SCOPE for improvement of direct care in early childhood: A Social COmmunication Programme supported by E-health for early identification and intervention of social communication problems possibly associated with autism in primary care

Published: 29-01-2019
Last updated: 15-05-2024

Primary Objective: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...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Communication disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON46538

Source
ToetsingOnline

Brief title
SCOPE

Condition

- Communication disorders and disturbances

Synonym
Autism, Autism spectrum disorder

Research involving

Human

Sponsors and support

Primary sponsor: Karakter, Expertisecentrum voor kinder- en jeugdpsychiatrie
Source(s) of monetary or material Support: Korczak Foundation

Intervention

Keyword: Autism Spectrum Disorder, Early intervention, E-health, Toddlers

Outcome measures

Primary outcome

The main study parameter of the current study is joint engagement in the parent-child interaction, measured by the scales of Bakeman & Adamson (1984, 2004, 2016). A 12 minute videotaped interaction between parent and child will be subsequently coded for the duration of six mutually exclusive engagement states (see p. 21 of the research protocol).

Secondary outcome

Secondary study parameters are the social-communicative development of the child (BOSCC, ADOS-T and N-CDI), global level of adaptive functioning (Vineland Screener), parental well-being (WEMWBS, OBVL), parental intervention skills (fidelty form), parental satisfaction about care (satisfaction questionnaire specially developed for this study) and assessment of health care resources (Tic-P-R).

For more information, see p. 21-25 of the research protocol.

Study description

Background summary

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 BEER (Blended E-health for children at Early Risk). BEER 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. In this submission, we will only focus on the third goal of SCOPE.

Study objective

Primary Objective:
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 the social-communicative development 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?

Study design

First, we will conduct a pilot study. In this pilot study, two well-baby clinic locations in Nijmegen (in Dukenburg and Oud-west) and two-well baby clinic locations in the province of Utrecht (in Oudewater and Houten) will be included. In this pilot study, we aim to test the feasibility of the proposed research design in a small sample (N=10).

The actual design of the study is a cluster randomized controlled trial (RCT) starting in the Nijmegen area with clusters defined by a number of well-baby clinic locations in the city of Nijmegen and surrounding areas, affiliated with GGD Gelderland Zuid. It is expected that we will, as a next step in the study, also include well-baby clinics from the province of Utrecht.

Intervention

The BEAR 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 on the CoSoS (*3) 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 JGZ-professional, under supervision of a (S)GGZ-professional. During the first and the last visit, the (S)GGZ-professional will accompany the JGZ-professional. For a specific outline of BEAR see Table 2 on p. 19 of the research protocol.

Study burden and risks

To our knowledge, the SCOPE program and BEAR. are not associated with any risk for the patient. Burden is estimated as low (see p. 36)

Contacts

Public
Karakter, Expertisecentrum voor kinder- en jeugdpsychiatrie

Reinier Postlaan 12
Nijmegen 6525 GC
NL
Scientific
Karakter, Expertisecentrum voor kinder- en jeugdpsychiatrie

Reinier Postlaan 12
Nijmegen 6525 GC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

A screen positive result (*3) 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

Exclusion criteria

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 BEER parent training.
Severe vision and hearing impairments.
Severe motor impairments.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-12-2019
Enrollment:	98
Type:	Actual

Ethics review

Approved WMO Date:	29-01-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-11-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20911
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL65479.091.18
OMON	NL-OMON20911