

# Prevalence of otitis externa 2010

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Aural disorders NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON35017

### Source

ToetsingOnline

### Brief title

POE2010

### Condition

- Aural disorders NEC

### Synonym

ear canal infection, swimmer's ear

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Ministerie van OC&W, deelnemende organisaties

### Intervention

**Keyword:** otitis externa, prevalence, risk factors

## Outcome measures

### Primary outcome

The primary study parameters are the point prevalence of otitis externa and the presence of risk factors.

### Secondary outcome

Secondary outcome are the presented symptoms of otitis externa.

## Study description

### Background summary

Otitis externa is a diffuse inflammation of the skin of external auditory canal. It can cause symptoms like pain, itching and discharge and sometimes (conductive) hearing loss. Otitis externa is an acute condition, but can also be a chronic problem, when the duration exceeds minimum four weeks or when more than four episodes occur in one year.

A break in the normal protective barrier of the external ear canal can lead to a disruption of local flora giving other micro-organisms a chance to invade and grow causing an infection.

Factors like excessive presence of cerumen leading to obstruction of the ear canal or trauma to the external ear canal, can lead to a break in the protective barrier of the external ear canal. A narrow external ear canal is prone to obstruction and therefore also a risk factor to develop otitis externa. People with an intellectual disability appear to have a higher prevalence of ear problems, amongst others otitis externa. Also, these people are not always capable to report ear problems. A search in literature databases Medline and Embase does not lead to any article reporting about otitis externa in people with intellectual disabilities. Therefore, we want to investigate the point prevalence of otitis externa in people with intellectual disabilities. Further, we want to investigate which risk factors are present and if carers recognised this condition among their clients.

### Study objective

The main objective of this study is to determine a point prevalence of otitis externa. Further, we want to determine the presence of risk factors and to obtain information about how otitis externa is presented by people with an intellectual disability. Therefore, we formulated the following study questions:

1. What is the (point)prevalence of otitis externa in adults with an intellectual disability, who are living within an organization for people with intellectual disabilities?
2. Which risk factors are most common?
  - 2a. Are these factors correlated?
3. Did carers of the participants recognise symptoms, when they appear to have an otitis externa at the moment of otoscopic investigation?
  - 3a. What are these symptoms?

## **Study design**

This study is observational and descriptive.

## **Study burden and risks**

This study has to be performed among people with an intellectual disability in order to be able to determine a pointprevalence and risk factors of otitis externa in this population. This information can enhance consciousness of this problem in doctors and guardians and therefore lead to a better management of recurrent infections of the external ear canal

The nature and extent of the burden of this study for the participants is minimal because many of them already receive an otoscopic examination regularly. The risks of the otoscopic examination, like damaging the skin of the external ear canal, are very rare.

When a participant shows physical or verbal resistance to the otoscopic examination or says that he or she doesn't want to participate anymore, this will be respected.

The study will be performed in observation of the Dutch law of medical research with people, the consensus guideline considering ethics in medical research among people with an intellectual disability of the NVAVG, and the privacy legislation. Data will be anonymously reported.

## **Contacts**

### **Public**

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### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

older than 18 years, having an intellectual disability, living within an organization for people with intellectual disabilities

### Exclusion criteria

atresia of the external ear canal

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2010
Enrollment:	600
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	24-06-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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	NL31375.078.10