities:

The actual chance of avoiding new cavities is 'what is left' when the other factors have taken their share. It was interesting to note the gradual significant increase in the actual chance of avoiding caries (reduced caries risk) during the study period after the short-term use of organic fluoride (amine fluoride) and inorganic fluoride (sodium fluoride) dentifrices.

STRENGTH OF THE PRESENT STUDY:

1. To the best of our knowledge, the present study is one of the first study to assess the changes in the caries risk after a fluoride based preventive program in the institutionalized geriatric population in Chennai city.
2. Ethical clearance was obtained from Institutional Review Board. The trial was registered in Clinical Trial Registry – India (CTRI)
3. Dispensing of the fluoride dentifrices and the use of fluoride dentifrices were regularly monitored and education regarding dispensing and using them appropriately were regularly provided.
4. This study assessed all the risk factors of dental caries using cariogram model.

LIMITATIONS OF THE PRESENT STUDY:

1. This study used a convenience sampling technique for selection of participants due to lack of fund and time.
2. Double blinding was not possible since the study compared two commercially marketed dentifrices (organic and inorganic fluoride) and hence allotment of subject to a particular group could not be blinded.
3. Though the study was done in an institutional set up, the dilution and diffusion effects by other fluoride sources could have affected this study results.

SUMMARY

The present intervention study was conducted to compare the effectiveness of two commercially available fluoridated dentifrices on the risk factors of dental caries among institutionalized geriatric population in Chennai city. The study participants were divided into two Groups: Group I (received organic fluoride (Amflor) dentifrice), and Group II (received inorganic fluoride (Colgate Total) dentifrice). Clinical examination was done in both groups to assess the risk factors using cariogram model. Oral examination was done to assess dental caries using Decayed – Missing – Filled Teeth index and plaque amount using Silness and Loe plaque index. An interview was carried out to record general related diseases, diet frequency, fluoride programme according to cariogram caries related factors. Saliva samples were collected from the participants of both groups to estimate saliva secretion rate, saliva buffer capacity, Streptococcus mutans count, and diet content (Lactobacillus count). The interventional study was conducted over a period of 6 months.

Ethical clearance was obtained from the Institutional Review Board of Ragas Dental College and Hospital, Chennai. Clinical examination and interview were conducted in the participants of old age homes (Vishranthi Home for Aged Destitute Women, Palavakkam, Chennai and Sir John Britto Old Age Home for

Women, Kovalam, Chennai). Saliva samples were analyzed at Department of Microbiology laboratory, Ragas Dental College and Hospital, Chennai.

A total of 80 participants with 40 subjects in each group were included, based on inclusion and exclusion criteria. The nature and purpose of the study was explained to all the participants. Only participants who were willing to participate voluntarily, and gave consent were recruited for the study. Demographic details of the participants of age, education was obtained before the clinical examination, interview and saliva sample collection. Statistical analyses were performed using Statistical package for Social Sciences software (SPSS version 20, USA). Normality of the data was assessed using Kolmogorov- Smirnov test and Shapiro-Wilk numerical test and it was found that all variables were normally distributed. Student's unpaired t- Test was used to compare the age, salivary flow rate, salivary buffer capacity, mean green sector, red sector, yellow sector, light blue sector and dark blue sector, Streptococcus mutans count, Lactobacillus count, Plaque index score, DMFT scores among two groups at baseline and after 6 months. Student's paired t-Test was used to compare the variables in each group at baseline and after 6 months.

The study results showed that

1. Organic fluoride (Amflor) dentifrice had higher chance of avoiding new cavities when compared with inorganic fluoride (Colgate Total)

dentifrice among the study participants with a mean scores of green sector being 75.85 (±8.28) and 73.40 (±15.6) respectively.

2. Among the Group I participants, significant decrease in the Streptococcus mutans and Lactobacillus CFU/ml was observed when compared to Group II participants over 6 months (p=0.000)
3. There was an increase in the salivary buffer capacity with increase in the salivary pH among participants in the Group I (p=0.017) compared to that of participants in Group II.

The study concluded that Streptococcus mutans and Lactobacillus CFU/ml were significantly reduced among the participants of Group I when compared with Group II participants. There was significant increase in the saliva buffer capacity among organic fluoride dentifrice participants than that of inorganic fluoride dentifrice participants. There was no significant difference in other caries risk factors (Diet frequency, related general disease and fluoride exposure) among the study participants in organic and inorganic fluoride dentifrice group. Thus, there was a higher chance of avoiding new cavities on use with organic fluoride (Amine fluoride) compared to that of inorganic fluoride (Sodium fluoride) amongst this study population

CONCLUSION

The prevalence of dental caries in India was about 82.3% among elderly population in the year 2012 and it may further increase in the near future to 90% due to increase in the elderly population.[55] Substantial body of evidence shows that the occurrence of dental caries among geriatric population can be prevented by the use of fluoride programs regularly.

Early diagnosis of initial carious lesion and regular use of fluoride compounds is necessary to prevent the tooth loss complications such as nutrition deficiency, cognitive loss, dementia, Alzheimer disease, stroke in elderly population.

The conventional inorganic fluoride dentifrice was an effective agent in reducing the risk factors of dental caries. Organic fluoride, due to its increased fluoride absorption and formation of a fluoride depot on the enamel, superior acid resistance for longer time periods, enhanced remineralization of initial caries lesions, antibacterial and antiglycolytic efficacy was found to be the superior agent to prevent dental caries. Since the use of fluoride compounds is simple and readily marketed, significant research is being carried out on organic fluoride in recent times among elderly. Hence, the present study was contemplated to assess the effectiveness of organic fluoride and inorganic fluoride dentifrices on the risk factors of dental caries among geriatrics.

The present study throws light on the potential use of organic fluoride for the prevention of risk factors of dental caries among geriatric population. The overall study results showed that the mean chance of avoidance of new cavities was high in organic fluoride dentifrice compared to inorganic fluoride dentifrice. There was a reduction in mean *Streptococcus mutans* and *Lactobacillus* CFU/ml, the potential risk factor of dental caries and also there was an increase in the salivary buffer capacity on use of organic fluoride dentifrice compared to use of inorganic fluoride dentifrice among geriatric population.

RECOMMENDATIONS

1. Double blinded randomized controlled trials are required to validate the use of organic fluoride dentifrice for prevention of dental caries among geriatric population.

2. Further long term studies are needed to assess the caries incidence pattern on use of organic fluoride dentifrice and inorganic fluoride dentifrice among geriatric population.

3. The roles of other adjuvant fluoride therapy such as fluoride mouth rinse, fluoride varnish, fluoride gel can also be assessed for prevention of dental caries among the vulnerable geriatric population.

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ANNEXURE – I

RAGAS DENTAL COLLEGE & HOSPITAL
(Unit of Ragas Educational Society)
Recognized by the Dental Council of India, New Delhi
Affiliated to The Tamilnadu Dr. M.G.R. Medical University, Chennai
2/102, East Coast Road, Uthandi, Chennai - 600 119. INDIA.
Tele : (044) 24530002, 24530003-06. Principal (Dir) 24530001 Fax : (044) 24530009

TO WHOMSOEVER IT MAY CONCERN

Date: 11.12.2017
Place: Chennai

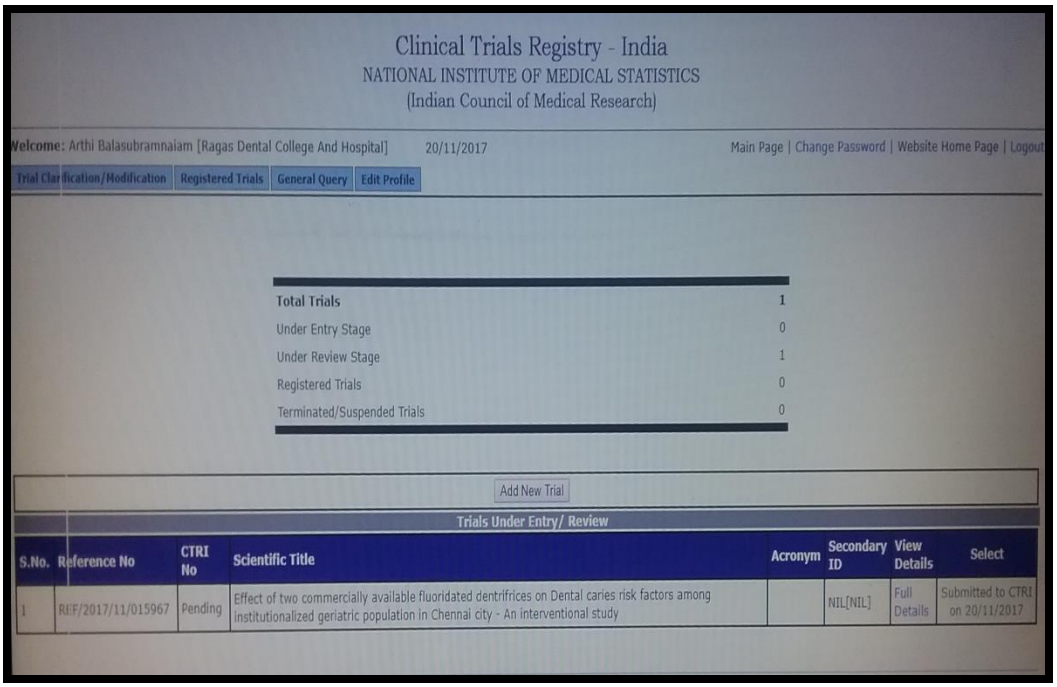
From
The Institutional Review Board,
Ragas Dental College and Hospital,
Uthandi,
Chennai – 600 119.

The dissertation topic titled **"Effect of two commercially available fluoridated dentifrices on the risk factors of dental caries among institutionalized geriatric population in Chennai city – an interventional study"** submitted by **Dr. B ARTHI.,** has been approved by the Institutional Review Board of Ragas Dental College and Hospital.

Dr. N.S. Azhagarasan
Member secretary,
Institution Ethics Board,
Ragas Dental College & Hospital
Uthandi, Chennai – 600 119.

RAGAS DENTAL COLLEGE Chennai

ANNEXURE – II



Clinical Trials Registry - India
NATIONAL INSTITUTE OF MEDICAL STATISTICS
(Indian Council of Medical Research)

Welcome: Arthi Balasubramnaiam [Ragas Dental College And Hospital] 20/11/2017 Main Page | Change Password | Website Home Page | Logout

Trial Clarification/Modification | Registered Trials | General Query | Edit Profile

Total Trials	**1**
Under Entry Stage	0
Under Review Stage	1
Registered Trials	0
Terminated/Suspended Trials	0

Add New Trial

Trials Under Entry/ Review

S.No.	Reference No	CTRI No	Scientific Title	Acronym	Secondary ID	View Details	Select
1	REF/2017/11/015967	Pending	Effect of two commercially available fluoridated dentrifrices on Dental caries risk factors among institutionalized geriatric population in Chennai city - An interventional study		NIL[NIL]	Full Details	Submitted to CTRI on 20/11/2017

ANNEXURE – III

Home :
No. 4/227, M.G.R. Salai, Palavakkam, Chennai - 600 041
Phone : 2449 0972, 2449 4757, Mobile : 98412 94757 (7.00 a.m. - 7.00 p.m.)

Admn. Office :
Flat No.1, "Sapthagiri Apartments"
No. 187 (Old No. 83), T.T.K. Road, Alwarpet, Chennai - 600 018
Phone : 2499 6634, 2499 4806 (10.30 a.m. - 5.00 p.m.)
E-mail : vishranthi_trust@yahoo.com
Web : www.vishranthi-trust.in

Date 04/11/17.

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Dr.B.Arthi , Postgraduate student, Department of Public Health Dentistry, Ragas Dental College and Hospital, was given permission to screen our inmates and conduct her study titled , **"Effect of two commercially available fluoridated dentifrices on the risk factors of dental caries among institutionalized geriatric population in Chennai city – An interventional study."**

She has successfully completed her study over a period of 6 months

Joint SECRETARY

ANNEXURE - IV

ph: 044-27472025

St. JOHN DE BRITTO HOME

FOR AGED WOMEN

East Coast Road, Kovalam- 603 112, Kancheepuram District, Tamil Nadu, South India.

Date:.....

Mother. Sebasty

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Dr.B.Arthi , Postgraduate student, Department of Public Health Dentistry, Ragas Dental College and Hospital, was given permission to screen our inmates and conduct her study titled , **"Effect of two commercially available fluoridated dentifrices on the risk factors of dental caries among institutionalized geriatric population in Chennai city – An interventional study."**

She has successfully completed her study over a period of 6 months

Sr. Sebasty
Mother Superior

ST. JOHN DE BRITTO HOME FOR AGED WOMEN
KOVALAM
603 112

ANNEXURE - V

INFORMED CONSENT FORM

TITLE:

EFFECT OF TWO COMMERCIALLY AVAILABLE FLUORIDATED DENTRIFRICES ON DENTAL CARIES RISK FACTORS AMONG INSTITUTIONALIZED GERIATRIC POPULATION IN CHENNAI CITY – AN INTERVENTIONAL STUDY

UNDERTAKING BY THE INVESTIGATOR:

Your consent for the above study is sought. We undertake to maintain complete confidentiality regarding the information and assessment obtained from you during the study. If you have any doubts regarding the study, please feel free to clarify the same. The investigator's name and contact number is given below:

Dr.Arthi.B, Mob no- 9894977838.

PARTICIPANT'S CONSENT

I _____, residing at_____
_____
___, do hereby solemnly and state as follows.

I am the deponent herein; as such I am aware of the facts stated here under.

I was informed and explained about the pros and cons of the study, the intervention that will be provided to me.I was explained that there would not be any invasive procedure done and any form of discomfort would be avoided to me during the study in the _____ language known to me.

I give my consent after knowing the full consequences of the study.

I have given voluntary consent for including me in the study without any individual pressure or duress.

I have also been informed about the purpose and procedures of the study that is to be conducted on me. I understand that if I give my consent for the study, I will have to provide the necessary details required for the study and co-operate to the assessment that will be made during the study.

I give my consent to be a part of this investigation.

Signature of the investigator. Signature of the Participant.

Date:

Place: Signature of the Witness.

ANNEXURE – VI

ஒப்புதல் கோரும் படிவம்

தலைப்பு:

சென்னையைச் சார்ந்த அமைப்பிலுள்ள முதியோர் பயன்படுத்தும் சந்தையில் கிடைக்கும் புளோரைட் உள்ள இரு பற்பசைகளின் பற்சொத்தை மீதான விளைவு மீதான அபாய அம்சங்கள் பற்றி இடையீட்டு ஆய்வு

ஆய்வாளரின் பொறுப்பு:

மேற்கூறப்பட்ட ஆய்விற்குத் தங்களின் ஒப்புதலைக் கோருகிறோம். இந்த ஆய்வின் போது தங்களிடமிருந்து பெறப்பட்ட தகவல்களையும் அதன் மீதான முடிவுகளையும் பற்றி முழுமையான ரகசியத்தைக் காப்போம் என்று உறுதி கூறுகிறோம். இந்த ஆய்வு பற்றி தங்களுக்கு ஏதேனும் சந்தேகம் இருந்தால் தயவுசெய்து அது பற்றி சுதந்திரமாகக் கேட்டுத் தெளிந்துகொள்ள விழைகிறோம். ஆய்வாளரின் பெயரும் தொலைபேசி எண்ணும் கீழே தரப்பட்டுள்ளன.

டாக்டர்.ஆர்த்தி.பி., அலைபேசி எண்:9894977838

தகவலாளியின் ஒப்புதல் படிவம்

நான்----------,----------

---------- என்ற முகவரியில் இருந்து கீழ்க்கண்டபடி உறுதியுடன் தெரிவித்துக் கொள்வது:

இங்கு நான் தகவலாளி, கீழ்க்கொடுத்திருக்கும் தகவல்களைப் பற்றித் தெரிந்துவைத்திருக்கிறேன்.

இந்த ஆய்வின் நல்லவை தீயவை பற்றியும் இதன் முடிவுகள் பற்றியும் எனக்கு விளக்கமாகச் சொல்லப்பட்டிருக்கிறது. இந்த ஆய்வின் போது எந்த விதமான துளையிடும் செயல்முறையும் செய்யப்படமாட்டாது என்றும் எந்த ஓர் அசௌகரியமும் எனக்கு நேராது எனவும் எனக்குத் தெரிந்த ----------மொழியில் விளக்கப்பட்டுள்ளது.

இந்த ஆய்வின் முழுமையான விளைவை அறிந்தே நான் என் ஒப்புதலைத் தருகிறேன். வலுக்கட்டாயமாகவோ தனிநபரின் நெருக்கடி காரணமாகவோ அல்லாமல் நான் சுயமாக என்னை இந்த ஆய்வில் சேர்ப்பதற்கு ஒப்புதலைத் தருகிறேன்.

என் மீது நடத்தப்படும் இந்த ஆய்வின் நோக்கத்தையும் செயல்முறையையும் பற்றி எனக்குத் தெரிவிக்கப்பட்டிருக்கிறது. இந்த ஆய்விற்கு ஒப்புதலைத் தருவதினால் ஆய்விற்குத் தேவையான முழுமையான தகவல்களை நான் சொல்ல சொல்லவேண்டும் என்பதையும் இந்த ஆய்வின் போது ஏற்படும் முடிவிற்கு நான் ஒத்துழைக்கவேண்டும் என்பதையும் நான் அறிந்திருக்கிறேன்.

நான் ---------- இந்த ஆய்வில் பங்கேற்க ஒப்புதலைத் தருகிறேன்.

ஆய்வாளரின் கையொப்பம் தகவலாளியின் கையொப்பம்

தேதி:

இடம்: சாட்சியின் கையொப்பம்

ANNEXURE – VII

SAMPLE SIZE CALCULATION

[1] -- *Thursday, September 29, 2016 -- 12:17:26*
t tests - Means: Difference between two independent means (two groups)

Analysis:	A priori: Compute required sample size	
Input:	Tail(s)	= Two
	Effect size d	= 0.8
	α err prob	= 0.05
	Power (1-β err prob)	= 0.80
	Allocation ratio N2/N1	=1
Output:	Noncentrality parameter δ	=2.8844410
	Critical t	= 2.0085591
	Df	= 50
	Sample size group 1	= 26
	Sample size group 2	= 26
	Total sample size	= 52
	Actual power	= 0.8074866

The requires sample size with 80 percent power is 26 per group, in total 52.

Since this is a two stage cluster sampling design, the sample size must be multiplies by design effect of 1.5.

52X 1.5 = 78
With loss of 5% follow up = 78+3=81 – approx = 40 in each group.

ANNEXURE – VIII

PLAGIARISM REPORT

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Urkund Analysis Result

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