The pediatric nurse as linking pin between pediatrics and youth health care: is it effective and efficient?

Published: 25-07-2017
Last updated: 12-04-2024

This study is aimed at optimizing the bridge between medical curative care and care that comes from the social domain, for children and adolescents. The primary goal is to offer the best fitting care to children with psychosocial- and social...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45420

Source
ToetsingOnline

Brief title
JIVES

Condition

- Other condition

Synonym
Social- and psychosocial problems

Health condition

sociale en psychosociale problematiek

Research involving
Human

Sponsors and support

Primary sponsor: GGD West-Brabant
Source(s) of monetary or material Support: ZonMw,Gemeente Breda

Intervention

Keyword: (Psycho)social, Interdisiplinary, Mental, Psychosomatic

Outcome measures

Primary outcome

In this study there are two primary outcome measures: parental/children*s* satisfaction and throughput.

Parental/children*s* satisfaction

One primary outcome measure is parental/children*s satisfaction with the new working method. A questionnaire that is regularly used in youth healthcare as an indicator for client satisfaction is the *Exit questionnaire youth and parenting help*.

The *Exit* questionnaire is a short validated questionnaire with a separate version for parents and children aged 12 years and over. It is the only questionnaire with an item concerning *whether a client can go on without help*, which is an important indicator of the effect of the intervention in our study. In the current research proposal, the *Exit* questionnaire will be used to measure parental/children*s satisfaction with the assistance they received during the study. Extra questions will be added to the questionnaire to evaluate the process of care.

The *Exit* questionnaire will be completed at two different moments:

immediately after completing the intervention (intervention group)/three months after the first consultation with the pediatrician (control group) and three months after completing the intervention (intervention group)/six months after the first consultation with the pediatrician (control group). De measurements in the control group, three and six months after the first consult with the pediatrician are based on the mean expected time that is necessary to accompany the child to the best fitting care.

For both groups, the goal of the first measurement is to evaluate whether the parents and children are satisfied with the care they received, directly after finishing the care process. With the second measurement it is evaluated whether this satisfaction continuous over time.

Throughput

The other primary outcome measure is the throughput (the time between the reference by the pediatrician to the point of fitting *follow-up* care) of the new working method compared to *care as usual*. With this outcome measure a better insight is derived ofwhether care is fast and timely delivered. With additional questions to the above mentioned *Exit* questionnaire we collect the following information:

Intervention group:

- The period from the first consultation with the pediatrician to the first consultation with the pediatric nurse. For this measurement a correction will be made for the time that will be taken by the informed consent and randomization procedure.

- The period from the first to the final consultation with the pediatric nurse.

Control group:

- The period from the first consultation with the pediatrician to the first consultation with youth healthcare or the general practitioner. For this measurement a correction will be made for the time that will be taken by the informed consent and randomization procedure.
- The period from the first consultation with youth care/general practitioner to follow-up care.

Secondary outcome

The pilot study showed that many problems the children face are related to the way they are parented. Therefore we also to study (changes in) parental feelings concerning parenting their children. In order to study this we use the parenting stress questionnaire. This questionnaire is developed for parents with children aged of 0 to 19 years, which makes it suitable for the purpose of this study. The questionnaire will be completed at two moments: immediately after inclusion and at the end of the intervention (intervention group)/3 months after the first consultation with the pediatrician.

Visual Analogue Scale and Strengths and Difficulties Questionnaire: parental perspective

There is no single standard instrument that measures changes in problem severity for children aged 0-19 years. Therefore we to use multiple instruments.

For children aged 0-2 years parents complete a *Visual Analogue Scale*(VAS) for the subjects: crying, sleeping, eating and development. A VAS is a psychometric instrument with which the problem severity can be measured. The VAS will be completed immediately after inclusion and end of the intervention (intervention group)/three months after the first consultation with the pediatrician (control group).

For children aged 2-19 years the parents complete a *Strengths and Difficulties Questionnaire* (SDQ). The SDQ is a questionnaire with which the social-emotional health of children can be measured. The SDQ total score shows the severity of social-emotional problems the children suffer from. By use of five subscales (behavioral problems, hyperactivity/attention deficit, problems with peers, pro social behavior) it can be studied in which field problems occur. The SDQ will be completed immediately after inclusion and at the end of the intervention (intervention group)/three months after the first consultation with the pediatrician (control group). Both parents and children aged 11 and over will complete this questionnaire.

Visual Analogue Scale: professional perspective

To get an impression of the perspective of the professional on (changes) in problem severity, pediatricians complete a VAS at the first and control consultation with the child. At the end of these consultations they give an overall score for problem severity.

Other study parameters

Professionals

In this study we value the professionals (pediatric nurses, pediatricians) experiences with the intervention. At months 8, 11 and 14 a focus group interview will be held with these professionals in which the program integrity, the efficiency and effectivity of the new working method, the collaboration process and the total approach will be evaluated. In this way there will be also an active knowledge exchange between different professionals and work fields.

Intervention costs and structural funding

With this study we are able to give an indication of the costs involved with the new working method. By use of qualitative analysis of a few cases the activities of pediatricians, pediatric nurses and supporting staff will be documented. In this way an overview of the variety in the cases can be given. Where possible, the costs of the different activities will be documented. For this purpose we use a cost manual (Hakkaart-van Roijen L, et al. Bijlage 1: Kostenhandleiding: methodologie van kostenonderzoek en referentieprijzen voor economische evaluaties in de gezondheidszorg. 2015. https://www.zorginstituutnederland.nl). Costs of activities that are not documented in this manual will be collected during interviews that will be held

with financial experts from the hospital, youth healthcare and the medical advisor of het health insurance company. In assessing the healthcare costs a differentiation will be made between costs for the municipality and the health insurance company.

During the interviews with experts from the health insurance company and youth healthcare it will be discussed how the new working method can be funded structurally and which factors have to be taken into account. The results from the expert interviews will be used into the recommendations concerning the costing of the new working method.

Study description

Background summary

In their diagnosis and care for children Dutch pediatricians face a wide variety of problems. Beside biological problems they face social- and psychosocial problems. The type of complaints within these problems varies. The Dutch Society of Pediatrics distinguishes six main groups:
1) Somatic diseases which give rise to psychosocial problems
2) Psychosocial problems that play a role in the development and cure of diseases
3) Somatic complaints that hide psychical problems
4) Development problems
5) Threatening of safety and health due to parental functioning
6) Specific referral because of psychical and social problems
According to the literature the incidence of the entire group of complaints varies between 6.3% (Central Bureau of Statistics) and 10% (Dutch Society of Pediatrics).

Because of the above mentioned complaints pediatricians feel the need to a more intensive collaboration with youth healthcare. This need has become even stronger since the decentralization of youth healthcare. Moreover, the pediatricians that are involved in the working method of this study, expect that the incidence of the above mentioned complaints is higher than described

by the Central Bureau of Statistics and Dutch Society of pediatrics. This expectation is based on their experience with this study group.
From studies into collaborations between youth healthcare and hospitals, we distinguish a few cooperation forms. From 2014 on doctors working in youth healthcare have the possibility to directly refer children to specialized care. Also there are initiatives in which pediatricians and doctors working in youth healthcare have agreements concerning the transfer of information of children with health risks. In addition there are examples of joint thematic meetings, which encourage informal acquaintance, knowledge exchange and alignment of referral patterns. It is expected that such collaborations, if implemented correctly, contribute to the quality of care for children. However, at current these collaborations are still limited in nature and scale and scarcely aimed at making psychological support available in pediatrics. Finally, from literature studies it appears that the collaboration between youth healthcare and pediatrics is slow and difficult. Sauer et al. Showed that youth healthcare and pediatrics have drifted apart in the last decades. He therefore pleads for a different, integral model for the organization of care for children in which both youth healthcare and pediatrics collaborate in patientcare, education and research.
The Amphia hospital (a hospital with establishments in Breda, Etten-Leur and Oosterhout, the Netherlands) has started with an integrated model of care for children with complaints in which social and psychosocial factors are involved. In this model there is an intensive collaboration between pediatricians and pediatric nurses. Since August 2015, pediatric nurses are seconded at the pediatric outpatient clinic during one shift per week. They are in close collaboration with children and their parents, pediatricians and other professionals in the youth- and social domain. In this way they are the linking pin between pediatrics and social domain.
The purpose of this working method is to accompany children with (psycho)social problems to the best fitting support in a faster way than can be done according the regular route. From the evaluation of a pilot study that was performed in 2016 there are indications that by the timely addition of the pediatric nurse and the quick reference to the best fitting support, worsening of problems can be prevented. The next step in the scientific foundation of this working method is to study the effectivity in terms of children*s and parental satisfaction with the intervention as well as the efficiency in terms of shortening the throughput time to the best fitting support.

Study objective

This study is aimed at optimizing the bridge between medical curative care and care that comes from the social domain, for children and adolescents. The primary goal is to offer the best fitting care to children with psychosocial- and social problems by a direct collaboration between pediatric nurses and pediatricians at the outpatient clinic. It is expected that by this collaboration, the throughput time to the best fitting care can be shortened and children and parents become more satisfied with the entire process. In

addition it is expected that this working method contributes to the reduction in psychosocial- and social problems in children in the long-term. The secondary goal of this study is to gather insight into the costs of the new working method and the way this working method can be funded on a regular base. In this study the goals will be evaluated comparing the added value of the new working method at process- and effect level to *care as usual*. The evaluation will be performed following the next research questions:
Primary questionnaires:
* Are parents/children from the intervention group more satisfied than parents/children that received *care as usual*?
* What are the effects of the intervention (the new working method), in terms of throughput time in comparison with *care as usual*?
Secondary questionnaires
* How do involved professionals experience the process (effectivity and efficiency) of the new working method in comparison to *care as usual*?
* How and where can the intervention be improved?
* Is there (from the perspective of the professional and the parents/children a difference in the development of problem severity in children that received the intervention compared to children that received *care as usual*?
* Is there (from the perspective of the parents) a difference in the development of parenting stress in families that received the intervention compared to families that received *care as usual*?
* What are the considered costs from the intervention and how can this be funded on a regular base?

Study design

As mentioned before this study is aimed at optimizing the bridge between medical curative care and care that comes from the social domain, for children aged 0-19 years. The primary goal is to offer fitting care to children with social- and psychosocial problems by a direct collaboration between pediatric nurses and pediatricians at the outpatient clinic. It is expected that by this collaboration, the throughput time to the best fitting care can be shortened and children and parents become more satisfied with the entire process. In addition it is expected that this working method contributes to the reduction in social- and psychosocial problems in children in the long-term.
Because of the relatively short duration of the study (2 years) it is yet not possible to study the effectiveness of the ultimate goal, lowering problem severity. However parental/children*s satisfaction with the new working method is indicative for the eventual effectivity of the care received. Therefore one the primary outcome measures of this study is parental/children*s satisfaction with the new working method. The other primary outcome measure is the throughput (the time between the reference by the pediatrician to the moment the best fitting *follow-up* care) of the new working method compared to *care as usual*.

This study is directed to demonstrate effects as well as to understand these

effects. The best fitting design to answer the research questions is a randomized controlled trial (RCT).The argumentation for this is as follows:
We study an experimental intervention, the new working method in the Amphia hospital. The intervention is performed with an experimental group (intervention group) which is compared to a group that receives *care as usual* (control group). To assure that by the start of the study there are no (prognostic) differences between the groups which may influence the results, the children will be randomly allocated to the intervention- or control group. The pediatricians as well as the researchers cannot influence the randomization process.
The content and execution of the study will be monitored by the researchers. In this way it is possible to perform a process evaluation in parallel to the effect evaluation. The process evaluation reveals insight in the question whether the new working method works, whether this method shows unexpected outcomes and how and where this method can be improved.

Intervention

Intervention
The intervention consists of the procedure that started in 2015 at the Amphia hospital, Breda, The Netherlands. In this procedure, pediatric nurses act as the linking pin between pediatrics, Dutch youth healthcare and youth counselors within the social domain.
Pediatric nurses are present at the outpatient clinic of the Amphia hospital during one shift/week for the execution of the intervention. In addition as part of the intervention, they have the availability to pay visits to other locations (i.e. the clients home) during 1.5 day/week.
The procedure starts at the moment a child (and its parents) consults a pediatrician. If it appears from the anamnesis by the pediatrician that the child suffers from problems in which (psycho)social factors are involved, the child can be considered for inclusion in the study. If so, the pediatrician explains the study to the child and its parents, hands them over the research information as well as an informed consent form. If so, the pediatrician explains the study to the child and its parents, hands them over the research information as well as an informed consent form. Once the informed consent form is signed, the child is included in the study and allocated by randomization to the intervention group, the child is referred to the pediatric nurse for (psycho)social problems. The pediatric nurse contacts the family by telephone within two weeks after the consultation with the pediatrician. In consultation with the child and the parents an appointment is made at the parents* house or at the outpatient clinic. During this consultation the pediatric nurse clarifies the problem and together with the parents and the child she considers which care fits best to the child. This procedure can take several consultations. If necessary, the pediatric nurse connects the child to other professional authorities in the field as for example the infant welfare center (i.e. teaching in upbringing) or specialized youth assistance. When it becomes clear that the family is able to go on by itself or when they are transferred

to another professional authority the pediatric nurse closes the contact after a written feedback to the family, the pediatrician and (with parental consent) the general practitioner and other professional parties involved. Three months after closing down the contact with the pediatric nurse the child visits the pediatrician for a control consultation. This consultation is not part of the intervention, but necessary for the scientific study.
Whenever the child suffers from somatic problems which need attention of a pediatrician, the pediatrician takes care of these problems.

Care as usual
For the control group the procedure starts with a consultation to the pediatrician as well. If it appears from the anamnesis by the pediatrician that the child suffers from problems in which (psycho)social factors are involved, the child can be considered for inclusion in the study. If so, the pediatrician explains the study to the child and its parents, hands them over the research information as well as an informed consent form. Once the informed consent form is signed, the child is included in the study and allocated by randomization to the control group, the child is offered *care as usual*. In this study *care as usual* implies that the parents/child get the advice to contact youth healthcare or their general practitioner. Whenever the child suffers from somatic problems which need attention of the pediatrician, the pediatrician takes care of this. Six months after the consultation with the pediatrician there is a control consultation with the pediatrician.

Study burden and risks

The study is non-invasive with respect to diagnostics and treatment. Medical treatment will not be denied or postponed and it does not involve medical risks. The study is an evaluation of a possibility to offer psychosocial care. Nevertheless, whenever a child suffers from a serious adverse event (SAE), this will be reported immediately to the employer A. van der Zijden, principal of GGD West-Brabant, and to the pediatrician A.A.P.H. Vaessen-Verberne, Amphia Hospital, Breda. The employer reports the SAE by the web portal *Toetsingonline* to the METC Brabant within seven days after she has taken knowledge of an SAE that resulted in the death or a life-threatening situation of a child that is included in the study. This report will be followed by an initial report within eight days. All other SAEs will be reported within a period of a maximum of 15 days after the employer has taken knowledge of the SAE. In case of a SAE that doesn*t need to be reported directly to the employer, this SAE will be reported to the pediatrician A.A.P.H. Vaessen-Verberne, Amphia hospital, Breda.*

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

All children, aged 0-19 years, who visit the outpatient clinic of the Amphia hospital from June 2017 to February 2018, and suffer from the following problems are eligible for the study:
1. Somatic diseases which give rise to psychosocial problems
2. Psychosocial problems that are involved in the development and cure of disease
3. Somatic complaints that hide psychic problems
4. Problems in development
5. Threat of safety and health as a result of parental functioning
6. Reference because of psychic and social problems.
Prior to the consultation with the pediatrician, the children will be randomized to the intervention or control group. During the consultation, the pediatrician checks whether the child is eligible for inclusion in the study. If a child is eligible, the pediatrician explains the study and hands over an informed consent form. At the moment a parent of the child or the

child itself (age 16 and over) has signed the informed consent, the child is included in the study.

Exclusion criteria

Whenever a child suffers from serious psychiatric problems or (complex) medical problems which needs immediate intensive care, the child will not be included. There can be two forms of urgency:
1. Acute care because of an other form of specialized medical care.
2. Acute care which needs extra assistance from the social domain.
whenever above mentioned problems present themselves during the studie, the child will be excluded from the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-11-2017
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	25-07-2017
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO Date:	12-04-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	03-04-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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
Other	26702
CCMO	NL61202.028.17