Implementing SPARK in Preventive Child Healthcare: Long-Term Outcomes and Cost-Effectiveness.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28521

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Parenting and developmental problems.

Sponsors and support

Primary sponsor: Municipal Health Service Zeeland (GGD Zeeland)
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Cost-effectiveness of SPARK, 1.5 year after implementation, from the perspectives of society, municipalities and PCHC-organizations.

Secondary outcome

Number of toddlers of 18 months with increased or high risk for parenting and developmental problems; Number of toddlers referred to specialized youth care in 1.5 years after the 18-month consultation; Difference in type of referrals/care needs/provided care; Difference in health-related quality of life; Difference in parent-reported shared decision making between; Difference in experiences of parents with care provided by PCHC; Costs of implementing the SPARK; Barriers and facilitators identified during SPARK implementation.

Study description

Background summary

A major task of preventive child healthcare (PCHC) is early detection of parenting and developmental problems. The validated Structured Problem Analysis of Raising Kids (SPARK) is a broad-scope structured interview for this early detection, using both the perspective of the parent(s) and the experience of the PCHC nurse.
Research has shown that the SPARK is effective, valid, reliable and usable in daily practice.

Broad implementation of existing validated instruments for early detection of parenting and developmental problems is hindered by the missing knowledge about long-term impact on parents and children, and by missing knowledge about the cost-effectiveness from the perspectives of different stakeholders. Robust evidence about long-term outcomes for the child, experiences from parents and cost-effectiveness of using the SPARK is essential for evidence-informed policy decisions by municipalities and PCHC-organizations.

A cluster-randomized stepped-wedge trial with 1.5 year follow-up will answer whether implementing the SPARK in PCHC-organizations leads to an improvement in detecting parenting and development problems, results in better health outcomes for children, better care experiences for parents, and lower total costs, compared to the current loosely structured regular consultation for children aged 18 months.

Study objective

Early detection and intervention in preschool children is expected to result in:
1) better wellbeing of child and parents; and
2) less use of expensive specialized youth social care.

Study design

- Single consultation at age of 18-months.
 Questionnaires for parents
 Summary of consultation
- Follow-up of 1.5 years at the age of 24- 30- and 36 months.

 Questionnaires for parents at the age of 24- 30- and 36-months
 Healthcare use from the health care perspective, by retrieving healthcare use from the electronic health care record of the Municipal Health Service and youth care organizations in the studied region.

Intervention

Intervention group: youth healthcare nurse brings a 40-minute home visit to parent(s) and their toddler at the age of 18-months, using the SPARK method.

The control group receives regular care: parents and their toddler are invited to the well-baby clinic for a 20-minute visit to the healthcare nurse at the age of 18-months.

Contacts

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Eligibility criteria

Inclusion criteria

All children in the studied region reaching the age of 18 months in the period July 2019 – October 2020, invited by the Municipal Health Service (GGD) for a 18-month contact moment.

Exclusion criteria

There are no exclusion criteria for participating in the trial, as PCHC aims to offer care to all children living within the municipalities of that organization.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-07-2019
Enrollment:	2496
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8036
Other	Confirmed by Medical Research Ethics Committee (MREC) Utrecht that the Medical Research Involving Human Subjects Act (WMO) does not apply to this study. Therefore, no official approval of this study by the MREC Utrecht is required under the WMO. : ZonMw: 531002022

Study results