







Comparison between *Citrus sinensis* flowers and *Mentha spicata* leave essential oils inhalation on lung function and exercise performance among a group of athlete students

Submission date 10/06/2016	Recruitment status No longer recruiting	 Retrospectively registered
		 Protocol not yet added
Registration date 20/09/2016	Overall study status Completed	 SAP not yet added
		 Results added
Last Edited 20/10/2017	Condition category Not Applicable	 Raw data not yet added
		 Study completed

Plain English Summary

Background and study aims

Recently, there has been a lot of interest in the effects of essential oils on athletic performance and health. Essential oils are natural oils which are taken from plants and other natural sources. They have been used for many years in alternative medicine, as they are thought to help improve the function of the mind and body. This study will look at oils from the *Citrus sinensis* (sweet orange) flower and *Mentha spicata* (spearmint) leaves to find out if they are able to improve lung function and athletic performance in healthy male athletes.

Who can participate?

Healthy male university students aged between 18 and 20 from the faculty of physical education at An-Najah National University in Nablus-Palestine.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group inhale *M. spicata* oil mixed with 2ml of normal saline (salt water) which has been turned into a vapor. Those in the second group inhale *C. sinensis* flower oil mixed with 2ml of normal saline (salt water) which has been turned into a vapor. Before and five minutes after inhalation, participants complete a breathing test using a spirometer (device used for measuring the amount of air breathed in and out) to test their lung function. In addition, before and after inhalation, participants run 1500 metres in a stadium to find out if inhaling the oil has improved their athletic performance.

What are the possible benefits and risks of participating?

Participants may benefit from improved lung function and athletic performance as a result of taking part in the study. There are no notable risks involved with taking part in this study.

Where is the study run from?
An-Najah National University (Palestinian Territory)

When is the study starting and how long is it expected to run for?
April 2016 to October 2016

Who is funding the study?
Investigator initiated and funded (Palestinian Territory)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
1/May/ 2016

Study information

Scientific Title
The effect of Inhalation of Citrus sinensis flowers and Mentha spicata leave essential oils on lung function and exercise performance: a quasi-experimental uncontrolled before-and-after study

Study hypothesis

The aim of this study is to compare the effects between the Citrus sinensis flower and Mentha spicata leaves essential oils inhalation among a group of athlete male students on their lung functions

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board (IRB) at An Najah National University, 03/05/2016, ref: 1/May/2016

Study design

Single-centre randomised parallel trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Other

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Condition

Exercise performance and lung function

Interventions

Twenty male university students from the faculty of physical education at An-Najah National University in Nablus-Palestine will be randomly assigned into two different groups. The study is single blind participant level.

Group 1: Participants will nebulize with M. spicata oil (0.02ml/kg of body mass of oil) mixed with 2ml of normal saline.

Group 2: Participants will nebulize with C. sinensis flower oil (0.02ml/kg of body mass of oil) mixed with 2ml of normal saline.

Participants in both groups completed a 1500m run test in a stadium race before and after inhalation of the oils, they inhaled the oils 5 minutes before running. Lung function tests are undertaken using a spirometer before and after inhalation.

Intervention Type

Other

Primary outcome measure

Lung function is measured using spirometry before and 5 minutes after inhalation of volatile oil.

Secondary outcome measures

Athletic performance is measured using a 1500 meter run test before and after inhalation of volatile oil.

Overall study start date

01/04/2016

Overall study end date

01/10/2016

Eligibility

Participant inclusion criteria

1. Healthy
2. Male university students from the faculty of physical education at An-Najah National University in Nablus-Palestine
3. Aged between 18-20 years

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

20 Years

Sex

Male

Target number of participants

20

Participant exclusion criteria

Suffering from any disease

Recruitment start date

22/06/2016

Recruitment end date

22/07/2016

Locations

Countries of recruitment

Palestinian Territory

Study participating centre
An-Najah National University
West Bank
Nablus
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Sponsor information

Organisation
An-Najah National University

Sponsor details
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Sponsor type
University/education

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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication of study results in a peer reviewed journal.

Intention to publish date

01/10/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/09/2016		Yes	No