The PICAS-study: Validation of the Sexual Knowledge Picture Instrument (SKPI); about the verbal- and the nonverbal ways sexually abused children reveal sexual knowledge.

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1) The validation of the SKPI used in children with a developmental age of 3 to 8 years old.Hypothesis:- By using the SKPI the examiner will be able to distinguish children who are victims of CSA from children who are not.2) The demonstration of the...

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

Summary

ID

NL-OMON55439

Source
ToetsingOnline

Brief title
PICAS (Picture Instrument for Child sexual Abuse Screening)

Condition

- Other condition
- Psychiatric and behavioural symptoms NEC

Synonym
signs of sexual abuse

Health condition

seksueel misbruik

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Geld vanuit het Transmuraal Academisch Samenwerkingsverband Kindermishandeling (TASK). Daarnaast liggen subsidie aanvragen bij een aantal fondsen. (oa. Innovatiefonds Zorgverzekeraars).

Intervention

Keyword: children, sexual abuse, social pediatrics

Outcome measures

Primary outcome

The knowledge and verbal statements from the child, and the nonverbal behaviors

are observed by the interviewer, and a score sheet is completed on this basis .

Secondary outcome

n.v.t.

Study description

Background summary

Sexual abuse in children is a major problem worldwide[4]. From all victims of sexual abuse, a quarter to a third are under 7 years of age[5]. By potentially affecting physical, mental and sexual health of the child, it can be a burden for many years into adulthood[2]. In a 2010 Dutch study, up to 9% of surveyed high school students reported ever being sexually abused[1]. A meta-analysis combining prevalence figures worldwide, shows a CSA prevalence of 12.7% in self-report studies and 0.4% in informant studies[4].
The differences in these prevalence numbers can be explained by study method, self-report vs. collecting data amongst professionals or organizations and varying definitions of CSA[6].

Despite the growing attention from pediatricians and other health care professionals, it is difficult to either reject or confirm a suspicion of CSA. There are almost never specific signs or *red flags* in the examination of

children suspected to be sexually abused, and the genital examination is often non-contributing[7].
Unfortunately, most children are unable or reluctant to talk about the abuse. Spontaneous disclosures are rare for multiple reasons, such as a conflict of loyalty, shame, guilt and limited verbal capacities of the child[8]. To assist in confirming the diagnosis or to make a risk assessment on CSA, a few questionnaires are available internationally, but none of these tools are validated in the Netherlands[6]. Also, these questionnaires mostly focus on child abuse in general, and not on CSA specifically[6].
Another problem is that young children are unable to fill in these questionnaires themselves. Therefore, at this point, a clinician*s confirmation of suspicions of CSA in young children is a highly subjective matter and mainly based on expert opinion.

Sexual Knowledge Picture Instrument
The Sexual Knowledge Picture Instrument (SKPI) was originally developed as a tool to reveal sexual knowledge in young children[3]. It is a child-friendly picture atlas, in which in addition to a number of illustrations about everyday routines, the following topics are shown: Physical differences between boys and girls, gender identity, genitals and their functions, reproduction, sexual behavior of adults and boundaries between physical intimacy and sexual acts[3]. The use of the SKPI with semi-structured questions from a developed guideline makes it possible for a trained clinician to conduct a conversation with the child about these matters, and to observe the child*s behavior at the same time.
In 2005, a preliminary SKPI study was performed by Brilleslijper-Kater[3]. Hypothesis was that sexually abused children experienced inadequate sexual behavior and therefore would show more deviant sexual knowledge. Pre-school children normally appeared to have very little knowledge of sexuality. They only exhibited basic knowledge of genital differences, gender identity, sexual body parts and (non-sexual) functions of the genitals. Non-abused children*s reactions were relaxed, open-minded and unprejudiced taking their own points of view and experiences as points of reference. This in contrast to abused children. At first glance they appeared to disclose (even) less information than non-abused children. Further analyses showed that abused children were much more reserved in revealing their knowledge. The most remarkable finding, however, was their nonverbal behavior. Examples of this, such as fidgeting, ducking under the table, or theatrical behavior seemed to distinguish the abused group from the non-abused group. To further investigate this, a second study, specifically aimed at the differences in nonverbal behavior between abused and non-abused children was conducted. Results showed that abused children exhibited significantly more nonverbal behavior compared to non-abused children[3].

Because of the non-verbal character of the SKPI we hypothesize that it is suitable for all children with a developmental age of 3 to 8 years old, regardless of their ethnic background. The SKPI is currently being used on a

daily basis at the outpatient clinic of the Social Pediatrics department in the Emma Children's Hospital. In our clinical practice the use of the SKPI makes an important contribution to the diagnosis of sexual abuse in young children.
To date, despite its frequent use, the SKPI has only been explored in a limited extent in the above-described preliminary study. Therefore it is the aim of our study to determine the accuracy and reliability of the SKPI, showing its potential as a valuable addition to the clinicians examination in young children suspected of CSA.
Currently a guideline on diagnostics in suspected CSA is developed by a multidisciplinary team commissioned by the Nederlandse Vereniging voor Kindergeneeskunde (NVK). This guideline will be published in 2016, under the leadership of A.H. Teeuw, pediatrician in the AMC and president of TASK-Amsterdam. While developing the guideline, professionals of child protection services, vice squad, forensic medicine and other health care professionals stated a need for accurate diagnostic instruments to investigate suspicions of CSA in children.

Study objective

1) The validation of the SKPI used in children with a developmental age of 3 to 8 years old.

Hypothesis:
- By using the SKPI the examiner will be able to distinguish children who are victims of CSA from children who are not.

2) The demonstration of the reliability of the SKPI by determining intra- and inter-observer reliability.

Hypothesis:
- The SKPI is a reliable instrument with high intra- and inter-observer reliability.

3) The validation of the SKPI in children with a non-Dutch ethnicity.

Hypothesis:
- By using the SKPI the examiner will be able to identify victims of CSA despite their ethnic background.

Study design

First, a systematic literature review of the *state of the art* on the following topics will be performed:
- The signs in young children during the investigation of CSA, and possible ethnic differences.
- The available tools contributing in detecting CSA.

- The use of interview techniques in young children.

Subsequently, our main study can be divided into three projects:

1) A (validation)study, establishing the diagnostic accuracy by calculating the predictive value, sensitivity and specificity of the SKPI in three different groups of children:

I. Case group (n=50): Known sexually abused children from 3-8 years, enrolled in cooperation with the Dutch vice squad.
II. Control group (n=100): Children who are not suspected to be sexually abused, enrolled in Dutch primary schools and health care centers (matched with cases on age, gender and ethnic background).

After determining the diagnostic accuracy of the SKPI in the complete sample, a subgroup analysis will be performed to compare the diagnostic accuracy of the SKPI in children with a Dutch ethnicity to children with a non-Dutch ethnicity.

III. Mixed CSA and non-CSA group (n=100): Children who come into care because of a (either low or high) suspicion of sexual abuse, recruited at our own outpatient clinic.

We consider it most relevant for the SKPI to be able to differentiate in this *real* daily practice population, and distinguish sexually abused children from the children who were not sexually abused, but may have experienced other (different) types of abuse. For these children, initially, it is not known if children are sexually abused. To determine abuse status, we will follow the children up and assess the reports of the child protection services and the police to determine if CSA has been confirmed or ruled out.

In all three groups, the researcher using the SKPI will be blind to the abuse status or any other diagnostic information.

2) A second (validation) study of the reliability of the SKPI is carried out, to determine the inter-rater and intra-rater reliability by scoring video recordings of interviews with the SKPI in our own outpatient clinic.

3) After finishing the validation study, a training program with certification will be developed. This is the first step in the implementation phase of the SKPI in the Netherlands. By completing this training, the pediatrician or other professional is able to use the SKPI along with its semi-structured interview technique. A pilot trial of this training in 20 pediatricians will be performed in our own clinic.

Study burden and risks

The researcher will be instructed by the manual, and tries to comfort the child as far as possible. The sexually abused children , however, may be fearful or otherwise affected during the investigation. If the child exhibits any signs of this, immediate psychiatric help will be consulted.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Index Group:
Children (3 / 8 years, n<=50) who have been proven victims of sexual abuse in the past.
Control group 1:
A "healthy" group of children (3 / 8 years, n<=100) enrolled in primary schools and preschools, in whom there is no suspicion of sexual abuse.
Control group 2:

Children (3 / 8 years, n<=100) included in our outpatient clinic , in whom there is a suspicion of sexual abuse (possibly in combination with another form of child abuse) .

Exclusion criteria

General criteria:
- Children (and parents) who do not speak the Dutch language sufficiently to conduct the interview.
- Children with cognitive disabilities or visual impairments.
- Children who have already been interviewed with the SKPI .
- Children with established psychiatric and / or behavioral disorders.
Control group 1:
Any child who is suspected of being sexually abused (either in present or past) .

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2017
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	17-12-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL50903.018.15