# SCOPE

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| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON20911

**Bron**
Nationaal Trial Register

**Verkorte titel**
SCOPE

**Aandoening**

Autism Spectrum Disorder (ASD)
Autisme Spectrum Stoornis (ASS)
Autism
Autisme

### Ondersteuning

**Primaire sponsor:** Karakter Child and Adolescent Psychiatry University Centre
**Overige ondersteuning:** Stichting Korczak Foundation for Autism and Related Disorders

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

The main primary outcome of the study is joint-engagement in the parent-child

interaction.<br>
A 12 minute videotaped interaction between parent and child will be collected for each parent-child dyad prior to the start of intervention, at the end of intervention (8 weeks later) and at 24 weeks follow-up. A standardized set of toys will be presented. Parents will be asked to engage in free play with their child as they normally would do. The videotapes will be coded by observers blind to the group status (BEAR condition or CAU condition) and time point scored (at baseline, end of treatment and follow-up) for the total of time in engagement states between parents and their young children with symptoms of ASD (Joint Engagement Rating Inventory; Adamson et al., 2004; Adamson et al., 2016). Recordings will be subsequently coded for the duration of six mutually exclusive engagement states (unengaged, on-looking, person engagement, object engagement, supported joint engagement and coordinated joint engagement; Adamson & Bakeman, 1984). The total time in supported joint engagement and coordinated joint engagement will be combined into one variable (joint-engagement), as is consistent with other studies (e.g. Gulsrud, Helleman, Shire & Kasari, 2015; Kasari, Freeman & Paperall, 2006; Patterson, 2013; Kaale et al., 2018).

# Toelichting onderzoek

### Achtergrond van het onderzoek

Autism Spectrum Disorders (ASD) are recognized rather late in the Netherlands, as elsewhere, which delays adequate early intervention. Growing scientific evidence indicates that early intervention improves long-term outcomes and reduces negative consequences such as comorbid problems, negative impact on families and high societal costs. The Social COmmunication Programme supported by E-health (SCOPE) aims to improve quality and efficiency of care, to accelerate procedures and to optimize collaboration between the youth-healthcare (JGZ) and the specialized mental healthcare (S-GGZ), so that timely detection of ASD followed by an early start of adequate intervention will be made possible.

SCOPE includes (1) raising awareness via an online platform for parents and professionals, (2) training and consultation for primary care providers, and (3) a short home-based early intervention named BEAR (Blended E-health for children at eArly Risk). BEAR is a parent training will be offered to parents of children (12-30 months) who are screened positive (and are therefore at risk for ASD) in regular well-baby clinic visits. The training will be offered before a full diagnostic assessment program has been performed.

### Doel van het onderzoek

The main objective of this study is to investigate the effectiveness of BEAR (a parent training combining e-learning and home visits) compared to care-as-usual (CAU) in young children (12-30 months) who are at risk of developing ASD, in a cluster randomized controlled trial.

The primary research question is:

1) What is the effectiveness of BEAR compared to CAU in terms of change in joint engagement in the parent child interaction, directly after the treatment at 8 weeks, and at follow-up at 24 weeks?

Secondary research questions are:

2) What is the effectiveness of BEAR, compared to CAU, in terms of social-communicative development and adaptive functioning of the child?

3) What is the effectiveness of BEAR, compared to CAU, in parental intervention skills and parental well-being?

4) What is the effectiveness of BEAR, compared to CAU, in terms of parental satisfaction about care?

5) What is the effectiveness of BEAR, compared to CAU, in time between first concerns of ASD and start of intervention?

6) What is the effectiveness of BEAR, compared to CAU, in cost efficiency?

**Onderzoeksopzet**

Baseline measure, two weeks before the start of treatment.

End of treatment measure, eight weeks after the start of treatment.

Follow-up, 6 months after the start of treatment.

**Onderzoeksproduct en/of interventie**

The BEAR (Blended E-health for children at eArly Risk) parent training. is a blended e-health intervention offered to children (12-30 months) who are considered to be at risk for ASD based on screen positive results of a screening list (the CoSoS, ¡Ý3) or based on clinical judgement, and their parents. The intervention consists of 7 home visits and 5 e-learning sessions and will be delivered by a professional working in the youth health care (JGZ), under supervision of professional working in the specialized mental Healthcare (S-GGZ). During the first and the last visit, the (S)GGZ-professional will accompany the JGZ-professional.

The BEAR parent training consists of several possible treatment modules, covering domains such as communication, social interaction and flexible behaviour. Three out of five treatment modules will be chosen based on personalized treatment goals.

# Contactpersonen

## Publiek

Karakter Child and Adolescent Psychiatry University Centre
Michelle Snijder

0646320116

## Wetenschappelijk

Karakter Child and Adolescent Psychiatry University Centre
Michelle Snijder

0646320116

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- A screen positive result (¡Ý3) on the Communication and Social development Signals (CoSoS), or children with a screen negative result (<3) but about whom serious concerns exist regarding the social-communicative development and/or play possibly associated with ASD, according to parents and/or professionals at the WBC¡¯s.

- Age between 12-30 months.

- At least one of the parents is able to understand and speak the Dutch or English language.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Family problems that limit the possibility to engage in an at home based intervention.

- Significant chronic illness of the child.

- Severe parental psychopathology, such as depression, psychosis, substance use disorder.

- Severe intellectual disability (IQ <20); the significant delay in all areas of the child¡¯s development makes it not possible for the child and it¡¯s parents to participate in the BEAR parent training.

- Severe vision and hearing impairments.

- Severe motor impairments.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |

**Controle:** Geneesmiddel

## Deelname

Nederland

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|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-05-2019 |
| Aantal proefpersonen: | 88 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 17-12-2018 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46538
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL7453 |
| NTR-old | NTR7695 |
| CCMO | NL65479.091.18 |
| OMON | NL-OMON46538 |

# Resultaten