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A Mixed-Methods Study Evaluating the Effectiveness of a Health Coaching Program in Primary Care for Children and Adolescents with Mental Health Problems (PrimA-QuO)

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I hereby declare, that the submitted thesis entitled:

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List of abbreviations

AIC	Akaike Information Criterion
BELLA	Befragung zum seelischen Wohlbefinden und Verhalten (Mental health module within the German Health Interview and Examination Survey of Children and Adolescents)
BKK-LV	Betriebskrankenkassen Landesverband Bayern (Regional Association of Statutory Health Insurance Funds in Bavaria)
BVKJ e. V.	Berufsverband der Kinder- und Jugendärzte (Professional Associations of Pediatricians in Germany)
CI	Confidence Interval
EQ-VAS	EuroQol Visual Analog Scale
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
HC	Health Coaching
HRQoL	Health-Related Quality of Life
ICD-10	International Classification of Diseases, 10th edition
IPTW	Inverse Probability of Treatment Weighting
KiGGS	Studie zur Gesundheit von Kindern und Jugendlichen in Deutschland (German Health Interview and Examination Survey of Children and Adolescents)
KINDL-R	Kinder-Lebensqualitätsfragebogen (Child Quality of Life Questionnaire)
LMU	Ludwig-Maximilians-Universität
MH	Mental Health
MHP	Mental Health Problem(s)
PaedNetz e. V.	Pediatrician network in Bavaria, Germany
PrimA-QuO	Optimierte primärärztliche Versorgung von Kindern und Jugendlichen mit psychischen Auffälligkeiten und Störungen (Optimized Primary Care for Children and Adolescents with Mental Health Problems)
PROMs	Patient-Reported Outcome Measures
REML	Restricted Maximum Likelihood
SCARED	Screen for Child Anxiety Related Emotional Disorders
SD	Standard Deviation
SES	Socioeconomic Status
SHI	Statutory Health Insurance
SK	STARKE KIDS Program

List of publications

Peer reviewed publications used for this doctoral thesis

Loidl V, Hamacher K, Lang M, Laub O, Schwettmann L, Grill E. Impact of a pediatric primary care health-coaching program on change in health-related quality of life in children with mental health problems: results of the PrimA-QuO cohort study. BMC Prim Care. 2023 Sep 8;24(1):182.

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1. Your contribution to the publications

1.1 Contribution to paper I

I, Verena Loidl (VL), conducted the background research along with the conception of the methods, and performed the data analysis for Publication 1, taking full responsibility for interpreting and reporting the results accurately.

I was jointly responsible for planning and conducting the cohort study, including the material preparation, development and pre-testing of baseline and follow-up questionnaires, as well as participant recruitment. My individual responsibilities included the implementing data protection measures and securing approval from the official data protection officer of the Ludwig-Maximilians-Universität (LMU) Munich. I oversaw the quality assessment, processing, and storage of the collected data, ensuring its integrity for Publication 1, under the supervision of Eva Grill (EG).

As the first author of Publication 1, I drafted the manuscript, including all figures and tables. I integrated feedback from co-authors into the final version, ensuring a collaborative and thorough review process.

EG supervised the publication, provided feedback on the project's conceptualization and analysis, and revised and approved the manuscript in multiple stages. Ralf Strobl (RS) reviewed the statistical methods and analyses. EK, Karina Hamacher (KH), Martin Lang (ML), Otto Laub (OL), and Lars Schwettmann (LS) reviewed and endorsed the final version.

The development of the study design and application for financial funding (grant number 01VSF16032) were planned and carried out by EG, Nicole Radewic-Pahl (NRP), Rolf Holle (RH), and Susanne Moser (SM).

As the first author, I drafted and published the study protocol of the PrimA-QuO study.

1.2 Contribution to paper II

I, Verena Loidl (VL), declare my co-authorship of Publication 2. I played a significant role alongside the first author, Siona Bührmann (SB), contributing extensively to the background research, methodological planning, and analysis strategy for this publication. I collaborated closely with SB on the initial research and planning stages, ensuring a solid foundation for our study. Under the supervision of Eva Grill (EG), SB and I developed and pre-tested interview guidelines for both adolescents and guardians, ensuring their relevance and clarity.

Along with SB, Karina Hamacher (KH), Martin Lang (ML), and Otto Laub (OL), I participated in selecting study participants, ensuring a representative sample for our research. SB and I jointly conducted telephone interviews, taking turns in asking questions and transcribing them verbatim to maintain accuracy.

SB and I independently analyzed all transcripts to enhance the reliability and validity of our findings. I actively engaged in discussions and reflections with SB and EG, ensuring transparency in our decision-making process and guiding the interpretation and presentation of results. I provided substantial support to SB in drafting the manuscript.

Throughout this process, EG provided feedback on the conceptualization, supervised the analysis, and contributed to manuscript revisions at multiple stages. The final version of this publication was reviewed and endorsed by all authors.

The research project PrimA-QuO, which formed the basis for Publication 2, was initially planned by EG, Nicole Radewic-Pahl (NRP), Rolf Holle (RH), and Susanne Moser (SM), who successfully secured the necessary funding (grant number 01VSF16032).

2. Introductory summary

2.1 Background

2.1.1 Relevance

The psychological burden on children and adolescents in Germany has reached a high in recent years. Findings from a German meta-analysis, which included 33 studies, indicated that 17.6% of children and adolescents were dealing with clinically relevant mental health problems (MHP) (1). The already high prevalence of MHP increased during the COVID-19 pandemic, and to this day, four years after the initial outbreak in Germany, it remains 5% higher than pre-pandemic levels (2–4). A major national cohort study (BELLA, ***BE**fragung zum see**L**ischen Woh**L**befinden und Verh**A**lten,* part of the *German Health Interview and Examination Survey for Children and Adolescents* – KiGGS), conducted over a period of eleven years, underscored the long-term effects of MHP, revealing that children and adolescents with MHP aged 7-17 continued to report MHP even six and eleven years later (5).

Based on a German study using health insurance claims data, MHP were among the five most common diseases (27%) in children and adolescents who received medical treatment at least once in 2017 (6). Although not the most prevalent, early-onset of MHP significantly affect the physical and social development of children and adolescents (7). The most common reasons for mental health (MH) treatment are developmental disorders (17%) and conduct disorders (11%) (8,9).

MHP significantly impact the daily lives of affected children and their families, detrimentally affecting social relationships, well-being, and school performance (10–12). Various studies have shown that children and adolescents with MHP experience lower health-related quality of life (HRQoL) compared to children without MHP (13–19). HRQoL, a multidimensional construct (20,21), encompasses various components of well-being and functioning, including 1) physical aspects (disease symptoms/health-related impairments), 2) mental, psychological, and emotional aspects (self-perception/self-worth), and 3) social aspects (perceived quality of relationships with parents, siblings or friends/well-being in school/preschool/kindergarten). Research indicates that the negative impact of MHP is not restricted to a single dimension but simultaneously impairs multiple dimensions of HRQoL, such as mental well-being, physical health, and social relationships (17).

Current research emphasizes the importance of incorporating the perspectives of children and adolescents affected by MHP into their care experiences. Utilizing these patient-reported experiences (PREs) can identify specific areas that require improvement for MH care and enhance MH research (22–24). Furthermore, the integration of patient-reported outcome measures (PROMs) – instruments assessing patient's health status or HRQoL from the patient's perspective (25) – into the evaluation of MH interventions allows for a more comprehensive insight into the success of treatment (26). It has been shown that PROMs support participatory decision-making and enhance communication between patients, families, and healthcare providers. As a result, this can contribute to reduced healthcare utilization and improve health outcomes (27,28).

For sustained MH stability over the long term, it is imperative not only to address acute symptoms but also to treat the underlying causes. However, MHP onsets during childhood and adolescence are often unrecognized and therefore remain untreated, increasing the risk of chronicity and persistence of MHP in adulthood, with negative consequences encountered in various contexts, such as their own families, school performance, social relationships, and later professional development (29–31). Due to the high impact of MHP, early detection, identification and accessible treatment of MHP in a timely manner play a decisive role (32).

Within the German healthcare system, general pediatricians (hereinafter 'pediatricians') are crucial for identifying and addressing MHP in children and adolescents. They are often the first point of contact during routine and preventive check-ups (33,34). Research has shown that over 97% of all children with MHP have contact with a pediatrician at least once a year (9). Ideally, pediatricians identify MHP and, depending on the underlying cause, initiate treatment or refer patients to psychiatric and psychotherapeutic providers if necessary. However, in reality, there are issues regarding both under- and over-provision of MH care. On the one hand, MHP often remain undetected due to insufficient diagnostic capabilities among pediatricians, leading to undertreatment of those who require intervention in the early stages of MHP. On the other hand, pediatricians frequently refer patients to specialized care centers, regardless of the severity of symptoms or underlying cause, either due to time constraints in outpatient practices or a lack of skills in treating MHP (35–38). This practice not only leads to an overtreatment of mild cases, but it also ties up resources in specialized care needed for more severe cases. Consequently, severely affected patients face prolonged waiting times and delayed initiation of MH therapy (39).

Policymakers recognized this issue and emphasized the imperative for enhanced integration of MH care for children and adolescents within general pediatric settings as stated in the *World Health Organization's Comprehensive Mental Health Action Plan 2013–2030* (40). In this framework, it is crucial to educate and empower pediatricians to employ screening tools for early diagnosis and to guide treatment decisions regarding MHP. According to this plan, children with mild symptoms should initially access low-threshold therapy at the pediatrician's practice, while more severe cases are promptly referred to specialized care. This coordinated approach ensures comprehensive MH support across various levels of need within the broader healthcare system.

2.1.2 Theoretical background of the Health Coaching Program

Given the high prevalence of MHP in children and adolescents and the shortfalls in current care, the regional association of statutory health insurance funds (BKK) in the state of Bavaria, Germany – *Betriebskrankenkassen Landesverband, BKK-LV* – in collaboration with professional associations of pediatricians – *Berufsverband der Kinder- und Jugendärzte (BVKJ e. V.* and *PaedNetz Bayern e. V.)* – developed the BKK STARKE KIDS Health Coaching Program (HC) for pediatricians treating children and adolescents with MHP in 2013 (41). The *BKK-LV* is an overarching organization for all BKK statutory health insurance funds (SHI) in Bavaria (58 SHI companies are offering the HC, as of May 2024), covering 2.5 million insured individuals in Bavaria (42). *PaedNetz Bayern e. V.* is a major network comprising 12 independent regional physician networks in Bavaria (43), representing 80% of practicing pediatricians in Bavaria.

The HC formed by this cooperation is part of the BKK STARKE KIDS (SK) (44), offering preventive services beyond legal requirements. Participation in the HC is free of charge for the families, with no additional co-payments. However, the program, which was previously offered exclusively to members of specific BKK SHI funds, has now become a care program that can potentially be transferred to other SHI companies.

Children and adolescents must not be older than 17 years and must be enrolled in the SK. SK is a program that offers exclusive health and preventive check-ups that go beyond the regular developmental screenings (44).

Figure 1 depicts the underlying concept of the HC. This concept suggests that pediatricians who have undergone HC training show changes in their behavior and work processes (pediatrician level), such as implementing early MH interventions in their daily practice. According to previous studies, the training of pediatricians is crucial for accurate MH diagnosis (45). By applying the HC and involving children, adolescents, and their parents or caregivers who take on a parental role (hereinafter 'parents') in decision-making processes, pediatricians enhance their understanding of their situation. This promotes self-management and competency skills (practice level), aiming to positively influence HRQoL and reduce the long-term effects or chronicity of MHP (patient outcome).

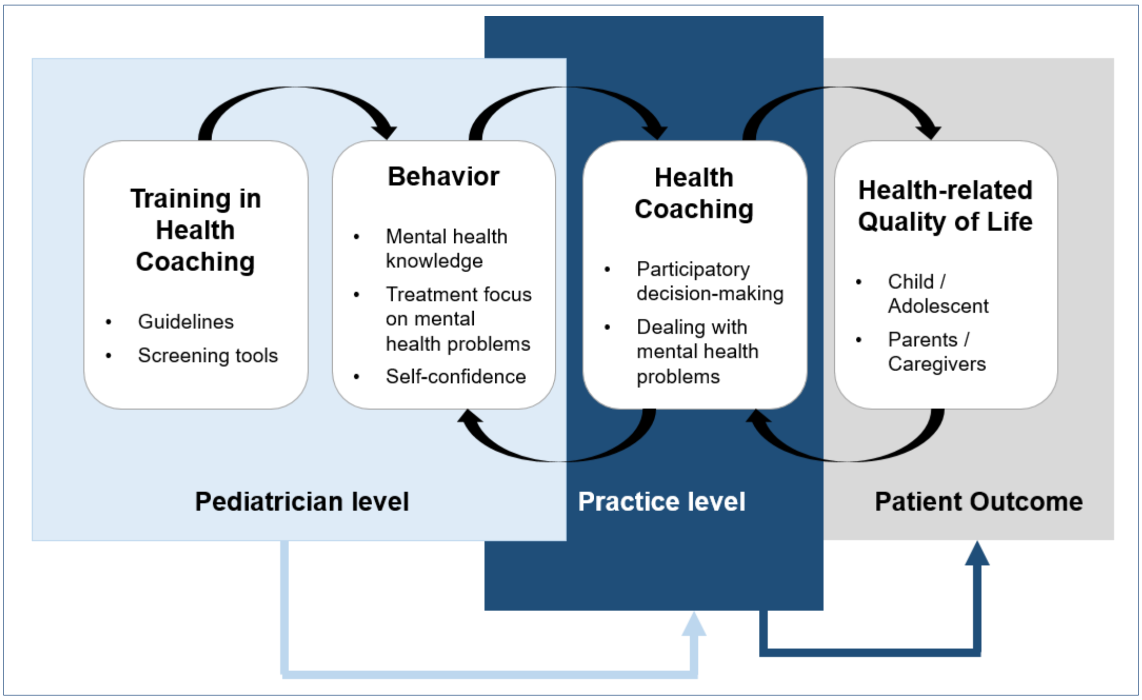

Figure 1: Effectiveness chain of the health coaching program on health-related quality of life of children with mental health problems and parental health-related quality of life (author's own illustration).

As stated above, MHP frequently remain unidentified in primary care (46,47). Additionally, many pediatricians describe themselves as unskilled in dealing with the treatment of MHP (48). To address both issues, the HC offers training to pediatricians and provides standardized screening procedures for diagnostic and specifically tailored guidelines for 17 selected MHP (as of 2024, Appendix, Table 1), e.g., developmental disorder of speech and language, attention-deficit/hyperactivity disorder, or anxiety disorder (44). This training aims to equip pediatricians with comprehensive knowledge to handle standardized guidelines effectively, enabling them to identify early risk factors or symptoms of MHP and offer appropriate support to mitigate the worsening of MHP. It has been shown that educational efforts for pediatricians have effectively enhanced their ability to address MHP, leading to reduced MH impairment experienced by both children and parents (49).

Ideally, the application of the HC modifies practice processes and the behavior of the participating pediatricians. KING et al., (2018) have demonstrated that the alteration of organizational processes and structures is crucial when integrating MH services into pediatric primary care (50). With the help of the guidelines and screening tools, pediatricians are able to gain increased confidence in diagnosing and treating MHP, empowering them to decide on adequate treatment options. When signs of MHP are identified, pediatricians should now be capable of conducting early therapy within primary care settings at an early stage of the disease. In addition, pediatricians trained in HC assume a navigator role, ensuring efficient allocation of resources, with specialized care reserved for those in genuine need, while also providing timely and appropriate treatment within general pediatric practice for less severe cases. Pediatricians selectively refer patients based on the urgency and severity of the MHP, which in turn may reduce the need for referrals to specialized care, as shown by VERHAAK et al., (2015) (51), and can mitigate the risk of overtreatment, particularly for children with minor impairments. The diagnostic and treatment guidelines outlined by the HC also hold promise for mitigating the inappropriate use of medication, especially in situations where non-pharmacological interventions are more appropriate (52).

A second central component of the HC is the active involvement of children and adolescents, as well as their families, in the treatment process using participatory decision-making. The emphasis of this approach lies on promoting self-management and competency skills for the whole family. This component also includes supportive measures and family interventions to support their resources and better cope with the child’s MHP. A current systematic review has shown that higher levels of caregiver participation were associated with greater improvements in children´s MHP (53). Children and their families are intended to receive low-threshold support from a pediatrician that they trust. Another systematic review has highlighted the important role parents play in accessing MH care. From their perspective, having access to services that are flexible to their needs and building up a trusting relationship with professionals are crucial (54). Altered attitudes and enhanced coping strategies in managing the child's MHP assist the family in better handling the situation, and the HC is intended to ultimately improve overall HRQoL. Enhancing the parents' understanding of their children's needs creates a supportive social environment, facilitating behavioral changes.

In order to address the lack of time and inadequate reimbursements, which are often mentioned by pediatricians as barriers (55), pediatricians who conduct the HC are given more time for a thorough consultation with the affected families and receive extra billing options accordingly as compensation for a more comprehensive care provision going beyond the daily practice routine (additionally to the standard care billing rate, 15 euros per 10 minutes can be charged, up to a maximum of 200 minutes per child (180 minutes until 31 December 2022)). This additional billing option enables pediatricians to dedicate more time to properly assess the underlying cause of MHP as well as fitting treatment options and participating in communication with families, involving them in shared decision-making processes. A positive example from the Netherlands, where an extended MH service was introduced in primary care, resulted in an increased identification rate for MHP (51).

2.1.3 The PrimA-QuO study

All publications included in this PhD project were produced within the PrimA-QuO study, which was conducted to evaluate the quality and effectiveness of the BKK health coaching (HC) (41). This was done in order to clarify whether the HC was to be integrated into standard care, extending it to all children and adolescents covered by the BKK SHI or even other SHI funds. The PrimA-

QuO study considered the following diagnostic groups: 1) developmental disorder of speech and language, 2) head and abdominal pain (somatoform), 3) conduct disorder, and 4) non-organic enuresis. The project was supported by the Innovation Fund of the Federal Joint Committee for 42 months from 2017 to 2020 (according to § 92b paragraph 3 SGB V; grant number: 01VSF16032).

This PhD focuses on two main aspects of the evaluation:

Firstly, it assessed the effect of the HC on the HRQoL of the participating children and adolescents and their parents, using data from a cohort study (Paper 1).

Secondly, it captured the perspectives of the stakeholders involved in the HC (children and adolescents and their parents treated according to the HC, and the pediatricians trained in HC) through a qualitative interview study (Paper 2).

2.1.4 Research questions and objectives

The overall aim of this PhD project was to investigate the impact of the HC on children and adolescents with MHP in primary care and to evaluate its implementation, taking into account all stakeholders.

Paper 1 aimed to assess the effectiveness of the HC program by comparing the HRQoL of the participants with those who did not receive the HC. Specifically, we wanted:

(1) To determine the impact of the HC on children´s HRQoL, compare those treated according to the HC to children with MHP receiving standard care.
(2) To ascertain the impact of the HC on parental HRQoL, compare parents whose children with MHP are treated according to the HC with those whose children with MHP receive standard care.

The modifications made by pediatricians in their treatment approaches as part of the HC were specifically designed to influence HRQoL outcomes for both patients with MHP and their parents. The conducted analysis thus aimed to provide nuanced insights into the multifaceted impact of the HC across different dimensions of HRQoL, encompassing changes in mental well-being, physical health, and social support from their family and friends. The focus on HRQoL as the primary outcome was supported by its direct utility as an indicator for assessing the effectiveness of health-related interventions (56).

Paper 2 of the doctoral research project aimed to assess the implementation of the HC program in comparison to the envisioned planned intervention. More specifically, the objectives outlined in Paper 2 were:

(1) To determine the acceptance of the HC program among pediatricians integrating the HC program as well as children and adolescents with mental health problems – treated within the HC program – and their parents.
(2) To identify barriers and facilitators of the HC in routine medical practice.
(3) To explore whether there are areas of under-implementation for augmenting the effectiveness of the HC program.

By employing qualitative interviews, the objective was to gain a nuanced understanding of the effectiveness of the HC's implementation and its impact on the experiences of patients, parents, and pediatricians. The barriers, challenges, and prior implementation experiences uncovered in these interviews were intended to inform the ongoing enhancement of the HC.

2.1.5 Overview of the PhD thesis

This PhD thesis encompasses two articles that were published in peer-reviewed journals. Paper 2 is also part of the dissertation of Dr. S. Bührmann (57).

I. **Loidl V**, Hamacher K, Lang M, Laub O, Schwettmann L, Grill E. Impact of a pediatric primary care health-coaching program on change in health-related quality of life in children with mental health problems: results of the PrimA-QuO cohort study. BMC primary care. 2023;24(1):182.

II. Decke S, Deckert K, Lang M, Laub O, **Loidl V**, Schwettmann L, et al. "We're in good hands there." - Acceptance, barriers and facilitators of a primary care-based health coaching programme for children and adolescents with mental health problems: a qualitative study (PrimA-QuO). BMC family practice. 2020;21(1):273.

2.2 Methods and analysis

2.2.1 Study design

This PhD project involves a mixed-methods study design with two main components: a quantitative part consisting of a prospective, questionnaire-based cohort study (Paper 1), and a qualitative part based on guided interviews (Paper 2), (Figure 2).

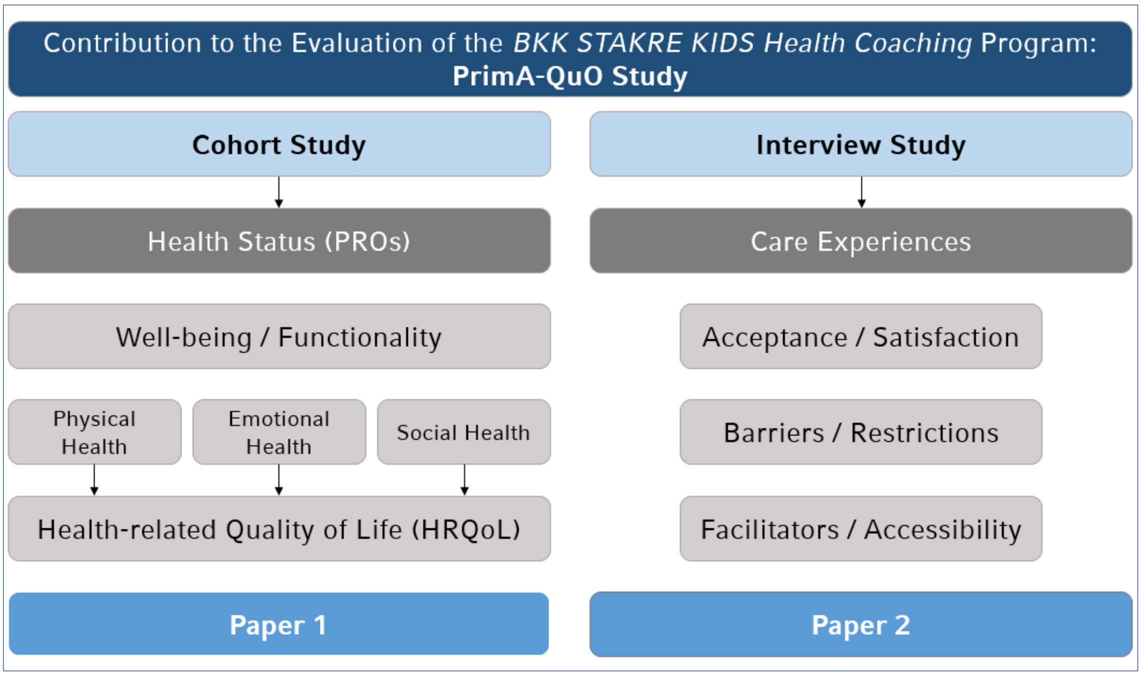

Figure 2: Research methodology overview: The cohort study evaluates the participants' reported health status, encompassing physical, emotional, and social well-being, as dimensions of health-related quality of life (patient-reported outcomes (PROs)). Interviews investigate care experiences. (Author's own illustration).

2.2.2 Study population

For Paper 1, children and adolescents under the age of 18 diagnosed according to the ICD-10 classification with at least one of the following MHP were included: developmental disorder of speech and language (F80.8-F80.9), head and abdominal pain (somatoform) (G44.2, G43.0, G43.1, F45.4, R10.4), conduct disorder (F68.8, F91.0-F92.9, F94.0-F95.9, F98.3-F98.9), and non-organic enuresis (F98.0). Participants had sought consultation – specifically due to this MH diagnosis – with a pediatrician in Bavaria, at least once within the preceding six months during the recruitment phase. All participants were insured by one of the SHI BKKs that offered the SK. The BKK screened their database for potential participants who met the inclusion criteria and provided the data to the LMU Munich to extend study invitations.

Participants who were treated by a pediatrician trained in HC were categorized into the intervention group, while all others were considered controls.

The qualitative study (Paper 2) was conducted in Bavaria, Germany. The study population included pediatricians, parents (if the child was younger than 14 years), and adolescents themselves (if 14 years and older). All participants were required to have prior experience with the HC – application of the HC (pediatricians) or the treatment according to the HC (families) – to ensure they provided comprehensive experiences. Participants were purposively sampled, considering maximum variation in terms of region (rural versus urban), contextual factors (age, gender, education), and diagnostic groups. Parents and adolescents had all participated in the questionnaire-based PrimA-QuO cohort study and had received HC treatment. Pediatricians were selected from a list within a pediatrician network (PaedNetz Bayern e. V., representing over 80% of pediatricians in Bavaria, and successfully trained in HC).

2.2.3 Data collection

To address the research questions in Paper 1, data from the PrimA-QuO cohort study were utilized. Baseline data collection occurred between January and November 2018. Insurees from the SHI BKKs underwent screening in the databases based on predefined inclusion and exclusion criteria. Upon meeting the inclusion criteria, insured individuals received a postal invitation to participate in the study, including a direct access link to the standardized online questionnaire. One year after the baseline assessment, study participants received a subsequent invitation with a link to the follow-up questionnaire from the study team.

The qualitative data collection (Paper 2) was conducted via telephone to enhance flexibility and accessibility, reaching participants from across Bavaria. Data collection spanned from November 2017 to November 2018. The structuring of the interviews was facilitated by a pre-developed interview guide, which underwent pilot testing. Open-ended questions allowed for deeper insights, and additional prompts and guides ensured that important topics were explored in-depth and narrative flow was maintained. When needed, deviations from the interview guides occurred, and extra questions were introduced. This was done, for instance, in cases of uncertainties regarding the mentioned interview content or when delving into more complex or novel topics. Two researchers (DR. S. BÜHRMANN, V. LOIDL), both trained and experienced in qualitative research, carried out the interviews. All interviews were audiotaped digitally, and field notes were taken by the researchers. Afterwards the audio recordings were transcribed verbatim using the audio transcription software f4transkript (58). The transcripts were anonymized and not returned to the participants for verification.

2.2.4 Ethics and data protection

Participants provided informed consent for both the qualitative and quantitative parts of the PrimA-QuO study. The Ethics Committee of the Ludwig-Maximilians University Munich approved the study (quantitative part: 17-497; qualitative part: 17-431), in accordance with the Declaration of Helsinki (59). The Data Protection Officer of the Ludwig-Maximilians University Munich approved all data protection aspects of the study in accordance with the EU General Data Protection Regulation (60).

2.2.5 Outcome variables

The change in HRQoL of children and adolescents from baseline and one year thereafter was the primary outcome in Paper 1. HRQoL was assessed by the generic and validated German-language instrument KINDL-R (*Kinder-Lebensqualitätsfragebogen*) (61), containing 24 items distributed across six dimensions (each containing four items): 1) physical well-being, 2) emotional well-being, 3) self-esteem, 4) family well-being, 5) peer/social well-being, and 6) school-related well-being (Figure 3). Each item aims to quantify the average emotions and experiences over the past week. Responses to each item are recorded on a five-point Likert scale, ranging from 'never' (1) to 'always' (5). The average score of each of the six subscales, as well as the total HRQoL score, are calculated by summing up the responses, where higher values indicate a greater HRQoL. The KINDL-R is beneficial because it offers versions for self- and parent-reported measures, as well as age-specific versions to consider the developmental changes of children and adolescents. We used the self-assessment version for children and adolescents for those aged 11 and older, while the parental version was completed for younger children. The KINDL-R demonstrates satisfactory reliability and validity (62). It has been successfully used in various studies to evaluate the HRQoL in children and adolescents.

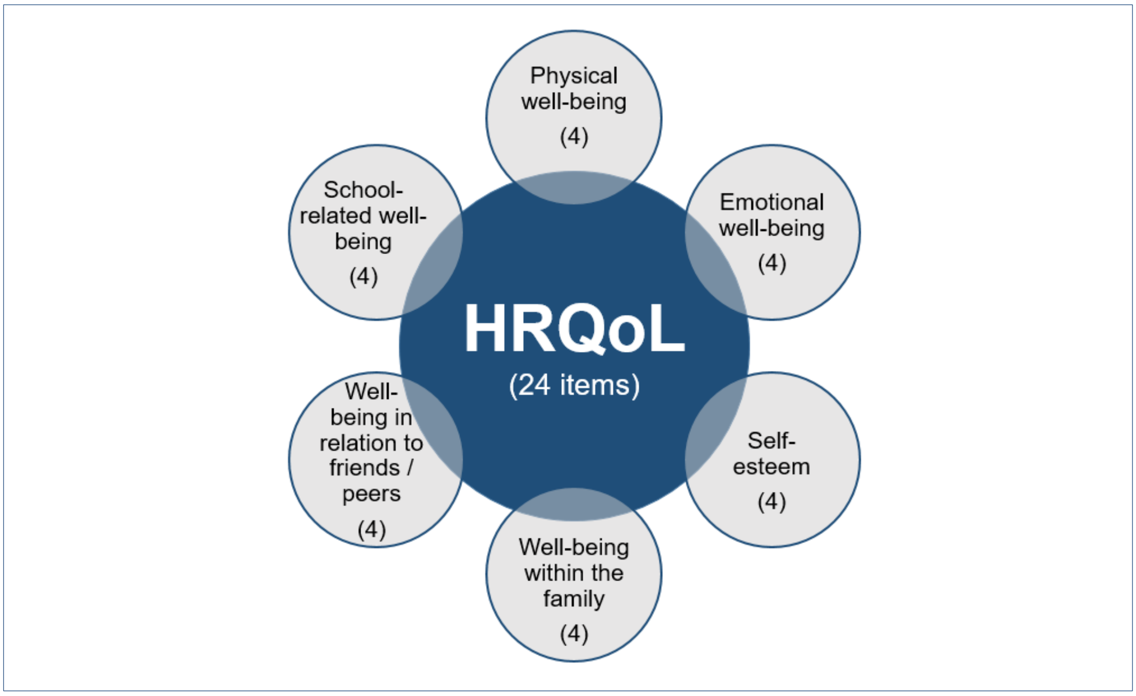

Figure 3: Overview of the generic KINDL-R questionnaire assessing children’s health-related quality of life (HRQoL) containing 24 items distributed across six dimensions (four items each) (author's own illustration).

Change in the parental HRQoL between baseline and one year apart was the secondary outcome in Paper 1. To assess self-perceived health, we used the EuroQoL Visual Analog Scale (EQ-VAS) (63). In the EQ-VAS, self-perceived health is represented on a continuous scale, with endpoints 'worst imaginable health' (0) and 'best imaginable health' (100).

Analyzing the EuroQoL EQ-5D-5L index resulted in problematic ceiling effects within the study sample, wherein many participants attained the highest possible score. Given that this index lacked the necessary level of detail for analysis, we opted to utilize the EQ-VAS instead to assess parental HRQoL. This decision was made to ensure more reliable results, as the EQ-VAS is not as affected by these ceiling effects compared to the EQ-5D-5L index. This simplified measure has also demonstrated robust psychometric properties (64).

2.2.6 Data analysis and statistical methods

For Paper 1, descriptive statistics were computed, presenting categorical variables as percentages and continuous variables as means. To assess differences in demographic and health-related characteristics between the intervention and control groups at baseline, bivariate non-parametric tests (Mann-Whitney-U test and Chi-squared test) were performed.

Given the non-random assignment of children to either the HC or usual care, a propensity score-weighted analysis was implemented to mitigate selection bias and simulate randomization effects (65). Propensity scores, estimating the likelihood of receiving HC based on observed covariates, were derived from a multiple logistic regression model incorporating age (continuous variable), sex, parents' educational level, and diagnosis group (categorical variables) at baseline. Data were then weighted using the inverse probability of treatment weighting (IPTW) method to achieve covariate balance between groups (66).

To evaluate the intervention's impact on children's HRQoL over the 1-year follow-up, linear mixed effects models with subject-specific random intercepts were employed. The flexibility of mixed effects models in accommodating participants with varying numbers of measurements is advantageous for longitudinal studies (67). The models utilized the KINDL-R total score as a continuous outcome, with each KINDL-R sub-scale score also being used as a continuous outcome in separate models. These models accounted for individual variations and changes over time. Similarly, parental HRQoL was assessed using the VAS as a continuous outcome, adjusting for the child's diagnosis group, intervention/control group, sex, and the educational level of the parent who completed the questionnaire (dummy coding), as well as the child's HRQoL and age (continuous variables).

Model fit was assessed using the Akaike information criterion (AIC), with lower AIC values indicating better fit. The models were fitted using a restricted maximum likelihood approach (REML), and both unadjusted and adjusted models were employed. The significance level was set at alpha 0.05, with p-values ≤ 0.05 considered statistically significant. All analyses were conducted using R software version 4.0.3 (68,69).

For Paper 2, qualitative content analysis based on PHILIPP MAYRING'S approach was utilized (70,71). This approach was chosen because it offers transparency as well as a combination of structure and flexibility. On the one hand, the interview material is categorized into predefined categories, while on the other hand, the method allows for the identification of new themes and meanings from the material. This enabled us to address our predefined research questions while potentially gaining new insights. All transcripts were coded independently and systematically analyzed by the two researchers to obtain a deeper comprehension of the barriers, facilitators and aims of the HC as well as its acceptance. Initially, the two researchers discussed relevant themes, categories and codes representing various aspects of HC. Pertinent statements from the interviews were allocated to the pre-defined themes and categories (deductive approach). When emergent statements could not be allocated to previously defined categories, new categories were introduced (inductive approach). After the initial coding, the categories were reviewed and, if necessary, refined or expanded (72). These iterations in the analysis process aimed to ensure that all pertinent aspects were addressed. The software MAXQDA was used for coding and analysis (73).

2.3 Main results

2.3.1 Quantitative cohort study – Paper 1

Study population

Over 7,000 children and adolescents, who were eligible based on the ICD-10 diagnosis groups and selected from the SHI database, were invited to participate in the cohort study. We enrolled 1,109 children and adolescents aged 0 to 17 years (40% female, mean age 6.9, SD 3.4). The total number of children receiving the HC intervention was 342 (31%). Intervention and control groups were similar regarding sociodemographic factors and HRQoL at baseline, except for MHP diagnoses, which significantly differed between the groups (Table 1 of Publication 1). Among all participants, 1,054 completed the KINDL-R questionnaire (84.5% parent proxy-report) at baseline. Information on the KINDL-R during follow-up was available for 55.5% of the baseline participants. At baseline, 1,083 parents had completed the VAS. Follow-up information regarding the VAS was available for 56.4% of these parents.

Analytical results of the children´s health-related quality of life

The HRQoL of children, as assessed by parents' reports using the overall KINDL-R score, remained relatively stable over time, with a mean score of 79.91 points (SD 10.73) at baseline and a similar score of 79.16 (SD 10.73) in the consecutive year.

Similarly, in the self-report version using the overall KINDL-R score, HRQoL remained stable over time: 71.95 (SD 14.51) points at baseline and 73.36 (SD 12.10) points at follow-up.

Adjusted linear mixed effects models (age, sex, diagnosis group, and parental education) showed no significant effect of the HC on children's HRQoL total score neither in the self-reported nor in the proxy-reported model. Analyzing the KINDL-R subscale scores in both the parent proxy-report and the self-report versions revealed no significant intervention effect on HRQoL. For further detailed results, refer to Table 3 and Table 4 of Publication 1.

Analytical results of the parental health-related quality of life

At baseline, the average VAS score was 84.39 points (SD 14.50), which increased to 86.38 points (SD 12.07) one year later at the follow-up. After adjusting for the parent's age, sex, and educational level, as well as the child's HRQoL, the linear mixed effects model showed a significant increase in the VAS score over time for both groups (2.59 points; CI [1.29; 3.88]). However, no significant effect of the children's participation on the HC and parental HRQoL was found (Table 5 of Publication 1).

2.3.2 Qualitative interview study – Paper 2

In total, 40 individuals – comprising 11.3% of those who had consented to interviews and were selected until saturation – participated in the qualitative study. This included 14 (60.9%) pediatricians, 4 (40.0%) adolescents with MHP and 22 (6.8%) parents (19 mothers, 3 fathers) of children with MHP, all of whom had experiences in the HC.

Building upon insights gained from preliminary interviews conducted prior to the primary data collection phase, we identified four distinct themes: acceptance, aims, facilitators, and barriers. Using this framework, we developed 17 codes derived from the interviews with pediatricians (Figure 4), alongside 13 codes generated from the interviews with parents and adolescents (Figure 5).

Acceptance and satisfaction with the Health Coaching

In the interviews, a high level of acceptance and satisfaction was observed among pediatricians, as well as among adolescents and parents. Affected families reported that they had not realized that their children were being treated under a program specifically tailored to their needs.

Aims and appropriateness of the Health Coaching

The aim of improving quality assurance in social pediatric work was achieved by using checklists and guidelines. These tools helped create a structured approach and made diagnostics more standardized and verifiable. However, there was a conflict with the goal of addressing the individual needs of patients and their parents. Specifically, incorporating psychosocial or emotional aspects into therapy proved to be a time-consuming process not adequately covered by the HC.

Facilitators of the Health Coaching

Pediatricians reported that the HC supported them in strengthening their competence in dealing with MHP and improving their abilities in diagnosis and treatment. The structured guidance provided by the guidelines was particularly advantageous for pediatricians. Parents appreciated the close relationship with the pediatrician as well as their appreciative approach. The pragmatic and situation-oriented approach was particularly valued.

Barriers to the Health Coaching

Pediatricians faced challenges in implementing processes within their daily practice routines, including a lack of time, despite the additional compensation intended to facilitate more thorough discussions with their patients. They highlighted that patients with complex family situations have still not been adequately reached despite efforts made through the HC. To address this, they proposed closer collaboration with other healthcare professionals, for instance psychologists and speech therapists, to streamline therapeutic interventions when necessary. There was a consistent desire for more time to be available for all patients, not just those enrolled in selective contracts like the HC.

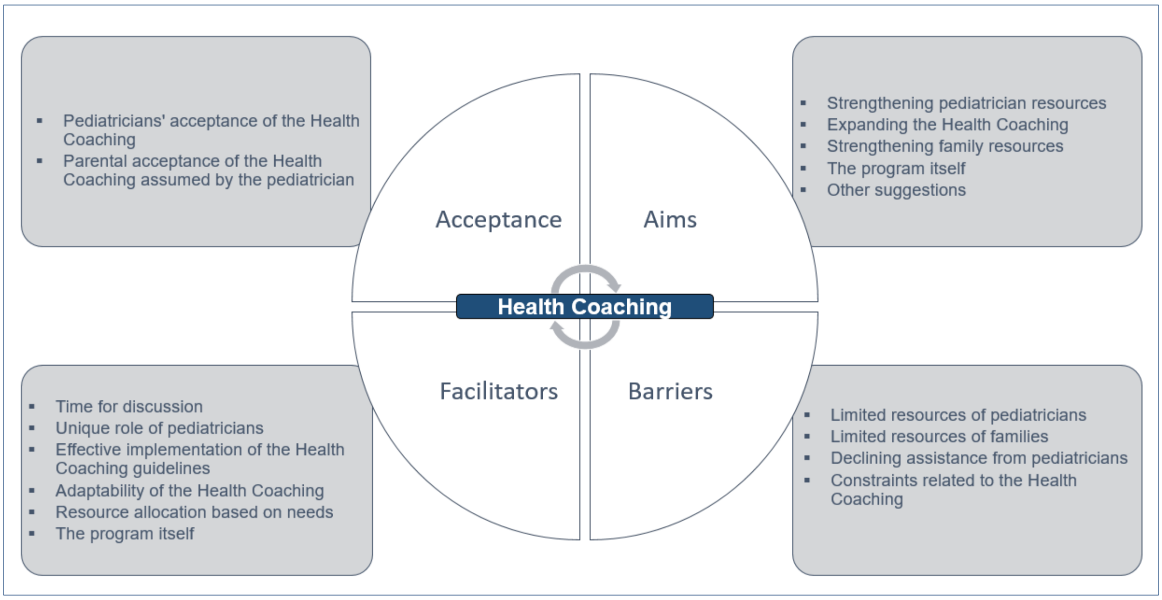

Figure 4: Results of themes and codes from interviews with **general pediatricians** regarding their experiences with the Health Coaching (author's own illustration).

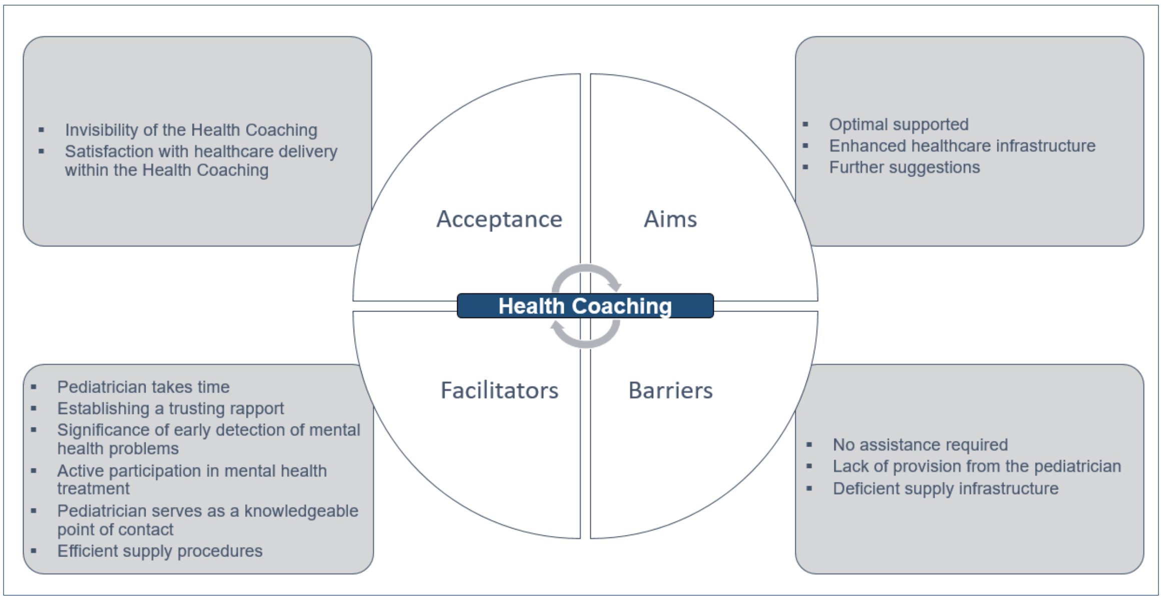

Figure 5: Results of themes and codes from interviews with **adolescents** with mental health problems and their **parents** regarding their experiences with the Health Coaching (author's own illustration).

2.4 Strengths and limitations

This cohort study revealed that children´s HRQoL did not change significantly over time, and no differences were observed between children and adolescents who were treated according to the HC and those who were not. Based on the conducted interviews, pediatricians, patients, and their parents reported high satisfaction with healthcare delivery within the context of the HC. Pediatricians described that the HC guidelines helped them enhance their competence in managing MHP and improve their skills in diagnosis and treatment. These findings are consistent with other studies that have shown improved clinical and public health outcomes following the release of pediatric guidelines (74,75). Pediatricians struggled to integrate new processes into their daily routines, citing a lack of time despite the additional compensation meant to support more comprehensive patient discussions. The tremendous barriers pediatricians face daily were also recently highlighted by IMFELD et al., (2023) (76).

An essential strength of this PhD project lies in its mixed-method approach, which entails the systematic integration of quantitative data from surveys and qualitative data from interviews. This approach facilitated a far more comprehensive understanding of the advantages and limitations of the HC and its impact on patient-relevant outcomes than the commonly used single-method approach of using either quantitative or qualitative data could have achieved. By employing such a combined approach in MH service research, this thesis effectively addressed the limitations described in single-method research, including the lack of limited flexibility or depth in quantitative data, and the absence of quantifiability or subjectivity in qualitative data (77).

An example will be given to illustrate the enriched understanding provided by the mixed-model approach. While both patients and pediatricians expressed considerable satisfaction with healthcare delivery within the HC framework in the interview study (Paper 2), we did not obtain significant effects of the HC on children´s HRQoL (Paper 1). Only through integrating the findings of the interview study, we gained a deeper understanding of the HC in the context of routine practice. This approach was instrumental in identifying relevant implementation challenges faced by each stakeholder group – challenges that might not have been systematically captured in the cohort study alone. For example, pediatricians identified limited time and financial resources as primary barriers to implementing the HC as described in the guidelines. This deviation from the standard HC protocol could have impacted the validity of the HC and offers one potential explanation for the non-significant results of the cohort study. The impact of such deviations not using different data sources has been discussed by others (78).

Moreover, the study stands out for its extensive participant cohort, comprising over 1,100 underage patients with sensitive diagnoses. This considerable number of participants was attained through an efficient recruitment strategy, which involved screening health insurance data using ICD-10 codes, and inviting all eligible participants to enrol in the study through their SHI. This recruitment strategy is noteworthy as many trials fail to recruit on time and within budget, leading to lower participant retention and significant research waste (79,80).

Several limitations associated with this project should be considered. Patient recruitment based on secondary data also has its shortcomings. We were unable to conduct detailed analyses to compare the effectiveness of the HC for different levels of MHP, such as severity or duration of the condition, or the presence of comorbidities. This might have influenced our results as research indicates that the severity of symptoms emerged as the strongest predictor of lower HRQoL (81). BAUMGARTEN et al., (2019) found a lower HRQoL among children and adolescents with chronic comorbidities like obesity (17), and multimorbidity of physical health problems and MHP was associated with even lower HRQoL than having either alone (82). However, despite challenges in precisely determining the stage of MHP, our study focused only on children and adolescents with incident diagnoses. This approach aimed to mitigate biases that could arise from including individuals at different stages of their MHP. By focusing on this more homogeneous group of participants, we sought to enhance the validity and reliability of our findings.

While ideally baseline data collection should have been undertaken before the enrollment of the child in the HC, this was not feasible using the selected recruitment strategy. There could be a delay of up to three to six months between the time of MH diagnosis and the dispatch of the baseline questionnaire since the billing of outpatient treatment costs occurs on a quarterly basis. During the time between visits to a pediatrician's practice and the completion of the questionnaire, patients' symptoms might have changed and the already started MH treatment might have influenced baseline variables, potentially introducing confounding. While we cannot fully exclude this possibility, it is worth mentioning that spontaneous improvements in the selected MHP are rare, and HRQoL is not expected to improve immediately but rather gradually over the course of the one-year follow-up period (83).

It is worth noting that the children´s HRQoL was already high even when they were enrolled in the study, despite the non-significant effect of the HC on the children's HRQoL over time. Although many studies have recognized that MHP could affect the HRQoL of children and their families adversely (16,19,81,82,84), the HRQoL levels observed in our study sample were comparable to those in the general population (85). Beginning with high levels of the outcome HRQoL presents a challenge for any intervention seeking to make further improvements and attain "optimal" values. In addition, the majority of our study participants had a high socioeconomic status (SES), which appears to contradict existing literature. For instance, a large cohort study conducted in Germany found that children and adolescents from families with low SES were more than twice as likely to be affected by MHP compared to their counterparts from high SES families (26% versus 10%; p<0.001) (86). Studies indicate that children with MHP with high SES tend to have better HRQoL (87–89). Furthermore, research demonstrates that higher levels of behavioral and emotional problems are associated with lower child HRQoL (90). The high SES may explain the initially high HRQoL, potentially diminishing the effect of the HC. Since all participants were affected by MHP, it could be possible that children with high SES experienced fewer pronounced problems and thus exhibited a more stable HRQoL compared to children from families with lower SES. This implies that the potential for changes through the HC in our participants was limited, as their baseline condition was already relatively stable and high. This underscores the likelihood of a positive self-selection of the sample among our participants.

All participating children (those with HC and the control group) were enrolled in a more generalized prevention program (BKK STARKE KIDS) offered by their SHI funds. It is known that participation in a care program is accompanied by a continuous support from a physician, which in turn facilitates behavior change and self-control in patients (91). Thus, it is possible that parents who had enrolled their children in the SK program took a proactive approach to their own and their children's health, resulting in already heightened awareness and better coping strategies that are not related to the HC. Hence, it is conceivable that the absence of significant effects of the HC on HRQOL may have been overlaid by the positive impacts of the generalized prevention program and a minimal disparity between the groups.

Through the cohort study alone, we would not be able to assess the fidelity of guideline implementation in practice. All children receiving treatment from a pediatrician trained in HC were assigned to the intervention group, given that these pediatricians were guided by clear guidelines on how to conduct the HC. Nevertheless, interviews indicated that pediatricians often faced difficulties in precisely following these instructions due to time constraints. This discrepancy between the guidelines and the actual implementation raises doubts about the completeness of the HC execution, which cannot be inferred from the billing data. For instance, this has also been recognized in the MH approach of VERHAAK et al., (2015) (51). Potential gaps in implementation could have resulted in the HC treatment not sufficiently differing from standard care, thereby influencing the results of the study. VROOM et al., (2022) have also mentioned this gap between research and practice, emphasizing the importance of improving internal capacity to overcome it (92). Another limitation of non-randomized group allocation is the potential for biases to arise. However, to mitigate this issue, we utilized propensity score matching.

This evaluation did not focus on the underpinning theories of the HC or on how well the HC has been adequately customized to meet the unique needs of each stakeholder, but rather on real world decision-making. According to a framework for developing and evaluating complex interventions, it is recommended to initially evaluate the development and feasibility of the implementation strategy (93,94) before assessing its effectiveness. However, since the HC was already successfully in place since 2013, our focus was on an in-depth evaluation of the HC effectiveness. Therefore, we applied diverse methods and perspectives to gain a more comprehensive understanding of the HC and contribute to its enhancement.

Lastly, we only included four selected MH diagnoses in our analysis, despite the fact that the HC was developed for 17 MH diagnoses until now (Appendix, Table 1). Furthermore, more than half of the children and adolescents included in the study were suffering from developmental disorders of speech and language (SLD). This is not remarkable, as a quarter of all children with MHP in Germany are affected by SLD (9). Following the guideline, children with SLD require thorough diagnostic assessments (pediatric audiology and phoniatrics) and are often referred to a speech therapist for specific therapy (95). Consequently, appropriate therapy options are not covered in primary care, and pediatricians mainly play a guiding role in this context, reducing the potential impact of the HC in these cases. As a result, we cannot exclude that the HC is better suited for certain MHP, which have not been considered in this study.

2.5 Contribution of the doctoral thesis and outlook

This PhD thesis made a notable contribution to the assessment of the effects of the HC program for children and adolescents with MHP in a primary care setting in Bavaria, Germany. It achieved this by conducting a comprehensive exploration of the HC's impact, applying patient-reported HRQoL measures, and conducting qualitative interviews involving pediatricians, adolescents with MHP, and their parents. From a methodological perspective, this thesis stands out for its use of a combination of quantitative and qualitative methodologies, providing a thorough and holistic understanding of the HC.

The conducted cohort study showed that the HC did not lead to significant improvements in the HRQoL of the children or their parents. Additional findings from the PrimA-QuO study indicated that the HC had no positive effect on the developmental course of MHP (96) or on cost-effectiveness (97). Based on these findings, the Federal Joint Committee's Innovation Fund (G-BA) has decided against endorsing the integration of the HC into standard procedures within the SHI sector (decision made on November 11, 2021 (98)). The criticism focuses specifically on indications of selection bias, the inability to account for potential confounders such as disease severity, the non-randomized participation of pediatricians in the HC, and the inability to infer the actual application of training content and guidelines from billing data.

However, the G-BA acknowledged the step towards more patient-centered care and recognized the potential of the HC, particularly its widespread acceptance among families and pediatricians, as confirmed by the findings of the qualitative evaluation. Both the positive feedback on the HC’s value reported by the participants and the barriers mentioned are valuable results that could be used for the adaptation of future programs.

In order to better understand the factors and prerequisites of the HC and its potential for significantly enhancing HRQoL, there is a need to investigate unresolved yet crucial aspects for its further development. As an approach for future studies, more balanced sample sizes regarding the diagnosis groups should be included to obtain a more comprehensive understanding of the impact of the HC on the HRQoL of children and adolescents with MHP. Moreover, future evaluations should encompass additional MHP for which the HC was designed to answer the question if there are differences in the change in HRQoL of children with different MHP diagnoses other than the four examined in this study. To consider specific aspects of the respective MH diagnosis, disease-specific or treatment-specific instruments should be utilized, alongside the evaluation of generic HRQoL, for instance the *Screen for Child Anxiety Related Emotional Disorders* (SCARED) (99) for assessing anxiety symptoms. Furthermore, future studies may consider the severity of MHP as well as interactions between MHP and additional physical health problems. Likewise, since both groups comprised a positive selection of insured individuals – as both are enrolled in a generalized prevention program – it is unclear how diverse the intervention and control groups were compared to each other. Further research should ensure that the interventions being compared are not too similar and also include children and adolescents who have not yet benefited from other healthcare programs or services.

From our experiences, we advocate for addressing children with MHP from socioeconomically disadvantaged backgrounds in future healthcare programs since we primarily included families with higher SES. The high SES of our study participants may have influenced the initially high HRQoL, potentially diminishing the effect of the HC.

While this PhD research project highlighted that current approaches to the HC may not be sufficient to improve the HRQoL of children and adolescents with MHP, the results from the interview study have identified important approaches to enhance standard care for children and adolescents with MHP. Improved diagnosis and therapy through guidelines, as well as enhanced healthcare structures that enable low-threshold access, thereby aim to expand capacities in specialized socio-pediatric services. If future research continues to address the remaining deficiencies in MH care, such as time constraints in primary care and prolonged waiting times in specialist care, this novel approach of the HC may serve as inspiration for further development of future MH care programs, contributing to significant improvements in the overall quality and accessibility of MH services.

In conclusion, this PhD project significantly advances our understanding of the impact of a selected HC program for children and adolescents with MHP in a German primary care setting, shedding light on patient-relevant outcomes. Through a combination of qualitative interviews and quantitative analyses, the study offered a comprehensive and nuanced perspective on the HC.

Despite the high satisfaction reported with healthcare-related medical services, the identification of implementation barriers such as time and financial constraints, as well as long waiting times, underscores the urgent need for improvement. Implications from the analyses in this PhD thesis revealed potential avenues to enhance standard care, particularly in socio-pediatric services, thereby emphasizing the importance of improved healthcare processes. Although the cohort study did not show a significant impact of the HC on HRQoL, it highlights the necessity of understanding the factors and underlying mechanisms influencing HRQoL improvement in children with MHP.

Future projects should expand to encompass a broader spectrum of MHP, integrate disease-specific assessment instruments, and prioritize vulnerable groups to address social inequalities in children's MH. The insights gathered from this PhD project provide a solid basis for the adaptation of the HC and the ongoing development of future healthcare programs specifically tailored to address the needs of children and adolescents with MHP. They hold promise for enriching resources for pediatricians and easing the burden on affected individuals, thus significantly contributing to the overall well-being of children and adolescents with MHP and their families.

3. Paper I

Impact of a pediatric primary care health-coaching program on change in health-related quality of life in children with mental health problems: results of the PrimA-QuO cohort study.

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Impact of a pediatric primary care health-coaching program on change in health-related quality of life in children with mental health problems: results of the PrimA-QuO cohort study

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Abstract

Mental health problems (MHP) have a considerable negative impact on health-related quality of life (HRQoL) in children and their families. A low threshold Health Coaching (HC) program has been introduced to bring MH services to primary care and strengthen the role of pediatricians. It comprised training concepts as a hands-on approach for pediatricians, standardization of diagnosis and treatment, and extended consultations. The aim of this study was to evaluate the potential effects of the HC on HRQoL in children with MHP and their parents.

We used data from the PrimA-QuO cohort study conducted in Bavaria, Germany from November 2018 until November 2019, with two assessments one year apart. We included children aged 17 years or younger with developmental disorder of speech and language, non-organic enuresis, head and abdominal pain, and conduct disorder. All included children were already part of the Starke Kids (SK) program, a more general preventive care program, which includes additional developmental check-ups for children enrolled in the program. In addition, treatment according to the HC guidelines can be offered to children and adolescents with mental health problems, who are already enrolled in the SK program. These children form the intervention group; while all others (members of BKK and SK but not HC) served as controls. HRQoL in children was assessed using the KINDL questionnaire. Parental HRQoL was measured by the visual analogue scale. To analyze the effects of the intervention on children´s HRQoL over the 1-year follow-up period, we used linear mixed effects models.

We compared 342 children receiving HC with 767 control patients. We could not detect any effects of the HC on HRQoL in children and their parents. This may be attributed to the relatively high levels of children´s HRQoL at baseline, or because of highly motivated pediatricians for the controls because of the selection of only participant within the Starke Kids program. Generally, HRQoL was lower in older children (-0.42 points; 95% CI [-0.73; -0.11]) and in boys (-1.73 points; 95% CI [-3.11; -0.36]) when reported by proxy. Parental HRQoL improved significantly over time (2.59 points; 95% CI [1.29; 3.88]).

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Although this study was not able to quantitatively verify the positive impact of this HC that had been reported by a qualitative study with parents and other stakeholders, and a cost-effectiveness study, the approach of the HC may still be valid and improve health care of children with MHP and should be evaluated in a more general population.

Keywords Health care service, Children and adolescents, KINDL-R, Health-related quality of life

Introduction

Mental health problems (MHP) have a considerable negative impact on health-related quality of life (HRQoL) in children and their families [1, 2]. Worldwide, it is estimated that 13% to 20% of children and adolescents suffer from MHP [3, 4]. In Germany, overall prevalence of MHP is stable on a high level [5], with over 17% of children and adolescents showing clinically relevant MHP [6]. Among these, developmental disorders (17%), followed by conduct disorders (11%) are the most frequent conditions [5, 7]. In addition, it has been shown, that the risk of chronification and persistence of MHPs in adulthood increases, when symptoms of MHP occur during childhood or adolescence [8–12]. To give an example, a German national cohort study has shown that externalizing as well as internalizing problems in childhood or adolescence are associated with poorer general mental health and a higher incidence of depressive symptoms, and a higher risk to suffer from eating disorder symptoms in adulthood [13].

Structural problems of the healthcare system such as a lack of intersectoral coordination – a complex approach, which is integrated across different health care sectors – timely access to care and adequate standardization of diagnostics and treatment have been mentioned as the main obstacles to adequate management of youth MHP in Germany [14]. In the German statutory health insurance (SHI) system, children are insured along with their parents without any additional charges. The SHI covers most of the costs associated with children's healthcare needs, including mental health care. Specifically, primary care has been mentioned as one key sector for early recognition and timely treatment of MHP in children and adolescents [15]. Primary care in Germany is provided by practices run by independent specialists (e.g. pediatricians (PD)) who offer services to patients under the statutory health insurance scheme. This is mandatory for the majority of the population. Within the framework of statutory health insurance, specialists in pediatrics can only treat children and adolescents up to the age of 18 and they can be consulted without any registration, gatekeeping, or referrals. Pediatricians are seeing children on a regular basis for routine checks and might therefore recognize mental health (MH) needs at an early stage [16, 17]. Typically, the PD would perform an initial screening, initiate treatment and recommend referral to specialized centers in severe cases. However, due to time constraints in daily practice and a potential lack of specific MHP expertise patient needs may not be addressed adequately [18]. It has been noted that referrals to specialized care tend to be the standard approach, irrespective of the severity of the problems, causing bottlenecks for those who need specialized care [19].

Against this background, a targeted but low-threshold MH primary care program – Health Coaching (HC) – was developed and implemented by a group of statutory health insurance funds (Betriebskrankenkassen Landesverband Bayern, BKK-LV [20]) in collaboration with pediatricians [21] in 2011 [22–24]. The BKK-LV – an umbrella organization for all BKKs health insurance funds in Bavaria (17 members) – is one of the biggest statutory health insurance companies in Germany and was involved in the development of the HC for children and adolescents with MHP. As all children and adolescents, participating in the study, were insured at the BKK funds no private funding was spent. The BKK is a major statutory health insurance funds in Germany with 10.9 (in Bavaria: 2.5:) of a total of 73.0 million insures. HC provides standardized and evidence-based diagnostic and management guidelines for 16 MH conditions, which are taught in aspecific training for PD. Participating PDs get familiarized with the use of the standardized guidelines to improve detection and treatment of MHP. They thus are supported in their decision-making process to decide if the child can be treated in primary care or – for severe cases – whether an immediately referral to a specialized care provider is necessary. The treatment guidelines of the HC also have the potential to counteract a misuse of medication in cases where non-pharmacological treatment is more appropriate. If pharmacological treatment is needed, the child will be referred to specialized care in order to receive the optimal pharmacological treatment. Moreover, standardized guidelines for actions support PDs to perform standardized treatment and the integration of person- and environment-related factors of the children and their families (e.g. better self-management skills, extended resources like care services available, or resilience factors. PDs receive an additional reimbursement from the health insurance fund for every child or adolescent inscribed into the program and treated according the HC specifications (additional amount of 15 euros per 10 min up to a cap of 180 min). While this is a promising approach to avoid overtreatment and misuse of medicalization there is a lack of evidence regarding its effectiveness.

Evidence of the benefits of integrating MH interventions in primary pediatric care is still weak. There is an example from the Netherlands of an effective program where pediatricians have been trained successfully in delivering MH services. They found an increased identification rate for MHP, more doctor´s visits because of MHP and less psychopharmacological prescriptions been issued [25]. Also countries like the UK [26], Australia [27, 28], and Canada [29] have already made successful steps to integrating MH services into primary pediatric care. In recent years, there has been growing interest to include patient-reported outcome measures in child and youth MH settings [30]. In this context HRQoL of children suffering from MHP is an essential outcome, because it shows the direct (e.g. change of behavioral problems) as well as the indirect (e.g. change in dealing with peers) effects of the HC [31]. HRQoL measures allow for a patient-centered approach to healthcare. By assessing the impact of the HC on childrens' daily lives, HRQoL measures provide a more comprehensive understanding of the benefits and limitations of the HC from the patient's perspective. Furthermore, the HC is complex and may have effects which go beyond the improvement of behavior problems and social skills. HRQoL measures can help to capture these diverse effects of the HC, since it also includes changes in physical function, psychological well-being, or social support by family and friends.

The aim of the study was to investigate the potential effects of the Health Coaching (HC) program [22–24] on health-related quality of life of children and adolescents with MHP and their parents compared to those children and adolescents with MHP and their parents, who did not receive the HC.

Methods

Study design

The prospective PrimA-QuO cohort study was conducted in Bavaria, Germany with measurements at two time points one year apart (baseline: from January to November 2018; follow-up: from January to November 2019). The collection of data was performed using an online questionnaire.

Participants

The population comprised children and adolescents aged 0 to 17 years with developmental disorder of speech and language (SLD), non-organic enuresis (NE), head and abdominal pain, somatoform (HAP) and conduct disorder (CD). Diagnoses were identified using the International Classification of Diseases diagnosis codes (ICD-10 [32]) namely: 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. All children were insured at a BKK SHI. The roof organization of the BKK SHIs is the BKK Landesverband Bayern (LV), with 2.5 million insures [33].

All children were insured at the BKK funds, had been enrolled in the BKK Starke Kids (SK) program, a health promotion program, which offers additional developmental check-ups for children and adolescents [34]. The program is offered to BKK-insured families free of charge and is available nationwide. It is part of the BKK's broader commitment to promoting health and wellbeing among its members and the wider community. Children have to be enrolled by their parents in this program. All children had at least one consultation for succeeding diagnoses at an office-based pediatrician in Bavaria, Germany, from July 2017 to November 2018. The identification of eligible children was based on billing data. As billing data were available with a delay of up to six months, the time point of enrollment of the child in the HC can only be approximately determined. Parents of eligible children, found in the BKK insurance database, were contacted by the BKK health fund via mail and provided with a link to the questionnaire. Survey data were collected online using SoSci Survey [35]. Access was regulated by users' authentication via their insurance number. The link for the follow-up questionnaire was provided by the study team via email one year after baseline. Families received a small monetary compensation for participation.

Children in the intervention group participated in the SK program and were treated by a pediatrician trained in the HC [22] – comprising standardized and evidence-based diagnostic and management guidelines and specific training for pediatricians (IG: members of BKK, SK, and HC). Children in the control group were members of the BKK, but not necessarily enrolled in the SK program (CG: members of BKK, SK or not SK, but not HC). The diagnostic and treatment guidelines were specifically developed and target for the diagnoses groups. There was confinement to subjects with complete data. Detailed information on the study design were published elsewhere [22]. We included 1109 children and adolescents and obtained a response rate of 17% at baseline (7.343 invitation letters sent) and 56% at follow-up (998 invitation letters sent) with regard to questionnaires. This response rate is not atypical when participants with specific diagnoses are identified from a health insurance database, which has several advantages, for instance the BKK health insurance database contains a large number of patients, which provides a larger potential sample size than traditional recruitment methods, and patients are not limited to specific geographical areas or health care institutions. Furthermore, it is an efficient method compared to other recruitment methods as potential patients with a specific diagnosis can be identified, which is especially useful for children with MHP because they are usually not treated by a pediatrician.

Approval had been obtained from the local ethics committee (approval number 17–497) and the Data Protection Officer of the Ludwig-Maximilians-University Munich. All procedures were designed in full compliance with European and national data protection legislation [36, 37]. Informed consent was elicited from the parents and from children/adolescents aged six or older. Participants received age-appropriate and detailed information regarding the background and implementation of the study. They were offered the opportunity to revoke their participation in the study at any time.

Measures and instruments

Primary outcome was the health-related quality of life (HRQoL) of children. We used the generic and validated German-language instrument *KINDL*^{R} (Kinder-Lebensqualitätsfragebogen) [38]. It consists of 24 items divided between six dimensions (with four items each) with reference to the past week: 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" to "always" coded with values between 1 and 5. The higher values indicating "better" HRQoL ratings. The total HRQoL score was calculated for all 24 items. The item scores per dimension (and the total score) were added and transformed into values between 0 and 100 (total sum = total mean * 24; total score = ((total sum – 24)/96)*100). The child and adolescent self-assessment version was used for children aged eleven years or older at baseline; for younger children the proxy version was completed by the parents. As several studies suggest, parental and self-assessment of the KINDL^R total score were reported separately for subsequent analyses [39, 40]. The KINDL questionnaire revealed good scale properties in terms of floor and ceiling effects as well as scale fit. In terms of reliability, the subscales showed moderate internal consistency [41]. In chronically ill population the psychometric properties appeared to be somewhat higher [42].

Secondary outcome was parental HRQoL of affected children, measured by the EQ-5D visual analogue scale (VAS) that records self-rated overall health state (range 0 to 100, with higher scores indicating better quality of life [43].

Sociodemographic information, namely age, and sex of the child, age, sex, and educational level of both parents, and disease related data, namely MHD group diagnosis were collected at baseline. Parental education was grouped into three categories: low (no formal qualification and secondary school), medium (intermediate school, no high school graduation) and high (high school or university graduation).

Statistical analyses

Descriptive statistics for categorical and continuous variables were expressed as percentages and means. Bivariate non-parametric tests (Mann-Whitney-U test, Chi-squared test) were used to test for differences between the intervention and control group at baseline.

Because children were not randomly assigned to receive HC or standard care, a propensity score-weighted analysis [44] was performed to reduce the effect of selection bias and simulate the effects of randomization. Propensity scores (the conditional probabilities of receiving HC or not given the observed covariates) were estimated using a non-parsimonious multiple logistic regression model based on age (continuous variable), sex, educational level of the parents and diagnoses group (categorical variables) at baseline. Data were weighted with the inverse probability of treatment weighting (IPTW) method [45], using stabilized weights. Covariate balance, indicating adequacy of the propensity score model specification, was checked with standardized differences (absolute values < 0.1 supported the assumption of balance between groups) [44].

To analyze the effects of intervention on children´s HRQoL over the 1-year follow-up period, we used linear mixed effects models with subject-specific random intercept. The continuous outcome of the models was the KINDL total score. Subsequently all KINDL subscale scores were used as outcome. When conducting the linear mixed effects models for the HRQoL of the children, we used the respective highest parental educational level as mothers' and fathers' educational levels were highly correlated. To account for potential differences between the intervention and control groups, all models were controlled for sex of the child and highest educational level of the parents as well as diagnoses group and intervention, which were introduced in the model with dummy coding. Additionally, age of the child was introduced as continuous variable. Taking into account by-subject variability, we had intercepts for subjects as random effects. To observe group differences in their changes in HRQoL we included the interaction with time. Time was introduced as a fixed slope as the model fit was better presented assessed by the Akaike information criterion (AIC), whereas a lower AIC indicates a better fit.

To analyze the effects of intervention on parental HRQoL over the 1-year follow-up period, we used linear mixed effects models with subject-specific random intercept. The continuous outcome of the models was the VAS. To account for potential differences between parents, whose children were in the intervention or control group, sex and the educational level of the parent who had completed the questionnaire, as well as diagnoses group and intervention of the child were introduced in the model with dummy coding. Age of the parent and HRQoL of the child were introduced as continuous variables. Taking into account by-subject variability, we had intercepts for subjects as random effects. To observe group differences in their changes in HRQoL we included the interaction with time. Time was introduced as a random slope as the model fit was better presented.

Mixed effect models are widely applicable in longitudinal research as they allow to include participants with different numbers of measurement points, meaning that participants with incomplete data at follow-up can still be included in the analysis [46]. Overall model fit was assessed by the AIC, whereas a lower AIC indicates a better fit. In order to compare the AIC from the different models, each model must be based on the same participants. Therefore, the number of participants with complete observations regarding all covariables was included in the models.

Models were fitted using a restricted maximum likelihood approach (REML). Unadjusted and adjusted models were fitted. The local significance level was set at alpha 0.05. *P*-values were regarded noticeable in case $p \leq 0.05$.

Plausibility checks were conducted before starting the analysis and deviations from homoscedasticity and normality were checked by visual inspection of residual plots. Analyses were performed using R version 4.0.3 [47, 48] and *nmle* [49] for linear mixed effects models.

Results

Study population

We included 1109 children and adolescents at the age of 0 to 17 years (40% female, mean age 6.9, SD 3.4). The total number of children receiving the intervention was 342 (31%). Table 1 shows the baseline characteristics of both groups. Groups were comparable regarding sociodemographic factors and HRQoL at baseline, with the exception of MHP diagnoses, which differed significantly between groups.

Of all participants, 1054 completed the KINDL questionnaire (84.5% parent proxy-report) at baseline. Information for the KINDL during follow-up was available for 55.5% of the baseline participants. On average, the KINDL total score for the parent proxy-report version was 79.91 (SD 10.73) points at baseline and 79.16 (SD 10.73) points at follow-up. On average, the KINDL total score for the child self-report version was 71.95 (SD 14.51) points at baseline and 73.36 (SD 12.10) points at follow-up.

The VAS was completed by 1083 parents at baseline. Information for the VAS during follow-up was available for 56.4% of the baseline parents. On average, the VAS score was 84.39 (SD 14.50) points at baseline and 86.38 (SD 12.07) points at follow-up.

Children´s health-related quality of life model

Results from the linear mixed effects models for the effect of the HC with children's HRQoL are shown in Table 2. The model for the parent proxy-report was based on $n = 891$ and the model for the child self-report was based on $n = 163$ participants. No effect between the HC and children´s HRQoL total score was found after adjusting for age, sex, diagnosis group, and parental education for both models. For the parent proxy-version higher age of the child was significantly associated with lower HRQoL (-0.42 points; 95% CI [-0.73; -0.11]), as was male sex.

Conducting this analysis with the KINDL subscale scores parent proxy-report version (Table 3), no effect between intervention and HRQoL was found. As for the KINDL overall score, older age was significantly associated with lower HRQoL levels for the subscales '*emotional well-being*' (-0.73 points; 95% CI [-1.08; -0.37], '*self-worth*' (-0.77 points; 95% CI [-1.17; -0.38] and '*school-related well-being*' (-0.67 points; 95% CI [-1.15; -0.18]. For the subscales '*self-worth*', '*friends*', and '*school-related well-being*' boys had on average lower HRQoL than girls ('*self-worth*': -1.96 points; 95% CI [-3.77; -0.16]; '*friends*': -2.45 points; 95% CI [-4.26; -0.64]; '*school-related well-being*': -4.12 points; 95% CI [-6.3; -1.93]). For the subscale '*physical well-being*' children diagnosed with *head and abdominal pain* (-5.55 points; 95% CI [-10.87; -0.23]) and for the subscale '*friends*' children with *conduct disorders* (-4.56 points; 95% CI [-8.69; -0.42]) had lower HRQoL levels.

There was also no effect between intervention and HRQoL found, when conducting this analysis with the KINDL subscale scores children self-report version (Table 4). Only for the subscale 'family' higher age of the child was significantly associated with lower HRQoL levels (-2.16 points; 95% CI [-3.88; -0.45]). Children in the intervention group had significantly decreased levels of the subscale 'self-worth' over time.

Parental health-related quality of life model

Results from the linear mixed effects models for the effect of the HC with parental HRQoL are shown in Table 5. The model was based on $n = 1005$ parents. There was no effect between the children´s

Table 1 Descriptive characteristics of the total cohort and by intervention group (HC) and control group (no HC) at baseline

Covariates ***N***	**Total** ***n*** **= 1109**	**No HC (Control)** ***n*** **= 767**	**HC (Intervention)** ***n*** **= 342**	***p*-value***
Age child [years][a]	6.9 (SD = 3.4)	6.9 (SD = 3.4)	7.01 (SD = 3.3)	0.476
Girls[b]	446 (40%)	311 (41%)	135 (39%)	0.787
Age father [years][a]	41.1 (SD = 6.1)	41.0 (SD = 6.1)	41.4 (SD = 6.2)	0.252
Age mother [years][a]	38.1 (SD = 5.2)	38.0 (SD = 5.4)	38.3 (SD = 4.9)	0.506
Highest educational level of both parents[b]				
low	106 (10%)	73 (10%)	33 (10%)	0.821
medium	433 (39%)	304 (40%)	129 (38%)	
high	569 (51%)	389 (51%)	180 (53%)	
Diagnosis group child[b]**				
Head and abdominal pain, somatoform	227 (20%)	171 (22%)	56 (16%)	0.030
Developmental disorder of speech and language	582 (52%)	443 (58%)	139 (41%)	< 0.001
Conduct disorder	272 (25%)	168 (22%)	104 (30%)	0.003
Non-organic enuresis	96 (9%)	36 (5%)	60 (18%)	< 0.001
Health-related quality of life				
KINDL-R parent proxy-report (*n* = 891)				
KINDL-R total parent proxy report[a]	79.9 (10.7)	79.9 (10.6)	79.9 (11.1)	0.990
KINDL-R subscales parent proxy reports[a]				
Physical well-being	80.7 (17.1)	80.7 (17.0)	80.8 (17.3)	0.899
Emotional well-being	85.1 (13.1)	85.1 (12.9)	85 (13.6)	0.874
Self-worth	75 (14.2)	75.1 (14.3)	74.7 (14.1)	0.730
Well-being in the family	80 (13.9)	79.8 (13.9)	80.3 (13.9)	0.626
Well-being related to friends	79.8 (14.8)	79.9 (15)	79.4 (14.3)	0.647
School-related well-being	79 (17.1)	78.7 (17.1)	79.6 (17.2)	0.493
KINDL-R child self-report (*n* = 163)				
KINDL-R total child self-report[a]	72 (14.5)	71.6 (14.7)	72.9 (14)	0.581
KINDL-R subscales child self-reports[a]				
Physical well-being	72.3 (19.8)	72.9 (19.4)	70.9 (20.8)	0.547
Emotional well-being	75.9 (17.1)	75.3 (17.6)	77.7 (15.7)	0.417
Self-worth	64.3 (17.8)	63.6 (18.3)	66 (16.7)	0.439
Well-being in the family	77.8 (18.9)	76.8 (19.5)	80.2 (17.5)	0.306
Well-being related to friends	71.8 (20.2)	71.4 (21.0)	72.9 (18.1)	0.672
School-related well-being	69.4 (19.9)	69.1 (19.8)	70.1 (20.4)	0.770
VAS parental health-related quality of life (*n* = 1083)				
VAS[a]	84.4 (SD = 14.5)	84.2 (SD = 15)	84.8 (SD = 13.1)	0.528

HC Health Coaching. *VAS* Visual Analogue Scale

* *P*-value from Chi2-test for categorical variables and from Kruskal–Wallis test for continuous variables

[a] mean (SD: standard deviation)

[b] n: number (percentage: %)

participation in HC and parental HRQoL after adjusting for age, sex, and educational level of the parent who answered the questionnaire, as well as treatment, diagnosis group of the child, and children´s HRQoL. The VAS score increased significantly over time (2.59 points; CI [1.29; 3.88]) for both groups. Higher HRQoL of the child was significantly associated with higher HRQoL of their parents (0.36 points; CI [0.30; 0.42]).

Discussion

We investigated a standardized primary care program for the management of children and adolescents with mental health problems (MHP) but could not detect any effects of the program on health-related quality of life (HRQoL) of children being treated by a pediatrician trained in the HC specifications or their parents. HRQoL was lower in older children and in boys when

Table 2 Results of the linear mixed effects models with the KINDL total score parent proxy-report and KINDL total score child self-report as dependent variables controlled for time, age (in years), sex, educational level of the parents and diagnoses

KINDL-R total	**Parent proxy-report ($n = 891$)**			**Child self-report ($n = 163$)**		
	Estimate	**95%-CI**	***P*-value**	**Estimate**	**95%-CI**	***P*-value**
Intercept	82.36	[77.86; 86.85]	< 0.001	82.73	[61.54, 103.92]	< 0.001
Time						
Baseline	Reference			Reference		
Follow-Up	-0.43	[-1.52, 0.67]	0.443	1.65	[-1.46, 4.76]	0.299
Group of the child						
Control	Reference			Reference		
Intervention	0.64	[-0.85, 2.14]	0.400	1.71	[-2.92, 6.35]	0.469
Age of the child (in years)	-0.42	[-0.73, -0.11]	0.007	-0.81	[-2.10, 0.49]	0.223
Sex of the child						
Female	Reference			Reference		
Male	-1.73	[-3.11, -0.36]	0.014	-0.18	[-4.60, 4.23]	0.936
Educational level of the parent						
Low	Reference			Reference		
Medium	1.62	[-0.95, 4.19]	0.217	1.61	[-5.36, 8.58]	0.651
High	0.58	[-1.92, 3.08]	0.649	-1.97	[-8.62, 4.68]	0.562
HAP[a]	-0.96	[-4.36, 2.44]	0.579	0.53	[-9.83, 10.90]	0.920
SLD[a]	0.82	[-2.32, 3.97]	0.607	-0.08	[-9.77, 9.61]	0.987
NE[a]	-0.69	[-4.14, 2.75]	0.693	-1.52	[-12.26, 9.23]	0.782
CD[a]	-2.18	[-5.30, 0.94]	0.171	-1.47	[-11.52, 8.58]	0.774
Interaction: Time × Group	-0.55	[-2.11, 1.02]	0.493	-2.43	[-7.33, 2.46]	0.329
Variance Intercept	67.02			116.55		
AIC[b]	10440.35			2011.67		

[a] *HAP* head and abdominal pain, somatoform, *SLD* developmental disorder of speech and language, *NE* non-organic enuresis, *CD* conduct disorder

[b] *AIC* Akaike information criterion

reported by proxy. Parental HRQoL improved significantly over time.

Arguably, the lack of observed change in children's HRQoL may be attributed to the relatively high levels of their HRQoL at baseline. Although MHP can have considerable negative impact on HRQoL of children and their families [1, 2], HRQoL levels of our sample were comparable with the general population, (mean 76.8 for parent proxy-report, 72.6 for child self-report) [39]. Also, in contrast to other studies, HRQoL remained stable or increased from baseline to follow-up [50, 51]. We hypothesize that both intervention and control group of our sample were a positive selection of insures because they had already been enrolled in an unspecific prevention program offered by the statutory health insurance funds.

Also, we could observe a distinct middle-class bias in our study population with over half of the participants reporting a high socioeconomic status. This seems surprising at first sight, since there is evidence that MHP are more prevalent in families with low socioeconomic status [14, 52–58]. To give an example, parental educational status was associated with persistence and severity of conduct disorders [59].

It can be argued that the HC might be better suited for some MH diagnosis groups. In our study, diagnoses were unevenly distributed with more than half of the participants being affected with developmental disorder of speech and language (SLD) which is also the most common single MH diagnosis in children in Germany (25% of all MH diagnoses) [5]. Having an aligned therapy meeting the needs of the present SLD and the related conditions, such as hearing, neurological, motor, cognitive, social, and emotional disorders, requires comprehensive diagnostic, in particular phoniatrics and pediatric audiology [60]. These multidisciplinary and elaborated assessments are not covered by primary care [61]. Likewise, children with SLD will be referred to speech therapists [61] leaving no real possibility for action for the primary care physician.

The results of our study provide supporting evidence in line with literature that children's HRQoL is lower with proceeding age in children and adolescents [14, 31, 39, 62]. Reasons could be challenges at

Table 3 Results of the linear mixed effects model with the KINDL subscale scores parent proxy-report as dependent variable controlled for time, age (in years), sex, educational level of the parents and diagnoses

***n* = 891**	**Physical well-being**			**Emotional well-being**			**Self-worth**			**Well-being in the family**			**Well-being related to friends/peers**			**School-related well-being**		
	Est.[a]	**95%-CI**	***P*-value**	**Est**	**95%-CI**	***P*-value**	**Est**	**95%-CI**	***P*-value**	**Est**	**95%-CI**	***P*-value**	**Est**	**95%-CI**	***P*-value**	**Est**	**95%-CI**	***P*-value**
Intercept	80.71	[73.72; 87.70]	< 0.001	87.36	[82.02; 92.69]	< 0.001	78.97	[73.04; 84.91]	< 0.001	81.53	[75.86; 87.19]	< 0.001	84.02	[78.1; 89.94]	< 0.01	82.99	[75.87; 90.11]	< 0.001
Time																		
Baseline	Reference			Reference			Reference			Reference			Reference			Reference		
Follow-Up	0.11	[-1.96; 2.18]	0.920	-0.55	[-1.90; 0.81]	0.429	0.24	[-1.35; 1.82]	0.772	-0.55	[-2.07; 0.97]	0.475	-0.84	[-2.49; 0.80]	0.314	-0.97	[-2.82; 0.89]	0.308
Group of the child																		
Control	Reference			Reference			Reference			Reference			Reference			Reference		
Intervention	0.29	[-2.05; 2.64]	0.807	0.57	[-1.22; 2.37]	0.531	0.41	[-1.57; 2.39]	0.682	1.78	[-0.13; 3.69]	0.068	-0.53	[-2.51; 1.46]	0.603	1.7	[-0.68; 4.08]	0.162
Age of the child (in years)	-0.16	[-0.62; 0.31]	0.508	-0.73	[-1.08; -0.37]	< 0.001	-0.77	[-1.17; -0.38]	< 0.001	-0.37	[-0.75; 0]	0.053	0.05	[-0.34; 0.45]	0.793	-0.67	[-1.15; -0.18]	0.007
Sex of the child																		
Female	Reference			Reference			Reference			Reference			Reference			Reference		
Male	-0.42	[-2.55; 1.71]	0.698	-1.01	[-2.66; 0.63]	0.227	-1.96	[-3.77; -0.16]	0.033	-0.90	[-2.64; 0.85]	0.313	-2.45	[-4.26; -0.64]	0.008	-4.12	[-6.3; -1.93]	< 0.001
Educational level of the parent																		
Low	Reference			Reference			Reference			Reference			Reference			Reference		
Medium	3.58	[-0.47; 7.64]	0.083	2.22	[-0.87; 5.31]	0.160	2.55	[-0.86; 5.97]	0.143	-0.30	[-3.59; 2.99]	0.858	0.46	[-2.97; 3.89]	0.793	0.65	[-3.46; 4.75]	0.757
High	3.95	[0.01; 7.89]		1.13	[-1.88; 4.14]		1.91	[-1.41; 5.23]		-2.31	[-5.51; 0.9]		-1.34	[-4.68; 1.99]		-0.05	[-4.05; 3.94]	
HAP[b]	-5.55	[-10.87; -0.23]	0.041	-0.42	[-4.47; 3.63]	0.839	-0.63	[-5.16; 3.90]	0.785	3.72	[-0.58; 8.02]	0.090	-1.61	[-6.11; 2.89]	0.484	-0.56	[-5.93; 4.82]	0.839
SLD[b]	-0.96	[-5.86; 3.94]	0.702	1.79	[-1.95; 5.54]	0.347	-0.19	[-4.37; 3.99]	0.929	2.40	[-1.57; 6.38]	0.236	-1.66	[-5.81; 2.50]	0.434	2.95	[-2.01; 7.91]	0.243
NE[b]	-4.31	[-9.61; 0.98]	0.110	-0.62	[-4.74; 3.5]	0.769	0.13	[-4.41; 4.68]	0.954	-0.12	[-4.48; 4.24]	0.957	-0.9	[-5.43; 3.62]	0.696	1.83	[-3.6; 7.27]	0.509
CD[b]	-2.15	[-7.03; 2.74]	0.389	-0.57	[-4.29; 3.16]	0.7659	-2.55	[-6.72; 1.61]	0.229	-1.58	[-5.54; 2.39]	0.436	-4.56	[-8.69; -0.42]	0.031	-1.64	[-6.57; 3.29]	0.514
Interaction: Time × Group	-1.45	[-4.41; 1.51]	0.336	0.51	[-1.44; 2.45]	0.609	-2.02	[-4.3; 0.25]	0.082	-0.78	[-2.95; 1.39]	0.482	0.54	[-1.81; 2.89]	0.653	-0.71	[-3.36; 1.93]	0.597
Variance Intercept	121.21			93.02			103.86			98.24			99.70			157.66		
AIC[c]	12168.30			11230.51			11559.19			11482.33			11604.12			11834.10		

[a] *Est* Estimate

[b] *HAP* head and abdominal pain, somatoform, *SLD* developmental disorder of speech and language, *NE* non-organic enuresis, *CD* conduct disorder

[c] *AIC* Akaike information criterion

Table 4 Results of the linear mixed effects model with the KINDL subscale scores children self-report as dependent variable controlled for time, age (in years), sex, educational level of the parents and diagnoses

n = 163	**Physical well-being**			**Emotional well-being**			**Self-worth**			**Well-being in the family**			**Well-being related to friends/peers**			**School-related well-being**		
	Est.[a]	**95%-CI**	***P*-value**	**Est**	**95%-CI**	***P*-value**	**Est**	**95%-CI**	***P*-value**	**Est**	**95%-CI**	***P*-value**	**Est**	**95%-CI**	***P*-value**	**Est**	**95%-CI**	***P*-value**
Intercept	90.62	[62.40; 118.83]	< 0.001	85.75	[60.86; 110.65]	< 0.001	65.02	[38.14; 91.91]	< 0.001	107.49	[79.39; 135.59]	< 0.001	61.01	[30.49; 91.53]	< 0.01	88.98	[60.90; 117.05]	< 0.001
Time																		
Baseline	Reference			Reference			Reference			Reference			Reference			Reference		
Follow-Up	-0.71	[-5.72; 4.29]	0.780	2.41	[-1.77; 6.59]	0.258	5.10	[0.78; 9.42]	0.021	-0.12	[-5.07; 4.83]	0.962	3.38	[-1.22; 7.98]	0.149	1.98	[-3.55; 7.50]	0.483
Group of the child																		
Control	Reference			Reference			Reference			Reference			Reference			Reference		
Intervention	-2.43	[-8.59; 3.72]	0.439	3.58	[-1.84; 9.00]	0.195	2.85	[-3.04; 8.74]	0.343	3.81	[-2.37; 9.98]	0.227	2.51	[-4.17; 9.18]	0.462	0.41	[-5.83; 6.65]	0.898
Age of the child (in years)	-1.45	[-3.17; 0.26]	0.097	-0.79	[-2.3; 0.73]	0.308	-0.30	[-1.94; 1.34]	0.721	-2.16	[-3.88; -0.45]	0.014	0.74	[-1.12; 2.61]	0.434	-1.24	[-2.95; 0.48]	0.158
Sex of the child																		
Female	Reference			Reference			Reference			Reference			Reference			Reference		
Male	4.68	[-1.17; 10.53]	0.117	-2.51	[-7.68; 2.65]	0.340	0.23	[-5.37; 5.82]	0.936	-4.13	[-9.97; 1.71]	0.166	-1.02	[-7.38; 5.34]	0.753	1.02	[-4.83; 6.86]	0.733
Educational level of the parent																		
Low	Reference			Reference			Reference			Reference			Reference			Reference		
Medium	2.54	[-6.20; 11.27]	0.569	4.12	[-3.61; 11.86]	0.296	0.33	[-8.47; 9.14]	0.941	1.94	[-7.21; 11.09]	0.678	2.03	[-8.00; 12.05]	0.692	-3.11	[-12.23; 6.01]	0.504
High	-0.25	[-8.49; 7.99]		-1.68	[-9; 5.63]		-2.83	[-11.21; 5.55]		0.00	[-8.69; 8.69]	1.000	-5.61	[-15.17; 3.95]		-4.46	[-13.08; 4.17]	
HAP[b]	-5.36	[-18.53; 7.82]	0.425	1.26	[-10.36; 12.88]	0.832	2.96	[-10.22; 16.15]	0.660	1.34	[-12.48; 15.17]	0.849	7.34	[-7.59; 22.28]	0.335	0.04	[-13.89; 13.96]	0.996
SLD[b]	-1.22	[-13.66; 11.22]	0.847	-0.48	[-11.45; 10.50]	0.932	3.02	[-9.30; 15.34]	0.631	-1.62	[-14.53; 11.29]	0.805	0.98	[-12.99; 14.94]	0.891	1.31	[-11.67; 14.30]	0.843
NE[b]	-4.76	[-17.69; 8.16]	0.470	-3.12	[-14.57; 8.33]	0.593	7.52	[-6.06; 21.11]	0.278	-4.46	[-18.60; 9.69]	0.537	0.16	[-15.30; 15.63]	0.983	0.73	[-13.38; 14.84]	0.919
CD[b]	0.79	[-11.89; 13.47]	0.903	-0.50	[-11.69; 10.68]	0.930	1.05	[-11.74; 13.84]	0.872	-2.47	[-15.88; 10.95]	0.719	1.12	[-13.36; 15.61]	0.879	-4.84	[-18.36; 8.67]	0.483
Interaction: Time × Group	0.72	[-7.14; 8.57]	0.858	-2.75	[-9.32; 3.82]	0.412	-8.48	[-15.27; -1.70]	0.014	-0.36	[-8.12; 7.41]	0.928	-0.97	[-8.20; 6.26]	0.792	-5.93	[-14.58; 2.73]	0.180
Variance Intercept	158.20			135.75			168.13			158.20			234.97			122.68		
AIC[c]	2208.18			2134.42			2146.79			2186.87			2197.44			2220.16		

[a] *Est* Estimate

[b] *HAP* head and abdominal pain, somatoform, *SLD* developmental disorder of speech and language, *NE* non-organic enuresis, *CD* conduct disorder

[c] *AIC* Akaike information criterion

Table 5 Results of the linear mixed effects model with the VAS score as dependent variable controlled for time, age (in years), sex, educational level of the parent who answered the questionnaire, and diagnosis and health-related quality of life of the child

	VAS[a] **(*n* = 1005)**		
	Estimate	**95%-CI**	***P*-value**
Intercept	56.07	[47.42, 64.72]	< 0.001
Time			
Baseline	Reference		
Follow-Up	2.59	[1.29; 3.88]	< 0.001
Group of the child			
Control	Reference		
Intervention	1.07	[-0.66; 2.80]	0.225
Age of the parent [years]	0.02	[-0.13; 0.17]	0.787
Sex of the parent			
female	Reference		
male	0.01	[-2.53; 2.56]	0.991
Educational level of the parent			
Low	Reference		
Medium	-0.74	[-3.23; 1.75]	0.561
High	-0.14	[-2.40; 2.69]	
Diagnosis group child[b]			
HAP	-0.95	[-4.93; 3.02]	0.638
SLD	-0.60	[-4.29; 3.10]	0.752
NE	-1.42	[-5.49; 2.65]	0.494
CD	-1.19	[-4.86; 2.48]	0.526
HRQoL child[c]	0.36	[0.30; 0.42]	< 0.001
Interaction: Time × Group	-1.72	[-3.59; 0.15]	0.071
AIC[d]	11,723.31		

[a] *VAS* Visual Analogue Scale to measure parental health-related quality of life

[b] *HAP* head and abdominal pain, somatoform, *SLD* developmental disorder of speech and language, *NE* non-organic enuresis, *CD* conduct disorder

[c] *HRQoL* Health-related quality of life

[d] *AIC* Akaike information criterion

school, puberty stage or limited leisure time. In boys, we observed lower levels in HRQoL, which is also consistent with literature showing stronger impairment for boys than for girls [63].

Past research found that MHP in children are associated with decreased HRQoL levels regarding physiological, psychological and functional aspects. In contrast to this, the present study has shown lower levels in HRQoL only for children with CD and only for the subscale ‘well-being with peers’. This finding is supported by studies in children with attention deficit hyperactivity disorder (ADHD).

Our findings are particularly important as they include a patient-centered approach. Furthermore, the results complement further qualitative and quantitative components of the PrimAQuO study as the HC is a complex intervention [64] and its components may pursue different goals simultaneously [23, 24, 65]. Comprehensive program evaluations are necessary for optimized care for children and adolescents with MHP in primary care.

Some limitations of our study should be noted. First, our results are based on a survey sample of parents and their children who agreed to complete an online questionnaire. However, self-selection bias can hardly be avoided in this kind of study. Second, we lack information on the time of enrollment of the child in the HC, the period of treatment in the HC, and the time between treatment in the HC and data collection, all three factors, which might affect HRQoL and might introduce recall bias. Unfortunately, we do not have any data about the exact date, when the intervention had been conducted and about the timeframe between consultations at a pediatrician’s practice and the completion of the questionnaire. The reason was that we identified eligible children based on billing data in the health insurance records. However, billing data was available with a delay of up to six months. Nevertheless, we belief that the HC does not have immediate effects on HRQoL and rather expect the change to happen over the time of the one year follow-up. Third, given the character of the study, there was no random allocation to groups and the diagnoses groups were not balanced. Yet, we used propensity scores to reduce the effect of selection bias and compensate that there was no randomization. We were only able to analyze children already enrolled in a prevention program, therefore, any comparison to usual care has to be considered with caution. Forth, we lack of information on pediatricians program fidelity and the ability to cluster results by pediatrician as we do not have identifying data. Lastly, there are some known limitations in the measurement of HRQoL in children with MHP under eight years of age, likewise, the use of proxy versions might only be an approximation of the child´s HRQoL [66].

Conclusion

This study made an attempt to verify the positive impact of this program that was found in a qualitative study with parents and other stakeholders [23]. Also, implementation of the program was found to be cost-neutral, which indicates that enrolled children caused less health care costs while effects were similar to usual care [24]. Although we could not show any quantitative effects, the approach of the HC may still be valid and improve health care of children and adolescents with MHP and should be evaluated in a more general population.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12875-023-02119-0.

Additional file 1.

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Authors' contributions

EG is the principal investigator. She conceived and supervised the project. VL conducted the data collection, data preparation and analysis. She wrote the first draft of the manuscript in close coordination with EG. All authors critically revised and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analysed during the current study available from the corresponding author (VL) on reasonable request. All statistical analyses were carried out using RStudio (Version 4.0.3). All R codes are provided by VL on request. For ethical concerns all the data cannot be publicly shared.

Declarations

Ethics approval and consent to participate

The PrimA-QuO study was approved by the Ethics Committees of Ludwig-Maximilians-Universität München (approval number: 17–497), and was positively reviewed by the data protection officer of Ludwig-Maximilians-Universität München. It was conducted in accordance with the Declaration of Helsinki, standards of Good Epidemiology Practice, and current EU-General Data Protection Regulations.

Written informed consent was elicited from the parents and from children/adolescents aged six or older. Participants received age-appropriate and detailed information regarding the background and implementation of the study. All participants were formally educated and none of the participants were illiterates.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Publisher's Note

4. Paper II

“We’re in good hands there.” – Acceptance, barriers and facilitators of a primary care-based health coaching programme for children and adolescents with mental health problems: a qualitative study (PrimA-QuO).

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"We're in good hands there." - Acceptance, barriers and facilitators of a primary care-based health coaching programme for children and adolescents with mental health problems: a qualitative study (PrimA-QuO)

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Abstract

Background: 11.5 % of girls and 17.8 % of boys are affected by a mental health problem (MHP). The most prevalent problem areas are behavioural problems (girls/boys in %: 11.9/17.9), emotional problems (9.7/8.6) and hyperactivity problems (4.8/10.8). Primary care paediatricians are the first in line to be contacted. Nevertheless, even for less severely affected patients, referral rates to specialised care are constantly high. Therefore, a major statutory health insurance fund introduced a Health Coaching (HC) programme, including a training concept for paediatricians, standardised guidelines for actions and additional payments to strengthen primary care consultation for MHP and to decrease referrals to specialised care. The aim of this study was to examine how the HC is perceived and implemented in daily practice to indicate potential strengths and challenges.

Methods: During a one-year period starting in November 2017, a series of guideline-based interviews were conducted by phone with HC-developers, HC-qualified paediatricians, parents and patients (≥14 years) treated according to the HC programme. Paediatricians were selected from a Bavarian practice network with a total of 577 HC qualified paediatricians. Parents of patients with the four most common MHP diagnoses were approached by their health insurance: [World Health Organization, 2013] developmental disorder of speech and language [Wille N, et al., 2008] head/abdominal pain (somatoform) [Holling H, et al., 2003-2006 and 2009-2012] conduct disorder [Plass-Christl A, et al., 2018] non-organic enuresis. 23 paediatricians, 314 parents and 10 adolescents consented to be interviewed. Potential participants were selected based on purposeful sampling, according to principles of maximum variance. All interviews were recorded and transcribed verbatim. Two researchers analysed the transcripts independently of each other. Structuring content analysis derived from Mayring was used for analysis.

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Results: 11 paediatricians, 3 co-developers, 22 parents and 4 adolescents were included. Families were generally satisfied with paediatric care received in the programme's context. The HC supported paediatricians' essential role as consultants and improved their diagnostic skills. Lack of time, financial restrictions and patients' challenging family structures were reported as major barriers to success.

Conclusion: The HC programme is perceived as a facilitator for more patient-centred care. However, structural barriers remain. Starting points for improvement are further options to strengthen families' resources and expanded interdisciplinary networking.

Keywords: Mental Health Problems, Children and Adolescents, Paediatrician, Health Coaching Programme, Qualitative Study

Background

Mental health problems (MHP) of children and adolescents can considerably affect individual health and quality of life as well as performance at school and later professional development [1, 2]. Besides the risk of chronicity, there is also the risk of developing comorbidities [3, 4]. Moreover, these conditions can be of economic burden for families and healthcare systems [5–7]. Therefore, MHP are of high public health relevance in all countries of the world [1, 8]. The prevalence of MHP in Germany is high: According to the German Child and Youth Health Survey (KiGGS), around 17 % of children and adolescents aged 3-17 years are affected [9]. Among MHP, developmental disorders (17%), followed by conduct disorders (11%) are the most frequent conditions encountered in paediatric care [10]. Effective and evidence-based therapies for children and adolescents with MHP have been established, e.g. cognitive-behavioural therapy [11] or speech therapy [12]. Nevertheless, it has been reported that appropriate medical care is available to only 30 % of children and adolescents with MHP in Germany [13] and other industrialised countries [14, 15].

In Germany, primary care paediatricians are often the first in line to be consulted for MHP [13] or detect MHP during the routinely and periodically conducted developmental checks [16]. Yet, it could be shown, that the majority of primary care paediatricians does not feel adequately trained to diagnose and to treat MHP and tends to underdiagnose and undertreat MHP patients in primary care [17, 18]. Depending on the respective diagnosis, a considerable part of children with suspected MHP are subsequently referred to paediatric centres with specific mental health expertise, to speech therapists or to psychotherapy [19]. As a consequence of referral to specialised services, a number of barriers may impede or delay timely access to professional assessment and therapy. Among these barriers, waiting time, settings that fail to meet parents' and childrens' needs, long travelling distances and lack of intersectoral communication and treatment have been identified as the most relevant [8]. Referral rates could be decreased by interventions targeted at the primary care sector. It has been shown that one of these promising interventions, enhanced training, permits primary care physicians to detect and deliver simple interventions [20–23].. However, acceptance and perception of paediatricians and families involved have been neglected.

With the aim of providing improved integrated care for children and adolescents with MHP, a major German statutory health insurance fund (BKK-LV) in collaboration with a professional association of paediatricians (BVKJ e.V.) has introduced a programme for their insurees targeted at primary care paediatricians (Health Coaching - HC) in 2013 [24]. This includes a training concept for paediatricians, standardised guidelines for actions for 16 defined diagnostic entities, and additional fees for paediatricians who undergo this specific training and demonstrably act according to the guidelines. This approach follows the International Classification of Functioning, Disability and Health - children and youth version (ICF-CY) and was based on mutual consultations of medical stakeholders. ICF-CY is a complex classification standard that provides a common language and framework for planning and formulating support, therapy and treatment goals [25]. It takes developmental peculiarities and special living environments of children and young people into account. For example, it covers the ability of combining words into sentences, social interactions and focusing attention.

The programme has not been systematically evaluated yet. As a result, acceptance and remaining barriers to effective care within this programme still need to be captured. The objective of this qualitative study was therefore to investigate how anticipated aims of the HC are perceived and accepted by paediatricians and affect children, adolescents and their parents. These results are likely transferable to other primary programmes involving families as well. Effectiveness of the programme will be examined elsewhere in an additional quantitative study. To facilitate reading, following abbreviations are used in this manuscript:

MHP: mental health problems
HC: health coaching

Methods

Study design

In a qualitative approach we conducted a series of structured interviews with an interview guide ("guideline-based"). Paediatricians who had completed the HC training, parents of children participating in HC (< 14 years of age) and participating adolescents (≥ 14 years of age) took part.

Setting and sample

HC is predominantly implemented in Bavaria, one of the largest federal states of Germany with a total of 13 Million inhabitants. Participating paediatricians were members of a Bavarian network of paediatricians ("PaedNetz Bayern"). Over 80% of the primary care paediatricians in Bavaria are members of PaedNetz Bayern. Currently, more than 700 members[1] are qualified to participate in the HC programme. We included resident paediatricians in Bavaria, qualified and experienced in the HC programme. Practices that only treat private patients were excluded. In total, 23 paediatricians consented to participate. Eligible paediatricians were approached by email and selected based on purposeful sampling regarding urban/rural distribution. Table 1 gives an overview of how many participants were recruited and interviewed in each category.

Parents were included if at least 1 of their children had been diagnosed with 1 of the 4 most frequent MHP diagnoses indicated by the ICD code[2] (10th revision), was insured by BKK, and had been included into the programme by a HC qualified paediatrician. Parents and children were only included if they were aware of the diagnosis (self-statement). Included diagnoses were a) developmental disorder of speech and language (ICD Codes: F80.0-F80.9), b) head and abdominal pain (somatoform) (G44.2, G43.0, G43.1, F45.4, R10.4), c) conduct disorder (F68.8, F91.0-92.9, F94.0-95.9, F98.3-F98.9) and d) non-organic enuresis (F98.0). Eligible parents were invited by their health insurance by letter. We interviewed parents of children under 14 and consenting adolescents aged 14 and older. All invited participants received age-appropriate study information with the possibility to contact the study centre in case of questions. In total, 322 parents and 10 adolescents were willing to be interviewed. By the time of response, 1 adolescent had reached majority age and was therefore excluded. A total of 128 parents fulfilled our inclusion criteria. Potential participants were then selected based on purposeful sampling, according to principles of maximum variance regarding diagnosis, age, gender, social class and urban/rural distribution.

Table 1 Overview of recruited and interviewed participants

	Paediatricians	**Parents**	**Patients (≥ 14 Jahre)**
Potential HC participants	577	565	29
Interested in an interview	23	322	10
Diagnosis is known	-	128	-
Withdrawals	*0*	*5*	*6*
Selection			
Interview feasible	**14**	**22**	**4**
	11 PAED 3 DEV		

Data protection and ethics

Approval from the Ethics Committee and the Data Protection Officer of the Medical Faculty of the Ludwig-Maximilians-Universität Munich was obtained prior to the start of the study. All study participants were informed of data protection measures and signed an informed consent form before each interview. Participation was voluntary. Paediatricians and families were offered a compensation of 30 and 40 Euro, respectively. The participants were informed about the confidentiality of the interview and their opportunity to withdraw at any time without giving any justification.

Data collection

Interviews were conducted exclusively via telephone because of geographical distances and feasibility reasons. Since the interviews were conducted via telephone and recorded using audio devices, field notes were not necessary. The interviews were conducted by 1 researcher (SD, VL) skilled in qualitative research. Interviews were also randomly and intermittently supervised by a second researcher (SD, VL, EG, all female (female study team)), for reasons of quality control. In this sense, assumptions and attitudes, occurrences of new themes and the point of data saturation were constantly checked and discussed by the researcher involved (internal and external validity).

Prior to the start of the actual data collection, we led an exploratory interview with the HC developer as named by PaedNetz (not shown in this publication). Problems of real-world programme implementation, facilitators and barriers of the programme and potential need for improvement were reported as most relevant issues. Based on this interview, we constructed interview

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[1] Status as of 1st March 2018

[2] The International List of Causes of Death (ICD) is a diagnostic classification standard for clinical and research purposes: "ICD defines the universe of diseases, disorders, injuries and other related health conditions, listed in a comprehensive, hierarchical fashion" [26].

guidelines for paediatricians and families. Our considerations were also substantiated by international studies assessing facilitators and barriers to manage MHP in paediatric care on the part of the doctors [17] as well as facilitators and barriers of parents seeking help for their child [27]. Following this, the guide contained questions regarding acceptability of the HC, satisfaction with MHP care in the context of the programme, quality of interaction with the paediatrician, decision making processes and shared decision making, as well as potential need for improvement. In a second step, we conducted interviews with HC qualified paediatricians incorporating their perception to further refine the interview guides for families. In this sense, we led exploratory interviews with 11 out of 21 parents before the interview guide was finalised. The guidelines were constructed according to Helfferich [28]. The structure of the interview guideline ensured that all important predetermined topics were covered, that the conversation could be guided in a targeted manner and that important topics were not forgotten. The open nature of the questions allowed expression of individual concern. Prompts and interview guides were subsequently pretested to assess understandability, phrasing and appropriateness of wording. All interviews were included in the analysis. The rigorous process of data triangulation is illustrated in Figure 1.

Interviews were audio-recorded and subsequently transcribed verbatim. Participants did not get the opportunity to review the transcripts. There were no repeat interviews. Interviewers were instructed on how to keep the conversation going by concrete inquiries of the interview guideline. In case of distress and sensitive issues, the researchers were trained to keep a friendly but professional conversation, to remain as neutral as possible and keep the focus on the topic of inquiry. Sample size was determined by saturation. The interview guides and supplementary information to the methodological approach are given in the additional file 1.

Data analysis

Two researchers (SD, VL) analysed the transcripts independently of each other. Following the structured interview guide, a content analysis approach derived from Philipp Mayring [29, 30] was applied.

The aim of this approach is to create a category system in which each text passage is classified, and the structure of the material is recorded. This is done by defining categories, using classic examples, and coding rules. Following this approach, the material is systematically analysed by the previously developed category system. A deductive and an inductive approach to coding were chosen, which allowed to deductively allocate statements from the interviews to the various main topics ("metacodes") of the interview guideline. Concurrently, the inductive

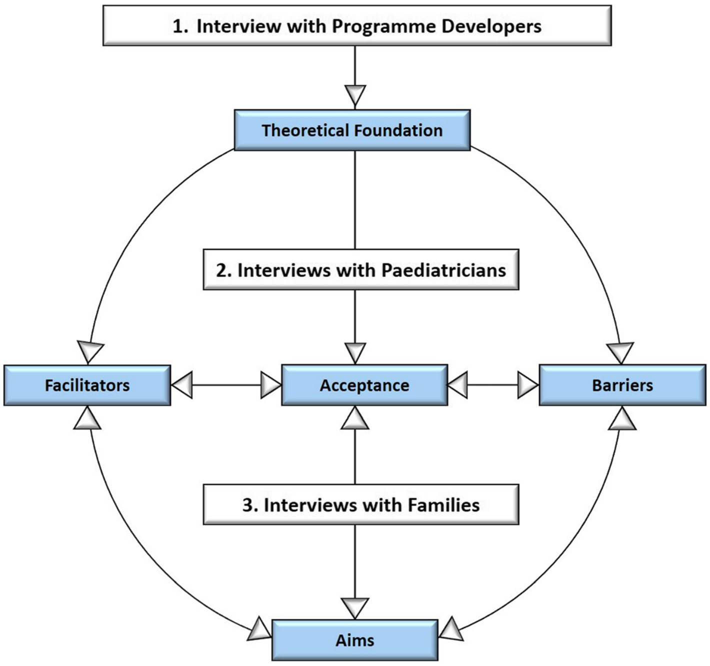

Fig 1 Process of data triangulation in the interviews with programme developers, paediatricians and families

procedure enabled the coding of the interviewees' statements within a priori defined categories while also developing new categories that had not previously been defined. Following this, the relevant text passages were systematically identified and assigned to the appropriate meta- and subcodes (Figure 2).

During the coding processes and generalisation of the material, new categories were added to the coding tree in cases where a statement could not successfully be assigned to one of the pre-specified codes (inductive approach). After having coded a small number of interviews, the coding tree was discussed among authors and adjusted accordingly. Added codes were then either differentiated or removed.

For example, the metacode “acceptance” comprises 2 subcodes in the paediatricians’ coding tree, and 1 subcode in the parental tree. Paediatricians’ acceptance of the HC was assessed, but paediatricians were also asked to describe the acceptance of the programme by the patient’s parents and the patients themselves (subcode: “Parental acceptance of the HC - perception *of the doctors”*). This was contrasted with the parental statements regarding their acceptance or rather satisfaction with medical care in the context of the HC.

Table 2 shows an extract of the parental metacode “facilitators” including the 1st and 2nd subcode (“doctor takes time” and “trusting relationship”) and classic interview statements within the respective category. The presentation of results is limited to this meta-level as the interviews and interview trees are too complex to show in detail.

As only 4 adolescents consented to be interviewed, data saturation could not be reached in this group. Instead of developing a separate coding tree, we used the adolescents’ statements as a supplement to the parental interviews. We therefore used the same coding system that was applied to the parents’ interviews.

F4 (version 2012. Dresing & Pehl GmbH, Marburg, Germany, http://www.audiotranskription.de/) was used for transcription, MAXQDA 18 (VERBI Software; Consult, Sozialforschung GmbH, Berlin, Germany) was used for coding and analysis.

COREQ (COnsolidated criteria for REporting Qualitative research) checklist was used to support

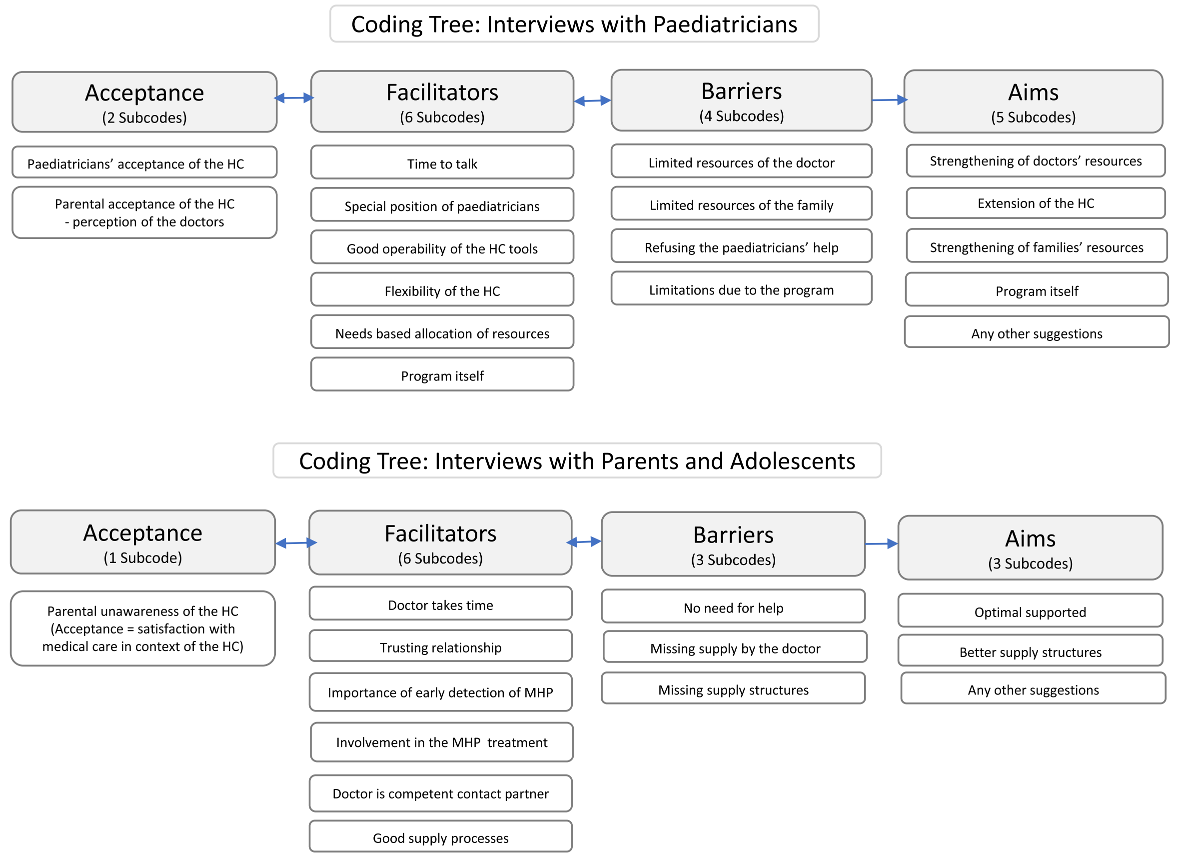

Fig 2 Extracted meta- and subcodes from the interviews with paediatricians, parents and adolescents

Table 2 Extract of facilitators within the parental coding tree

Extract of facilitators	Subcodes	Category	Classic example
	Doctor takes time	extensive consultation	"That's really one of the points why we've never changed. She really takes a lot of time for us." (P11)
		doctor is there (in hard times)	"He said, 'Please come immediately' and he did not react the day after tomorrow or on Monday. " (P15)
		uncertain cases are clarified in depth	"...they are thinking about it and are catching up with the opinion of the colleague, that has often been the case" (P19)
	Good relationship with the doctor	doctor is person of trust	"I really trust her and her opinion." (P11)
		knowledge of the family background	"In such a situation it helps enormously that the doctor also knows about the situation of the child" (P1)
		in good hands	"I just feel comfortable with her. She already has helped me a lot in certain respects." (P16).
		empathy	"When it got emotional, she called for a helper to occupy him (her son) so that we could continue talking privately" (P20)
		likeable person	"Then I came to the doctor that was even more cordial." (P20)
		get along well with children/ability of treating children well	"The children also like to go there" (P15)

the complete and transparent reporting of our research. The complete checklist is provided (see additional file 2).

Results

From November 2017 to November 2018, 14 paediatricians, 22 parents and 4 adolescents were interviewed. They were randomly selected from a total of 23 consenting paediatricians, 322 consenting parents and 10 adolescents, until saturation was reached. 5 parents who had initially given their consent and were randomly selected, withdrew their participation once they were contacted. Reasons were lack of motivation or time. All consenting adolescents were contacted and 6 withdrew. In 2 cases, their parents agreed to be interviewed instead. All randomly selected paediatricians participated as shown in Table 3.

Description of study participants

11 of the 14 interviewed paediatricians were male. 3 paediatricians stated that they had also been involved in contract negotiations regarding HC and in HC development. 8 practices were located in a major city, 6 were located in a small or medium-sized town. Duration of interviews was 11 minutes on average (range: 5-23). The characteristics of the interviewees are shown in Table 3.

Regarding parents, a total of 19 mothers (age range 32-49) and 3 fathers (age range 39-47) were interviewed. Number of children per family ranged from 1 to 3. In 5 families, the child had a migration background.[3] The majority of the families (n=12) were inhabitants of a small (> 5.000) or medium-sized town (> 20.000). 7 families were residents of a major city (> 100.000 inhabitants). Average duration of interviews with parents was 18 minutes (range: 4-46), with adolescents 13 minutes (range: 3-17).

Metacodes and subcodes

Based on the results of the exploratory interviews prior to the start of the actual data collection, we defined 4 metacodes “acceptance”, “facilitators”, “barriers” and “aims”. For these, we defined 17 subcodes for paediatricians and 13 subcodes for parents/adolescents. All metacodes and subcodes are shown in Figure 2. The following short forms are used: “DEV” (HC co-developers), “PAED” (paediatricians), “PAR” (parents) and “ADOL” (adolescents) to facilitate reading.

Metacode “Acceptance”

All DEV stated that the aim of the programme was to facilitate diagnosis and treatment of MPH in primary paediatric care to reduce the need for referrals. Separate from some rejection and indifference in the beginning

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[3] Migration background was defined based on information about the country of birth of the child and the country of birth and nationality of the parents. In this sense, children and adolescents who had immigrated from another country and had at least 1 parent not born in Germany and/or of non-German citizenship had a migration background [31].

Table 3 Demographic characteristic of paediatricians, parents and adolescents

Demographic Characteristics	**Paediatricians (*n*=14)**	**Parents (*n*=22)**	**Adolescents (*n*=4)**
Gender (female /male)	3/11	19/3	2/2
Age range in years	n.a.	32-49	14-17
Age of the child (<14 years) Mean (range)	n.a.	7.1 (3-14)	n.a.
Diagnosis of the child / adolescent			
- Head and somatoform abdominal pain	n.a.	3	1
- Developmental disorder of speech & language		5	-
- Non-organic enuresis		4	-
- Conduct disorder		5	1
- Combination of two		5	-
- None of them / do not know		-	2
Highest educational qualification	n.a.		n.a.
- University degree		6	
Higher education entrance qual.		5	
- Intermediate secondary school		6	
- Secondary school		4	
- Other		1	
School currently attended by children			
- University of applied sciences	n.a.	n.a.	1
- Intermediate secondary school			3
Migration background	n.a.	5	0
Population size of place of residence			
Major city (> 100,000)	8	7	4
Medium sized town (>20,000)	4	4	-
Small town (> 5,000)	2	8	-
Country town (≤ 5,000)	-	2	-
n.a.	-	1	-

among their ranks, this intention was generally well received among colleagues. PAED perceived their own competence for children with MHP as improved.

> I simply can’t imagine general routine work without it anymore. (Transcription of Interview partner D5 (DEV), p. 1, lines 14-20)

PAED had the impression that PAR did not care about being in a specific programme but appreciated their increased efforts.

> They are happy when the medical conditions we are dealing here with (…) can be treated in the practice of their confidence on an outpatient and on-site basis. (Transcription of Interview partner D5 (DEV), p. 3, lines 86-91)

Accordingly, PAR and ADOL reported that they did not realise that there was a programme specifically designed for their needs.

Metacode “Facilitators”

DEV stated that flexibility and operability of the programme were planned and implemented right from the start. PAED appreciated the additional allocation of resources as a token of trust and valuation. Repeatedly, PAED reported that the material provided by HC was helpful and facilitated diagnosis and decision-making. They also valued the continuing training opportunities.

> It allows and structures the approach, in the diagnostics itself in the practice, but also for the diagnosis and, finally, in the decision whether we want and we are able to continue the treatment in the

> practice. (Transcription of Interview partner D14 (PAED), p. 1, lines 12-16)

PAR and ADOL felt that their PAED allocated a large part of his consultation time to their problems. This was perceived as an indication of high quality of care. PAR mostly reported that they trusted their PAED even with more sensitive issues. Quality of communication and an inclusion in the process of decision-making were appreciated.

> I am very satisfied, got a lot of advice and I think, if I go there again now and say: "Well, it has not worked yet", I will be well advised again. At the moment, I cannot think of a better way. (Transcription of Interview partner P13 (PAR), p. 9, lines 348-351)

Interaction between care providers, e.g. good connections between PAED and speech therapists, was positively noted.

Metacode "Barriers"

Although substantial financial resources were allocated through the programme, PAED still perceived their opportunities for interaction with the patients as limited. Time and budgetary restrictions were still reported as major barriers to success. Due to the large amount of managed care contracts PAED also reported feeling overwhelmed.

DEV admitted that a realistic resource estimate should be made before the enrolment of a patient into the HC. PAED reported that it was still difficult to refer patients, and that parents might have problems to follow-up on that referral.

> We detect children with MHP, but it still takes far too long until they receive therapy. (Transcription of Interview partner D13 (DEV), p. 6, lines 205-213)

PAED perceived distinct social disparities, and cultural and linguistic barriers which could not be resolved by the programme. Also, they felt that parents would not necessarily trust their expertise for sensitive issues in MHP.

Some PAR reported feeling reluctant about contacting a physician for MHP of their children, either because this might be too trivial for the paediatrician, or because more specialised help would be needed. However, PAR also reported that they had delayed consulting the PAED because they had underestimated the problems.

> Because of such small things like abdominal pain I do not go to the doctor." (Transcription of Interview partner P16 (parent), p. 4, lines 160-161)

PAR explained this by their impression that the PAED seemed to be stressed and in a rush. In this vein, PAED were perceived as hardly encouraging and not participative in treatment decisions, withholding treatment options or disregarding parents' concerns. One mother felt that she was not sufficiently empowered to support her child's therapy more actively.

> When you have a problem, you need to convince the doctors to support you. (Transcription of Interview partner P14 (PAR), p. 1, lines 16-17)

PAR reported problems with secondary and tertiary care, namely long waiting lists for specialist appointments, long distances to the next specialised clinic, limited prescription options of the PAED, and a general lack of insurance coverage for many treatment options. Recommendations were perceived as not compatible with the daily life of a family.

Metacode "Aims"

DEV and PAED underlined the need for improved interdisciplinary networking. DEV also mentioned conflicts with specialist care providers and proposed establishing mandatory care pathways. Several detailed recommendations for programme improvement were made, e.g., to facilitate prescription, and to add options to directly strengthen the resources of families (e.g. assistant at home, language support).

PAED still proposed higher reimbursement of their services and improved quality control of HC. Universal coverage by all statutory health insurance funds was mentioned.

> Our goal and our hope are that at some time all insurances will take over this service and will also take for granted that they are responsible for MHP. (Transcription of Interview partner D5 (DEV), p. 6, lines 207-210)

Generally, PAR/ADOL felt sufficiently supported. However, PAR proposed to improve access to services, e.g. by allowing telephone consultations, a better communication between providers, and a more convenient localisation of specialised services.

> Specialists for both of these topics are spread quite widely over the country. You really need a connection on site and if there were more cooperation with the paediatricians, that would be great. (Transcription of Interview partner P17 (PAR), p. 11, lines 326-333)

PAR proposed to involve other health professionals such as midwives and alternative practitioners in the programme. Opening treatment options e.g. including homeopathy, and financial aids were additionally mentioned.

Discussion

This qualitative evaluation of a primary care-based programme for children and adolescents with mental health problems revealed high appreciation and acceptance of the programme among paediatricians and families. Adolescents and parents were generally satisfied with the care provided although they did not realise that the programme was specifically targeted at their needs. Furthermore, they mentioned barriers and opportunities for improvement.

Our results are in line with the international literature reporting a good applicability of structured MHP programmes in paediatric care with? increasing screening rates and treatment of MHP in primary care settings but reports for Germany remain scarce [20–23, 32]. However, paediatricians' potential for early detection of MHP in primary care is well documented, based on a high participation rate and acceptance of primary preventive medical examination in children and adolescents [16, 33]. In the Netherlands, politicians have been promoting MHP treatment within primary healthcare for several years now [20, 34]. Almost all Dutch residents are registered with a general practitioner (GP) and the majority of children and adolescents visit their GP at least once a year. The structure of the Dutch Project 'Eureka' is quite comparable to the HC programme: GPs receive a lump-sum for the comprehensive assessment of children presumed to have a MHP, as well as any further treatment of the MHP in primary care. In addition, cooperation between primary and secondary mental healthcare was stimulated, leading to an increase in the provision of social workers and primary care psychologists. As a result, GPs in the intervention group were able to identify more emotional and behavioural problems than GPs in the control practices and were more reluctant to prescribe psychopharmacological medication to children. Referral rates to mental healthcare remained relatively steady, but the referrals switched from specialised to primary mental healthcare. However, feedback of the patients and parents was not included. The question whether the improved screening leads to improved access to care and improved outcomes was not addressed either.

Parents and adolescents in our study reported satisfaction with the care provided and with the involvement in treatment decisions. As parents are the gatekeepers to seeking help for their child, parental perception of barriers and facilitators to MHP treatment access are paramount. In literature, systemic and structural issues, views and attitudes towards services and treatment, the knowledge and understanding of MHP and the help-seeking process as well as the family circumstances were found to be crucial determinants for parents' decision to seek help [27]. This is in line with the observations expressed by paediatricians in our study. It indicates that the HC programme should focus more intensely on these barriers. Our interviewed paediatricians made several suggestions to address these barriers (e.g. assistant at home). In addition, enhancing parental awareness of MHP and their perception of paediatricians' expertise might reduce the risk of delayed therapy.

A recent meta-analysis found that a lack of providers and resources, extensive waiting lists, and financial restrictions were major barriers for successful MHP management in children and adolescents [17]. Quite similarly, paediatricians in our study complained about time and budgetary restrictions. This was unanticipated given that the HC programme was specifically designed to facilitate access by bringing more resources into the system. Increasing funding for billable services will not necessarily be part of the solution. In contrast, it might be important to strengthen and to expand formal and informal networks as well as systematically and officially include allied health professionals into structured care pathways as shown in the Eureka project. For instance, a model programme in Baden Württemberg, Germany, successfully implemented inter-professional quality circles that subsequently increased collaboration and networking [35], or collaborative nurse-led self-management support for primary care patients [36].

Our study is the first evaluation of a primary care-based programme for children and adolescents with mental health problems reflecting the patients´, parents' and paediatricians´ perspectives. Our approach enables greater depth to the application of the programme. We also want to identify related barriers, facilitators and need for improvement in the treatment of children and adolescents with MHP. These findings will also complement the results of the cohort study among 800 patients with MHP on effectiveness and utilisation of the HC programme (currently examined elsewhere). By integrating the professional experiences of the paediatricians and families involved, further optimisation of the programme can be achieved. Furthermore, we believe our results are most likely to be applicable and transferable to other programmes involving paediatricians and families in primary care with the aim of providing optimal care and support to patients and their parents.

The main strength of our study lies in the naturalistic approach and the openness of all interviewees. Despite the sensitive topic, we felt that participants did not hold back their opinions and were eager to talk about their experiences. The inclusion of three co-developers of the HC among the interviewed paediatricians enriched our findings, too, enabling the distinction of the HC's anticipated goals as compared to its feasibility in everyday practice.

Nevertheless, this study has some limitations. As for all studies relying on qualitative research, interviews are always at least to some degree subject to the assumptions and attitudes of the researchers involved. Thus, the assumptions were repeatedly critically examined with respect to the methodological approach and the interpretation of results. However, we are confident that the qualification of interviewers and coders has minimised this potential bias.

HC covers 16 MHP, but the evaluation of the HC programme initially focused on four selected indications. Arguably, these are the four most common MHP showing up in paediatric practices and responding well to the HC, as specified by paediatricians of PaedNetz Bavaria, but this evaluation needs to be extended. The HC is currently limited to persons insured at the BKK funds (condition: enrolled in the programme "BKK STARKE KIDS"). Since the BKK is one of the larger statutory health insurance funds with 10.9 (Bavaria: 2.4) of a total of 73.0 million insured persons in Germany[4] [37], the results of our study are most likely to be generalisable for Germany. Furthermore, as shown in the International context, primary care programmes like the HC can be integrated into different health system structures [20, 21].

When interpreting the study results, there is a risk of attributing the described differences to the implementation of the HC. It has to be noted that physicians' personal commitment will still be a major driver of positive experiences and high satisfaction of the families.

Conclusion

Primary care paediatricians are providing low-threshold care and have decisive potential in the care of children and adolescents with MHP. The HC programme currently focuses on paediatricians' resources. Our study showed several strengths but also shortcomings of this approach. A promising future direction would be to involve all necessary care providers to avoid referral bottlenecks. Furthermore, inclusion of parents and their children in decision-making should be expanded.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12875-020-01344-1.

Additional file 1:. Contains the interview guides, in- and exclusion criteria of study participants and additional information to the methodological approach of Mayring.

Additional file 2:. Contains the completed COREQ (COnsolidated criteria for REporting Qualitative research) Checklist.

Abbreviations

MHP: Mental health problems; HC: Health coaching; DEV: HC co-developers; PAED: Paediatricians; PAR: Parents; ADOL: Adolescents

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Authors' contributions

SD was the principal author of this article and. Material preparation, data collection and analysis were performed by SD and VL. KD, ML and OL contributed to the study conception and design. EG supervised the project. EG and LS provided critical feedback and helped shape the research, analysis and manuscript. The first draft of the manuscript was written by SD. All authors contributed to the final version of the manuscript.

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Availability of data and materials

Due to the nature of this research, participants of this study did not agree for their data to be shared publicly and as a result supporting data is not available. MAXQDA 18 (VERBI Software; Consult, Sozialforschung GmbH,

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[4] Status as of 1st July 2019

Berlin, Germany) was used for coding and analysis. The coding system can be provided on demand.

Ethics approval and consent to participate

Prior to inclusion, all participants had to sign a written informed consent form. Written informed consent was also obtained from a parent or guardian for all minor participants under the age of 18. The study was approved by the ethical committee of the Ludwig-Maximilians-Universität München (reference number 17-431) and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. The study was also reviewed by the data protection officer of the Ludwig-Maximilians-Universität München.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

Additional File 1: Supplementary Information

to

“We’re in good hands there.” - Acceptance, barriers and facilitators of a primary care-based health coaching programme for children with mental health problems: a qualitative study (PrimA-QuO)

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Contents

Appendix A: Inclusion and exclusion criteria of study participants

A) Children/adolescents with mental health problems and their parents

Inclusion criteria:

- children aged 0-17 years insured by BKK and enrolled in the programme “BKK STARKE KIDS” and their parents
- Children had been diagnosed at least with one of the four most frequent MHP diagnoses:
  - developmental disorder of speech and language (ICD-10: F80.0-F80.9);
  - head and abdominal pain (somatoform) (ICD-10: G44.2, G43.0, G43.1, R10.4, F45.4);
  - conduct disorder (ICD-10: F68.8, F91.0-92.9, F94.0-95.9, F98.3-F98.9)
  - nonorganic enuresis (ICD-10: F98.0);
- Last paediatrician visit less than six months ago
- Attending paediatrician was qualified in HC and offered the BKK HC programme to the child
- Signed informed consent for children aged six years and older
- Signed informed consent from parents

General exclusion criteria:

- Tentative diagnosis of MHP
- Insurance gap >30 days

B) Paediatricians

Inclusion criteria

- Resident paediatrician in Bavaria
- Written consent and invitation to participate accepted
- Qualified to participate in the HC programme

Exclusion criteria

- Practices that treat private patients only

Appendix B: Interview guidelines

A) Interview guideline for paediatricians

1. First, could you tell us when and how you became aware of the BKK health coaching programme?
2. Do you notice any changes in comparison to a standard treatment?
3. In your opinion, how work-intensive is the implementation of the programme?
4. Could you describe the acceptance of the programme by the patient's parents and the patients themselves?
5. To which extent are the general principles participation, patient orientation and strengthening of existing resources fulfilled by the programme? What do you think?
6. Is there anything you particularly like about the programme? If so, what is it?
7. Is there anything that bothers? Where do you see need for improvement?
8. Where do you believe that additional support concerning the care of the patients and their parents is required?
9. Apart from that, is there anything else that is particularly important for you concerning patient care that you would like to address?

optional: additional questions

B) Interview guideline for parents of patients

Part 1 (getting started): Relationship with the paediatrician

1. First, could you briefly tell us how you heard about your child's paediatrician?
2. How would you describe the relationship with your paediatrician?

Part 2: Health Coaching experiences in the doctor's office

3. In our study, we focus on four diagnoses. These are (1) head and abdominal pain, (2) conduct disorder, (3) enuresis and (4) developmental disorder of speech and language. When you think of your child's last visit to the doctor due to any one of these diagnoses, could you describe how you experienced this visit?
4. How would you describe the health development of your child throughout the last year?

Part 3: Health Coaching principles: participation, patient orientation and strengthening of existing resources

5. As parents, would you like to be involved in the treatment of your child, and if so, how do you feel about the conversations with your paediatrician?

6. To what extent are you involved in the treatment of your child and the decisions made by your paediatrician?
7. Have you received any information material from your paediatrician that either you or your child found helpful? If so, what did you receive?

Part 4: Theoretical knowledge about the Health Coaching programme

8. Maybe you know that your child is treated according to the BKK Health coaching programme of your health insurance. Can you tell us what you know about the programme?

Part 5 (ending): points for improvement

9. Where do you see additional need for support concerning the care of your child? What do you think could be improved?
10. Apart from that, is there anything else that is particularly important for you, when it comes to your child’s care, that you would like to talk about?

optional: additional questions

c) Interview guideline for Adolescents (≥ 14 years)

Part 1 (getting started): Relationship with the paediatrician

1. When you answered the questionnaire, you may have noticed that we are referring to 4 complaints. These are headache and abdominal pain, difficulties in social behavior, bedwetting and language problems. When you think about your last visit to your paediatrician, could you tell us what you found memorable from this visit?
2. How do you feel when you are at your doctor’s office?
3. Can you describe how you get along with your paediatrician?
4. Concerning your health: How do you realize that you are feeling better or worse?

Part 2: Health Coaching principles: participation, patient orientation and strengthening of existing resources

5. As an adolescent/young adult, would you like to participate and decide what is happening to you at the doctor’s office?
6. Can you describe how you and your doctor are talking to each other?
7. Can you describe how your paediatrician involves you and your parents in the treatment?
8. Did the doctor give you any materials or tell you something that helps you to handle your problems better?

Part 3: Theoretical knowledge about the Health Coaching programme

9. Maybe you know that you are treated according to the BKK health coaching programme. That's a programme from your health insurance. What do you know about this programme?

Part 4 (ending): points for improvement

10. What else do you want/ wish from your paediatrician or from others?
11. Is there anything else you would like to talk about that we haven't discussed yet?

Optional: Additional questions

Appendix C: Methods appendix

Structuring content analysis by Mayring

The process model of qualitative content analysis according to Mayering [1,2] comprises of nine steps (ESM_Fig. 1).

Structuring content analysis by Mayring
1. Determination of the material
2. Analysis of the emergence situation
3. Formal characteristics of the material
4. Determine the direction of the analysis
5. Theoretical differentiation of the question
6. Determination of the analysis techniques, definition of the concrete process model
7. Definition of the analysis units
8. Analysis steps using the category system (Abstract/ Explication/Structuring) and review of the category system of theory and material
9. Interpretation of the results in the direction of the question and application of content-analytical quality criteria

ESM_Fig. 1*: Structuring content analysis by Mayering*

After description of the starting material follows the elaboration of the analysis question (step 1 and 2). This was followed by the definition of the analysis technique, the determination of the process model and the determination of the analysis units (step 4-7). The analysis should provide information on the acceptance, barriers, funding factors and potential for improvement of the HC programme. In addition, the question was how the demands of patients and parents of the medical care of the child and the actual offer match. The interviews were segregated into distinct manageable units ('meaning units'), which were subsequently defined. Meaning units are text passages which relate to one topic, enabling the creation of a coding guideline with meta- and subcodes. The coding tree with the metacodes 'acceptance', 'facilitators', 'barriers' and 'aims' for the HC programme and subcodes were created based on theoretical considerations before starting the analysis. For instance, a 'trusting relationship with the paediatrician' and 'communication at eye level and participation during treatment' are examples of subcodes within the metacode 'facilitators'. Subsequently, the subcodes were arranged according to their content within the predefined metacodes. The category system was applied and revised based on the material (step 8). The meaning units were systematically identified by two independent researchers (first and second author) and assigned to the appropriate meta- and subcodes. Concrete passages that fall under one category and are considered as typical examples of this category are cited as so-called 'anchor examples'. Coding rules were set where demarcation issues between codes arose to allow clear mapping. In the course of the coding processes and generalization of the material, new categories were added in the coding tree in cases where a meaning could not be successfully assigned to one of the pre-specified codes (inductive approach). In a continuous process, the coding guide was refined by differentiating the added codes in a more meaningful way or by removing them.

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Appendix

Table 1: Disease indications covered by the BKK STARKE KIDS Health Coaching. Bolded indications were chosen for the evaluation in the PrimA-QuO study.

No	Indication	ICD-10 Code
1	Crying infants	F43.2
2	**Developmental disorders of speech and language**	**F80.0 – F80.9**
3	Attention disorders/hyperkinetic syndrome (ADHD)	F90.0, F90.1, F90.8, F90.9
4	Parenting problems	F92.0
5	Defiant behavior	F91.3
6	**Non-organic enuresis**/soiling/enuresis nocturna	**F98.0**, F98.1, K59.0, K59.1
7	Sleep disorders	F51.0, F51.2, F51.3, F51.4, F51.5, G47.0, G47.2, G47.9
8	Emotional disorders	F93.0, F93.1, F93.2, F93.3, F93.8, F93.9
9	**Conduct disorders**	**F68.8, F91.0, F91.1, F91.2, F91.8, F91.9, F92.8, F92.9, F94.0, F94.1, F94.2, F94.8, F94.9, F95.0, F95.1, F95.2, F95.8, F95.9, F98.3, F98.4, F98.5, F98.6, F98.8, F98.9**
10	**Head and abdominal pain (somatoform)**	**R10.4, G43.0, G43.1, G44.2, F45.4**
11	Eating disorders (anorexia/obesity/bulimia)	F50.0, F50.1, F50.2, F50.3, F50.4, F50.5, F50.8, F50.9, F91.0
12	Sexual abuse	T74.0, T74.2
13	Feeding disorders	F98.2
14	Developmental disorders	F83, F80.1, F81.0, F81.9, F82.0, F82.1, F89
15	Anxiety disorders	F40.0, F40.00, F40.01, F40.1, F40.2, F40.8, F40.9, F41.0, F41.1, F41.2, F41.3, F41.8, F41.9, F43.1
16	Suspected abuse	T74.9
17	Suspected media addiction (since 01/01/2023)	F63.8

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