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# **Original Article**





# Parental Adherence to At-Home Fluoride Varnish Application for Their Children in Southeast Iran: A feasibility study

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#### Abstract

**Background:** Fluoride varnish (FV) is applied to tooth surfaces to prevent dental caries. Thus, this study aimed to experimentally assess parental adherence to FV application for their children at home.

Methods: This acceptability study was conducted in two phases. The first phase was to create an acceptability questionnaire asking questions about applying FV, including self-efficacy, perceived effectiveness, and intervention coherence. The content validity index and content validity ratio were used to evaluate the questionnaire's content validity, while test-retest and internal consistency procedures were used to examine its reliability. The second part of the study examined adherence to the intervention following an educational session, where parents of children aged three to fourteen years in the Kerman Province cities of Bardsir and Mahan were given FV packets to apply to their children's teeth at home.

**Results:** A 13-item survey was developed during the first phase. The content validity index and validity ratio scores were satisfactory for all items except one. The reliability calculation, which yielded acceptable results (Cronbach's  $\alpha$ =0.78, Cohen's kappa=0.44), included 11 items. Phase two included delivering the varnish kits and accompanying education to 3,205 parents. A total of 91.3% of parents followed the treatment plan—78.5% after the first follow-up and 12.8% after the second. Parents with higher education levels were more likely to adhere to the treatment (P=0.001), and over 75% of mothers reported that they could apply the varnish independently.

**Conclusion:** Based on the results, over 90% of parents successfully applied FV, indicating that this method could effectively increase FV coverage in the target population.

**Keywords:** Fluoride varnish, Prevention, Dental caries, Adherence, Parents

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### Introduction

The use of sodium fluoride varnish (FV) to prevent dental caries dates back to the 1960s (1). Since then, professional associations such as the US Preventive Services Task Force, the American Academy of Pediatric Dentistry endorsed FV as a caries-inhibitory agent (2). FV has a sticky consistency and is painted on the surface of the teeth, which, by releasing fluoride ions, prevents dental decay (3). There is ample evidence that confirms the effectiveness of FV when applied 2–4 times per year, in preventing caries in both permanent and primary dentition among children (4).

The World Health Organization estimates the percentage of children affected by dental caries to be 60–90% (5). Dental caries is more than just a cavity; it can have farreaching consequences for children's health and well-being (6). Tooth pain, increased sensitivity to stimuli and certain

meals and drinks, the risk of abscess formation, dental phobia, exorbitant dental costs, and self-consciousness about one's smile and social interactions are all effects of dental disease (6).

Despite the significant number of dentists in Iran over the last 30 years, we have witnessed a continuous increase in primary and permanent tooth decay cases between 1990 and 2017 (7, 8). The main reason for this increasing trend has been the lack of pervasive preventive services, including FV, in oral health. In order to overcome this shortcoming, the Ministry of Health, in cooperation with the Ministry of Education, started performing FV in schools in 2015 (9). However, this program encountered challenges due to the closure caused by the Corona pandemic and the lack of human resources and infrastructure in schools (10, 11). Therefore, the need to change the direction of oral health system policies and to implement community-based



interventions seems obvious (7).

Depending on an individual's risk of tooth decay, a dental expert can apply FV two to four times a year as a preventative treatment. This safe, painless, effective, and easy-to-apply technique makes promoting oral health and lowering dental caries, particularly among vulnerable populations, easier (4).

Cochrane reviews show that children at high risk of dental caries can benefit from using FV twice a year, which can reduce cavities by as much as 46% (12). Similar reductions of 24% with fluoride toothpaste, 26% with mouthwash, and 28% with fluoride gels have been reported (12).

Studies have shown that concerns about time and cost often prevent patients from visiting dentists for preventive treatments (13). Recently, it was recommended to employ non-dental professionals to apply FV due to the shortage of dental and oral health personnel and the high costs associated with their services during a conference in Australia aimed at increasing FV coverage for children, particularly in underserved areas (14). FV can be applied by non-dental professionals since, unlike fissure sealants and other preventive treatments, it does not necessitate a high degree of technical sensitivity and is deemed a safe method (15). Mothers could be a good option for applying FV for children since it has been shown that the cooperation of mothers plays an important role in promoting children's oral health (16). Two Iranian preliminary studies with low sample sizes have shown that if mothers are trained, they can properly apply FV to their children with acceptable performance (17, 18). To the best of our knowledge, no other study examines the adherence to and acceptability of at-home FV applications for children by their mothers. Considering the very important role of mothers in promoting children's oral health on the one hand and the ease of using varnish and its harmless nature on the other, this study sought to educate mothers on how to apply FV at home to decrease expenses, improve accessibility, and raise the availability of the product for the community, especially for children. Parents are more likely to stick to the program if it is acceptable to them (19). Therefore, we assessed their adherence by designing an acceptability questionnaire and conducting a pilot study in two counties in Kerman Province.

#### Method

This study was part of a quasi-experimental study, with a non-randomized control group, designed to evaluate the effectiveness of FV application by parents for their children at home, facilitated by an educational intervention. At the first stage, we designed a pilot acceptability study with only one group to examine parental adherence to at-home FV applications for their children. Our acceptability study consisted of two phases:

Phase 1 of the Study: In this phase, we developed

an acceptability questionnaire regarding the parental application of FV to the children. The questionnaire includes domains related to the acceptability of the FV application (20). Both deductive (i.e., literature review and assessment of existing tools) and inductive (i.e., expert opinions) approaches were employed to develop the questionnaire items (21). The questionnaire domains were designed based on the conceptual framework and study objectives (reference 3). The questionnaire items were inductively derived from an expert panel and an extensive literature review (14, 17, 18, 22). Accordingly, a questionnaire draft was generated, which consisted of three domains and 13 items with response options 'Yes,' 'No,' or 'Somewhat' (Appendix). Five experts were assembled to evaluate the questionnaire's content validity. These experts specialized in various areas such as community medicine, oral health, pediatric dentistry, restorative dentistry, oral health, and community dentistry. Researchers used the content validity index (CVI) and the content validity ratio (CVR) to measure the efficacy of the content. Each item was evaluated for its relevance using a CVI scale that offered four possible ratings-irrelevant, requires major revision, relevant with some room for improvement, and completely relevant. The necessity of each item was evaluated using the CVR scale with options: unnecessary, useful but not essential, and essential. According to the decision-making table for CVR and CVI, with five experts participating, the minimum acceptable CVR was set at 0.99; for CVI, the threshold was 0.79. Based on expert feedback, the necessary revisions were made to the questionnaire. Three items were revised based on the suggestions of the experts.

Reliability was assessed using two methods: internal consistency, measured by Cronbach's alpha, and reproducibility, assessed by the test-retest method using Cohen's kappa analysis on 29 participants with a two-week interval.

Phase 2 of the Study: In this phase, adherence to the intervention was assessed in a pilot study conducted in two cities, Bardsir and Mahan, in Kerman Province. These cities were selected for their accessibility, cultural characteristics, and differing management infrastructures to maximize the study's external validity. All children aged 3 to 14 years registered in the Ministry of Health's integrated health system were invited to participate in the study. According to the system, the number of children aged 3 to 14 in Bardsir and Mahan was 10,473 and 5,569, respectively. A sample size of 3,800 was calculated based on a pilot study with 80% power and  $\alpha$ =0.05, with an expected attrition rate of 20%.

The recruitment process consisted of three stages:

- 1. Installing banners at the entrances of health centers and health houses.
- 2. Inviting parents via healthcare workers through phone calls.

 Announcements in six different virtual community channels.

A 10-minute video was prepared and provided to teach them how to apply FV. Parents were invited to attend an educational session on how to apply FV to their children using face-to-face training at the health center. The FV kits were distributed at the health center. Due to the high volume of work, the high number of visitors to the centers, and the shortage of healthcare providers, it is practically impossible to apply varnish in the health center.

Two follow-up checks were conducted to ensure the application of varnish: the first three days after distributing the kits and the second one week later. Both follow-ups were done via phone calls to parents who received the varnish kits. In order to evaluate the parents' adherence, two questions were asked: "Have you come to get a varnish package?" and "Have you applied varnish to your child's teeth?"

#### **Results**

# Phase 1: Development of the Acceptability Questionnaire

Initially, 13 items were designed based on self-efficacy, perceived effectiveness, and intervention coherence. All questions, except for two, were approved based on the CVI and CVR indices (Table 1). Thus, 11 items proceeded to the reliability assessment phase. Cohen's kappa coefficient for test-retest reliability was 0.47, and Cronbach's alpha was 0.78 overall.

# Phase Two: Evaluation of Adherence and Acceptability of Fluoride Varnish Application

In total, 3,803 mothers with children aged 3 to 14 were invited to the health center via phone, in addition to using

promotional banners and posters in virtual group settings, to receive training and an FV package (Fig. 1).

In the first and second follow-ups, which were done by phone, 2,515 individuals (equivalent to 78.5%) and 410 individuals (equivalent to 12.8%) had applied the varnish, respectively. Considering the 3,205 individuals who received the varnish pack and training, the total adherence rate reached 91.3%.

Table 2 shows the demographic and behavioral variables of the adherence group sample. The children were a minimum age of three and a maximum age of 14. The mean  $\pm$  standard deviation of the children's ages who received the varnish was  $7.9 \pm 2.9$  years.

The education level of parents who did not agree to varnish compared with those who did is shown in Table 3. In the Temkin group, the percentage of mothers and fathers having a university degree was higher (P < 0.05).

Table 4 presents the participants' responses to the final 11 acceptability questionnaire items in implementation, behavior, and criticism.

#### Discussion

The results of the first phase of this study, considering the acceptable validity and reliability coefficients and the high level of parental adherence, indicate that the questionnaire is valid and reliable. In the second phase, more than 90% of parents applied FV correctly, reflecting the effectiveness of the training in enabling parents to perform FV therapy on their children's teeth.

The first step in promoting preventive care is increasing parents' awareness and attitudes toward the importance of these measures, as parents play a crucial role in establishing healthy oral habits in children and are responsible for

Table 1. Content validity and repeatability indices of the questionnaire items

Row	Acceptability Tool Items	CVI	CVR	Карра
Self-efficacy				
2	I was able to apply the varnish for my child with the information provided to me.	1	1	0.46
8	Family members cooperated with me in applying the varnish.	0.8	1	0.35
9	I was able to apply the entire substance as instructed correctly.	1	0.6	
10	I applied the substance to all my child's teeth.	1	1	0.35
12	The procedure was tolerable for my child.	1	0.6	
13	I felt I needed someone else's help to perform the task.	1	1	0.84
Perceived effectiveness				
4	I am confident in the usefulness of this substance.	1	1	0.20
5	I am confident that this substance is harmless for my child.	1	1	0.37
11	The amount of the substance was sufficient for all my child's teeth.	1	1	0.35
Intervention coherence				
1	I learned how to apply the varnish through the training provided by health workers.	1	1	1.0
3	I had enough confidence to apply the varnish to my child.	1	1	0.35
7	My child followed the post-procedure instructions.	1	1	0.46
6	My child cooperated with me sufficiently for the varnish application.	1	1	0.46

**Table 2.** Demographic and behavioral variables of families who applied fluoride varnish

Variable	Number	Percentage
Child's Gender		
Female	138	50.4
Male	136	49.6
Mother's Education		
University-educated	180	65.7
Non-university educated	94	34.3
Father's Education		
University-educated	191	69.7
Non-university educated	83	30.3
Mother's Occupation		
Housewife	241	88.0
Employed	33	12.0
<b>Toothbrushing Frequency</b>		
Never	33	12.0
Two times or less	40	14.6
Every other day	37	13.5
Once a day	133	48.5
Two times or more	31	11.3
Flossing Frequency		
Never	213	77.7
Two times or less	30	10.9
Every other day	9	3.3
Once a day	13	4.7
Two times or more	9	3.3
Dental Visit Frequency		
Less than six months	49	17.9
Every six months	42	15.3
Every six months (need clarification)	65	23.7
More than six months	118	43.1
Number of Children		
1	123	44.9
2	78	28.5
3	54	19.7
4	19	6.9

maintaining and improving their children's oral health (23). Numerous studies have examined parental awareness and attitudes toward fluoride therapy and the use of FV (23,24). These studies emphasize the importance of knowledge acquisition and the need to change beliefs and behaviors, particularly among mothers, to improve children's oral health (16, 25). Therefore, they highlight the necessity of educating parents on the significance of oral hygiene and preventive measures and the vital role of FV in promoting children's oral health (23).

However, research has shown that many parents have insufficient knowledge about FV programs and that numerous obstacles and negative perceptions are prevalent among them. The reason for this is inadequate education and information on the subject, which may be influenced by cultural and social factors. Studies have underscored the positive impact of educational interventions in increasing awareness, promoting healthy behaviors, and simultaneously reducing barriers related to the FV program (17, 23).

According to many randomized controlled trials, dental caries can be reduced by 18% to 63% with FV (26,27). According to the American Academy of Pediatric Dentistry, young children at risk of dental cavities should have FV applied every three to six months (28). Globally, dentists and/or dental assistants regularly utilize FV-a safe and effective way to protect children's teeth from cavities—(4). The teeth are brushed with a little brush containing a concentrated form of topical fluoride. Sodium fluoride, present at a concentration of 22,600 ppm (2.26%), is the active component in FV. Kids love it, and its implementation is simple and effective. Aside from protecting teeth from cavities, FV has the added benefit of being administered swiftly and simply during a child's appointment, taking only one to four minutes. This is especially helpful for families who may not have easy access to dental care (29).

As previously mentioned, dental treatments can be costly and may strain healthcare budgets, particularly

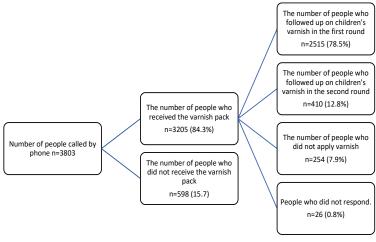


Figure 1. Algorithm of the study flow

in some developing countries (29). Research has shown that implementing caries prevention measures in primary healthcare settings can significantly reduce healthcare costs (30,31). Additionally, the topical application of fluoride does not necessarily need to be performed by a dentist, and trained individuals can perform this task as effectively as dentists (29).

However, research on the use of parents to apply FV at home is limited. In an intervention and educational study, Jafari et al. trained 15 mothers using two methods: six were educated through a video, and nine through a video combined with a question-and-answer session. The results showed that mothers with higher education levels trained using the video and discussion method could be considered for non-dentist FV applications (29).

This study is the first to experimentally assess parental adherence to at-home FV application for children in two cities in Kerman Province. The findings indicated the educational program's success in enabling parents to apply FV at home. Given the high cost of treatment in clinics, it seems that many parents welcomed this training and were able to perform the treatment effectively and independently.

 $\textbf{Table 3.} \ \ \text{Comparison of the frequency (\%) of demographic variables between the compliance and non-compliance groups}$ 

Demographic Variable	Group		P value	
	Adherent (n=274)	Non-adherent (n = 254)		
Child's Gender				
Girl	138 (50.4%)	115 (45.3%)	0.242	
Boy	136 (49.6%)	139 (54.7%)		
Mother's Education Level				
University-educated	94 (34.3%)	57 (22.4%)	0.003	
Non-university educated	180 (65.7%)	197 (77.6%)		
Father's Education Level				
University-educated	83 (30.3%)	46 (18.1%)	0.001	
Non-university educated	191 (69.7%)	208 (81.9%)		

The present study also demonstrated that a significantly higher percentage of parents in the adherence group had university-level education. Although no study exactly mirrors the current one, the research conducted by Almehmadi et al. in Saudi Arabia (24) on parents' awareness of FV use for their children showed a strong and significant positive correlation between parents' educational background and their level of awareness regarding fluoride. This finding was largely due to the more accurate reporting of fluoride's effects and the use of FV by individuals with higher education degrees. However, in the study by Hendaus et al. in India (29), while higher education was positively associated with parents' awareness of and willingness to use FV, the relationship was not statistically significant. In addition to parental education, other socio-cultural factors also influence their actions, making the acceptance and use of topical fluoride a complex and multifactorial process (32). As mentioned earlier, various factors, such as insufficient oral health knowledge, fear of local anesthesia, and lack of social support, contribute to delayed dental visits and parents' reluctance to accept topical fluoride treatment for their children.

In Chahhbra et al. (31), on parents' knowledge and attitudes toward dental care for preschool children in India, it was found that a lack of awareness and anxiety discouraged parents from seeking treatment and preventive care for their children's dental caries. Chi (32), in a systematic review, suggested that addressing resistance to fluoride use might require a behavioral approach that includes shared decision-making and building consensus. Improving parents' awareness of dental caries prevention and enhancing their self-efficacy can influence their decision-making regarding accepting FV (33, 34). Dentists and healthcare professionals must recognize that many parents are concerned about the use of fluoride. Based on the results of this study, parents are more likely to agree to fluoride treatment if they are informed about the risks of dental caries, understand the importance of FV in

 $\textbf{Table 4.} \ \text{Answers to the questions of the finalized acceptability questionnaire in the examined sample } (n=274)$ 

Row	Item	Domain	Yes (%)	No (%)	Somewhat (%)
1	I learned how to apply the varnish through the training provided by health workers.	Intervention coherence	265 (96.7)	3 (1.1)	6 (2.2)
2	I was able to apply the varnish for my child with the information provided to me.	Self-efficacy	271 (98.9)	3 (1.1)	0
3	I had enough confidence to use fluoride varnish for my child.	Intervention coherence	262 (95.6)	2 (0.7)	10 (3.6)
4	I am confident in the usefulness of this substance.	Perceived effectiveness	230 (83.9)	19 (7.0)	25 (9.1)
5	I am confident that this substance is harmless for my child.	Perceived effectiveness	212 (77.4)	31 (11.3)	31 (11.3)
6	My child cooperated with me sufficiently for the varnish application.	Intervention coherence	229 (83.6)	28 (10.2)	17 (6.2)
7	My child followed the post-application instructions.	Intervention coherence	229 (83.6)	29 (10.6)	16 (5.8)
8	Family members cooperated with me in applying the varnish.	Self-efficacy	198 (72.3)	74 (27.0)	2 (0.7)
9	I applied fluoride varnish to all of my child's teeth.	Self-efficacy	247 (90.1)	19 (6.9)	8 (2.9)
10	The amount of varnish provided was sufficient for all of my child's teeth.	Perceived effectiveness	216 (78.8)	48 (17.5)	10 (3.6)
11	I felt I needed someone else's help to perform the task.	Self-efficacy	67 (24.5)	206 (75.2)	1 (0.4)

preventing caries, and find the therapy easy and practical to implement.

## **Strengths and Limitations**

The strength of this study was its novelty in using the potential of mothers to apply FV for children at home. Another strong point was the relatively large sample size of this study. Since this study relied on questionnaires to collect data, some parents may be swayed to give more favorable answers when asked about their children's dental health habits. In Kerman Province, different ethnic groups live, so it was preferable that we also asked about socio-economic status and ethnicity in our study. The findings might not apply to different eras or places, which is another limitation.

#### Conclusion

The acceptability questionnaire for applying FV was shown to have strong validity and reliability. In addition, almost 90% of parents applied FV correctly. Based on this study, parents who receive proper training on FV therapy can effectively perform this preventive measure.

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#### **Competing Interests**

The authors have no conflict of interest in any aspect of this study.

#### **Ethical Approval**

The interviewers, who had received training from healthcare professionals or health educators, thoroughly explained the study's goals and the questionnaire's format before administering the interviews. The confidentiality of the questionnaires and the answers provided by participants was also guaranteed. Reassuring mothers that their participation in the interview was entirely voluntary and would not affect the standard of care they received was another important aspect of the study. All participants were asked to sign a document indicating their informed consent. The Ethics Committee of Kerman University of Medical Sciences approved this study with the code IR.KMU.REC.1400.487.

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Appendix 1. The fluoride varnish acceptability questionnaire domains and items

Row	Item	Domian
1	I learned how to apply the varnish through the training provided by health workers.	Intervention coherence
2	I was able to apply the varnish for my child with the information provided to me.	Self-efficacy
3	I had enough confidence to apply the varnish to my child.	Intervention coherence
4	I am confident in the usefulness of this substance.	Perceived effectiveness
5	I am confident that this substance is harmless for my child.	Perceived effectiveness
6	My child cooperated with me sufficiently for the varnish application.	Intervention coherence
7	My child followed the post-procedure instructions.	Intervention coherence
8	Family members cooperated with me in applying the varnish.	Self-efficacy
9	I was able to apply the entire substance as instructed correctly.*	Self-efficacy
10	I applied the substance to all my child's teeth.	Self-efficacy
11	The amount of varnish provided was sufficient for all of my child's teeth.	Perceived effectiveness
12	The procedure was tolerable for my child.*	Self-efficacy
13	I felt I needed someone else's help to perform the task.	Self-efficacy

<sup>\*</sup>Items 9 and 12 were removed from the final questionnaire due to low CVR.