

Assessing the effects of smell training on the brains of patients with an impaired sense of smell after surgery

Submission date 30/05/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 02/06/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 02/06/2020	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Olfactory dysfunction is the inability to perceive smells. Its treatment is challenging due to limited therapeutic options. Olfactory training has been shown to improve smell identification, discrimination, and the threshold for odour detection of patients with olfactory dysfunction with postinfectious etiology (i.e. after an infection). The aim of this study is to assess the effect of olfactory training in patients with olfactory dysfunction after pituitary surgery (post-surgical etiology) using functional magnetic resonance imaging (fMRI scan) to see if it induces neural (brain) reorganization processes.

Who can participate?

Patients with post-surgical olfactory dysfunction lasting for at least 1 year after endoscopic transsphenoidal pituitary surgery

What does the study involve?

Participants undergo an examination that includes a nasal endoscopic evaluation. They are also tested using an olfactory measurement test (Sniffing Stick test) and undergo an fMRI scan. Participants are randomly allocated to undergo olfactory training for 12 weeks or no treatment. Olfactory training is performed using four essential oils. Participants are instructed to expose themselves twice a day to each odour taking deep sniffs for 30 seconds and resting 10 seconds between each oil. Additionally, they are instructed to evoke a memory or feeling during the odour exposure that is associated with the smell of the essential oil. Participants are contacted monthly to maintain compliance and motivation during the training period. At the end of the 12-week training period, both groups are assessed using the olfactory performance test and fMRI, and the control group receive olfactory training.

What are the possible benefits and risks of participating?

The possible benefits are the partial or complete recovery of olfactory function after olfactory training. This study does not have any risks for the participants.

Where is the study run from?
Pontificia Universidad Catolica de Chile (Chile)

When is the study starting and how long is it expected to run for?
May 2017 to May 2021

Who is funding the study?
Fondo Nacional de Desarrollo Científico y Tecnológico (Chile)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
170728010

Study information

Scientific Title
Neuroplasticity assessment using fMRI after olfactory training in post-surgical olfactory impaired patients

Acronym

NOTFMRI

Study objectives

Olfactory training will induce neuroplasticity processes on associated olfactory areas in patients with post-surgical olfactory dysfunction.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 05/09/2017, the scientific ethics committee of Pontificia Universidad Catolica medical faculty (Marcoleta 381 – fourth floor, Office 42, Santiago, Chile; +562 (0)23548173; Cecmeduc@med.puc.cl), ref: 170728010

Study design

Single-center interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post-surgical olfactory dysfunction

Interventions

All participants undergo an olfactory measurement test to diagnose olfactory dysfunction and assess severity. Also, they are examined by an ENT specialist's including a complete physical exam and nasofibroscope, to exclude other conditions that could be causing smell impairment. For the scanning sessions, an odour infusion system is attached to a single air-line, to perform the sniffing paradigm, which is characterized by an odour intake of eucalyptus essential oil through a nasal cannula.

Also, a trigeminal activation paradigm is performed to assess the indemnity of the trigeminal system, characterized by the intake of odourless CO₂ through a nasal cannula. After the first fMRI and olfactory performance assessment, the smell-impaired cohort is randomized into two groups. Participants are randomized by simple randomization using computer-generated random numbers. The allocation is concealed from the research team. No masking is used.

Intervention: Olfactory training for 12 weeks

Control: No treatment

Olfactory training is performed using four essential oils: lemon (limonene 67.08% and b-pinene 12.52%), eucalyptus globus (1-8-cineole 60%), clove (eugenol 75.49% and eugenol acetate 13.59%) and lavender (linalool 36.53% and linalyl acetate 32.80%). Patients are instructed to expose themselves twice a day to each odour taking deep sniffs for 30 seconds and resting 10 seconds between each oil. Additionally, they are instructed to evoke a memory or feeling during the odour exposure that is associated with the smell of the essential oil. Patients are contacted monthly to maintain compliance and motivation during the training period.

At the end of the 12-week training period, both groups are assessed using olfactory performance test and fMRI, and the control group receive olfactory training.

Intervention Type

Other

Primary outcome(s)

Activation areas and functional connectivity during olfactory stimulation measured using functional MRI images before olfactory training and 12 weeks after the intervention

Key secondary outcome(s)

Olfactory function assessed using olfactometric measurements before olfactory training and 12 weeks after the intervention

Completion date

01/05/2021

Eligibility

Key inclusion criteria

1. Referred post-surgical olfactory dysfunction lasting for at least 1 year
2. Only patients with a definite diagnosis of olfactory dysfunction were finally included
3. No history of psychiatric or neurodegenerative diseases

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Olfactory dysfunction not related to surgical procedures
2. Associated psychiatric or neurodegenerative diseases
3. Pediatric age

Date of first enrolment

01/10/2017

Date of final enrolment

31/12/2020

Locations

Countries of recruitment

Chile

Study participating centre
Pontificia Universidad Catolica de Chile
Marcoleta 352
Santiago
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8330033

Sponsor information

Organisation
Pontifical Catholic University of Chile

ROR
<https://ror.org/04teye511>

Funder(s)

Funder type
Government

Funder Name
Fondo Nacional de Desarrollo Científico y Tecnológico

Alternative Name(s)
National Fund for Scientific and Technological Development, El Fondo Nacional de Desarrollo Científico y Tecnológico, FONDECYT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Chile

Results and Publications

Individual participant data (IPD) sharing plan

The data that is stored are the demographic data of each patient, the olfactometric results and the fMRI images of each of the patients. This data is private and the ethics committee only authorizes its use by the authors for scientific publication protecting the anonymity of the participants. There are no web links available, and data is stored in the Bioimaging center of the University.

IPD sharing plan summary

Stored in repository