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Clinical and cost effectiveness of *Curcuma longa* mouthwash versus Listerine® mouthwash in controlling halitosis among a group of Egyptian children: A randomized clinical trial

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Aim: Due to the many adverse effects of certain synthetic medications as well as the evolution of bacterial resistance, the present study aimed to compare the clinical and cost-effectiveness of mouthwash containing *Curcuma longa* (Turmeric extract) to Listerine® mouthwash and placebo mouthwash in reducing halitosis in a group of Egyptian youngsters.

Materials and Methods: The study was a randomized clinical trial with a three-arm, parallel-group, and blinded allocation. Thirty healthy children aged 8-12 were recruited, subjected to full-mouth clinical rehabilitation before allocation, and divided into groups A, B, and C, assigned for turmeric mouthwash, Listerine, and Placebo, respectively. All participants were instructed to use the given mouthwash with 10 ml twice daily for two weeks, stop using it for two weeks, and then re-use it for two weeks. Halitosis score was recorded using Tanita HC-312F device after 2, 4, and 6 weeks of using mouthwashes. Cost-effectiveness was recorded, and halitosis-positive and negative subjects; clinical parameters were compared using the Chi-square test at $P < 0.05$.

Results: Regarding halitosis scores, there was a significant difference between the tested groups at recruitment and after 2 and 6 weeks. All groups' clinical effectiveness revealed that groups A and B were 100% effective. Group B had the highest average cost, followed by groups A and C.

Conclusion: It was concluded that turmeric mouthwash was equally clinically effective and more cost-effective than Listerine® mouthwash.

Keywords: Halitosis, Essential oil mouthwash, Listerine®, *Curcuma longa*, Turmeric mouthwash.

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Introduction

Halitosis is a severe oral health issue, which is sometimes referred to as bad breath, and is a prevalent problem in oral health.[1] The main reasons for foul breath are putrefying bacteria on the tongue's dorsum and volatile sulfur compounds (VSCs) produced by meal remnants.[2] Identification of the presence of halitosis, followed by the type and its severity, allows for an effective management protocol. Mouthwash is a therapy option for offensive breath. Mouthwash is a rinseable solution that freshens the mouth by eliminating food and bacteria. The mouthwash composition can use synthetic or naturally occurring active components. [3] Medicinal herbs have been used to create mouthwash with antibacterial qualities and few adverse effects. [1] When choosing a mouthwash for treating halitosis in children, it is crucial to consider its safety and appropriateness for their age. [4] Considering all the above claims and facts, this research evaluates the clinical and cost-effectiveness of mouthwashes containing *Curcuma longa* (Turmeric) versus Listerine® mouthwash and placebo mouthwash, composed of plain water with peppermint oil in reducing halitosis in a group of Egyptian youngsters.

Materials and methods

The current study was a randomized clinical trial following the CONSORT statement 2010 with a three-arm, parallel-group design, and a 1:1:1 blinded allocation ratio. It was registered on www.clinicaltrials.gov with ID: NCT04905940 and ethical approval number: (61221) 28\12\2021.

1. Sample selection:

Thirty healthy children aged 8-12 years with halitosis visited the outpatient clinic at the pediatric dentistry department, Faculty of Dentistry, Cairo university. Selected patients were divided into three randomized groups, each of ten. Before starting the trial, patients were offered full-mouth restorative treatment, if needed, to exclude the possibility that halitosis was caused by food impaction in carious teeth.

2. Eligibility criteria

2.1. Inclusion criteria:

- Children aged 8 to 12 years old.
- Cooperative children.
- Both genders.
- Medically free to exclude systemic halitosis cause. [5]
- Bad breath scored 3 or more by the Tanita Fitscan device.

2.2. Exclusion criteria:

- Children use any other oral hygiene aid other than routine teeth brushing.
- Parents refuse to participate in the trial.
- Treatment by antibiotic within one month before the trial.[6]

3. Informed consent and Assent:

All participants were informed with complete information regarding the risks and benefits of the study, and written informed consent was obtained.

4. Randomization and allocation concealment:

The child in the current trial was randomly assigned to one of the three groups using closed white envelopes (simple randomization 1:1:1 ratio). Three types of mouthwash were tested for their clinical and cost-effectiveness against halitosis: turmeric powder mouthwash, Cool Mint Listerine Antiseptic® (Johnson & Jhonson, USA), and placebo mouthwash (Figure 1).

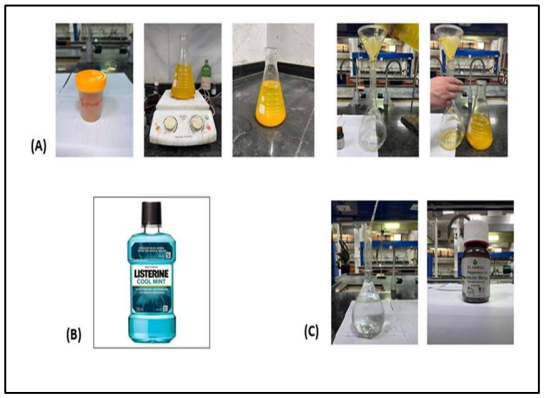

Figure 1: (A) Turmeric mouthwash lab preparation; (B) Listerine mouthwash; (C) Placebo mouthwash lab preparation

5. Intervention:

- **For all groups:**

Children were randomly divided into three groups: experimental and comparator groups. The tested mouthwashes were put into identical opaque glass bottles labeled with the codes A, B, and C for concealment.[6]

- **Group A (Experimental group):**

Ten children used 10 ml of the prepared turmeric mouthwash [7] twice daily under their parent's supervision for two weeks.

- **Group B (The 1st comparator group):**

Ten children used 10 ml of the commercial Cool Mint Listerine® mouthwash (Johnson & Johnson Pvt. Ltd.) twice daily under their parent's supervision for two weeks.

- **Group C (The 2nd comparator group):**

Ten children used 10 ml of the prepared placebo mouthwash [8] twice daily under their parents' supervision for two weeks.

Each participant was allowed to use two mouthwash bottles of the same group label that they were allocated to. Patients were given standard written oral hygiene instructions and mouth-washing instructions to rinse twice daily with 10 ml for 1 minute under their parents' supervision for two weeks.[9]

6. Follow-ups:

The first follow-up visit was after two weeks of using mouthwash, and the halitosis score was recorded numerically. Patients were then instructed to stop rinsing for the next two weeks while maintaining other oral hygiene instructions, such as teeth brushing twice daily. The 2nd follow-up visit was after four weeks, and patients measured in halitosis were given the second bottle and instructed to rinse twice daily with 10 ml for another two weeks. The last follow-up visit was after six weeks, and the final halitosis score was recorded.

7. Halitosis measurement:

Halitosis was measured using Tanita HC-312F FitScan Breath Checker (Tanita Corporation of America Inc., China), and the results were displayed in six color-coded levels (Figure 2). Patients who showed red color were included in the current study.[10]

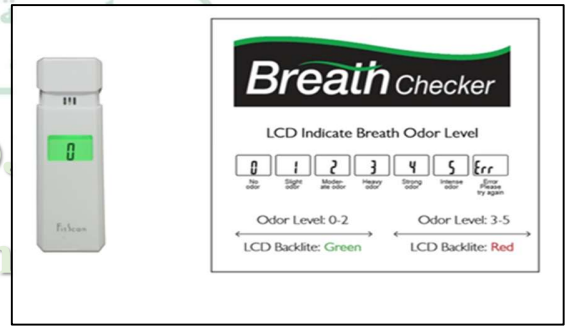

Figure 2: Tanita HC-312F FitScan Breath Checker

8. Cost-effectiveness calculations:

The cost-effectiveness was calculated based on the following measures:

- Economic measures (USD) were calculated as the total cost of Turmeric and Listerine mouthwash on every visit.[11]
- The cost-effectiveness was calculated using the Incremental Cost-Effectiveness Ratio (ICER) equation.[12]

9. Statistical analysis:

Statistical analysis was performed with SPSS 22.0 (Statistical Package for Social Sciences, USA) version 22.0.0 software, GraphPad Prism, and Microsoft Excel 2016. Clinical parameters were compared using the chi-square test in halitosis-positive and negative subjects. The significance level was declared at P <0.05 for all statistical evaluations.

Results

1. Demographic data:

The research included 42 youngsters, 30 of whom met the inclusion criteria and were diagnosed with halitosis. Twelve children were excluded: ten for not meeting the inclusion requirements and two for refusing to participate. The participants' ages varied between 8 and 12. The participants were separated into three groups, each consisting of 10 children. The participant's flow diagram is shown in Figure 3.

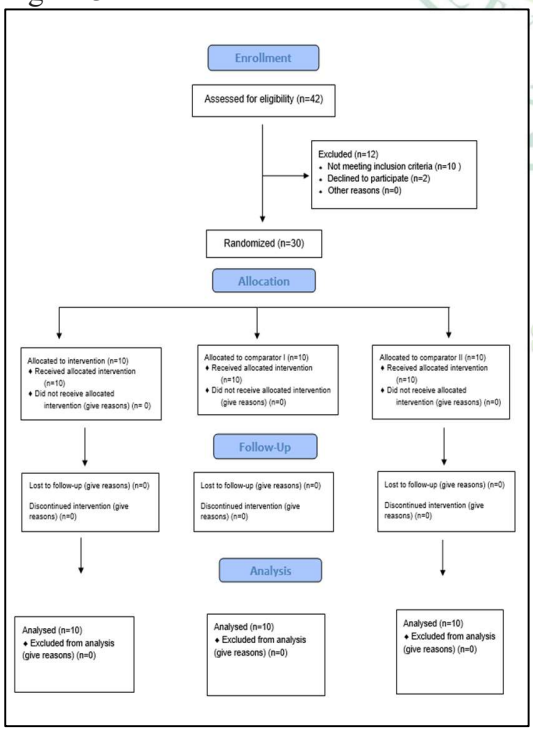

Figure 3: CONSORT Flow Chart of the study design

2. Halitosis score:

2.1. Inter-group evaluation at different intervals:

The frequency and percentages of different halitosis scores in all groups at different intervals are presented in Table 1.

Table 1: Halitosis scores after using turmeric, Listerine, and placebo mouthwashes after different intervals

Intervals		Mouthwash						Chi-square test	
		Turmeric mouthwash		Listerine mouthwash		Placebo mouthwash		P value	Chi-square
		N	%	N	%	N	%		
Recruitment	score 0	0	0.0%	0	0.0%	0	0.0%	0.036*	6.66
	score 1	0	0.0%	0	0.0%	0	0.0%		
	score 2	0	0.0%	0	0.0%	0	0.0%		
	Sco0re 3	0	0.0%	0	0.0%	0	0.0%		
	score 4	0	0.0%	0	0.0%	3	30.0%		
	score 5	10	100.0 %	10	100.0%	7	70.0%		
After full mouth rehabilitation	score 0	0	0.0%	0	0.0%	0	0.0%	0.117	7.38
	score 1	0	0.0%	0	0.0%	0	0.0%		
	score 2	0	0.0%	0	0.0%	0	0.0%		
	score 3	1	10.0%	0	0.0%	0	0.0%		
	score 4	2	20.0%	7	70.0%	3	30.0%		
	score 5	7	70.0%	3	30.0%	7	70.0%		
After 2 weeks	score 0	0	0.0%	0	0.0%	0	0.0%	0.001*	26.6
	score 1	2	20.0%	2	20.0%	0	0.0%		
	score 2	7	70.0%	8	80.0%	0	0.0%		
	score 3	1	10.0%	0	0.0%	5	50.0%		
	score 4	0	0.0%	0	0.0%	1	10.0%		
	score 5	0	0.0%	0	0.0%	4	40.0%		
After 4 weeks	score 0	0	0.0%	0	0.0%	0	0.0%	0.511	3.28
	score 1	0	0.0%	0	0.0%	0	0.0%		
	score 2	0	0.0%	0	0.0%	0	0.0%		
	score 3	5	50.0%	6	60.0%	3	30.0%		
	score 4	3	30.0%	2	20.0%	2	20.0%		
	score 5	2	20.0%	2	20.0%	5	50.0%		
After 6 weeks	score 0	0	0.0%	1	10.0%	0	0.0%	0.002*	28
	score 1	7	70.0%	7	70.0%	0	0.0%		
	score 2	3	30.0%	2	20.0%	1	10.0%		
	score 3	0	0.0%	0	0.0%	5	50.0%		
	score 4	0	0.0%	0	0.0%	1	10.0%		
	score 5	0	0.0%	0	0.0%	3	30.0%		

***: Significant difference at P<0.05**

The study results indicated that there was no statistically significant difference between the tested mouthwashes during complete mouth rehabilitation and after 4 weeks of use (P= 0.117 and 0.511, respectively). All individuals scored 5 in recruitment while using turmeric and Listerine mouthwash. 70% of individuals exhibited a score of 5, whereas 30% had a score of 4 when given placebo mouthwash. There was a significant difference (P= 0.036) seen in the comparison of the three kinds of mouthwash at recruitment. After 2 weeks, 70% of subjects scored 2 for turmeric and 80% for Listerine mouthwash. Conversely, 50% of subjects who used a placebo mouthwash had a score of 3. There was a notable disparity in the effectiveness of the tested mouthwash after 2 weeks of use (P= 0.001). After 6 weeks of using the tested mouthwash, 70% of subjects scored 1 while using turmeric and Listerine mouthwash, whereas 50% scored 3 when using the placebo mouthwash. There was a substantial disparity across the mouthwashes examined, with a p-value of 0.002.

3. Cost-effectiveness ratio:

The average cost-effectiveness of each tested mouthwash was computed and shown in Table 2.

Table 2: Cost-effectiveness analysis of turmeric, Listerine, and placebo mouthwashes

Parameter	Group A	Group B	Group C
Average cost Economic measure	0.142 USD	4.35 USD	0.14 USD
Clinical effectiveness (halitosis decrease)	100.00%	100.00%	10.00%
Average cost-effectiveness ratio (ACER) (USD)	0.00142 USD	0.0435 USD	0.014 USD

The study revealed that Listerine mouthwash had the highest average cost of 4.35USD, followed by turmeric mouthwash 0.142USD and placebo mouthwash 0.14USD. The study found that turmeric and Listerine mouthwash were the most clinically efficient in reducing halitosis, with a 100% drop in the halitosis score by continuous use of both mouthwashes. Using placebo mouthwash did not result in a drop in the halitosis score based on a clinical effectiveness evaluation (10%). The average cost-effectiveness ratio (ACER) for turmeric, Listerine, and placebo mouthwashes were 0.0014, 0.043, and 0.014, respectively. Table 3 displays the incremental cost-effectiveness analysis (ICER) comparing turmeric and Listerine mouthwashes. The study found that turmeric mouthwash had a lower Incremental Cost-Effectiveness Ratio (ICER) than Listerine when compared to the placebo mouthwash group (0.00002 and 0.04678, respectively).

Table 3: Incremental cost-effectiveness analysis (ICER) for turmeric and Listerine mouthwashes

Tested mouthwash	ICER
Turmeric mouthwash (Placebo mouthwash Comparator)	0.00002
Listerine mouthwash (Placebo mouthwash comparator)	0.04678

Discussion

Identification of the presence of halitosis, followed by the type and its severity, allows for an effective management protocol. Due to the many adverse effects of certain synthetic medications as well as the evolution of bacterial resistance, several investigations were now leaning toward this ancestral approach. Akkaoui and Ennibi [13] reported that 23 herbal plants were used for the

treatment of halitosis in the Moroccan population. Patients were offered full mouth clinical rehabilitation if necessary to ensure they finished the follow-up time and rule out dental issues as the source of their bad breath.[14] Many clinical trials had performed full mouth clinical rehabilitation before testing the mouthwash as an antimicrobial treatment, [15] and against halitosis.[16,17] The results obtained were following Saad et.,[18] who evaluated the efficacy of Listerine in reducing mouth malodor and found a marked effect of Listerine in reducing malodor and VSC after 30, 60, 90, and 180 min. as assessed by Organoleptic scale, halimeter, and the Oral-Chroma. Moreover, Alqumber and Arafa [19] showed similar results when applying Listerine specifically to reduce VSC and mouth malodor. The success in treating halitosis by tested mouthwashes may be attributed to the fact that Turmeric has antibacterial properties.[20] Turmeric contains curcumin, a compound with antibacterial properties. These properties may help to reduce the number of bacteria in the mouth that cause halitosis.[21] Moreover, Listerine contains essential oils, such as menthol and eucalyptol.[22] These oils have antiseptic and anti-inflammatory properties that may help to reduce halitosis.[23–25] The placebo mouthwash may not be as effective at reducing halitosis because it contains no antibacterial or antiseptic properties.[26] The average cost-effectiveness was calculated for each tested mouthwash. Results showed that the cost for mouthwash quantity needed for 6 weeks that, Listerine mouthwash had the highest average cost (4.35$), followed by turmeric mouthwash (0.142$) and placebo mouthwash (0.14$).

This suggests that both turmeric and Listerine mouthwashes are clinically effective treatments for halitosis. But Turmeric mouthwash is much more cost-effective. In this context, the study had some limitations. The procedures of using mouthwashes were carried out under parents' supervision, taking into consideration that professional supervision is non-applicable.

Conclusion

Turmeric mouthwash could be a very good, cost-effective alternative to essential oil Listerine mouthwash with fewer side effects.

Ethics approval and consent to participate:

The present study adhered to the principles of the "Declaration of Helsinki" (64th WMA General Assembly, Fortaleza, Brazil, October 2013). The study was revised and approved by the Research Ethics Committee, Faculty of Dentistry, Cairo University on 28th December 2021. It was registered on www.clinicaltrials.gov with ID: NCT04905940.

Consent for publication:

The patient's parent or guardian signed an informed consent form for each case after a thorough explanation of the study. All participants were informed with complete information regarding the risks and benefits of the study, and written informed consent was obtained.

Availability of data and materials:

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Competing interests:

The authors declare that they have no competing interests.

Funding:

The current study was self-funded. The funding body did not cover the research design, data statistical analysis, or writing of the manuscript.

Authors' contributions:

This work was carried out in collaboration among all authors. Authors EME, EE, and PN designed the study. EME and PN performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Authors EME, EE, and PN managed the study's analyses. Author EME managed the literature searches. All authors read and approved of the final manuscript.

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Not applicable.

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