

# INCAS Validation: Parenting capacity in mothers with severe mental illness

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The main goal of this study is to establish the reliability (internal consistency and interrater reliability) and validity (discriminant, construct and predictive validity) of the INCAS. Differences between the SMI and healthy group will be studied (...)

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Maternal complications of pregnancy
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON40092

### Source

ToetsingOnline

### Brief title

INCAS Validation

### Condition

- Maternal complications of pregnancy
- Psychiatric disorders NEC

### Synonym

psychopathology, severe mental illness

### Research involving

Human

### Sponsors and support

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

**Source(s) of monetary or material Support:** Sophia Stichting Wetenschappelijk Onderzoek (SSWO)

## Intervention

**Keyword:** early child development, observational assessment, parenting, severe mental illness

## Outcome measures

### Primary outcome

Parenting capacity: maternal sensitivity, quality of the home situation.

Correlates of parenting capacity: psychopathology, executive functioning, attachment experiences, mind-mindedness, oxytocin, cortisol stress respons.

Consequences of parenting capacity: social-emotional development, mental and motor development, behavioral and physical regulation, attachment quality and cortisol stress response.

### Secondary outcome

Prevalence of child somatic disorders; excessive crying, gastro-esophageal reflux and constipation (collaboration with Department of Pediatrics of the Zuwe Hofpoort Hospital in Woerden) and its association with maternal SMI.

## Study description

### Background summary

Physicians and psychiatrists regularly encounter infants at developmental risk due to maternal severe mental illnesses (SMI). Maternal SMI predicts a higher risk of child mortality; deficits in cognitive development; child psychopathology and behavioral problems. Parenting is a multidimensional construct, consisting of basic provision and knowledge, but also sufficient planning and flexibility, empathy, and warmth. Parenting domains can be negatively affected by factors such as executive functioning deficits, mother\*s bad experiences in close relationships, and maternal psychopathology. Deficits in parenting domains are related to neurobiology in the mother and the child, such as lower maternal oxytocin levels and elevated child cortisol stress response. There are however no instruments that can assess the combination of

specific parenting dysfunctions. Furthermore, there are no evidence-based criteria available to decide whether parenting offered by SMI mothers is \*good-enough\* and provides for the necessary care for the child. In this study, the \*Infant Caregiving Assessment Scales\* (INCAS) instrument will be validated for the Dutch population, in collaboration with the Universities of Sydney (the initiator of the INCAS) and Oregon. With this instrument parenting of SMI mothers will be divided in multiple testable domains of basic skills, flexibility, and planning (instrumental care), and empathy, affection, and interaction (emotional care). This fine-grained information will allow practitioners to conduct focused assessment and treatment to benefit both mothers and children.

## **Study objective**

The main goal of this study is to establish the reliability (internal consistency and interrater reliability) and validity (discriminant, construct and predictive validity) of the INCAS. Differences between the SMI and healthy group will be studied (discriminant validity). The association between specific INCAS domains and other measures of parenting capacity and maternal correlates, such as psychiatric disorder and executive functioning will be investigated (construct validity). Furthermore, the predictive value of the INCAS domains on specific aspects of child development and cortisol stress response are investigated (predictive validity).

## **Study design**

In this naturalistic follow-up study at 30 weeks (pregnancy) and at 1.5, 6, 9, and 14 months post partum, parenting capacity, maternal correlates of parenting and parenting outcomes are assessed. The INCAS yields ratings of early parenting capacity that are task-specific, criterion-referenced, and ecologically valid. Parenting will be assessed from videotaped interactions in naturalistic settings during core tasks of caring, to approach real-life situations. Clinical impressions and subjective views are excluded from this assessment. With this 60-minute assessment, parenting will be divided in sub domains of instrumental and emotional care needs resulting in a more specific quantification of parenting on nine-point Likert scales.

## **Study burden and risks**

There are no known specific risks associated with participation in this study. The study will contribute significantly to clinical practice and the existing scientific knowledge base in the field of early parenting capacities and psychopathology. With the results of this study the INCAS instrument can be further improved and the empirical foundation of observational diagnostics can be strengthened and expanded.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

### Inclusion criteria

Infant no older than 7 weeks

Severe mental illness

- DSM axis-I or axis-II disorder (does not apply to control group)

- Illness duration of > 2 years

- Substantial interference with or limit one or more major life activities (GAF < 50).

### Exclusion criteria

Severe medical condition/intellectual disability (IQ < 80)

(Impending) Outplacement of the infant or biological mother is not the primary caretaker

## 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:	Recruiting
Start date (anticipated):	15-05-2013
Enrollment:	320
Type:	Actual

## Ethics review

Approved WMO	
Date:	18-03-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	14-10-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	14-04-2014
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	23-06-2014
Application type:	Amendment
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	NL42662.078.12