**Official Title of the study:** Effect of breathing exercise on some physiological parameters, sleep quality and vitality in elderly.

NCT number: not yet have

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# Description of the clinical study

The present study was planned to examine the effect of a breathing exercise intervention, which was administered to the elderly residents of a nursing home in Ankara, on some physiological parameters, sleep quality and vitality. Breathing exercises can be performed at any time of the day. Due to the effect of some breathing exercises on sleep status, it is not recommended to be applied close to sleeping at night. It is important to evaluate the physical environment in terms of environmental stimuli such as sound, heat, and light, as it affects focusing during breathing exercise. No special clothing or materials are needed during breathing exercises. In order to make the exercise more understandable and fun, various materials have been used in some studies (balloon, wind rose, etc.). In the literature, there are study results showing that physiological effects are seen as a result of applying respiratory exercise to the elderly individuals for three months, three days a week, 30 minutes, in small groups.

Breathing exercises can be done in different ways. Below are the features of the most frequently applied respiratory breathing exercises.

Pursed Lip Exercise: This exercise reduces the number of breaths by keeping the airways open longer. It increases the amount of air flow to the lungs. To apply, it is enough to breathe through the nose and give the lips by contracting. Breathing should be like blowing a candle. The exhalation period should be extended by double the breathing time.

Diaphragmatic Breathing Exercise: The diaphragmatic breathing exercise shows its effectiveness by helping this muscle stretch to work more effectively. While sitting comfortably or lying down, one hand is placed on the chest and the other hand on the abdomen, it is necessary to feel that the abdomen moves out by breathing through the nose. If the abdomen moves more than the chest, the activity is done correctly. Exercise should be repeated as much as possible during the day.

Cough Exercise: Cough exercise is a breathing exercise designed to effectively get rid of mucus without the need to feel very tired. In some individuals, it can create a sense of inhibition when coughing mucus. In a comfortable sitting position, after taking and breathing two normal diaphragm breaths, the third one is breathed and the breath is given twice by making "huh huh sound". This breathing should be like blowing into a mirror to allow the mirror to evaporate. Cough exercise should be less tiring than a traditional cough

### **Research hypotheses**

 $H_01$ : There is no difference in lung functions between the intervention group of elderly individuals subjected to breathing exercises, and those in the control group.

 $H_02$ : There is no difference in cardiac functions between the intervention group of elderly individuals subjected to breathing exercises, and those in the control group.

 $H_03$ : There is no difference in sleep quality between the intervention group of elderly individuals subjected to breathing exercises, and those in the control group.

 $H_04$ : There is no difference in subjective vitality between the intervention group of elderly individuals subjected to breathing exercises, and those in the control group.

## Study design and participants

The study was planned in a pre-test– post-test, randomized controlled (parallel) and experimental design. The study will include individuals aged 65 years and older residing in a nursing home in Ankara, who had a Mini Mental Test score of 2415, had no acute or chronic lung diseases, and had no physical/mental disabilities or limitations and conditions16,17 that might present any obstacle to participate in breathing exercises.

In order for the elderly to perform breathing exercise, he / she should not have acute or chronic lung disease, cognitive functions, physical / mental disability or restriction and disease that would prevent them from participating in respiratory exercise. Especially; ear, brain, spinal cord surgery, acute retinal hemorrhage vertebral fracture and diaphragmatic rupture, hiatus or abdominal hernia, acute myocardial infarction, unstable angina pectoris, severe coronary artery disease, congestive heart failure, severe heart valve disease, acute myocarditis, acute and breathing exercises are not recommended for diseases and health problems such as unstable musculoskeletal injuries, uncontrolled systemic hypertension, severe dementia and behavioral disorders. While examining the inclusion criteria, information about the health status of elderly individuals will be obtained from the files of the nursing home's health unit, and the mini mental test will be applied by the researcher.

After the ethical and institutional permits are obtained for the implementation of the study, the elderly individuals (except the mini metal test score) meeting the researcher nursing home will be identified on 21.01.2019 and the mini mental test measurements of the elderly individuals will be made in the library of the nursing home between 22.01.2019 -28.01.2019. Elderly individuals who agree to participate in the study will be identified by informing the appropriate individuals about the study. In addition, if any of these situations occur during the exercise program, the researcher will be informed by the health unit and the elderly individual will be separated from the study.

### Clinical trial facility location and property

The research was carried out in the 75th Year Nursing Home Elderly Care and Rehabilitation Center, affiliated to Ankara Family and Social Policies Provincial Directorate. The institution, which has a capacity of 294 people, has a director and three deputy directors, 10 nurses, three social workers, two psychologists and a sociologist and four physiotherapists. Breathing exercises program is not included in the routine practices of the nursing home. In addition,

activities such as hobby works, handicrafts, music studies, sports activities, exhibitions and kermes activities, excursions, cinema days, panel - conferences are carried out. Exercise will be held in the group activity hall of the physical therapy unit, which is determined as the most suitable area for elderly individuals and exercise application with the joint decision of the nursing home management and researcher.

## **Prevention of interaction of groups**

In order to reduce the interaction of elderly individuals in the intervention and control groups with respect to breathing exercise, the exercise room of the physical therapy unit located in a different area than the section where the elderly live is determined as the application area of the exercise. In addition, even if there is a sharing about breathing exercise among elderly, the application should be applied regularly and consciously under the supervision of a specialist in order to reveal the desired success. In this sense, it is thought that the interaction between the groups has no significant effect.

# **Pre-test**

The pre-test application is planned to be done between 29.01.2019 -03.02.2019. In the physical therapy unit of the nursing home, a suitable area will be determined by the researcher and specialist physiotherapist, and measurement devices will be placed, elderly individuals in both groups will be called from the room phone and called for measurement. In order to prevent the data from being affected by the measurements, introductory information data sheet, Pittsburg Sleep Quality Index, Subjective Vitality Scale will be applied, individuals will be rested during this period, and then cardiological parameters will be evaluated, and finally lung functions will be evaluated.

A manual sphygmomanometer and a pulse oximeter device will be used to assess heart function. Sphygmomanometer is of Perfect Aneroid type. The manometer chamber and the spoon spoon are nickel plated chrome. The manometer is 48 mm in diameter, the cuff outer cloth dimensions are 13x47 cm (+/- 2 cm), the cuff outer cloth is hooked, the cuff inner tube hoses are made of double-layer, vulcanized rubber. It is suitable for adult use. Finger pulse oximetry device has arterial oxygen saturation and pulse measurement feature. It provides a graphical view of the pulse. It is suitable for all ages. Evaluation steps are as follows;

• The individual is informed before evaluating his heart functions.

• The individual is placed in a position where the individual can be comfortable from the measurement. He should not have used tea, coffee and cigarettes until 15 minutes before the measurement.

- The individual is rested for 3-5 minutes
- Heart rate is measured from the radial artery for one minute

• For the systolic / diastolic blood pressure, the appropriate arm is selected, the clothes are relaxed / removed, the arm is positioned (must be at 45 heart level), the appropriate sleeve is selected (wrap the arm sufficiently). Next, the location of the brachial artery is determined, the air of the cuff is completely evacuated, the lower edge of the cuff is taken 2-2.5 cm above the place where the brachial artery is palpated, the middle point of the cuff is placed on the brachial artery. The receiver of the stethoscope is placed on the brachial artery without touching the sleeve and clothes and the earpiece is placed on the ear, the cuff is inflated to 30 mmHg above the previously determined systolic blood pressure value, then the cuff air is discharged to be 2-3 mmHg / second.

• Blue, black, green, brown, red nail polish, if any, in the individual before the oxygen saturation measurement is deleted, artificial nail is removed,

- It is placed on the hand and / or toenail of the light source part of the pulse oximeter,
- Measurements are made for 30 seconds and then the device is removed from the finger
- The data are recorded on the data form created by the researcher.

Evaluation of lung functions will be done in the presence of a specialist physiotherapist. The specialist physiotherapist does not know the elderly individuals in the experimental and control groups. Spirometry will be used to evaluate lung function. Spirometry is the basic device of respiratory function test laboratories. It consists of the electronic part where the measurement is made and the mouthpiece that the patient breathe. Cosmed Pony FX - Desktop Spirometer and disposable mouthpieces suitable for the device will be used in the study. This type of spirometer enables testing without the need for a computer. It has an internal memory where patient information can be stored. It is used with two-way digital turbine flowmeter. Pulse function test measurement application steps are as follows;

- Elderly individuals are informed before spirometry is applied.
- The height of the elderly person, body weight is measured and recorded with his age
- Individual disposable mouthpiece is placed in the entry section of the tool.

• The individual puts the mouthpiece in his mouth with his lips, but not to bite with his teeth. It is important that the lips close well. Otherwise, leakage will occur. This causes incorrect measurement.

• The nose of the individual who is connected to the spirometer device with the help of a mouthpiece is closed with a special latch before the measurement.

- The individual breathes calmly first (4-5 times)
- It takes a hard, deep and fast breath after normal breathing.

• It is also fast, challenging and exhaled with the command to exhale. Breathing should take at least 6 seconds.

• This process must be repeated at least 3 times.

The test results are compared with the expected values (predicted values) pre-calculated in healthy individuals of the same age, height and gender by the software found in the spirometer

device and expressed as a percentage of these values. The obtained results will be sent to the researcher within 15 days in pdf format by the authorized firm of the spirometer device.

# Application steps in the intervention group

The literature has been examined in determining the duration of respiratory exercise to be applied to elderly individuals in the study group. Taking into consideration the methods and suggestions of all these studies, respiratory exercises are planned in this study. Breathing exercises; Between 18.02.2019 -09.05.2019, for 12 weeks, three days a week (Monday, Tuesday, Thursday) in groups of 5-6 people (2 groups of 6 people, 4 groups of 5 people in total, 10.00-15.30 hours) between each group at the same time of the day, 30 min. will be applied for a while. During the breathing exercise, no special clothing or supplies will be needed. Disruptions in participating in the exercise program will be compensated for at the specified time and day in partnership with the elderly individual and the researcher. The wind rose to be used during the exercise will be provided by the researcher. All types of breathing exercises will be taught to older individuals on the first day of application and will be shown again by the researcher prior to the application throughout the application. Dizziness that may occur during breathing exercise may occur. Elderly individuals will be reminded of this before each application, and if they experience dizziness, they will be asked to wait for the dizziness to pass by pausing the exercise for a short time. The application of the breathing exercise program is as follows;

- I. Pursed Lip Breathing Exercise (using the Wind rose)
- The individual is seated in a position where he feels comfortable and with clothes,
- First, breathe slowly through the nose,
- Lips contract like a whistle
- The wind rose is kept at the level of the mouth at a distance of 25 cm,

• The breath is discharged slowly and for a longer period of time (at least twice the breathing) by blowing from the shrunken lips to the wind rose,

- Power should be used to exhale,
- This process continues until the breath is interrupted,
- A break is taken for 30 seconds, then the procedure is repeated (Total 10 minutes)
- 2 minutes break.
- II. Diaphragmatic breathing exercise
- The active hand is placed on the stomach and the other hand on the chest,
- Breathing slowly through your nose,
- The abdomen is filled with air and the hand rises,
- The rib cage should rise less than the abdomen,
- Then, breathing slowly through the mouth,

- 30 seconds break and the process is completed (10 minutes in total),
- 2 minutes break.
- III. Cough exercise
- Then a deep breath is taken through the nose,
- After the chest is fully enlarged, mouth is exhaled,
- This process is repeated twice,
- Take a deep breath for the third time and hold it for 2 seconds,
- Then, two times, "huh huh" sound is made and the mouth is exhaled,
- 30 seconds break,
- Then this process is repeated (Total 10 minutes).

# Application steps in the control group

No breathing exercise will apply to elderly in the control group. Individuals will continue their daily lives.

### Post-test

One day after the end of breathing exercise application, between the dates 10.05.2019 - 14.05.2019, elderly individuals will be called by calling from the room telephones in the physical therapy unit. will be re-evaluated in individuals in both groups