

# The efficacy and applicability of a daytime alarmtraining in children (age 5-12 years) with urine incontinence

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Is the day alarm a usefull tool for parents and children to gain more insight in there urine incontinence. By getting a signal at the moment of wetting, parents and children can be trained in a more efficient way to gain more control of their...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON43453

### Source

ToetsingOnline

### Brief title

INKT study

### Condition

- Other condition
- Bladder and bladder neck disorders (excl calculi)

### Synonym

urine incontinence

### Health condition

urine-incontinentie bij kinderen

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Kindergeneeskunde

**Source(s) of monetary or material Support:** Afdeling kindergeneeskunde van het Jeroen Bosch ziekenhuis te 's- Hertogenbosch

## Intervention

**Keyword:** Children, Daytime alarm, Urine incontinence

## Outcome measures

### Primary outcome

Complete control of urine incontinence

Partial control of urine incontinence

No respons

### Secondary outcome

does not apply

## Study description

### Background summary

This study is evaluating the applicability en efficacy of a day time alarm in children age 5-12 years.

### Study objective

Is the day alarm a usefull tool for parents and children to gain more insight in there urine incontinence. By getting a signal at the moment of wetting, parents and children can be trained in a more efficient way to gain more control of their bladder function.

### Study design

quasi experimental study with pre- and posttest

### Study burden and risks

no risk

## Contacts

### Public

Selecteer

Henri Dunantstraat 1  
's-Hertogenbosch 5223 GZ  
NL

### Scientific

Selecteer

Henri Dunantstraat 1  
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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

Boys and girls age 5-12 years  
Daytime urine incontinence  
Already received basic training in urine incontinence  
Informed Consent parents  
Dutch speaking

### Exclusion criteria

Obstipation  
Anatomical bladder or bowel anomalies  
Unstable home environment  
No training motivation child and/or parents  
Simultaneous participation in other study

## 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): 03-02-2016

Enrollment: 25

Type: Actual

### Medical products/devices used

Generic name: Clippo daytime alarm

Registration: Yes - CE intended use

## Ethics review

Approved WMO

Date: 16-02-2016

Application type: First submission

Review commission: METC Brabant (Tilburg)

Approved WMO

Date: 10-05-2016

Application type: Amendment

Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	20-12-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

## 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	NL56153.028.15