U-SNIFF * validation of an odor identification test for children

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To assess the feasibility of using the U-SNIFF in various European countries (e.g. the Netherlands). To validate the developed odor identification test for children (U-SNIFF), in various European countries. (e.g. the Netherlands). To assess the test...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON46389

Source
ToetsingOnline

Brief title
U-SNIFF

Condition

- Other condition

Synonym
smell function; odor identification

Health condition

geen aandoeningen: zintuigelijk onderzoek naar het reukvermogen

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: children, identification, smell function

Outcome measures

Primary outcome

Odor identification scores (total amount of correct answers) at the first and

second test session.

Secondary outcome

n/a

Study description

Background summary

Tools for measuring olfactory function in adults have been well established. Although studies have shown that olfactory impairment in children may occur as a consequence of a number of diseases or head trauma, until today no consensus on how to evaluate the sense of smell in children exists in Europe. To determine childrens' smell function, recently an odor identification test has been developed in Germany (U-SNIFF). However, no cross-cultural validation has been done to assess its use in other countries within and outside of Europe.

Study objective

To assess the feasibility of using the U-SNIFF in various European countries (e.g. the Netherlands).
To validate the developed odor identification test for children (U-SNIFF), in various European countries. (e.g. the Netherlands).
To assess the test-retest reliability of the U-SNIFF.

Study design

This protocol is part of a larger multicenter study, including Argentina,

Brazil, China, Iran, the Netherlands, Norway, Oman, the Philippines, Rumania, Russia, Thailand, and is headed by Uniklikum TU Dresden, Germany. This is an observational study, that will twice measure olfactory function in children. Duration of each test session will be approximately 15-30-minutes; the test sessions will be at least two days apart.
The smell test consists of 12 pens filled with the following odors: apple, banana, butter, coffee, grass, fish, rose, lemon, onion, orange, peach, strawberry.

Study burden and risks

This is a group-related study: participation of the children is essential in this study, since the purpose of the study is to validate an odor identification test for use in children. Results for adults cannot be extrapolated to children. The study is non-therapeutic to the participant. The risk of participating in the study is negligible and the burden of participating is minimal. The total study duration will be maximally 60minutes per participant and consist of smelling every-day odors. Odors will be used in concentrations that can be found in consumer products, that are non-toxic and/or can be considered safe.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

children, aged 6, 7, or 8 years
Self-reported normal sense of smell
Permission from their parents to participate
Willing to participate

Exclusion criteria

- Known smell dysfunction
- Disease that is known to influence the sense of smell (e.g. renal failure, epilepsy)
- Acute and chronic rhinosinusitis/sinusitis
- Has known allergic or aversive reactions to certain odors

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-06-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	19-02-2018
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL63829.081.17