OFFİCİAL TİTLE OF THE STUDY:

EFFECT OF DİLUTED THYME HONEY ON DRY MOUTH IN INTENSİVE CARE UNİT PATİENTS EXPOSED TO OXYGEN FLOW THERAPY: A RANDOMİZED CONTROLLED STUDY

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- **Ethics Statement**

To conduct this research, ethics committee approval (number 56786525-050.04.04/737202) dated November 30, 2022, was obtained from the Ankara University Rectorate Ethics Committee. Institutional approval (meeting number 0137) dated September 18, 2022, was obtained from the Ankara Training and Research Hospital, where the research was conducted. This study was completed as a master's thesis in the Nursing Department program at Ankara University, Institute of Health Sciences.

- **Data Availability Statement**

We have confirmed that the methods used in data analysis are appropriate. They were applied to our data within the study design and context, and the statistical results were applied and interpreted correctly. As a condition of journal submission, we accept responsibility for ensuring that the selection of statistical methods is appropriate and is performed and interpreted correctly. The data and original materials contained in this study can be obtained by contacting Esra Yaprak Göktürk, one of the authors of this study, at eyk1994.ek@gmail.com

APPLICATION PROTOCOLS

During the implementation period, a total of 136 patients were hospitalized in both intensive care units. Forty-eight of these patients were not included in the study because they did not meet the inclusion criteria. Five patients refused to participate in the study.

Tools and Equipments to be used during the application

- Thyme honey
- Distilled water
- Kidney bathtub
- 0.9% NaCl
- Disposable cup
- Pine-tipped injector

Procurement of Thyme Honey Used During the Application, Chemical Analysis and Certificates of the Company

Thyme honey used during the study was obtained from a supermarket chain. Information about the manufacturer company was not included in the thesis to avoid conflict of interest. However, the necessary documents were submitted to the relevant institutions when obtaining ethics committee and institutional permission. The chemical analysis of the thyme honey to be used during the application was carried out by the producer company and complies with the standards of the Turkish Accreditation Agency (Türkak). The analyzes and certificates published by the producer company are presented in the annex by hiding the company information.

Dilution Ratio of Thyme Honey to be used during the application

The thyme honey solution to be used in the study was prepared by the researcher. For every 100 ml of distilled water, 20 ml of thyme honey was diluted.

Intervention Group Implementation Protocol

- After obtaining informed consent from the participants who agreed to be included in the study, they were asked to draw one sealed envelope from a bag containing sealed envelopes with numbers from 1 to 64. The envelopes drawn by the patients were opened in the presence of the patient. According to the number on the envelope, the researcher determined whether the patients were included in the intervention or control group.
- The participants included in the intervention group were first asked the Patient Information Form. Then, the questions in the 'Subjective Dry Mouth Evaluation Form' using the Visual Comparison Scale were asked to the participants before starting the application. Each score given in response to the questions was recorded in the Patient Follow-up Form.
- Patients were educated about the importance of dry mouth, the types of foods and liquids to avoid, the necessity of adequate salivation, the functions of saliva, methods of coping with dry mouth, and the necessary precautions to identify and report any side effects that may occur due to thyme honey (as part of the safety of the application).
- Patients were questioned at the beginning of the study whether they had a known allergy to the honey used, and no unknown allergic reaction was encountered in the patients after the application started. In case of a possible allergic reaction, the necessary medical intervention was planned to be given by healthcare professionals under intensive care conditions.
- For the reliability of the study, the applications were performed by a single nurse practitioner. Before starting the study, the nurse practitioner was given detailed information about dry mouth, its importance, types of foods and liquids that may cause dry mouth, the necessity of adequate salivation, the functions

of saliva, methods of coping with dry mouth, the need to report a reaction that may develop in the patient due to thyme honey, how to apply the solutions and the forms and scales included in the study. The nurse practitioner was a nurse from outside the institution with an intensive care nursing certificate. The nurse practitioner was present at the relevant institution during practice hours.
- A mouthwash solution was prepared by mixing each 20 ml of thyme honey with 100 ml of distilled water by the researcher using a pine-tipped syringe. The prepared solution was delivered to the nurse practitioner. The nurse practitioner gave the solution to the patient through disposable cups.
- The application was repeated four times a day for three days during the patient's intensive care treatment at 12:00-18:00-24:00-06:00 hours. Patients who were hospitalized in intensive care outside the application hours were included in the study at the nearest standard application time. Patients were instructed to gargle for at least 30 seconds by taking the entire solution into the mouth and to slowly spread the solution over the oral and pharyngeal mucosa. Patients were informed in advance not to swallow the gargling solution and were expected to remove the solution into the kidney tub at the end of the application.
- At the end of the third day, the questions in the Subjective Dry Mouth Evaluation Form were asked to the patients again and dry mouth was evaluated again. The answers were recorded in the Patient Follow-up Form.

Control Group Application Protocol
- After obtaining informed consent from the participants who agreed to be included in the study, they were asked to draw one sealed envelope from a bag containing sealed envelopes with numbers from one to 64. The envelopes drawn by the patients were opened in the presence of the patient. Patients were assigned to the intervention or control group according to the number on the envelope.
- The participants in the control group were first asked the Patient Information Form. Then, the questions in the Subjective Dry Mouth Evaluation Form were asked to the participants before starting the application. Each score given in response to the questions was recorded in the Patient Follow-up Form.
- Patients were educated about the importance of dry mouth, the types of foods and liquids to avoid, the necessity of adequate salivation, the functions of saliva, methods of coping with dry mouth, and the necessary precautions to identify and report any side effects that may occur due to thyme honey (as part of the safety of the application).
- Since the study was to be conducted in a double-blind design, both the nurse practitioner and the patients did not know which group they were in. The solutions were prepared by the investigator and given to the nurse practitioner. For the reliability of the study, the applications were performed by a single nurse practitioner. Before starting the study, the nurse practitioner was given detailed information about dry mouth, its importance, types of foods and liquids that may cause dry mouth, the necessity of adequate salivation, the functions of saliva, methods of coping with dry mouth, the need to report any reaction that may develop in the patient due to thyme honey, how to apply the solutions and the forms and scales included in the study. The nurse practitioner was a health professional who worked outside the hospital and had an intensive care nursing certificate.
- The mouthwash solution was prepared with 120 ml NaCl drawn by the researcher using a pine-tipped syringe. The prepared solution was delivered to the nurse practitioner. The nurse practitioner gave the solution to the patient through disposable cups.
- The application was repeated four times a day at 12:00-18:00-24:00-24:00-06:00 hours for three days during the intensive care treatment of the patient. Patients were instructed to gargle for at least 30 seconds by taking the entire solution into the mouth and to slowly spread the solution on the oral and pharyngeal mucosa. Patients were informed in advance not to swallow the gargling solution and were expected to remove the solution into the kidney tub at the end of the application.

- At the end of the third day, the questions in the Subjective Dry Mouth Evaluation Form were asked to the patients again and dry mouth was evaluated again. The answers were recorded on the Patient Follow-up Form.

DATA COLLECTION TOOLS

Patient Information Form, 'Subjective Dry Mouth Evaluation Form' prepared by using Visual Comparison Scale and Patient Follow-up Form were used to collect the data of the study.

Patient Information Form

It was created by the researcher based on previous studies. In total, there are 13 question titles with subheadings. This form includes the patient number, the practice group the patient is included in, the patient's diagnosis, the patient's age, the patient's gender, the patient's chronic diseases, the patient's previous diseases, the patient's treatments for previous diseases (radiotherapy-chemotherapy), the patient's continuous medications, the patient's medications used in the hospital environment, the patient's allergy status, the patient's oral health assessment (teeth, oral care habits, presence of existing carious teeth, use of tobacco products, feeling of dry mouth before receiving nasal oxygen flow treatment). In addition, at the end of the study, patients were asked an open-ended question about their opinions on thyme honey.

Subjective Dry Mouth Assessment Form

This form was prepared by Duruk in 2012 in line with the literature. In order to evaluate dry mouth, “dry mouth”, “difficulty swallowing”, “difficulty speaking”, “waking up from sleep”, “dry tongue”, “burning in the mouth”, “burning in the throat”, “dry throat”, “thirst”, “bad taste in the mouth”, There are questions about the symptoms of “saliva quantity” and “bad breath”, and the answers are evaluated by scoring between 0-10 using 11 Visual Analogue Scale (VAS) for each question. Scoring starts with 0-“not at all” and 10-“very much”.

The Visual Comparison Scale (VSS) used in the form is accepted as a safe, valid and usable measurement tool that is ten cm long, can be used in horizontal or vertical form, and can be used in repeated measurements.

Patient Follow-up Form

This form includes the pre-test and post-test scores of the patients in response to each question in the 'Subjective Dry Mouth Evaluation Form' and their answers to an open-ended question about their opinions on thyme honey in the Patient Information Form. The purpose of this form was to facilitate data entry by collecting pre-test and post-test scores in a single form.

Data Collection

The data of the study were collected between November 2022 and December 2022. Before the data collection, the participants were informed in detail about the purpose and importance of the study and their written informed consent was obtained.

In order to determine the socio-demographic characteristics and dry mouth level of the participants, the Patient Information Form and the Subjective Dry Mouth Evaluation Form by Duruk (2012) were used to evaluate the symptoms of dry mouth (dry mouth, difficulty swallowing, difficulty speaking, waking up from sleep due to dry mouth, dry tongue, burning in the mouth, dry throat, thirst, bad taste in the mouth, amount of saliva and bad odor in the mouth). The Patient Information Form and Subjective Dry Mouth Assessment Form were administered to the patients before the start of the study to collect their information and to determine their dry mouth levels. At the end of the third day, the Subjective Dry Mouth Assessment Form was asked once again to the patients who were included in the study and who were treated for three days, and their dry mouth was evaluated again. Thus, data on the dry mouth level of the patient before and after the intervention were collected. The scores of the patients in the

intervention and control groups for each question in the Subjective Dry Mouth Evaluation Form before and after the intervention and an open-ended question about their opinions about thyme honey were included in the Patient Follow-up Form.