

# BMJ Open Mixed-methods evaluation of a structured primary care programme for children and adolescents with mental health problems (PrimA-QuO): a study protocol

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## ABSTRACT

**Introduction** More than 17% of German children and adolescents have clinically relevant mental health problems (MHP). Typically, general paediatricians are often the first contact for children with MHP, and referrals to specialised care tend to be the standard approach. A statutory health insurance fund developed a programme for children with MHP (Health Coaching (HC)) aiming to offer targeted but low-threshold services. However, little is known about whether HC has the potential for optimising patient care. The aim of the PrimA-QuO study is to examine the effectiveness and the acceptance, barriers and facilitators of all stakeholders of this structured primary care programme for children affected by the most frequently encountered MHP in paediatric practice.

**Methods and analysis** In this mixed-methods approach, children (n=800; aged 0–17 years) with MHP meeting all inclusion criteria will be identified in the health insurance database according to International Classification of Diseases, 10th Revision diagnoses between 2018 and 2019. The qualitative component uses a series of semistructured interviews with programme developers, paediatricians trained in HC, adolescents with MHP treated according to the programme guidelines and their parents. In addition, a prospective, pragmatic, parallel-group cohort study will be conducted using an online questionnaire to examine the effects of HC on health-related quality of life of affected children and their families as well as on change in MHP. Children treated according to the HC guidelines form the intervention group, whereas all others serve as controls. Primary data from the cohort study are linked to children's health insurance claims data to calculate the costs of care as proxies for healthcare utilisation. The hypothesis is that HC is an effective and efficient primary care programme with the potential to improve patients' and their families' health outcomes.

**Ethics and dissemination** The study was approved by the Ethical Committee of Ludwig-Maximilians-Universität München. Grant number 01VSF16032 (funded by the German Innovationsfonds)

## Strengths and limitations of this study

- This study is a promising approach because it focuses on office-based paediatricians offering easily accessible care for children with mental health problems.
- Another strength of this study is its mixed-methods design, while qualitative interviews will allow deeper insights into barriers and facilitators of programme implementation.
- An additional economic evaluation will increase transparency and assist policy decisions.
- A limitation of the study is that patients can only enter the programme if they are insured by one specific health fund, so results may not be easily generalisable.
- However, searching the health insurance funds database for eligible children and adolescents is an efficient recruitment strategy, and a large sample size will most probably be obtained.

## INTRODUCTION

More than 17% of German children and adolescents have clinically relevant mental health problems (MHP).<sup>1</sup> Among these, developmental disorders (17%) followed by conduct disorders (CD) (11%) are the most frequent conditions, with considerable impact on daily life, functioning and participation of the affected children and their parents.<sup>2</sup>

In Germany, general paediatricians are often the first contact for children with MHP during prescribed examinations.<sup>3</sup> Typically, the primary care physician would perform an initial screening, initiate treatment and recommend referral to specialised centres in severe cases. However, due to time constraints in daily practice and potential training deficits of the respective physician, MHP may not

be addressed adequately.<sup>4</sup> It has been noted that referrals to specialised care tend to be the standard approach, irrespective of the severity of the problems, causing bottlenecks for those who need specialised care.<sup>5</sup>

The German healthcare system facilitates the establishment of medical programmes driven by the statutory health insurance system if there is potential for optimising patient care. Against this background, a statutory health insurance fund (Betriebskrankenkassen (BKK (Betriebskrankenkassen) LV (Landesverband))) in collaboration with a paediatricians' network ('PaedNetz Bayern') developed a programme for children and adolescents with MHP in 2011 (Health Coaching (HC)). This programme is part of a more general preventive paediatric care programme (BKK STARKE KIDS (SK)) that aims to improve, for example, early screening coverage and immunisation rates.

The aim of HC is to offer targeted but low-threshold services. It includes a training concept for paediatricians providing standardised and evidence-based guidelines for 16 mental health-specific conditions.<sup>6</sup> Paediatricians certified by HC receive additional reimbursement and will thus be able to invest more time and attention. During the training, paediatricians gain knowledge in dealing with the standardised guidelines to diagnose children with MHP correctly. In addition, the training is supposed to empower paediatricians to decide on adequate treatment options or refer children, if necessary, as soon as possible to the appropriate specialist care. By applying these direct stepped-care principles, HC has the potential to avoid overtreatment and medicalisation particularly for children with minor impairments, and at the same time, it should counteract the shortage in specialist care for more severe cases. As compensation for an extended consultation, paediatricians certified by this HC are paid an additional fee.

Uptake of HC including trainings for paediatricians started in 2013 in Bavaria and is currently only available for persons insured at the BKK funds. To decide whether HC should be maintained or even rolled out to other regions and for insureds of other health funds, the effectiveness of the programme and its barriers and facilitators have to be confirmed. In addition, an evaluation may point at unmet needs of stakeholders as well as indicate whether and where modifications should be planned.

To evaluate effects, costs, facilitators and barriers of the programme, a mixed-methods study that integrates qualitative and quantitative design aspects was planned.

The aim of the study is to examine the effectiveness and the acceptance, barriers and facilitators of all stakeholders of a structured primary care programme for children and adolescents affected by the most frequently encountered MHP in paediatric practice.

Specifically, we want to examine the following:

1. The theoretical foundation and the achievement of anticipated targets of HC from the developer's perspective of HC.

2. The acceptance, barriers and facilitators of HC on the levels of (a) primary paediatricians trained in HC, (b) children and adolescents treated according to HC and (c) guardians of affected children and adolescents, who are treated according to HC.
3. The effects HC has on (a) children's health-related quality of life (HRQoL), (b) parenteral HRQoL and (c) MHP of children and adolescents treated according to HC compared with children of the same diagnosis, who receive standard care.
4. The utilisation of health services of children and adolescents treated according to HC compared with children of the same diagnosis, who receive standard care. In addition, a cost-effectiveness analysis including children's HRQoL will be performed.

## METHODS AND ANALYSIS

The mixed-methods approach allows us to answer two important research questions. The qualitative component emphasises the acceptance of the programme among paediatricians and families, whereas the quantitative component analyses whether HC has the potential to change HRQoL and MHP over time.

### Qualitative methods

The qualitative component of this study aims to indicate potential strengths and challenges of HC. Therefore, it uses a series of semistructured interviews with the leading programme developers, paediatricians who are trained in HC, adolescents ( $\geq 14$  years of age) with MHP treated according to the programme guidelines and parents of children ( $< 14$  years of age) with MHP also treated according to the programme guidelines.

### Participants and data collection procedures

Paediatricians trained in HC will be chosen from the participating Bavarian paediatricians' network ('PaedNetz Bayern'; <https://www.paednetz.de/startseite/>) and invited to participate. Over 80% of office-based paediatricians in Bavaria are members of PaedNetz Bayern.

Adolescents (at least 14 years old) and parents of children younger than 14 years will be asked to participate in qualitative interviews via the online questionnaire. Volunteers are then selected based on purposeful sampling, according to principles of maximum variance regarding, for example, diagnosis, age, social class and gender, by the interviewers.

All three leading HC developers have been recruited during a project meeting in May 2017 and have agreed to participate.

Sample size will be determined by saturation.<sup>7</sup> Recruitment will be stopped if no new themes emerge during the interviews. Saturation will be determined by mutual agreement.

Interviews are conducted via telephone starting in November 2017.

In preparation for the semistructured interviews, guidelines are constructed according to Helfferich<sup>8</sup> to ensure

that important predetermined topics are covered. The subdivision into key questions, subquestions and checks ensures that the conversation is guided in a targeted manner and important topics are covered. Similarly, an open atmosphere is created for a narrative of one's own experiences or an expression of individuals' concerns. The interview guide can be developed further during the course of the study. There are no questions or advance information provided by the interviewers prior to the interview.

The final interview guideline including the age-appropriate version for adolescents is pretested with a selection of voluntary adults and adolescents to detect, for example, any problems of comprehension, difficulties with the sequence or phrasing of the questions, or the use of improper youth slang. After subjects gave an informed consent and permission for audio recording, the interviews started. Paediatricians, parents and children receive allowance and financial compensation for participation.

### Research team and reflexivity

Interviews are conducted by project scientists (Master of Public Health) and those with formal training in quantitative and qualitative research.

### Analysis and findings

All interviews are transcribed verbatim and are independently analysed by the authors (the first and second author). The transcripts are not returned to study participants for control or correction. On the basis of the interview guideline, the structured content analysis approach derived from Mayering<sup>9 10</sup> is applied. Following Mayering, a deductive and an inductive approach for coding is performed. This offers, on the one hand, a deductive allocation of statements from the interviews to categories and codes identified in advance. On the other hand, the inductive procedure enables to derive new categories and codes from the data and thereby extend the coding tree by statements, which cannot be appropriately assigned to one of the a priori defined categories or codes. In an ongoing reconciliation between the authors, the coding tree is refined by differentiating the added codes in a more meaningful way or by removing them.

Guiding questions in the programme developers' interviews are the reflection of the key principles and the theoretical foundation of HC, regarding how its anticipated targets are already achieved in practice and request for further development.

Guiding questions in the paediatricians' interviews are the challenges in the implementation of HC in daily practice routine, investigating successful and impractical aspects of HC from the users' perspective.

Guiding questions in the children's and parents' interviews are their satisfaction with the medical care, their relationship to the paediatrician, the degree of participation in the paediatricians' decisions and the desire for further support and improvement.

### Quantitative methods

To examine the effects of HC on HRQoL of affected children and their families, a prospective cohort study will be conducted using an online questionnaire. To analyse health service utilisation, primary data from the cohort study are linked to children's health insurance claims data from 2017 and 2018.

### Participants and data collection procedures

Children and adolescents aged 0–17 years will be included if they are insured at the BKK funds and had been enrolled in the BKK SK programme; it means in effect that they benefit from enhanced screenings and had at least one consultation at an office-based paediatrician in Bavaria, Germany, during the last 6 months for developmental disorder of speech and language (SLD), non-organic enuresis (NE), head and abdominal pain, somatoform (Head and abdominal pain (HAP)) and conduct disorder (CD) (International Classification of Diseases, 10th Revision (ICD-10) diagnoses: SLD: F80.0–F80.9; NE: F98.0; HAP: G44.2, G43.0, G43.1, R10.4, F45.4; CD: F68.8, F91.0–F92.9, F94.0–F95.9, F98.3–F98.9). Informed consent is elicited from legal guardians/parents and from children/adolescents aged 6 years or older. As this trial is performed in a real-world setting, allocation to the intervention group is formed if the child has been treated by a Health Coach, meaning that a paediatrician had undergone a specific training and is able to demonstrably act according to the training concept and to use its standardised guidelines for actions (members of BKK, SK and HC). All others serve as controls (members of BKK and SK but not HC).

Parents of eligible children are contacted by mail and given a link to the online questionnaire. Access is regulated by users' authentication via their insurance number. For the follow-up survey, consenting parents are contacted again 12 months after their participation in the questionnaire. Parents receive a small compensation for participation. All procedures are designed in full compliance with European and national data protection legislation.<sup>11 12</sup>

For the linkage of survey data to routine data, a temporary pseudonym based on the participant's insurance number will be provided.<sup>13</sup> For purposes of verification, month and year of birth and sex are additionally transmitted. Based on the temporary pseudonym, primary data will be linked to the routine data by a third independent person providing a second pseudonym. The linkage process is monitored by a legal data protection officer who saves the list with the first and second pseudonym.

### Measures—outcomes

The primary outcome is HRQoL of children. We will use the generic and validated German-language instrument *KINDL*<sup>R</sup>.<sup>14</sup> It consists of 24 items divided between six dimensions (with four items each): physical well-being, emotional well-being, self-worth, well-being in the family, well-being related to friends/peers and school-related well-being. Each item provides answer on a five-point



Likert scale ranging from never, seldom, sometimes, often and always. The total score will be transformed into values between 0 and 100, where higher values indicate a better HRQoL. The child and adolescent self-assessment version is used for children aged 11 years or older; for younger children, the proxy version is to be completed by the parents.

Secondary outcomes are HRQoL of parents and MHP of children. HRQoL of parents is measured using the *EuroQol Five-Dimensional Five-Level Questionnaire* (EQ-5D-5L), including the *Visual Analogue Scale* (EQ-VAS) assessing self-rated health.<sup>15 16</sup> It comprises five dimensions (with one five-point Likert-scaled item each): mobility, self-care, usual activities, pain/discomfort and anxiety/depression ranging from no problems (1) to extreme problems (5). The EQ-5D-5L utility score ranges between death (-0.661) and perfect health (1) and is calculated based on the value set devised by Ludwig *et al.*<sup>17</sup> In the EQ-VAS, the self-rated health is visualised on a continuous VAS with end points labelled the worst imaginable health (0) and the best imaginable health (100).

MHP of children are measured using the German version of the *Strengths and Difficulties Questionnaire*.<sup>18-21</sup> It consists of 25 items divided between five dimensions (with five items each): emotional symptoms, conduct problems, hyperactivity/inattention, peer-related problems and prosocial behaviour. Each item is scored on a three-point scale ranging from not true, somewhat true to certainly true. Higher scores indicate greater MHP except for the prosocial behaviour dimension, for which a higher score indicates more positive behaviour. The subscores of the problem dimensions will be summed up to build the total difficulties score ranging from 0 to 40, where higher values denote greater difficulties.<sup>22</sup> The child and adolescent self-assessment version is used for children aged 11 years or older, whereas the proxy version is completed for younger children.

All outcomes are listed in [table 1](#).

### Measures—Independent variables

In addition, sociodemographic data (for instance, age, sex, migrant background or educational level of the guardians) and health-related data (for instance diagnosis group) are assessed.

### Indicators for health service utilisation

Costs of care are calculated as proxies for healthcare utilisation from a statutory health insurance perspective. Costs of care are included if the child receives a confirmed MHP diagnosis in the outpatient setting or a primary diagnosis during hospitalisation. Outpatient ICD diagnoses in Germany have to be categorised as ‘Z’=condition after, ‘A’=exclusion diagnosis, ‘V’=suspected diagnosis and ‘G’=confirmed diagnosis.

We analyse (1) disease-related specialised care, (2) disease-related paediatrician care and (3) overall disease-related care separately. First, disease-related specialised care involves costs for specialised institution and for

specialised outpatient physician and outpatient psychotherapist visits. Here, specialised institutions include outpatient hospital visits in social paediatric centres and university outpatient clinics as well as hospitalisations to psychiatric departments or institutions. Furthermore, specialised outpatient physician costs are included if the physician’s specialty or subspecialty was psychiatry or psychotherapy, while outpatient psychotherapist costs are calculated by accounting for visits to a psychotherapist.

Second, we calculate costs of disease-related paediatrician care.

Third, we look at the overall disease-related care. Here, we include all costs of disease-related outpatient and inpatient care as well as pharmaceutical costs for MHP-related drugs (psycholeptics, psychoanaleptics) and MHP-related therapist costs (speech therapists, ergotherapists, physiotherapists).

All expenditures are calculated on a per quarter base. While outpatient physician costs and costs for social paediatric centres and university outpatient clinics are already based on quarters, the other cost domains have to be transformed. Inpatient care refers to a specific period, with a possible overlap between quarters. Here, we calculate the costs proportionally to time of service use. Drugs and therapist care are based on exact prescription dates. The costs of all prescriptions within a quarter are summed up to get per quarter values.

### Statistical analysis

Regarding descriptive statistics, means and SD are used for continuous variables and absolute and relative percentages for categorical variables. For comparisons between children and adolescents with MHP treated according to the HC guidelines and those who receive standard care bivariate, non-parametric and parametric tests stratified by sociodemographic and disease-related variables will be conducted at baseline.

The association of the dependent variable of change in children’s HRQoL over time with the HC intervention will be performed by generalised estimating equations (GEE)<sup>23</sup> as the GEE model takes into account the correlation between repeated measurements within the same subjects. It will be adjusted for sociodemographic factors and diagnosis group. Interactions with time/follow-up will be included to observe significant group differences in their changes in HRQoL.

In a similar way, we will investigate the associations between HC and change in outcomes in parental HRQoL and change in MHP.

To estimate the group differences in healthcare utilisation, we use generalised linear models<sup>24</sup> with Gamma-distributed cost variables (ie, the responses are non-negative). In addition, a cost-effectiveness analysis including HRQoL might be performed.

### Sample size considerations

The sample size for the cohort study is calculated based on the recommendations for the minimally important

**Table 1** Overview of research outcomes and instruments.

Outcome	Instrument	No. of items	Dimensions (items per dimension)	Children/adolescents $\geq 11$ years	Parents/guardians	Baseline (t0)	Follow-up (t1)
Health-related quality of life (children/adolescents)	KINDL <sup>R</sup>	24 (+6 for dimension 7)	1. Physical well-being (4) 2. Emotional well-being (4) 3. Self-esteem (4) 4. Domestic well-being (4) 5. Well-being regarding friends/peers (4) 6. Scholastic well-being (4) 7. Long-lasting sickness (6)	x	x (if child <11 years old)	x	x
Health-related quality of life (guardians)	EQ-5D-5L and VAS	5	1. Mobility (1) 2. Self-care (1) 3. Usual activities (1) 4. Pain/discomfort (1) 5. Anxiety/depression (1)		x	x	x
Behavioural problems	SQD	25 (+2 for t <sub>1</sub> )	1. Emotional symptoms (5) 2. Conduct problems (5) 3. Hyperactivity/inattention (5) 4. Peer relationship problems (5) 5. Prosocial behaviour (5)	x	x (if child <11 years old)	x	x

EQ-5D-5L, EuroQol Five-Dimensional Five-Level Questionnaire; SDQ, Strengths and Difficulties Questionnaire; VAS, Visual Analogue Scale.

differences in quality of life instruments to be half an SD.<sup>25</sup> Accordingly, an effect size of 0.5 for the difference and a sample size of 85 children and adolescents for each group of indication can be assumed. Considering a drop-out of 15% between data collection waves, we have estimated an overall sample size of 800 individuals (control and intervention arms with 400 each). The sample size allows a level of precision of  $\pm 3.4$  of the mean-value estimation of the KINDL<sup>R</sup> per indication group (assumed SD of 16.0).

### Patient and public involvement

Children and adolescents with MHP and their guardians participated in assessing the phrasing of the interview guide. There is no plan to involve participants in the recruitment process and in conducting the study. Results of the study will be disseminated via email contacts to guardians as well as via social and print media.

### DISCUSSION

The study examines the effectiveness of a standardised primary care programme regarding its potential to impact HRQoL of children with MHP and their parents. Also, cost-effectiveness of the programme and potential for improvement will be investigated.

This programme is a promising approach because it focuses on the office-based paediatrician offering easily accessible care for children with MHP.<sup>26</sup> One strength of the planned study is its mixed-methods design. Qualitative interviews will allow deeper insights into the barriers and facilitators of programme implementation. An additional economic evaluation will increase transparency and assist policy decisions.

It has to be kept in mind that patients can only enter the programme if they are insured of one specific health fund, so results may not be easily generalisable. However, we anticipate that the results of this evaluation will motivate the design of similar programmes that strengthen the competence of primary care.

### Ethics and dissemination

The PrimA-QuO study is conducted in accordance with the Declaration of Helsinki,<sup>27</sup> standards of Good Epidemiology Practice<sup>28</sup> and current EU-General Data Protection Regulations.<sup>12</sup> It was approved by the Ethical Committees of Ludwig-Maximilians-Universität München (approval number for the qualitative part: 17-431; approval number for the quantitative part: 17-497) and positively reviewed by the data protection officer of Ludwig-Maximilians-Universität München.

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