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zum Erwerb des Doctor of Philosophy (Ph.D.)
an der Medizinischen Fakultät der
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Optimised primary care for children and adolescents with mental health problems – Evaluation of a Health Coaching programme (PrimA-QuO)

– A mixed methods approach comprising a cohort study and a qualitative semi-structured interview study

vorgelegt von:
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I hereby declare, that the submitted thesis entitled:

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is congruent with the printed version both in content and format.

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List of abbreviations

BKK-LV Bayern	Betriebskrankenkassen Landesverband Bayern (Bavarian State Association of company health insurance funds)
BVKJ	Berufsverband der Kinder- und Jugendärzte (a professional association of paediatricians in Germany)
HC	Health Coaching
ICD	International Classification of Diseases and Related Health Problems
ICF	International Classification of Functioning, Disability and Health
IPTW	Inverse Probability of Treatment Weighting
LME	Linear mixed effects (model)
MHP	Mental health problems
SDQ	Strengths and Difficulties Questionnaire (SDQ-P/SDQ-S: parental/self-assessment version)
SHI	Statutory health insurance
SK	STARKE KIDS programme; with the SK, enhanced screenings for children and adolescents throughout Germany are available

List of publications

This cumulative thesis comprises two scientific first authorship articles that were published in international peer-reviewed journals:

(1) Decke S, Deckert K, Lang M, Laub O, Loidl V, Schwettmann L, Grill E. “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 21, 273 (2020). https://doi.org/10.1186/s12875-020-01344-1. (Hereafter termed “Publication I”)

(2) Decke S, Hamacher K, Lang M, Laub O, Schwettmann L, Strobl R, Grill E. Longitudinal changes of mental health problems in children and adolescents treated in a primary care-based health-coaching programme – results of the PrimA-QuO cohort study. BMC Primary Care 23, 211 (2022). https://doi.org/10.1186/s12875-022-01780-1. (Hereafter termed “Publication II”)

1. Contribution to the publications

1.1 Contribution to publication I

I, Siona Bührmann (SB, née Decke), hereby declare that I am the first author of the scientific publication “”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)”.

Eva Grill (EG), Otto Laub (OL), Martin Lang (ML), Karina Hamacher (KH, née Deckert) and Lars Schwettmann (LS) and I were involved in planning the interview study. Under the supervision of EG, I planned and prepared the data collection, analyses and publication of results. This includes obtaining ethics vote, implementing data protection measures, preparation of interview guidelines, pretesting of interviews, conduction of a pilot study and elaboration of an analysis strategy. I, KH, OL and ML were involved in selecting the study participants. I conducted the interviews, collected and analysed all data. The transcripts were also independently analysed by VL to increase validity of the results. I drafted the manuscript and designed all figures and tables. EG and LS provided critical feedback and helped shape the research, analysis and manuscripts. All authors contributed to the final version of the publication.

1.2 Contribution to publication II

I, Siona Bührmann (SB, née Decke), hereby declare that I am the first author of the scientific publication “Longitudinal changes of mental health problems in children and adolescents treated in a primary care-based health-coaching programme – results of the PrimA-QuO cohort study”.

Eva Grill (EG), Lars Schwettmann (LS), Otto Laub (OL), Martin Lang (ML) and Karina Hamacher (KH, née Deckert) and I were involved in planning the cohort study. I planned and prepared the collection of data including the implementation of data protection measures, obtaining ethics vote, planning the baseline and follow-up questionnaire as well as planning the invitation procedure. I conducted a pilot study and pretested the online questionnaire. I, KH, OL and ML were involved in the selection of study participants. I supervised the responses and established measures to increase response rate. I planned and performed the data analysis. Ralf Strobl (RS) provided statistical advice and helped shape the analyses. I drafted the manuscript and designed all figures and tables. EG supervised the study, provided critical feedback and helped shape the research, analysis and manuscripts. All authors contributed to the final version of the publication.

2. Introductory summary

2.1 Introduction

2.1.1 Relevance

In Germany, every fifth child between 3 and 17 years struggles with mental health problems (MHP) (3). Developmental disorders are by far the most frequent diagnosis, but there are differences in terms of age and gender of the child (4). The child's quality of life and well-being can deteriorate. In addition, MHP can negatively affect the family and social environment, school performance and later professional development (5-7). There is a risk that MHP will become chronic or be accompanied by comorbidities (7, 8). In addition, MHP can place an economic burden on families and health systems (9-11) and are therefore considered an especially important public health problem worldwide (12, 13).

It is estimated that barely 30% of children and adolescents suffering from MHP in Germany (14) or different industrial countries (15, 16) receive suitable medical treatment. There are efficacious treatment options (e.g. speech and language therapy) that are based on empirical and scientific evidence (17-19). However, adequate and timely treatment is still a major challenge for care. The main barriers hindering or retarding timely identification and access to professional MHP treatment are long waiting times for an appointment accompanied by time-consuming travelling distances, facilities failing to meet the needs of children and their parents and a lack of multisectoral involvement (12). Parents have a key role in seeking help for their child. In addition to the before mentioned aspects, parents' opinions and perception of MHP treatment options and possible services are highly relevant. What they know about and how they understand MHP and the whole process of receiving help plus other circumstances in the family were determined as major aspects in deciding whether help is sought or not (20).

Parents usually address primary care paediatricians first in case of MHP, or paediatricians discover MHP in regular screening examinations (21, 22). They can detect and treat MHP relatively early especially due to a high acceptance of the check-ups, a large number of children who take these examinations and because of a relationship of trust that has often been built up over many years (21, 23). However, many paediatricians appear to lack adequate training in identifying and treating MHP in primary care (24, 25). Many children and adolescents suspected of having MHP are – depending on the diagnosis – referred to social paediatric centres offering special knowledge of MHP, to logopaedics or psychotherapists (26) – even though low-threshold services would be more appropriate. This in turn jeopardises timely treatment of more serious cases that need immediate treatment.

In-depth training has shown particular promise in strengthening and supporting paediatricians' qualifications in identifying and in treating MHP, as shown in international primary care studies (27-30). After training, screening rates and treatments in primary care went up. In this context, an essential statutory health insurance fund in Germany (Betriebskrankenkassen Landesverband (BKK-LV)), in cooperation[1] with a professional association of paediatricians (Berufsverband der Kinder- und Jugendärzte (BVKJ e. V.) offered a programme for their policyholders in 2013 (31). The Health Coaching (HC) programme aims to standardise MHP anamnesis and treatment procedures by training primary care paediatricians. The paediatricians are provided with guidelines for recommended actions and working materials for 16 (current status) frequently occurring MHP. They receive training in the use of these guidelines (double

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[1] The BKK contract working groups (VAG) of Bavaria, Baden-Wuerttemberg and Hesse in cooperation with BVKJ and PaedNetz Bayern e.V. resolved a framework contract in accordance with Book V of the German Social Code (SGB V, § 140 a et seq. in conjunction with § 43 para. 1 no.2).

training attendance). Additional fees are available if they have completed the training and treat their MHP patients according to the guidelines[2]. In doing so, integrative care for young people suffering from MHP is meant to be improved.

The HC is assumed to be effectual and a successful programme that improves the patients' health. However, it has not yet been systematically evaluated. The benefits of the programme as well as the acceptability of HC qualified paediatricians, patients and parents involved are still unknown.

2.1.2 Theoretical content of the HC programme

In 2011, the development of the HC programme began, and all medical stakeholders involved agreed on mutual consultations that formed the basis for it. The International Classification of Functioning, Disability and Health in the version for children and adolescents (ICF-CY) (32) forms the basis for the HC components. The ICF-CY considers the particularities of developing functions and the special living environments of children and adolescents. It enables a differentiated description of unusual developmental courses. It provides the basis for interdisciplinary planning and implementation of interventions and for the management of services and resources. The HC programme's basic pillars are patient-centred medical care, participatory involvement in the treatment process and strengthening the existing resources of the child and it's family. According to these, it aims to provide children and their parents with targeted information about the various treatment options and to teach them personal management skills.

The BKK provides further financial resources for the implementation of the HC standard guidelines and it goes beyond the regular statutory health insurance (SHI) service spectrum (33, 34). The HC is based on the BKK STARKE KIDS (SK) programme, offering additional developmental check-ups for children and adolescents that are part of the SK[3]. Insured ones with MHP can also be provided with the HC programme as shown in **Publication II (Figure 2)**. In order for the HC to be implemented and services to be billable[4] the following conditions must be fulfilled: 1) the paediatrician takes part in the SK programme and 2) has completed the HC training. 3) The child is SK participant.

Currently, the HC programme is mainly applied in Bavaria, Germany[5]. Over 700 Bavarian HC qualified paediatricians are listed. Since 2015, the HC also exists throughout Germany with more than 2,100 qualified paediatricians and around 36,000 children and adolescents with MHP being treated accordingly.

To decide whether the HC programme has the potential to optimise MHP patient care and therefore, if it should be maintained or included in standard care of the SHI, the benefits of the programme and implementability in daily practice must be confirmed. In Germany, the Innovation Fund is a central health policy instrument for the promotion of new forms of health care and health services research. Funds from the SHI are used to support innovative, cross-sectoral new health care forms and projects in practice-oriented health care research, with the aim of further developing and improving SHI health care in Germany.

For this purpose, the project "PrimA-QuO – Optimised primary medical care for children and adolescents with MHP" was initiated. PrimA-QuO is a health services research project funded from 2017 to 2020

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[2] The content is not open to the public.

[3] In Germany, there is free choice of health insurance fund, and each fund can offer additional programmes for advertising purposes. Currently, 69 of the approximately 100 company health insurance funds are offering the SK programme.

[4] The HC allows for additional billing of 15 euros per 10 minutes with a cap of 180 minutes per child (on top of standard care).

[5] Bavaria is among the most populous German federal states (total population: around 13 million).

from the Innovation Committee at the Federal Joint Committee (grant number: 01VSF16032) (35). All analyses und publications presented here evaluating the effects of the HC programme were funded and produced within the framework of PrimA-QuO. A detailed study description and the methodological procedure is provided in the study protocol (36).

2.2 Research questions and objectives

The aim of the PhD project was to answer the following research questions:

1. <u>Acceptance, barriers and facilitators of the programme</u>

At first, it was examined how HC qualified paediatricians, children and adolescents (suffering from MHP and treated accordingly) and their parents perceive and accept the HC. Following this, possible strengths and weaknesses of the programme were meant to be indicated. Specifically, the following research questions were addressed:

- How is the programme accepted by paediatricians and families involved?
- What are facilitators and weaknesses of the programme’s implementation in daily practice?
- What are the facilitators and barriers of the treatment in the context of the HC programme?
- Where is need for improvement and further support?

2. <u>Effectiveness of the programme</u>

In a second step, the programme’s effectiveness in treating children and adolescents with MHP was investigated. The leading research questions were:

- What are the demographic and health-related characteristics of HC participants as compared to children and adolescents who receive standard paediatric care (control group)?
- What is the prevalence of MHP in the HC and control group?
- How do MHP change over time?
- What are the determinants of MHP over time?
- Does HC programme participation influence the change of MHP in the course of time?

2.3 Methods and analysis

The PhD project follows a mixed methods approach comprising a cohort study and a semi-structured interview study. In this sense, the strengths of both research strategies are used, and the results are interwoven interpretatively in the sense of a convergent mixed method design (37) as shown in **Figure 1.**

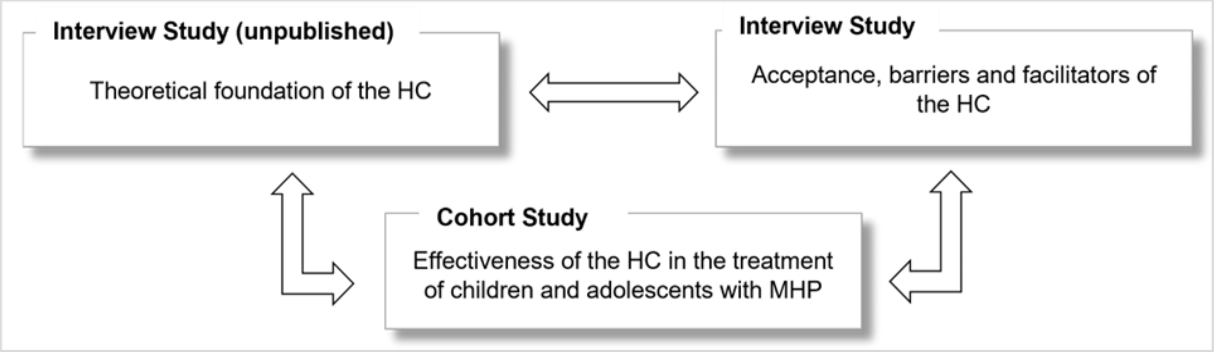

Figure 1: Mixed methods approach of the PhD thesis

The focus was on the participatory involvement of children and adolescents suffering from MHP (patients) and their parents in the qualitative and quantitative study.

Prior to the start of the PhD thesis an expert interview was conducted with the programme developers to understand the programme’s theoretical background and its objectives. Details are shown in the Appendix. Based on these findings, the guidelines for the structured interviews with paediatricians, patients with MHP and parents were developed.

An overview of the cohort study and the embedded interview study is shown in **Figure 2.**

2.3.1 Interview study (qualitative approach)

2.3.1.1 Study design

Following a qualitative approach, several structured (guideline-based) telephone interviews were conducted from November 2017 onwards. Paediatricians with HC qualification, patients with MHP receiving HC treatment and parents of patients were interviewed.

2.3.1.2 Participants and data collection

HC qualified paediatricians
In Bavaria, most of the paediatricians are members of a respective network (PaedNetz). 23 qualified and HC experienced paediatricians were recommended by PaedNetz from their own ranks and consented to participate (response rate=100%). The following inclusion criteria were applied: 1) member of PaedNetz, 2) Bavarian primary care paediatrician, 3) HC qualified and HC experienced. Doctor’s surgeries merely treating private patients were not included[6]. Paediatricians who met the inclusion criteria were contacted via email. The selection was based on purposeful sampling in terms of urban and rural variation.

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[6] Patients insured by SHI were necessary to obtain BKK billing data.

Patients with MHP and parents of patients receiving HC treatment

Parents were selected if they had at least one child (≤17 years of age) with a concrete diagnosis of one (or several) of the four most frequent MHP[7] as defined in **Table 1**. The diagnoses were indicated by the ICD code[8] (38). The child(ren) had to be enrolled in the SK programme and had to have been treated in accordance with the HC programme in the past six months by a paediatrician who had the appropriate HC qualification. Parents and patients with MHP had to know about the diagnosis to be included (self-report).

Table 1: Included MHP diagnoses indicated by ICD code

ICD code	MHP Diagnosis
F80.0-F80.9	Developmental disorder of speech and language
G44.2 G43.0 G43.1 F45.4 R10.4	Head and abdominal pain (somatoform)
F68.8 F91.0–92.9, F94.0–95.9, F98.3-F98.9	Conduct disorder
F98.0	Non-organic enuresis

The BKK invited families who met the inclusion criteria in written form. Purposeful sampling was applied in the selection of interview candidates. In doing so, the principles of maximum variance concerning demographic characteristics (age, gender, social class), MHP diagnosis and place of resident (rural or urban area) were met. Parents of patients with MHP (<14) and consenting adolescents (≥14) were interviewed.

Data collection

All interviews were conducted by telephone. This was required as the interview participants were spread all over Bavaria. The interviews were audio-recorded using F4 version 2012 (Dresing & Pehl GmbH, Marburg, Germany). The records were transcribed verbatim afterwards.

2.3.1.3 Data analysis

The data were analysed using an approach to content analysis according to Philipp Mayring (39, 40). This method was chosen because of the structure of the interview guidelines. Both deductive and inductive coding was performed. In that sense, relevant interview statements were deductively assigned to the different main themes of the structured interview guide. Inductive coding also has significant advantages: On the one hand, it makes it possible to contextualise material by means of the predefined categories. On the other hand, it allows for an in-depth exploration, which can result in further categories. The coding tree and details of the analyses are presented in **Publication I.** The transcripts were independently analysed by the PhD candidate and another researcher, both qualified in qualitative research to increase validity of results. The process of coding and analysing was performed with the help of MAXQDA 18 (VERBI Software; Consult, Sozialforschung GmbH, Berlin, Germany).

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[7] These MHP diagnoses were specified by paediatricians of PaedNetz Bayern as the four most common MHP emerging in paediatric care.

[8] International Statistical Classification of Diseases and Related Health Problems (ICD) in the 10th revision.

2.3.2 Cohort study (quantitative approach)

2.3.2.1 Study Design

In 2018 and 2019, a prospective cohort study was carried out in Bavaria, Germany, evaluating the treatment outcomes of patients with MHP treated by a paediatrician who had HC qualification (intervention group) compared to those suffering from MHP receiving standard paediatric care (see **Figure 2**).

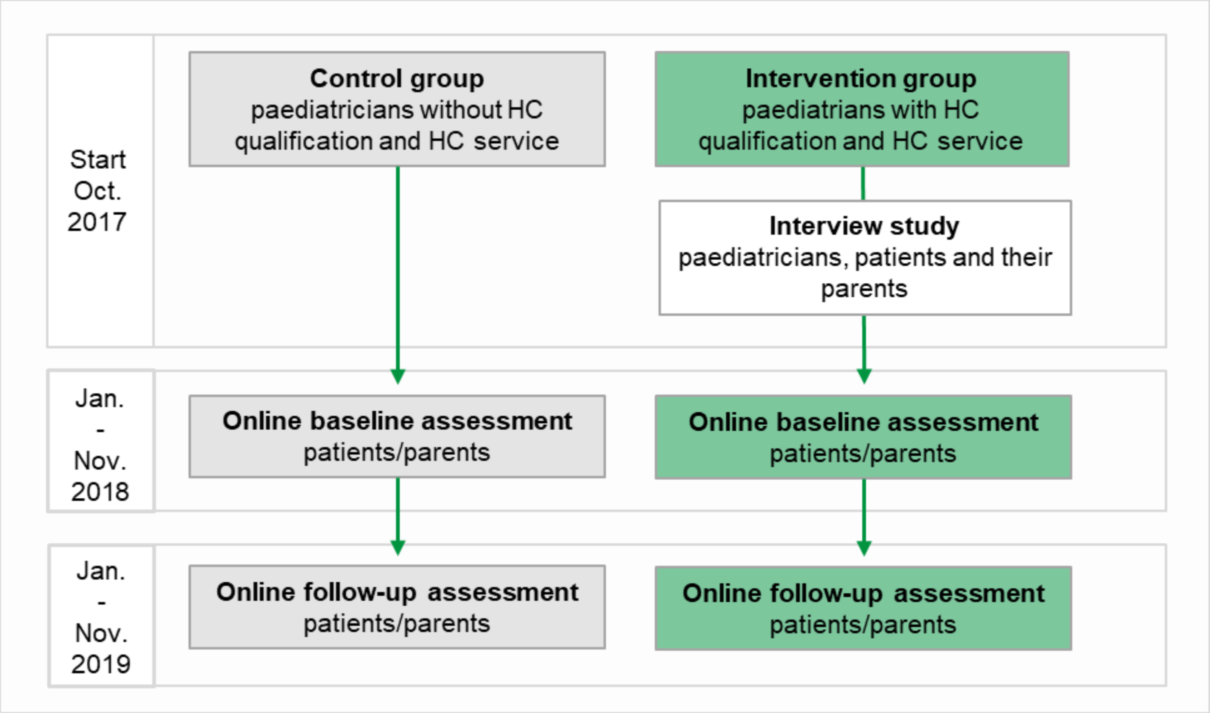

Figure 2: Overview of the cohort study and the embedded interview study

2.3.2.2 Participants and data collection

Patients with MHP and parents of patients

Parents were invited to participate if they had at least one child (≤17 years) who had been diagnosed with one (or several) of the MHP defined in **Table 1** and if they had at least one consultation with a Bavarian primary care paediatrician for MHP in the past six months. The child had to be insured with a BKK offering the SK programme[9]. The BKK identified participants who met the listed inclusion criteria on the basis of billing data which was available within about half a year.

Intervention and control group

Children and adolescents of the control group could either be SK or non-SK participants, they did not have to be enrolled in the SK programme[10] (see **Publication II Figure 2**). The control group was treated by a paediatrician who offered the SK programme. HC services had not been billed.

All participants in the intervention group were SK+HC. The intervention group was therefore SK participant, was treated by a HC qualified paediatrician and HC service(s) had been billed.

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[9] Required for retrieving performance data.

[10] The mixed control group was due to PrimA-QuO requirements. A distinction between SK and non-SK participants and consequently an evaluation of the SK programme was not up for discussion.

Data collection

All data were collected via online questionnaire. Eligible families were invited by their BKK in writing and they received the link to the baseline assessment. One year later, all participants obtained the invitation as well as access data for the follow-up questionnaire per email.

Outcome of interest

The change in MHP was meant to be examined. Children's and adolescents' MHP were assessed at two time points with the Strengths and Difficulties Questionnaire (SDQ) (41, 42). The SDQ is a valid instrument for the early detection of MHP. The total difficulties score (range 0-40) is a sum of scores of 20 items whereas higher scores indicate more serious problems. A total score of more than 13 (parental assessment) or 15 points (self-assessment of the child) is considered as "at risk" for MHP. A change of more than two points in the total score is considered clinically meaningful (43). Details regarding SDQ are shown in the **Additional File to Publication II**.

2.3.2.3 Statistical methods

Details of the statistical analyses are presented in **Publication II**. For continuous variables at baseline and follow-up, mean values, standard deviation and absolute frequencies with associated percentages for categorical variables were reported. Differences between the HC and control group concerning demographic or health-related characteristics were compared using the Chi-square test or Kruskal-Wallis test. In the longitudinal analyses, the changes in the SDQ total score in both groups were compared, and determinants of SDQ change were evaluated with Linear mixed effects (LME) models. Between-subject variability were taken into account. Age, gender and MHP, paediatric care group (HC vs. control) and the level of parental education were included as covariates in the analyses. International literature served as a basis for this selection (44-47). Due to the study design, randomisation in group assignment could not be performed. Therefore, Inverse Probability of Treatment Weighting (IPTW) was applied (48, 49). At first, an unadjusted model with time and paediatric care group as the only covariates was calculated. In a second model, age and sex of the child were introduced additionally. Thirdly, a fully adjusted model was reported. To calculate whether HC participation influences the change in MHP over time, an interaction term of time and paediatric care group (HC or control group) was calculated. The IPTW weights were introduced into all models. Akaike information criterion (AIC) was used to assess overall model fit. Lower values are indicating better model fit. All statistical analyses were carried out using SAS software, version 9.4 (SAS Institute, Cary, NC, USA).

2.4 Main results and scientific contribution

Two scientific first authorship articles were published in international peer-reviewed journals. The articles document a five-year research process aimed at answering the above-mentioned research questions.

2.4.1 Interview study (Publication I)

Within one year, starting in November 2017, 14 HC qualified paediatricians, four adolescents with MHP (treated accordingly) and 22 parents were interviewed. All participants who were recruited and interviewed can be found in **Publication I (Table 1).** Participants were selected from 23 consenting paediatricians, 322 parents and ten adolescents up to the point of saturation. Three paediatricians indicated that they were also involved in HC programme contract negotiations and development. In **Box 1** the scientific contribution of Publication I is summarised.

2.4.1.1 Acceptance of the programme

The interviews showed that HC qualified paediatricians valued the programme to a great extent. Parents said they were content with the care they received by their paediatrician even though they did not know that the HC programme was particularly tailored to their needs. This is in line with the adolescents' statements.

2.4.1.2 Facilitators and barriers of the programme – paediatricians' point of view

HC qualified paediatricians rated the programme material as very helpful and said that it facilitated diagnosis and decision-making in the treatment of MHP patients. The extra allocation of funds was considered as an expression of trust. However, paediatricians viewed their ability to interact with MHP patients and their parents as restricted. Time and budget constraints were cited as the main obstacles to implementing the programme as desired. Paediatricians also perceived cultural and linguistic barriers and distinct social disparities. In additions, barriers related to secondary and tertiary care arose because it might be difficult for parents to follow-up on referrals. A few paediatricians felt that parents could doubt their competence in dealing with MHP.

2.4.1.3 Facilitators and barriers of the treatment – patients & parents' perspective

Patients and parents appreciated being involved in treatment decisions and had sufficient trust for their paediatricians even with regard to more precarious issues. An extensive counselling time offered by the paediatrician and interaction between care providers were positively noted. The following aspects were mentioned as the main barriers to appropriate and timely MHP treatment: waiting too long for a specialist appointment and specialised clinics being too far away, thus appointments being hardly compatible with working and family life. The fact that a lot of prescriptions and treatment options are not covered by the health insurance was also mentioned. Some parents reported that they underestimated the child's MHP and therefore, consulting help was delayed. A few parents were reluctant to consult their paediatrician for MHP as the problem seemed too trivial or, on the contrary, a specialist was needed.

2.4.1.4 Need for programme improvement and further support

Paediatricians emphasised the need for enhanced interdisciplinary communication and networking. Strengthening parental resources, increasing parents' awareness of MHP and improving paediatricians' knowledge in MHP were mentioned to address the barriers and to lower the chance of receiving therapy too late or late in general.

In general, families felt sufficiently supported. Parents suggested improving access to MHP services, improving exchange between providers and better accessibility of specialised services. The involvement of other health professionals and inclusion of other treatment options were also suggested.

Box 1: Scientific contribution of Publication I

- Publication I is the first to evaluate a primary care-based MHP programme that reflects the perspectives of paediatricians, young patients with MHP and their parents. Three paediatricians had been involved in HC programme development, which was fruitful for the analyses.
- Important facilitators, barriers and approaches to improve the treatment of patients with MHP in primary care were identified. These findings could help improve the programme in the future.
- The interview study contributed to a better understanding of the HC programme and its application in daily practice. The initial qualitative findings influenced the focus of quantitative data collection. Publication I also contributed to the interpretation of the results of the cohort study on the effectiveness of the programme (Publication II).

2.4.2 Cohort study (Publication II)

In total, more than 7,000 families met the inclusion criteria and were invited to participate. 1,250 families took part in the baseline assessment in 2018. The flow chart is shown in **Publication II**. The response rate at baseline was 17%. After having excluded persons with missing information on the outcome of interest (SDQ) or basic covariates (age, gender), 1,090 children and their parents could be included in the cross-sectional analyses. The follow-up survey, in which 654 persons (response rate=56%) participated, took place 1 year later. A total of 599 participants were included in the longitudinal analyses. Exclusions (n=55) were necessary due to missing SDQ assessment.

2.4.2.1 Prevalence of MHP at baseline

In total, 30.6% were treated according to HC. Conduct disorder (29.7%) and enuresis (17.1%) more frequently occurred in the HC group (control group: 21.5% and 4.6%, respectively). In the control group developmental disorders of speech and language (57.3%) and abdominal pain (22.2%) occurred more often (HC: 41.1% and 16.5%). Overall, the SDQ score indicated 23.5% “at risk”. No significant SDQ differences between HC and control group were found.

2.4.2.2 MHP developmental course

During the follow-up, no remarkable distinctions between the two groups were detected. This holds true for both the change of the SDQ total score and the change in SDQ items. The highest scores were apparent for participants with conduct disorder. For boys in both groups, a decrease of about two points in the self-assessment could be observed. Sensitivity analyses: 46.7% in the control group as compared to 26.2% in the HC group had improved SDQ cut offs. There was no change in most of them, and a sizeable proportion worsened.

2.4.2.3 Determinants of MHP over time and effect of HC participation

Time but not HC treatment were associated with lower SDQ scores in the unadjusted model. In the fully adjusted model, a high level of parental education was significantly associated with lower levels of SDQ. Child's male gender was significantly linked to higher SDQ scores. Older age (15–17) was also associated with higher SDQ values (no significant effect). In the control group, a significant improvement in SDQ scores was observed over time. In the HC group, the scores did not change remarkable.

Box 2: Scientific contribution of Publication II

- Publication II provides a first assessment of the HC programme's patient-related impact.
- A comprehensive SDQ assessment was conducted including the assessment of specific differences regarding age, gender and MHP between HC and control group.
- There was no significant impact of the programme concerning the MHP developmental course detectable.
- Publication II is in line with the international literature showing that higher SDQ levels were significantly linked to male gender of the child and lower educated parents. The results prove that MHP-related stressors, coping abilities and availability of help are not distributed equally yet.

2.5 Strengths and limitations

The studies conducted have certain major strengths. A particular strength of the qualitative study is based on its intuitive approach and the respondents' candour. Although the topic of MHP is a sensitive issue, the interviewees freely talked about their views and experiences. The fact that three of the interviewed paediatricians had also been involved in the programme development enriched the findings and enabled distinction between the anticipated goals of the HC programme and its everyday feasibility. Yet, some limitations in the interview study must also be mentioned. In qualitative research, interviews are always influenced by suppositions and attitudes of the corresponding researchers, at least to some extent. It should be also noted that the personal commitment of the paediatricians is still an essential factor for positive experiences of the families and their satisfaction with the care provided. Therefore, the assumptions regarding the methodological approach and the interpretation of the results were critically questioned and discussed by the researcher. The researcher's qualifications may have also minimised this possible bias.

A comprehensive health assessment of more than 1,200 underaged patients with MHP and their parents at two time points one year apart is the main strength of the cohort study conducted. The MHP of the child and its health development course were extensively analysed. Differences related to age, gender and MHP between HC and control group were also obtained. The cohort study has two main limitations. First, due to the methodological conditions, an average time gap of three to four quarters between the first MHP diagnosis and the invitation to participate in the study was given. In this sense, several months passed after the intervention before the baseline health assessment of the child took place. That might have contributed to a blurring of a possible significant effect that the programme might have had on the child's course of MHP development. The time gap may also explain the low response rate at the beginning of the study and the high number of lost-to-follow-up. Regarding the lost-to-follow-up, no demographic or health differences were found between HC and control group that could have biased the results. Secondly, it was not possible to include participants by non-participating or participating paediatricians' surgeries. Instead, participants were invited by letters from the health insurance company based on billing data. Therefore, it might be possible that paediatricians in the control group finished the HC training and offered HC services but did not bill for the service. This contamination of the control group was accepted since it resulted in a more conservative result and a lower difference between the two groups in theory.

2.6 Discussion and outlook

This dissertation is the first evaluation of the patient-related impact of the HC programme on the health of children and adolescents with MHP. It is also the first evaluation of a primary-based MHP programme that reflects the perspectives of primary care paediatricians, children and adolescents with MHP and their parents.

The mixed methods approach provided a unique opportunity to profoundly understand the programme's content, its implementation and effectiveness. The two different approaches complemented each other in precious ways: The qualitative approach contributed to a better understanding of the HC programme and its implementation in daily practice. In addition, the qualitative approach was helpful in focusing the quantitative study and interpreting the results on the programme's effectiveness in treating children and adolescents with MHP. The integration of quantitative and qualitative data resulted in a confirmation of results and an expansion of understanding. The results were summarised in a coherent narrative report.

The qualitative study with HC qualified paediatricians, patients with MHP and their parents provided a unique opportunity to look 'behind the treatment doors'. The programme's objectives were evaluated up to the practical feasibility while the waiting room is full of patients. The feasibility of the doctor's recommendations between work, everyday life, and family and the well-being of the people at the centre – young patients with MHP – were assessed. The openness of all participants made it possible to address problems and concerns. The interview study revealed several strengths but also shortcomings of the programme. In this sense, the programme could not always be implemented as desired or was skipped due to time or organisational restrictions or due to family circumstances requiring too many resources to be carried out. These systemic, structural and private issues may partly explain the blurring of a significant effect of the programme concerning the change in MHP in the one-year course as found in the cohort study. Methodological circumstances (e.g. duration until the billing data were available) also led to a more conventional effect estimate.

With the decision of the Innovation Fund of 11 November 2021, no recommendation was made for the programme to be included in standard care of statutory health insurance (50). This decision was based on the lack of impact of the programme on the children's health outcomes (2) as well as on the frequency of MHP diagnoses of MHP, on treatment pathways and on costs (51). Nevertheless, the results presented here provide important indications for further programme development and improvement of integrated care for young patients with MHP. As the HC programme aims to facilitate and standardise anamnesis and treatment pathways of young patients with MHP to enable more timely treatment of severe MHP, the primary care programme has still proven helpful in identifying MHP and in determining what the best treatment option is. Time and financial restrictions, lack of family resources and the fact that it still takes too long until specialised help is available, were cited as the main barriers to implementing the programme. An increase in services that paediatricians can charge for will not remedy this situation. Rather, better support networks involving other health professional groups could help strengthen the resources of paediatricians and families. To help reduce MHP it might be also useful to focus on families with low parental education first. Increased awareness of MHP among parents and their trust in the paediatrician's expertise in MHP should also be focused on to reduce the risk of delayed MHP treatment in the future. These insights may partially be transferred to other MHP programmes to optimise primary medical care for all persons affected with MHP.

3. Publication I

Publication I: “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:

[11]

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[11] During the publication process, an error occurred in the printed version. References were printed within the abstract that were not included in the originally submitted version. The incorrect presentation was reported to the journal but has not been corrected yet.

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

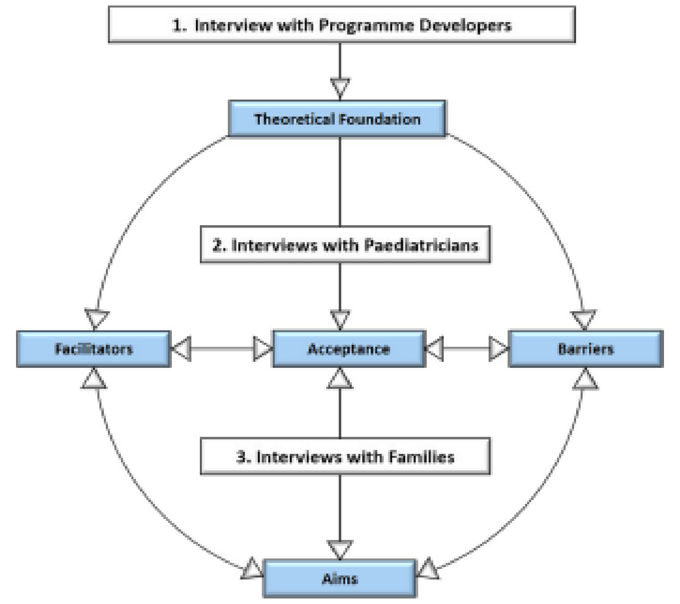

Fig 1 Process of data triangulation in the interviews with programme developers, paediatricians and families

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

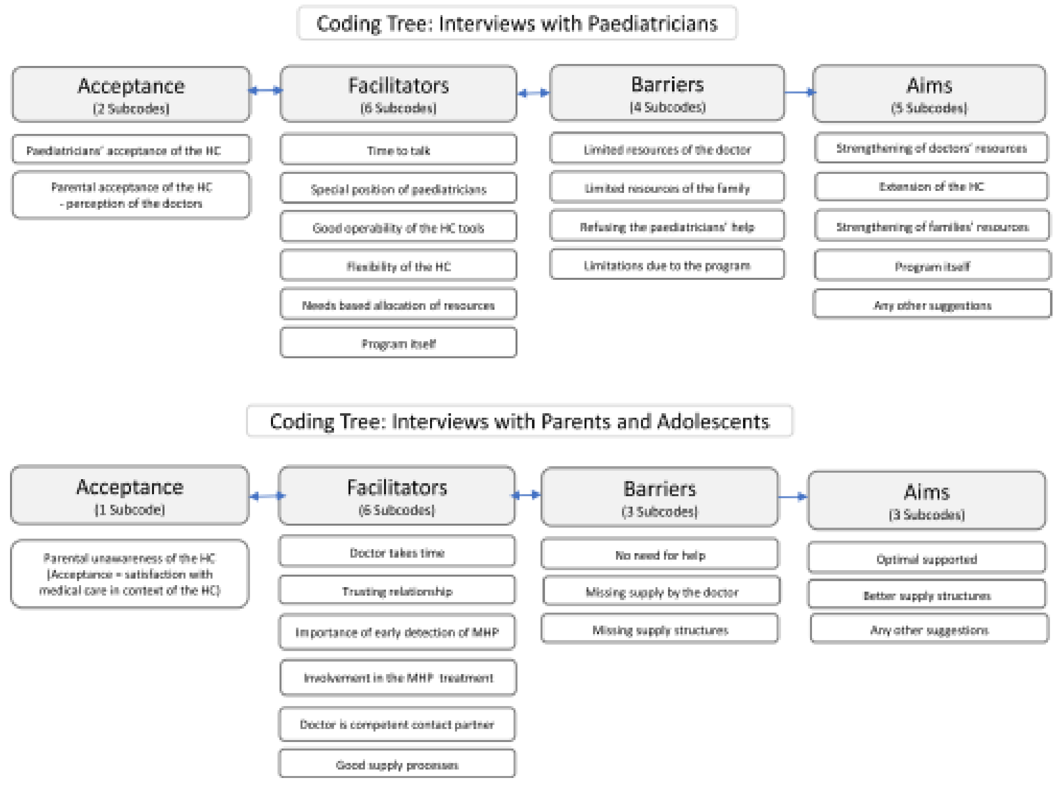

Fig 2 Extracted meta- and subcodes from the interviews with paediatricians, parents and adolescents

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].

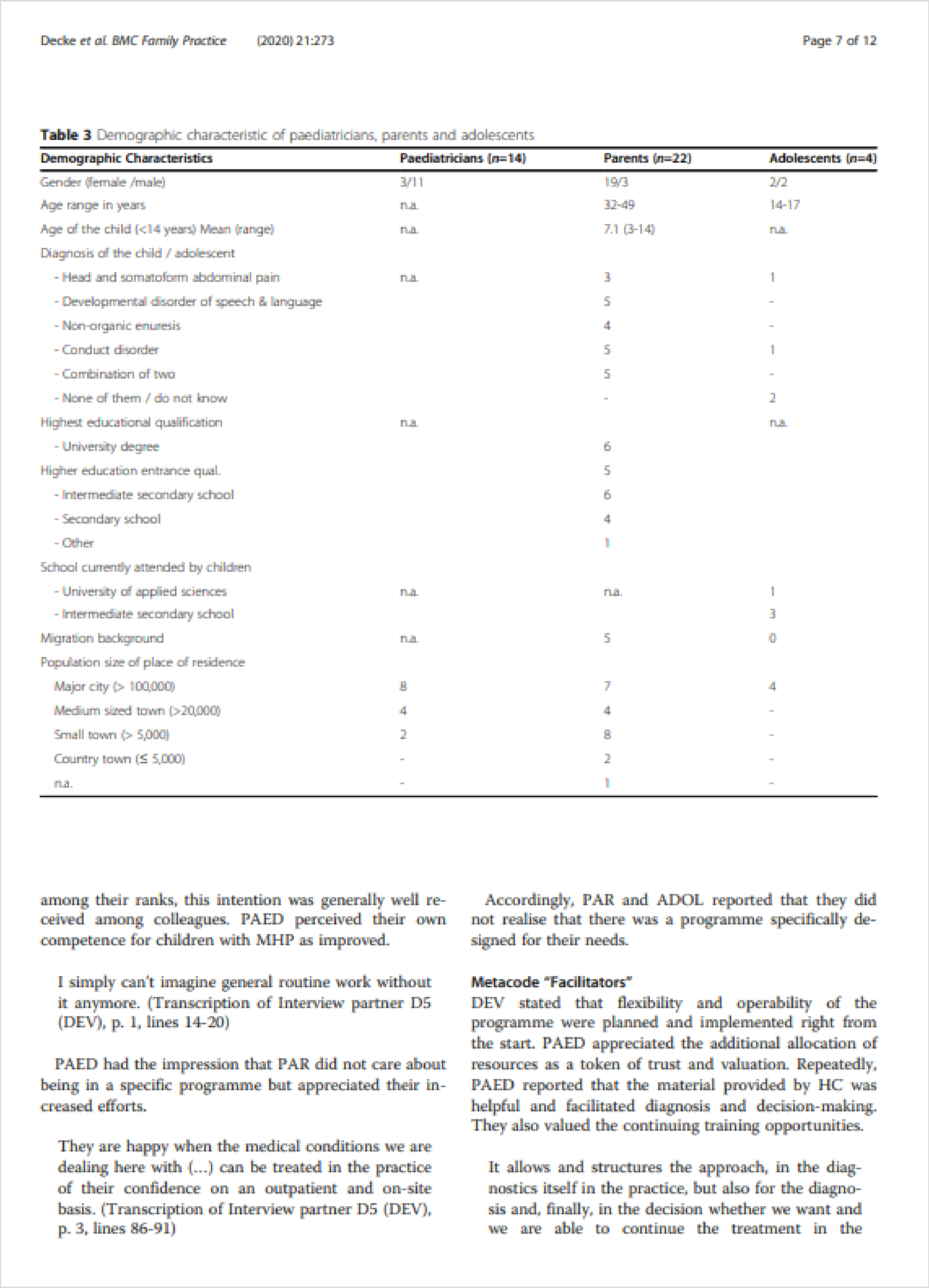

Table 3 Demographic characteristic of paediatricians, parents and adolescents

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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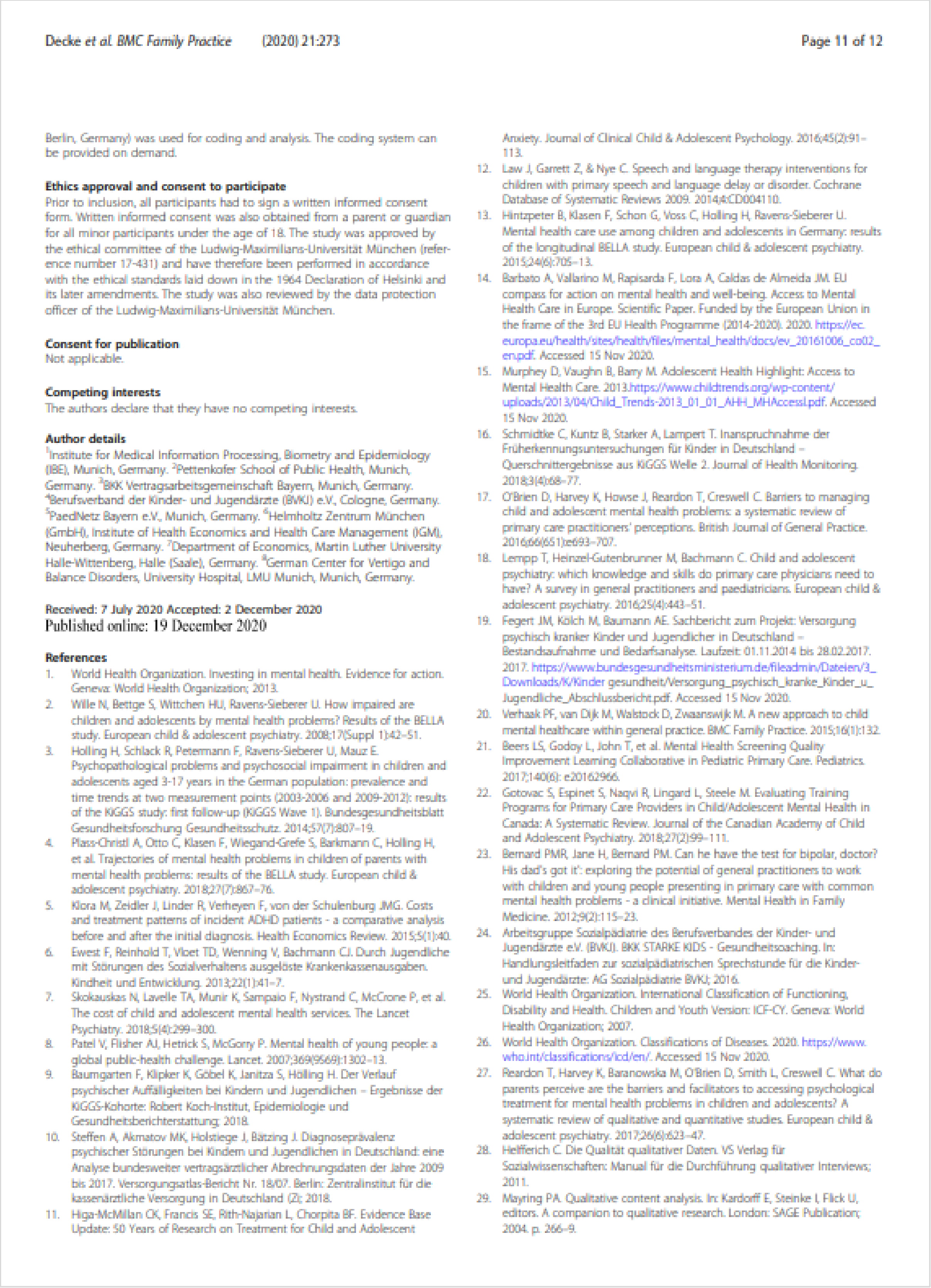
[4] Status as of 1st July 2019



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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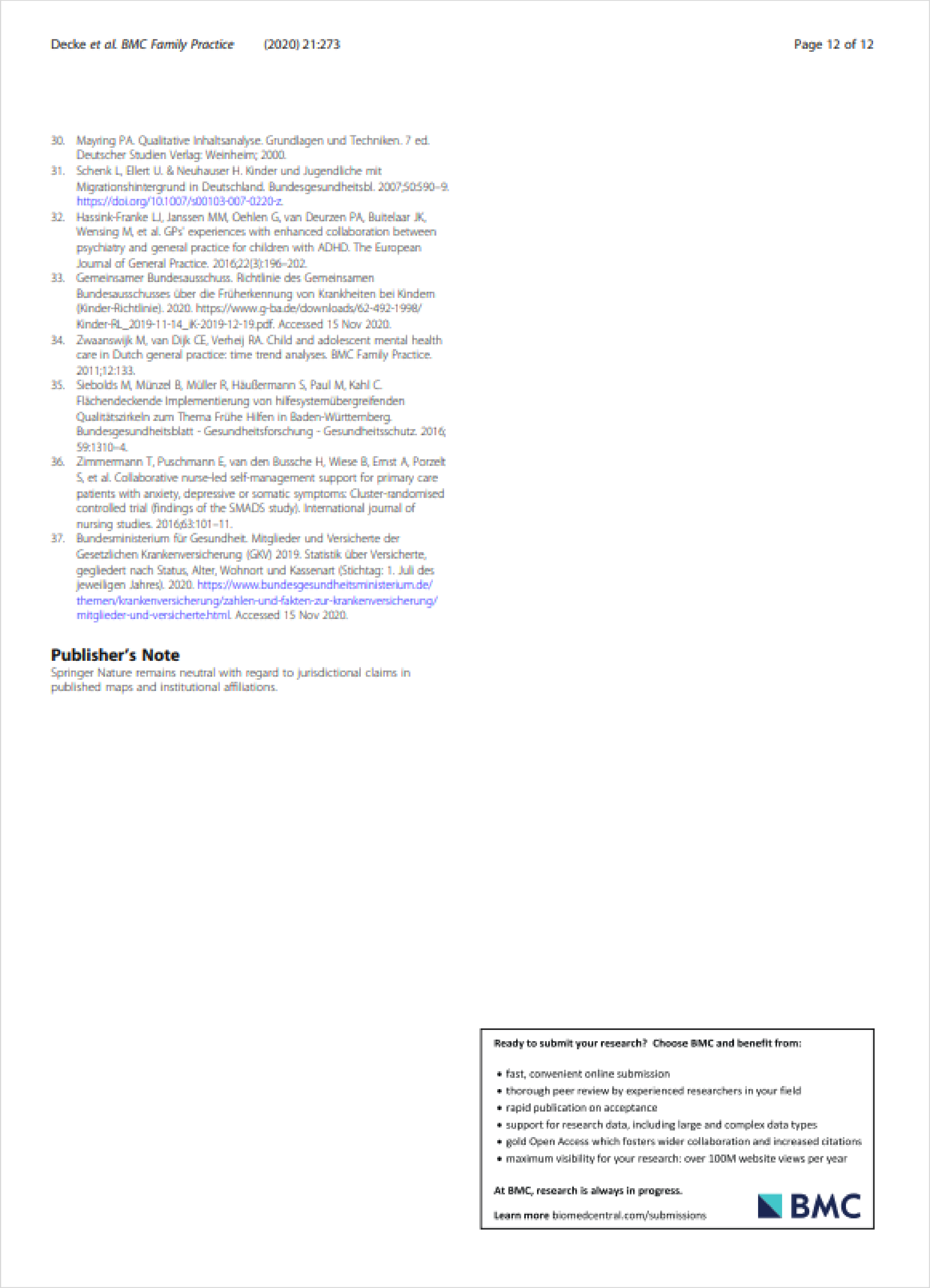

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Publisher's Note

Electronic Supplementary Material

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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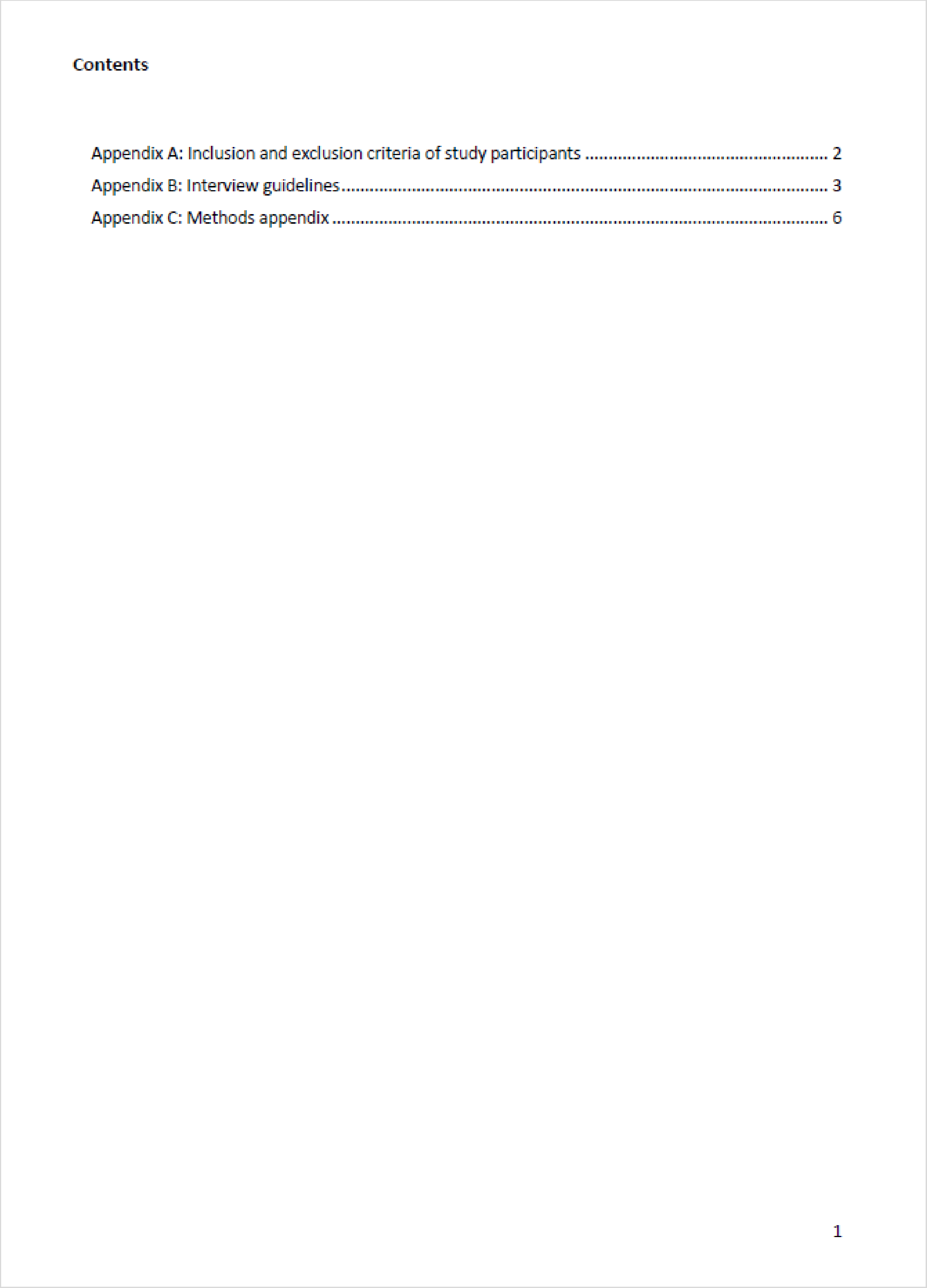


Contents

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

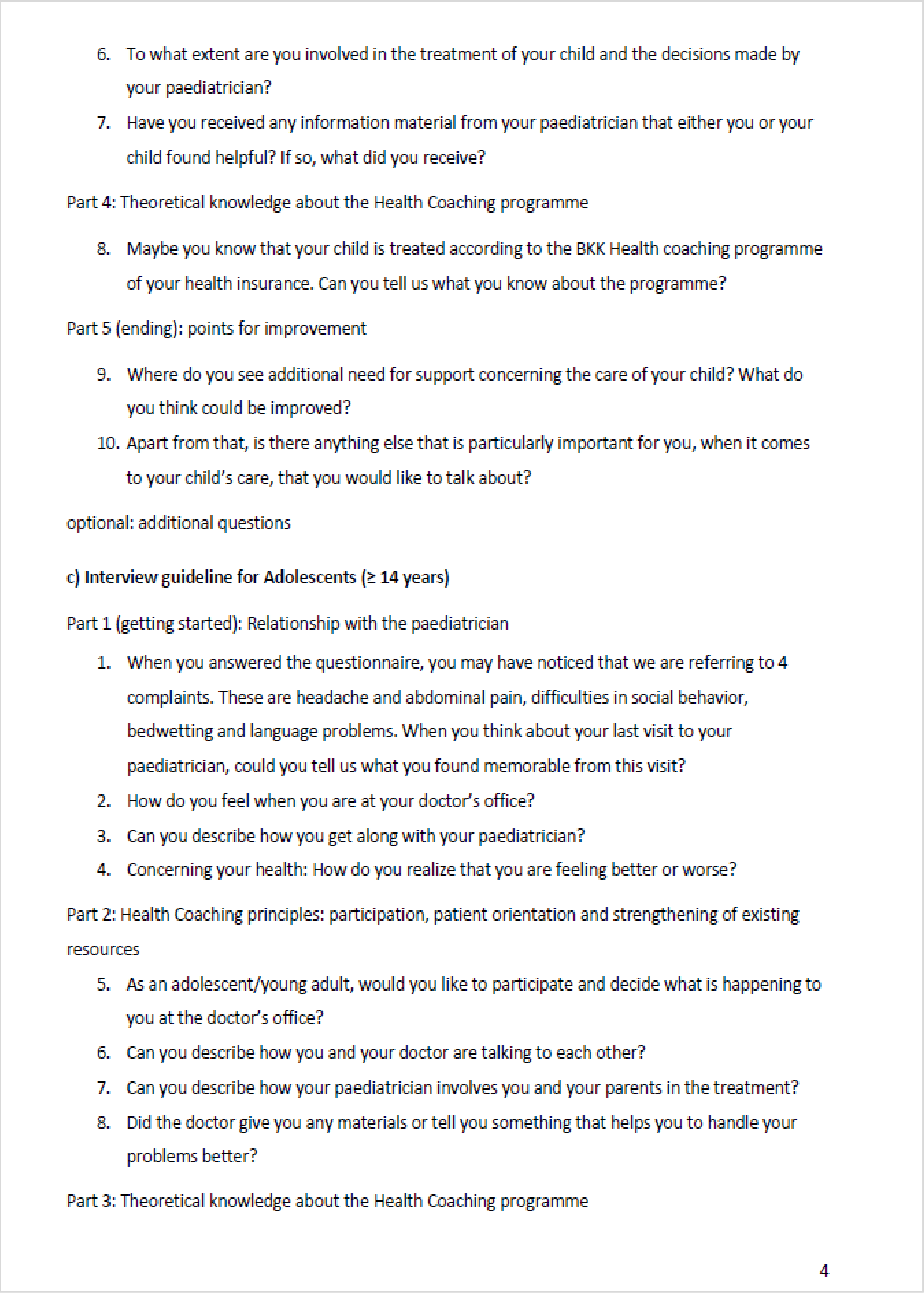
1. First, could you briefly tell us how you heard about your child's paediatrician?
2. How would you describe the relationship with your paediatrician?

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)

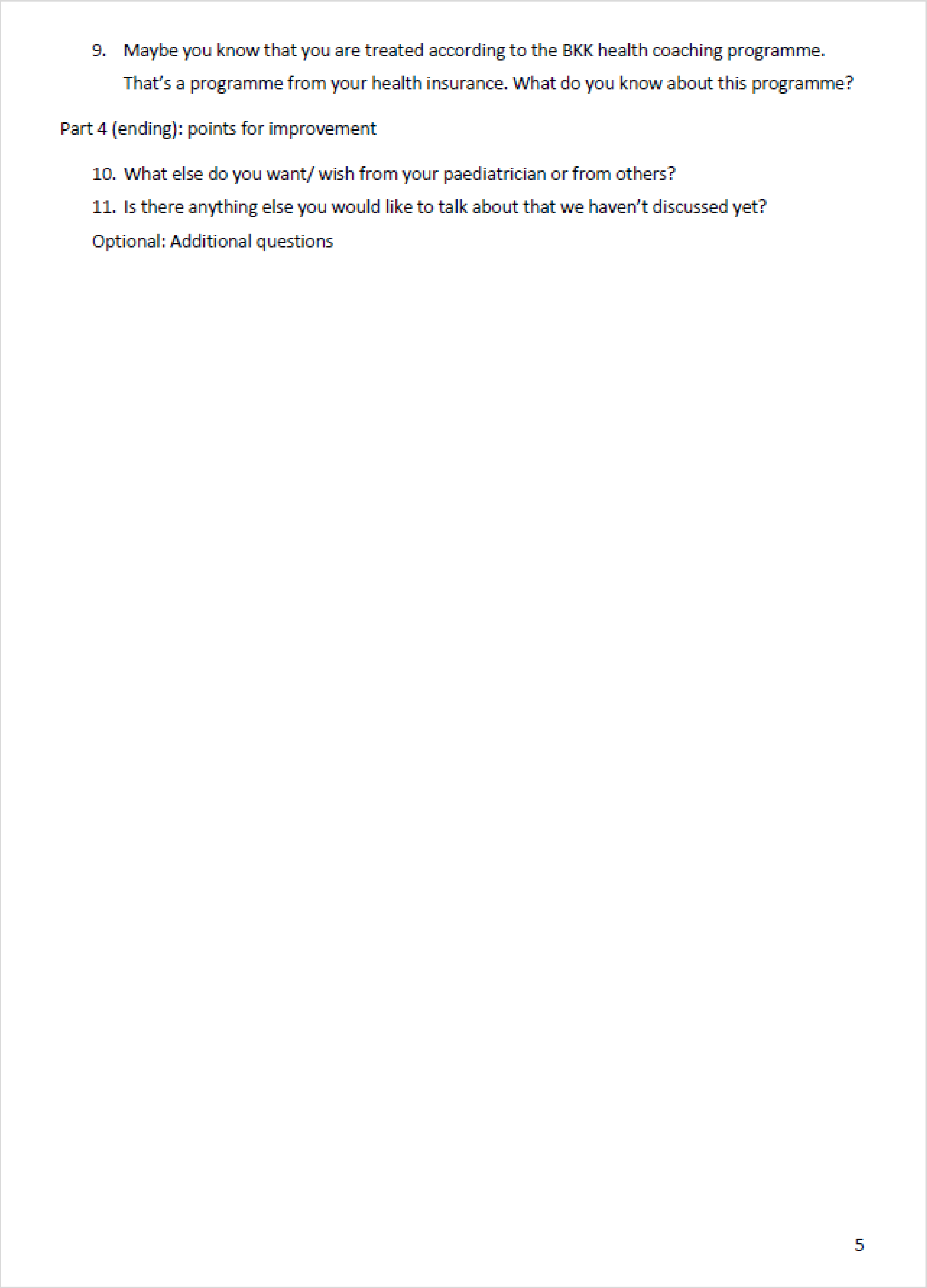
Part 1 (getting started): Relationship with the paediatrician

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

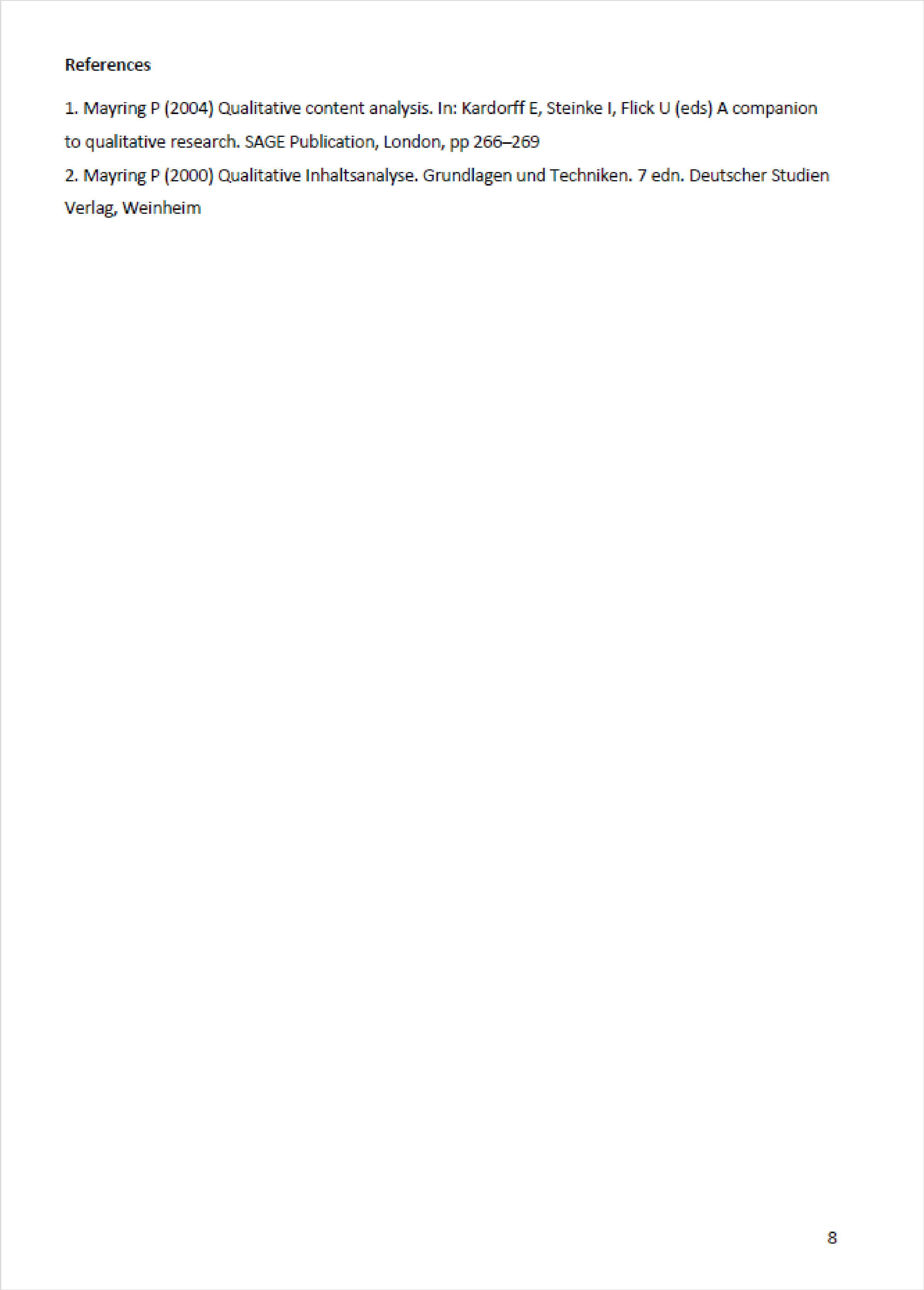
The process model of qualitative content analysis according to Mayering [1,2] comprises of nine steps (ESM_Fig. 1).

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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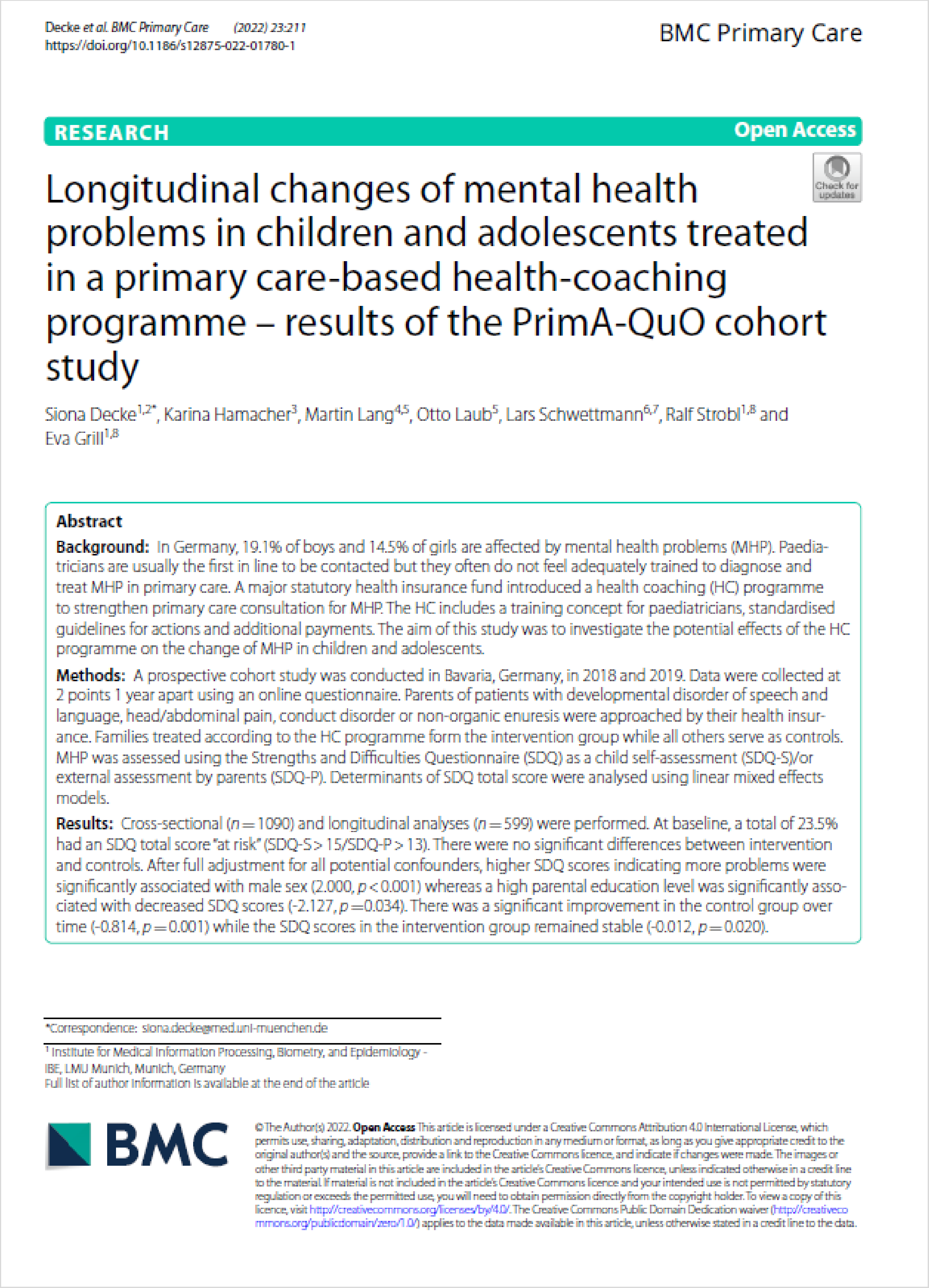
4. Publication II

Publication II: Longitudinal changes of mental health problems in children and adolescents treated in a primary care-based health-coaching programme – results of the PrimA-QuO cohort study.

Decke S, Hamacher K, Lang M, Laub O, Schwettman L, Strobl R, Grill E. Longitudinal changes of mental health problems in children and adolescents treated in a primary care-based health-coaching programme – results of the PrimA-QuO cohort study. BMC Primary Care 23, 211 (2022). https://doi.org/10.1186/s12875-022-01780-1.



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BMC Primary Care

RESEARCH **Open Access**

Longitudinal changes of mental health problems in children and adolescents treated in a primary care-based health-coaching programme – results of the PrimA-QuO cohort study

Siona Decke[1,2*], Karina Hamacher[3], Martin Lang[4,5], Otto Laub[5], Lars Schwettmann[6,7], Ralf Strobl[1,8] and Eva Grill[1,8]

Abstract

Background: In Germany, 19.1% of boys and 14.5% of girls are affected by mental health problems (MHP). Paediatricians are usually the first in line to be contacted but they often do not feel adequately trained to diagnose and treat MHP in primary care. A major statutory health insurance fund introduced a health coaching (HC) programme to strengthen primary care consultation for MHP. The HC includes a training concept for paediatricians, standardised guidelines for actions and additional payments. The aim of this study was to investigate the potential effects of the HC programme on the change of MHP in children and adolescents.

Methods: A prospective cohort study was conducted in Bavaria, Germany, in 2018 and 2019. Data were collected at 2 points 1 year apart using an online questionnaire. Parents of patients with developmental disorder of speech and language, head/abdominal pain, conduct disorder or non-organic enuresis were approached by their health insurance. Families treated according to the HC programme form the intervention group while all others serve as controls. MHP was assessed using the Strengths and Difficulties Questionnaire (SDQ) as a child self-assessment (SDQ-S)/or external assessment by parents (SDQ-P). Determinants of SDQ total score were analysed using linear mixed effects models.

Results: Cross-sectional ($n=1090$) and longitudinal analyses ($n=599$) were performed. At baseline, a total of 23.5% had an SDQ total score "at risk" (SDQ-S > 15/SDQ-P > 13). There were no significant differences between intervention and controls. After full adjustment for all potential confounders, higher SDQ scores indicating more problems were significantly associated with male sex (2.000, $p<0.001$) whereas a high parental education level was significantly associated with decreased SDQ scores (-2.127, $p=0.034$). There was a significant improvement in the control group over time (-0.814, $p=0.001$) while the SDQ scores in the intervention group remained stable (-0.012, $p=0.020$).

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Conclusion: This evaluation of the HC programme could not prove a clinically relevant intervention's effect on the MHP developmental course. Nevertheless, (HC) paediatricians have crucial potential to improve the care of MHP patients. Targeting families with less access to support measures might help reduce the burden of MHP and be a step towards continuous improvement of care.

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

Background

Mental health is an important prerequisite for happiness, quality of life and wellbeing [1]. Mental health problems (MHP) of children and adolescents can constitute health impairments with major implications regarding daily and social functioning, performance at school and later professional development [2, 3]. Moreover, these conditions can cause economic burdens for families and healthcare systems [4–6]. MHP of children and adolescents are therefore regarded as a highly relevant public health issue in all countries of the world [7, 8]. According to the German Child and Youth Health Survey (KiGGS), 19.1% of boys and 14.5% of girls aged 3–17 years are affected by MPH in Germany [9]. Among MHP, developmental disorders (17%) and conduct disorders (11%) were the most common conditions seen in paediatric care [10].

Effective and evidence-based therapies for children and adolescents with MHP such as cognitive-behavioural therapy have been established [11–13]. However, only 30% of minors with MHP in Germany [14] and other industrialised countries [15, 16] have access to appropriate medical care. Waiting time, settings that fail to meet parents' and children's needs, long travelling distances and lack of intersectoral communication and treatment have been identified as the most relevant barriers to impede or delay timely access to professional assessment and therapy [7]. In Germany, paediatricians in primary care are often either the first in line to be consulted for MHP [14] or they detect MHP during the developmental examinations that are routinely and regularly carried out [17]. Yet, it has been shown that many primary care paediatricians do not feel adequately trained and therefore tend to underdiagnose and undertreat MHP patients in primary care [18, 19]. Enhanced training has been shown to be a promising intervention to strengthen and support the paediatricians' skills in the detection of MHP and in the delivery of simple interventions [20–23].

Against this background, a major German statutory health insurance fund ("Betriebskrankenkassen Landesverband Bayern"—BKK-LV Bayern) in cooperation[1] with a professional association of paediatricians ("Berufsverband der Kinder- und Jugendärzte" – BVKJ e. V.) has introduced a programme for their insured members that targets primary care paediatricians (Health Coaching—HC) in 2013 [24]. The programme development started in 2011 and was based on mutual consultations of medical stakeholders. The HC programme includes a training concept for paediatricians, standardised guidelines for actions for 16 specific mental health conditions and additional fees for paediatricians who complete this training and treat children and adolescents with MPH according to the guidelines.[2] The BKK funds provide an additional budget for the use of the standardised guidelines for 16 defined MHP beyond the conventional statutory health insurance (SHI) service spectrum regarding social-paediatric-oriented in-depth counselling, discussion and/or clarification as well as continuing social-paediatric-oriented care[3] [25, 26]. The HC aims to provide improved integrative care for children and adolescents with MHP in paediatric practice by training paediatricians in the detection and treatment of MHP. Furthermore, the programme tries to impart self-management skills to the children and their parents and purposefully inform them about the various care services available. The basic programme's principles are participation, patient orientation and strengthening of existing resources. The underlying model of the HC and its intervention components is the International Classification of Functioning, Disability and Health in the version for children and adolescents (ICF-CY) [27]. ICF-CY is a complex classification standard. It takes developmental peculiarities and special living environments of children and young people into account and provides a framework and common language and for formulating and planning support, therapies and treatment goals. Prior to the present analysis, an expert interview with the programme developers was performed (not published). In addition, the implementation of the programme in paediatric practice and the perception of patients and families involved was assessed by Decke et al. [28]. Among the interviewed paediatricians,

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[1] The BKK contract working groups (VAG) of Bavaria, Baden-Württemberg and Hesse in cooperation with BVKJ and PaedNetz Bayern e.V. concluded a framework agreement according to the social security code (§ 140a et seq. SGB V in conjunction with § 43 para. 1 no.2 SGB V).

[2] The contents of the HC training programme are not publicly accessible.

[3] Further information on SHI services can be found in the literature on the corresponding fee schedule items "EBM 04,355" and "EBM 04,356" [25, 26].

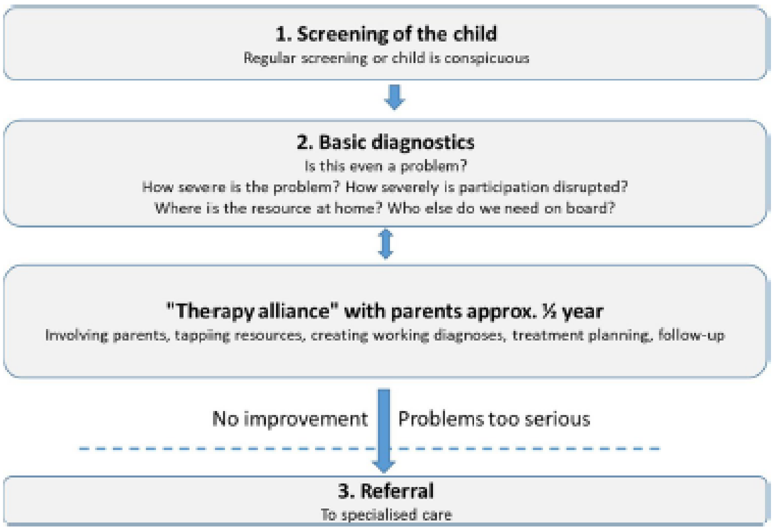

Fig. 1 Three steps model of social-paediatric diagnostics

3 paediatricians stated that they had also been involved in contract negotiations and in HC development, which enriched the findings too. The interviews revealed that the programme is well received by paediatricians, patients and their families [28]. However, the HC programme has not been systematically evaluated yet. It is hypothesised that the HC is an effective primary care programme improving patients' and their families' health outcomes. The objective of this study was therefore to investigate the potential effects of the HC programme on the change of MHP in children and adolescents. Medical utilisation and cost effects were examined by Marijic et al. [29]. A detailed description of the study objectives, the study design and the methodological procedure can be found in the study protocol [30].

The term "children" includes children and adolescents aged 0–17 years.

Methods

Study design

A prospective cohort study was conducted in Bavaria, Germany, from January 2018 up to November 2019. The collection of data was performed using an online questionnaire. Data were collected at 2 time points 1 year apart.

Intervention

The HC is mainly implemented in Bavaria, one of the largest federal states in Germany with a total population of 13 million people. The HC has been available nationwide since October 2015. More than 700 paediatricians in Bavaria and more than 2100 nationwide are currently qualified to participate in the HC programme and approximately 36,000 children with MHP have been treated according to the programme. The HC includes a training concept for paediatricians based on a dual training participation, standardised action guidelines for 16 MHP (e. g. developmental disorder of speech and language, enuresis, head and abdominal pain) and additional fees for paediatricians who undergo this specific training and demonstrably act according to the guidelines as shown in Fig. 1. With the HC, an additional 15 euros per 10 min can be billed up to a cap of 180 min per child (in addition to the SHI standard care).

The BKK programme "STARKE KIDS" (SK) forms the basis of the HC. With the SK programme, further developmental check-ups are available for children enrolled in the programme. In addition, the HC programme can be offered to children and adolescents with MHP as shown in Fig. 2. To implement the HC programme, the paediatrician must participate in the SK programme and complete a dual HC training participation while the child needs to be enrolled in the SK programme so that HC services are billable. The paediatricians' participation in two HC training courses is mandatory for billing the programme. More details are given in the Supplement.

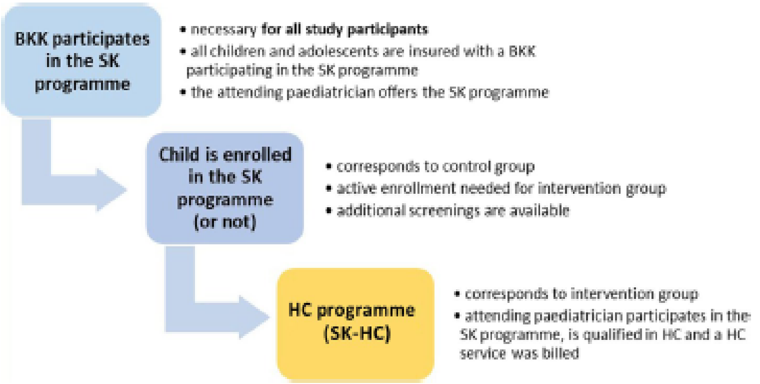

Fig. 2 Overview of the intervention (SK-HC) and control group (enrolled in SK or not)

Setting and sample

Parents of patients were included if at least 1 of their children (up to 17 years old) had been diagnosed with 1 (or more) of the 4 most common MHP diagnoses indicated by ICD codes[4] (10th revision), if they were insured with the BKK health insurance company and had at least 1 consultation at an office-based paediatrician in Bavaria, Germany, due to a MHP of their child/children in the last 6 months. Included diagnoses were 1) developmental disorder of speech and language (ICD Codes: F80.0-F80.9), 2) head and abdominal pain (somatoform) (G44.2, G43.0, G43.1, F45.4, R10.4), 3) conduct disorder (F68.8, F91.0–92.9, F94.0–95.9, F98.3-F98.9) and 4) non-organic enuresis (F98.0) [31].

All children had to be insured with a health insurance fund participating in the SK to enable the retrieval of performance data. With the SK programme, enhanced screenings for minors throughout Germany are available.[5] Further information is given in the additional file.

Children in the intervention group are SK participants and were treated due to 1 of the MHP included according to the HC programme. Hence, they were treated by a paediatrician with HC qualification and a HC service had been billed.

Children in the control group did not necessarily have to be enrolled in the SK programme themselves (see Fig. 2) and could therefore be SK or non-SK participants. Controls were treated according to 1 of the included MHP by a paediatrician who offers the SK programme, but no HC services had been billed.

All participants who met the inclusion criteria were identified by the BKK based on the billing data. Billing data were available with an average delay of 6 months. Eligible parents were invited by their health insurance company by letter and provided with a link to the online questionnaire. After 1 year, all participants received their follow-up invitation and login details per email. The questionnaire was answered by the parents or by the children themselves (if aged 11 or older).

All participants invited received age-appropriate study information with the possibility to contact the study centre in case of questions. Participants were informed about the data protection measures and signed an informed consent form before starting the questionnaire. Informed consent was obtained from the parents and the child if aged 6 years and older. Participation was voluntary. Participants also received information about the confidentiality of the questionnaire and the opportunity to stop participation at any time without giving any justification. Families were offered a small monetary compensation for their participation.

Approval from the Ethics Committee (registration number 17–497) and the Data Protection Officer of the Medical Faculty of the Ludwig-Maximilians-Universität Munich (LMU) was obtained prior to the start of the study. All data protection measures fulfilled the European and national data protection regulations (EU-DSGVO and BDSG) [32]. The STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) checklist was used to support the complete and transparent reporting of our research.

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[4] The International Statistical Classification of Diseases and Related Health Problems (ICD) is a diagnostic classification standard for clinical and research purposes: "ICD has been the basis for comparable statistics on causes of mortality and morbidity between places and over time" [31].

[5] More information regarding the SK and the HC programme is given here: https://www.bkkstarkekids.de/startseite/

Variables and measurements

Outcome of interest was the change of the child's MHP. The assessment of MHP in our sample was carried out using the Strengths and Difficulties Questionnaire (SDQ) [33, 34]. The SDQ is a screening instrument of 25 items that contains 5 different subscales measuring 1) emotional symptoms, 2) conduct problems, 3) hyperactivity-inattention, 4) peer relationship problems and 5) pro-social behaviour. Each of the SDQ items is scored on a 3-point Likert scale with 0 = not true, 1 = somewhat true or 2 = certainly true. Higher scores indicate greater problems, except for pro-social behaviour, where a higher score indicates more positive behaviour. A total difficulties score (range 0–40) can be obtained by summing the scores of the subscales 1–4. Higher values in the total score or in the 4 problem scales indicate a higher symptom burden, whereas higher values in the strength scale 5) pro-social behaviour indicate an increase in pro-social behaviour. Moreover, using the SDQ impact supplement, the study provides information on psychosocial impairment following child and adolescent MHP. The SDQ is available as a parental (SDQ-P) or self-assessment version (SDQ-S) for children aged 11 years or older. In agreement with this age cut, the SDQ-S version was completed by the child, or the proxy version (SDQ-P) was completed by the parents for younger children (< 11 years of age). Because sample size was too small in diagnostic subgroups, parental and self-assessment of the SDQ were combined for subsequent analyses. In accordance with German normative data [35, 36] and the cut-offs used in KiGGS [9], a SDQ score of > 13 (SDQ-P) and > 15 (SDQ-S), respectively, were considered as indicative of a mental health problem.

Sociodemographic data, namely age and sex of the child as well as age, sex and educational level of parents were collected at baseline. Age of the child was categorised (< 3 years of age, 3–5, 6–8, 9–11, 12–14 and 15 years or older) according to the KiGGS study [9]. The highest educational level of both parents was used and categorised into low (no qualification or secondary school), medium (intermediate school, no high school graduation) and high (high school or university graduation). The questionnaire was presented in German. Therefore, it must be assumed that families with a migrant background are not a representative sample of all migrant families living in Germany. This is why we decided not to report migrant background. The parents' income was not assessed in our study.

Statistical analysis

We report means and standard deviations for continuous variables as well as absolute frequencies and percentages for categorical variables. We compared SDQ scores of children with MHP receiving HC treatment (HC group) to children with the same diagnosis receiving standard paediatric care (control group). We compared the change in the scores (follow-up minus baseline score) in both groups as well as the change in MHP subgroups. The linear trend for each subject was visualised. P-values for differences in characteristics were based on Chi-square tests for categorical and Kruskal–Wallis tests for continuous variables. Significance level was set at $p = 0.05$.

Determinants of SDQ total score were analysed using linear mixed effects models (LME). LME allow to model the longitudinal relationship of different risk factors on an outcome by taking correlation structure of repeated measurements into account [37]. Random subject-specific intercepts were included to adjust for variance in the outcome between the subjects. Interaction terms of times and the respective risk factors were included to model the effect on the change of the SDQ values over time. According to the SDQ authors, a minimal difference of more than 2 points in the SDQ total score over time is considered relevant. Model fit was assessed by the Akaike Information Criterion (AIC) with lower values indicating better fit. Covariate selection was based on the literature indicating differences in MPH according to the age and sex of the child, migrant background and educational level of the parents and differences depending on which MHP is involved [38–41]. Therefore, age and gender of the child, intervention group (HC vs. control), parental educational level and the 4 indications (head and abdominal pain, developmental disorder of speech and language, enuresis and conduct disorder) were included in each model. We report an unadjusted model with time as the only covariate, a model with age and sex, and a fully adjusted model.

Inverse Probability of Treatment Weighting was calculated and introduced into each of the models to compensate for the lack of randomisation in group allocation [42, 43]. Only randomisation guarantees an equal distribution of all known and unknown patient characteristics in an intervention and a control group and thus allows causal conclusions about the treatment effects of therapy. When randomised controlled trials are not feasible, studies are at risk for treatment selection bias. Propensity scores minimise this bias by balancing the known confounders between treatment groups. The propensity score (PS) is defined as the probability of a patient receiving the therapy to be tested. The PS is estimated in a first step. In a second step, the actual therapy effect of interest is estimated including the PS.

All statistical analyses were carried out using SAS (Version 9.4, SAS Institute, Inc., Cary, NC, USA).

Sensitivity analysis

Results might be sensitive to categorisation of the outcome. Internationally, varying SDQ cut-offs are available, which impedes comparability [44]. In Germany, a SDQ total score of >13 (SDQ-P) and >15 (SDQ-S), respectively, are considered as indicative of a mental health problem ("at risk"). Our main analysis focused on the change in the total score as recommended by the SDQ authors [45]. Nevertheless, we also modelled the change in the SDQ cut-offs "not at risk" (SDQ-P ≤ 13/SDQ-S ≤ 15) and "at risk" (>13/>15). Absolute frequencies and percentages in the SDQ cut-offs for both groups were reported. *P*-values for differences in the change paths "improvement" (at risk at baseline and not at risk at follow-up), "deterioration" (not at risk at baseline and at risk at follow-up) as well as "no change" (still not at risk or still at risk) were based on Chi-square tests (significance level: $p=0.05$). In addition, the age of the child was introduced as a continuous instead of a categorised variable. In the main analyses, SDQ-P and SDQ-S were combined for subsequent analyses due to the small number of children completing the self-assessment version. In the assessment of externalising problems such as hyperactivity or conduct disorder, the parents' judgement is considered valid. With regard to emotional problems, especially in adolescents, the self-assessment is considered as more sensitive [3]. We therefore decided to model both, the change in SDQ subscales and the change in SDQ-P and SDQ-S additionally.

Results

The overall response rate at baseline was 17% and 56% at follow-up. More information is given in the supplement.

Baseline characteristics

Overall, 1090 children and their parents were included at baseline. A flow chart is shown in Fig. 3.

The questionnaire was mainly answered by mothers (80.3%). The number of children per family ranged from 1 to 5. Boys represented 60.2% of the participants. The children's mean age was 6.9 years (SD 3.3). Characteristics of the participants stratified by intervention are shown in Table 1. About $^1/_3$ (30.6%, $n=333$) of the children received HC treatment. Conduct disorder (29.7 vs. 21.5%) and enuresis (17.1 vs. 4.6%) were more frequent in the intervention group, while developmental disorders of speech and language (57.3 vs. 41.1%) and abdominal pain (22.2 vs. 16.5%) were more frequent in the control group. The SDQ-P was completed for 922 children aged up to 11 years. 168 minors completed the self-assessment version (SDQ-S). The overall SDQ at baseline was 8.4 (SD 5.7) and 11.1 (SD 6.4), respectively. A total of 23.5% had an "at risk" score (SDQ-P >13: 23.2%, SDQ-S >15: 25%) at baseline. There were no significant differences in the SDQ assessment between intervention and control group.

Longitudinal analyses

The follow-up questionnaire was answered by 654 participants. After excluding 55 participants with missing values in the outcome of interest (SDQ) there were no further exclusions necessary due to missing data in basic covariables. In total, 599 participants had sufficiently complete data to be included in the longitudinal analyses as shown in the flow chart (Fig. 3).

During the follow-up, there were no significant differences between the two groups neither in the change of the SDQ total score, nor in the change in SDQ items. The individual change in SDQ total score (SDQ-P and SDQ-S combined) by intervention and control group was visualised (Supplementary Fig. 4). There were no remarkable changes detectable. The overall change in the SDQ total score by intervention and control group as well as the change by diagnosis group are shown in Table 2. There was a slight decrease (-0.6, SD 4.1) in the control group, which was not significant ($p=0.065$). The highest scores (10.6, SD 5.7) were observed in children with conduct disorder, but there were no significant differences between intervention and control group ($p=0.559$).

Linear mixed effects model

Results from the unadjusted and adjusted models of the SDQ total score are shown in Table 3.

In the unadjusted model, time (-0.414, $p=0.017$) but not HC treatment (0.484, $p=0.312$) were associated with lower SDQ scores. After full adjustment for all potential confounders, higher SDQ scores were significantly associated with male sex (2.000, $p<0.001$). A higher age (15–17 years) was associated with higher SDQ scores, but the effect was not significant (1.533, $p=0.513$). A high educational level of the parents was significantly associated with lower SDQ scores (-2.127, $p=0.034$). There was a significant improvement in the control group over time (-0.814, $p=0.001$). SDQ values in the intervention group remained stable (-0.012 points) over the 1-year course ($=(-0.814)+0.802$; $p=0.020$).

Sensitivity analyses

In our sensitivity analyses, we modelled the change in SDQ cut-offs as shown in Fig. 4. At follow-up, 26.2% of the children in the HC (intervention) group and 46.7% of the control group showed an improvement in SDQ

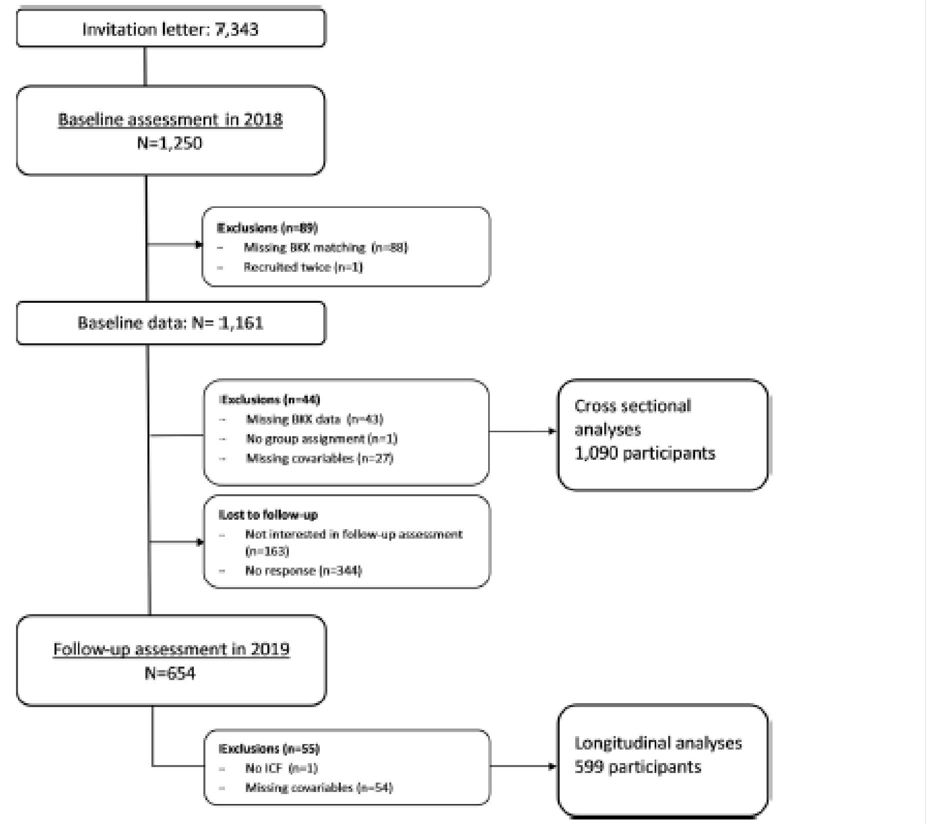

Fig. 3 Flow chart of the study population

cut-offs ("at risk" at baseline and "not at risk" at follow-up). However, the vast majority showed no change (still at risk: 73.8 vs. 53.3%) and a sizeable proportion worsened ("not at risk" at baseline and "at risk" at follow-up: 11.9 vs. 7.5%). The change paths between the two groups were not significant ($p = 0.056$).

Also, we analysed the parental (SDQ-P) and the self-assessment version (SDQ-S) separately and compared the change in SDQ items (Supplementary Table 3). However, we could not find any significant differences between the two groups. There was a decrease in SDQ-S scores in boys (HC: -2.8, SD 4.1; control group:—2.2, SD 4.2), which was not statistically significant ($p = 0.879$). Using the different SDQ classifications yielded similar results compared to the total score. In contrast to using cut-offs, the age of the child was significantly associated with higher SDQ scores (0.161, $p = 0.021$) when introduced as a continuous variable.

A table presenting the characteristics of participants with missing follow-up can be found in the supplementary material (Supplementary Table 4). There were no significant health-related or demographic differences compared to participants with complete follow-up. Main stated reason in the lost to follow-up questionnaire was a lack of time.

Discussion

In this cohort of children and adolescents with MHP, the SDQ scores were significantly associated with male sex and the educational level of the parents at baseline. In the follow-up period of 1 year, there was a significant improvement in SDQ scores in the control group while the scores in the intervention group remained stable.

The SDQ is a valid instrument to identify MHP in children and adolescents at an early stage. According to the SDQ authors, a minimal difference of more than 2 points in the SDQ total score is considered relevant. The

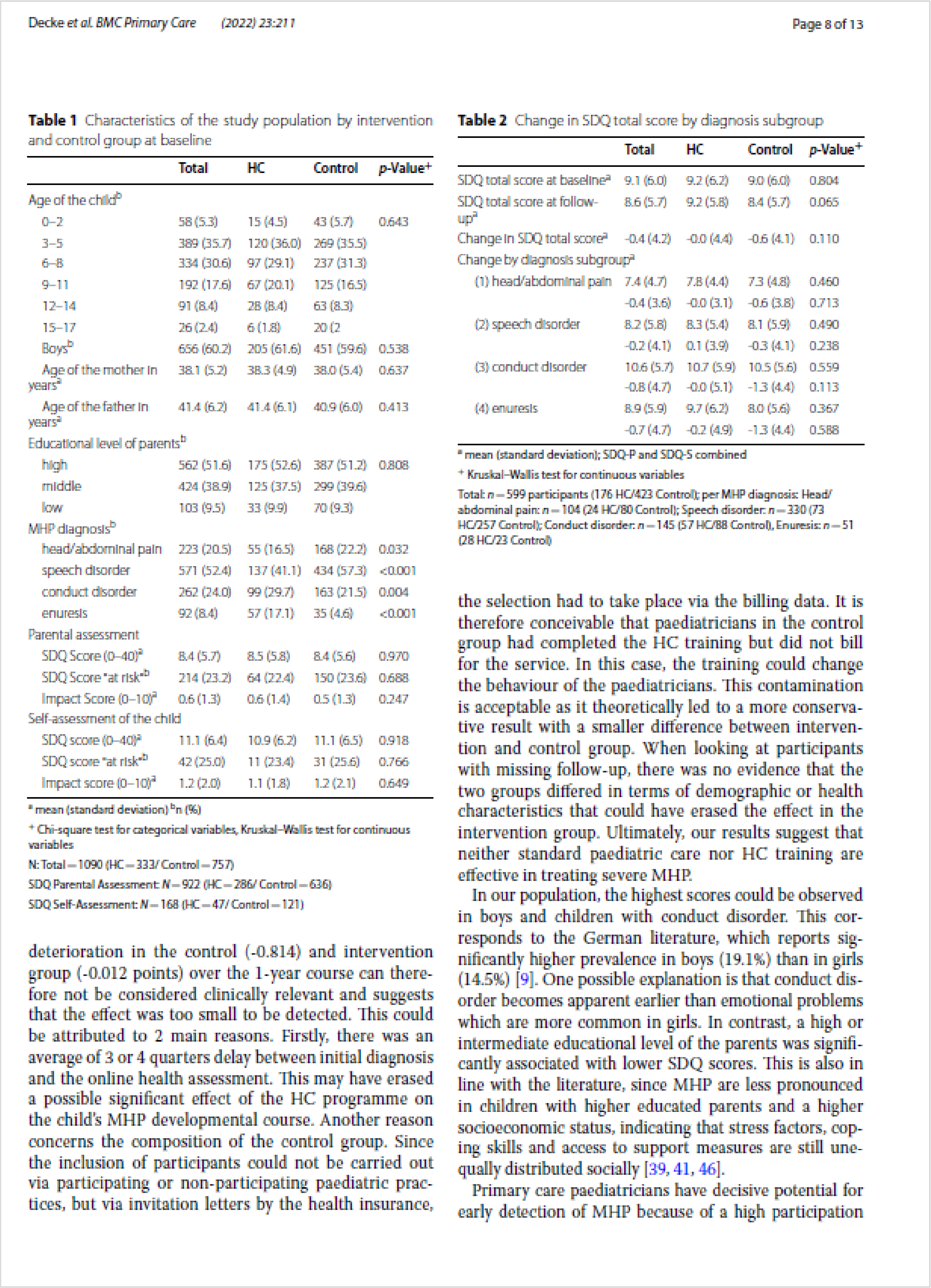

Table 1 Characteristics of the study population by intervention and control group at baseline

	Total	HC	Control	*p*-Value⁺
Age of the child[b]				
0–2	58 (5.3)	15 (4.5)	43 (5.7)	0.643
3–5	389 (35.7)	120 (36.0)	269 (35.5)	
6–8	334 (30.6)	97 (29.1)	237 (31.3)	
9–11	192 (17.6)	67 (20.1)	125 (16.5)	
12–14	91 (8.4)	28 (8.4)	63 (8.3)	
15–17	26 (2.4)	6 (1.8)	20 (2	
Boys[b]	656 (60.2)	205 (61.6)	451 (59.6)	0.538
Age of the mother in years[a]	38.1 (5.2)	38.3 (4.9)	38.0 (5.4)	0.637
Age of the father in years[a]	41.4 (6.2)	41.4 (6.1)	40.9 (6.0)	0.413
Educational level of parents[b]				
high	562 (51.6)	175 (52.6)	387 (51.2)	0.808
middle	424 (38.9)	125 (37.5)	299 (39.6)	
low	103 (9.5)	33 (9.9)	70 (9.3)	
MHP diagnosis[b]				
head/abdominal pain	223 (20.5)	55 (16.5)	168 (22.2)	0.032
speech disorder	571 (52.4)	137 (41.1)	434 (57.3)	<0.001
conduct disorder	262 (24.0)	99 (29.7)	163 (21.5)	0.004
enuresis	92 (8.4)	57 (17.1)	35 (4.6)	<0.001
Parental assessment				
SDQ Score (0–40)[a]	8.4 (5.7)	8.5 (5.8)	8.4 (5.6)	0.970
SDQ Score "at risk"[b]	214 (23.2)	64 (22.4)	150 (23.6)	0.688
Impact Score (0–10)[a]	0.6 (1.3)	0.6 (1.4)	0.5 (1.3)	0.247
Self-assessment of the child				
SDQ score (0–40)[a]	11.1 (6.4)	10.9 (6.2)	11.1 (6.5)	0.918
SDQ score "at risk"[b]	42 (25.0)	11 (23.4)	31 (25.6)	0.766
Impact score (0–10)[a]	1.2 (2.0)	1.1 (1.8)	1.2 (2.1)	0.649

[a] mean (standard deviation) [b] n (%)

⁺ Chi-square test for categorical variables, Kruskal–Wallis test for continuous variables

N: Total = 1090 (HC = 333/ Control = 757)

SDQ Parental Assessment: *N* = 922 (HC = 286/ Control = 636)

SDQ Self-Assessment: *N* = 168 (HC = 47/ Control = 121)

deterioration in the control (-0.814) and intervention group (-0.012 points) over the 1-year course can therefore not be considered clinically relevant and suggests that the effect was too small to be detected. This could be attributed to 2 main reasons. Firstly, there was an average of 3 or 4 quarters delay between initial diagnosis and the online health assessment. This may have erased a possible significant effect of the HC programme on the child's MHP developmental course. Another reason concerns the composition of the control group. Since the inclusion of participants could not be carried out via participating or non-participating paediatric practices, but via invitation letters by the health insurance, the selection had to take place via the billing data. It is therefore conceivable that paediatricians in the control group had completed the HC training but did not bill for the service. In this case, the training could change the behaviour of the paediatricians. This contamination is acceptable as it theoretically led to a more conservative result with a smaller difference between intervention and control group. When looking at participants with missing follow-up, there was no evidence that the two groups differed in terms of demographic or health characteristics that could have erased the effect in the intervention group. Ultimately, our results suggest that neither standard paediatric care nor HC training are effective in treating severe MHP.

Table 2 Change in SDQ total score by diagnosis subgroup

	Total	HC	Control	*p*-Value⁺
SDQ total score at baseline[a]	9.1 (6.0)	9.2 (6.2)	9.0 (6.0)	0.804
SDQ total score at follow-up[a]	8.6 (5.7)	9.2 (5.8)	8.4 (5.7)	0.065
Change in SDQ total score[a]	-0.4 (4.2)	-0.0 (4.4)	-0.6 (4.1)	0.110
Change by diagnosis subgroup[a]				
(1) head/abdominal pain	7.4 (4.7)	7.8 (4.4)	7.3 (4.8)	0.460
	-0.4 (3.6)	-0.0 (3.1)	-0.6 (3.8)	0.713
(2) speech disorder	8.2 (5.8)	8.3 (5.4)	8.1 (5.9)	0.490
	-0.2 (4.1)	0.1 (3.9)	-0.3 (4.1)	0.238
(3) conduct disorder	10.6 (5.7)	10.7 (5.9)	10.5 (5.6)	0.559
	-0.8 (4.7)	-0.0 (5.1)	-1.3 (4.4)	0.113
(4) enuresis	8.9 (5.9)	9.7 (6.2)	8.0 (5.6)	0.367
	-0.7 (4.7)	-0.2 (4.9)	-1.3 (4.4)	0.588

[a] mean (standard deviation); SDQ-P and SDQ-S combined

⁺ Kruskal–Wallis test for continuous variables

Total: *n* = 599 participants (176 HC/423 Control); per MHP diagnosis: Head/abdominal pain: *n* = 104 (24 HC/80 Control); Speech disorder: *n* = 330 (73 HC/257 Control); Conduct disorder: *n* = 145 (57 HC/88 Control), Enuresis: *n* = 51 (28 HC/23 Control)

In our population, the highest scores could be observed in boys and children with conduct disorder. This corresponds to the German literature, which reports significantly higher prevalence in boys (19.1%) than in girls (14.5%) [9]. One possible explanation is that conduct disorder becomes apparent earlier than emotional problems which are more common in girls. In contrast, a high or intermediate educational level of the parents was significantly associated with lower SDQ scores. This is also in line with the literature, since MHP are less pronounced in children with higher educated parents and a higher socioeconomic status, indicating that stress factors, coping skills and access to support measures are still unequally distributed socially [39, 41, 46].

Primary care paediatricians have decisive potential for early detection of MHP because of a high participation

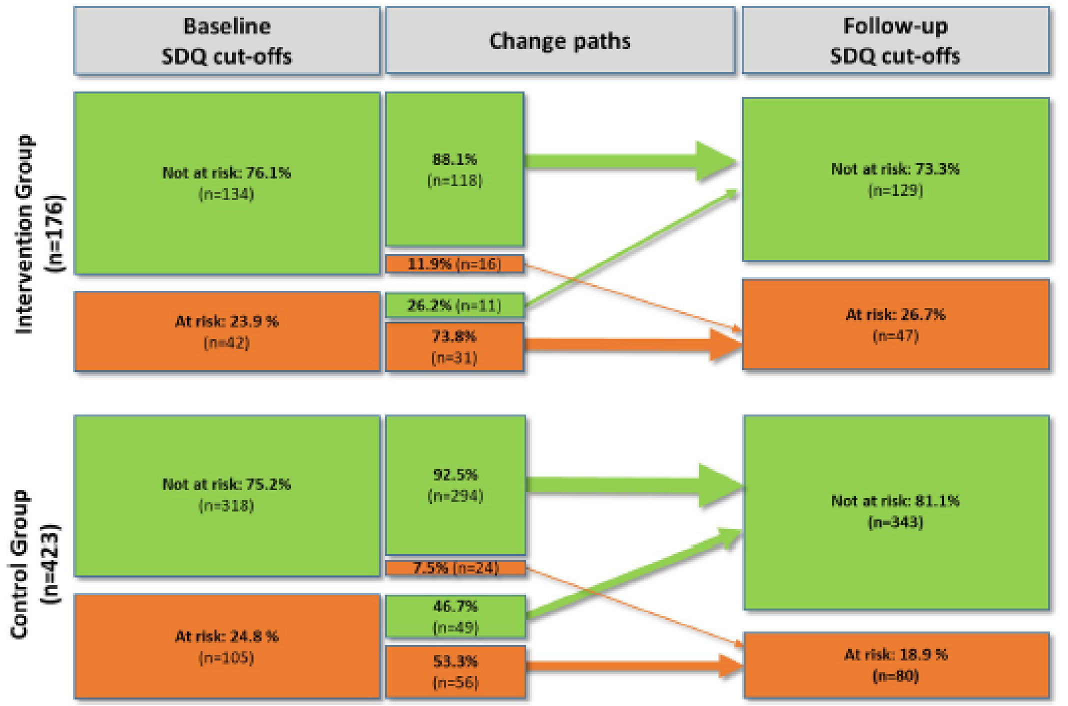

Fig. 4 SDQ cut-offs at baseline as compared to follow-up in the HC and control group

that could be observed in our study as well as in Germany in the last few years [9].

Our findings are particularly important as they generate the first evaluation of patient-related effects of the HC programme. In addition, our results will complement the qualitative PrimAQuO study [28] and the evaluation of costs of the HC programme [29] resulting in a comprehensive, mixed method programme evaluation. Programme evaluations are needed to make evidence-based decisions for the optimal care of children and adolescents with MHP in primary care.

The present study has several important strengths. The main strength of our study is an online health assessment of more than 1200 children with MHP and their parents. The children's and adolescents' health development could be followed over 1 year. We conducted a comprehensive SDQ assessment and were able to survey parents and the children themselves regarding their health development. We also obtained age-, gender- and indication-specific differences between intervention and control group.

Nevertheless, our study has some limitations. First, SDQ was only measured at 2 time points. We therefore had to model a linear association which might not reflect the true trajectories over time. Second, based on billing data, children meeting the inclusion criteria could be identified by the BKK with an average delay of 2 quarters, so that the baseline assessment took place months after the intervention. This may have erased an effect between both groups. Currently, the HC programme is limited to insured persons of the BKK funds. The BKK is a major statutory health insurance funds in Germany with 10.9 (in Bavaria: 2.4) of a total of 73.0 million insurees[6] [52]. Therefore, the results of the present study are most likely to be generalisable for Germany. In addition, it has been shown in the international context that primary care programmes are likely to be integrable into different health system structures [20, 21]. How the corona pandemic — accompanied by school closures, discontinuation of school entry examinations and an increase in domestic violence — will affect the prevalence of MHP and care needs is still unknown.

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[6] Status as of 1.st July 2019.

Conclusion

Our evaluation could not prove a clinically relevant effect of the HC programme on the developmental 1-year course of MHP among children and adolescents. Paediatricians provide low-threshold care and have crucial potential for early detection and treatment of mild MHP cases. Although neither the programme nor standard paediatric care showed significant improvements in MHP, the programme could be helpful in identifying MHP patients and choosing the best treatment option. Targeting families with low parental education might help reduce children's and adolescents' MHP and could be a step towards continuous improvement of care.

Abbreviations

MHP: Mental health problems; HC: Health coaching; BKK-LV Bayern: Betriebskrankenkassen Landesverband Bayern (Bavarian State Association of company health insurance fund); BVKJ: Berufsverband der Kinder- und Jugendärzte (a professional association of paediatricians in Germany); SHI: Statutory health insurance; ICF: International Classification of Functioning, Disability and Health; ICD: International Statistical Classification of Diseases and Related Health Problems; SK: STARKE KIDS programme; with the SK, enhanced screenings for children and adolescents throughout Germany are available; SDQ: Strengths and Difficulties Questionnaire (SDQ-P/SDQ-S: parental/self-assessment version).

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12875-022-01780-1.

Additional file 1. The additional file contains the in- and exclusion criteria of study participants, additional programme information, sensitivity analyses, information to the non-responder and lost to follow-up participants.

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Authors' contributions

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

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Availability of data and materials

The data that support the findings of this study are available from the corresponding author, (SD), upon request. All statistical analyses were carried out using SAS (Version 9.4, SAS Institute, Inc., Cary, NC, USA). The SAS codes can be provided on demand.

Declarations

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 17–497) 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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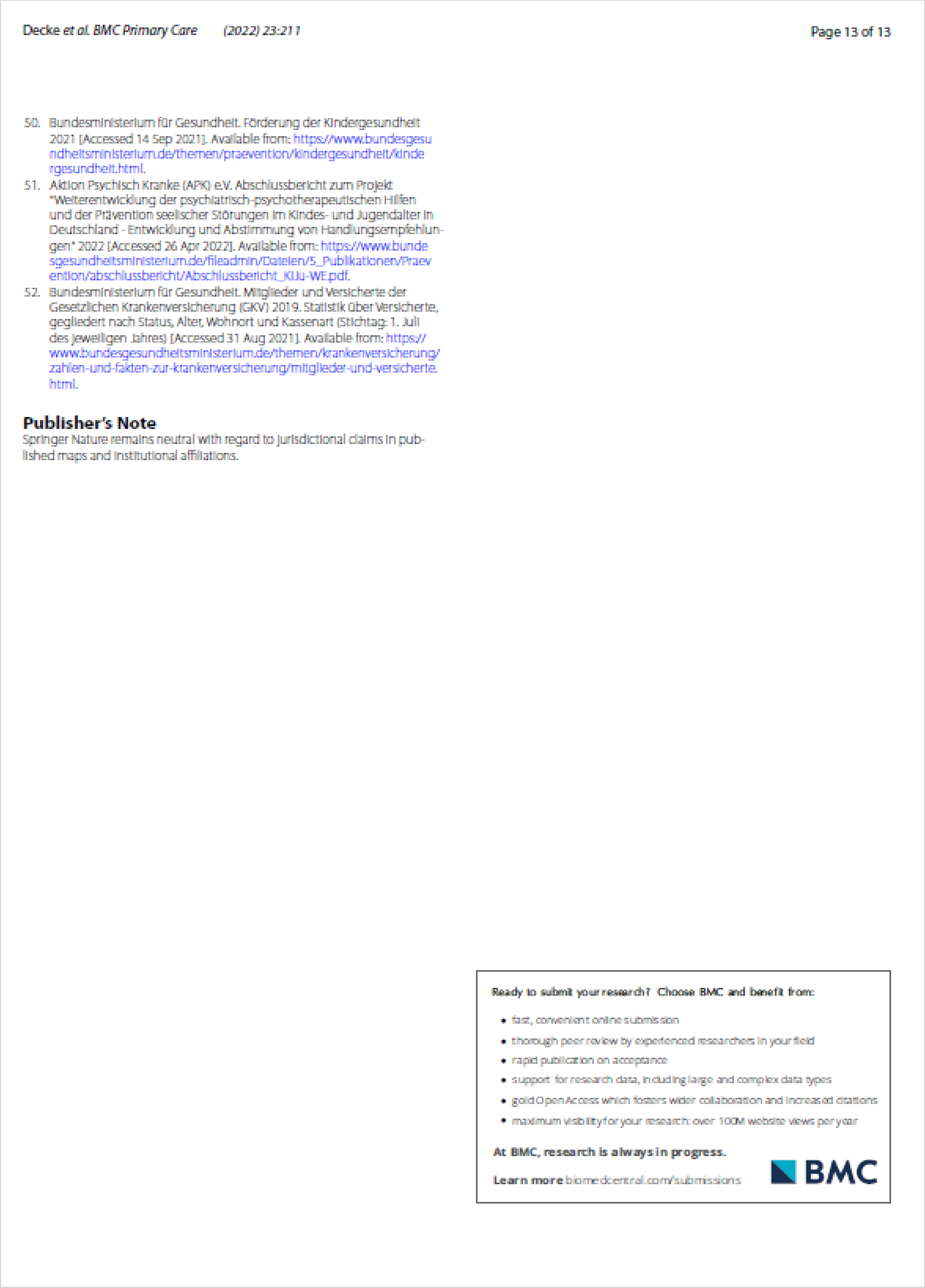

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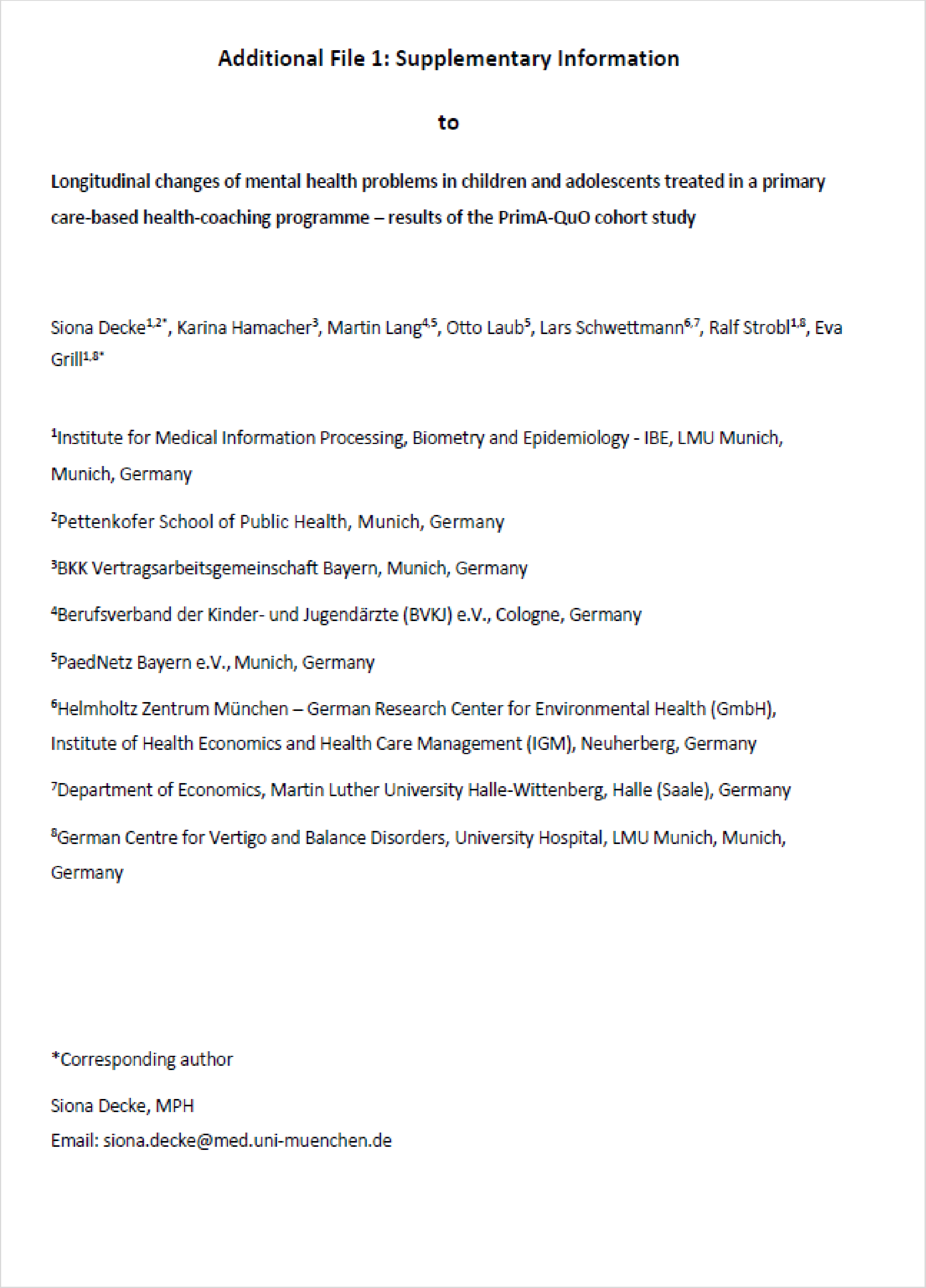

Additional File 1: Supplementary Information

to

Longitudinal changes of mental health problems in children and adolescents treated in a primary care-based health-coaching programme – results of the PrimA-QuO cohort study

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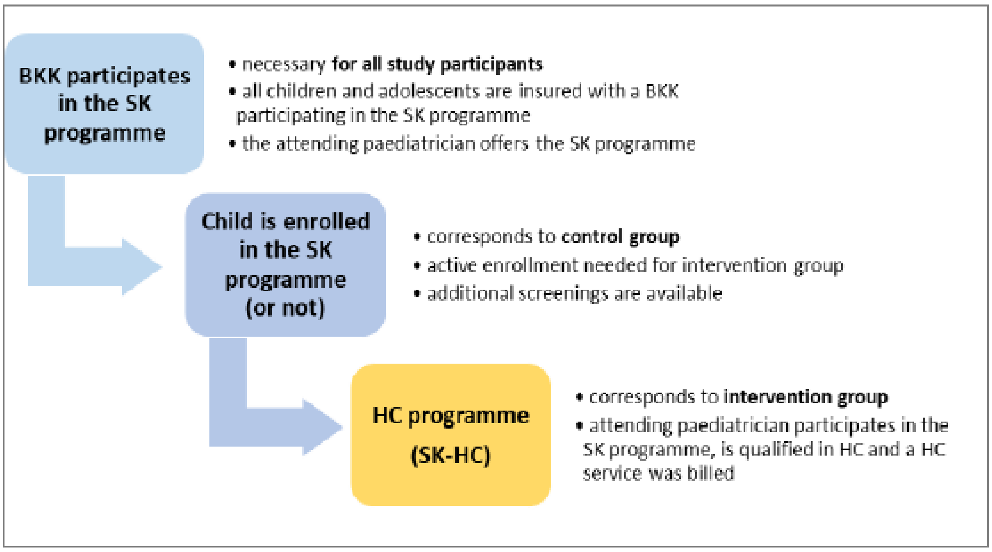
Contents

Appendix A: The Health Coaching (HC) programme

In 2013, a major German statutory health insurance fund ("Betriebskrankenkassen Landesverband" - BKK-LV) in collaboration with a professional association of paediatricians ("Berufsverband der Kinder- und Jugendärzte" – BVKJ e. V.) has introduced a programme for their insurees targeted at primary care paediatricians (Health Coaching - HC). The foundation of the HC is the BKK programme "STARKE KIDS"[1] (SK). With the SK programme, additional developmental check-ups are available for children enrolled in the programme. In addition, the HC programme can be offered to children and adolescents with mental health problems (MHP) as shown in Supplementary Figure 1.



Supplementary Figure 1: Overview of the BKK STARKE KIDS (SK) and the Health Coaching (HC) programme

The HC is predominantly implemented in Bavaria, one of the largest federal states of Germany with a total of 13 million inhabitants. The HC has been available nationwide since October 2015. More than 700 paediatricians in Bavaria and more than 2.100 ones nationwide are currently qualified to participate in the HC programme and approximately 36.000 children with MHP have been treated accordingly to the programme. Paediatricians play a central role in this context. The aim of the patient education is to impart self-management skills to the children and their parents and purposefully inform them about the various care services available. The HC includes a training concept for paediatricians based on a dual training participation, standardised action guidelines for 16 MHP (e. g. developmental

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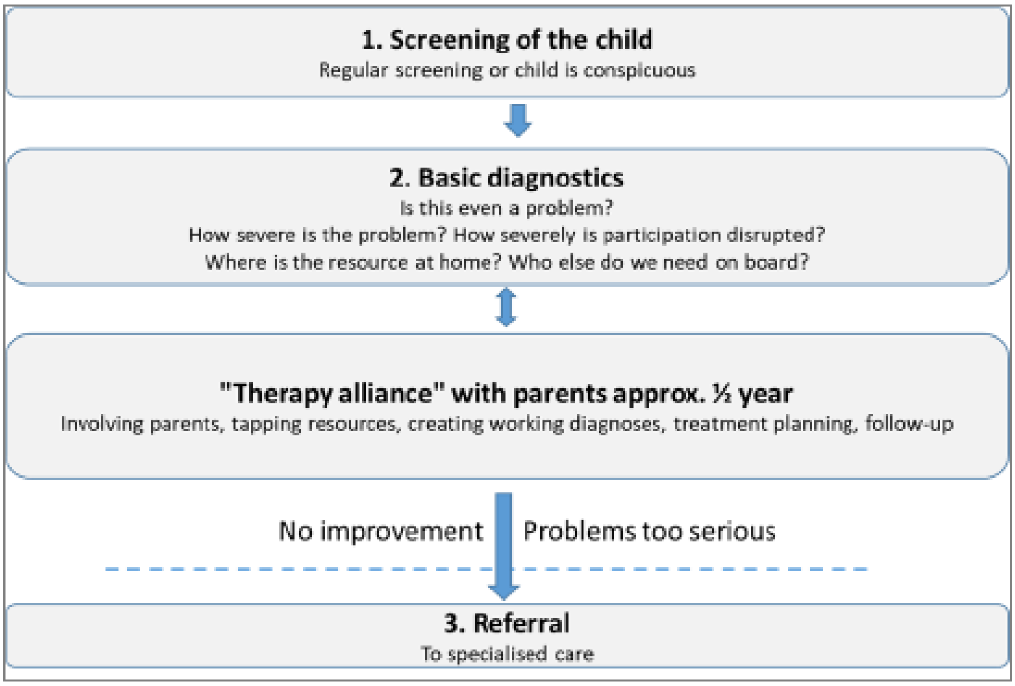
[1] Further information can be found here: https://www.bkkstarkekids.de/unser-leistungsangebot/vorsorgeuntersuchungen-fuer-kinder-und-jugendliche

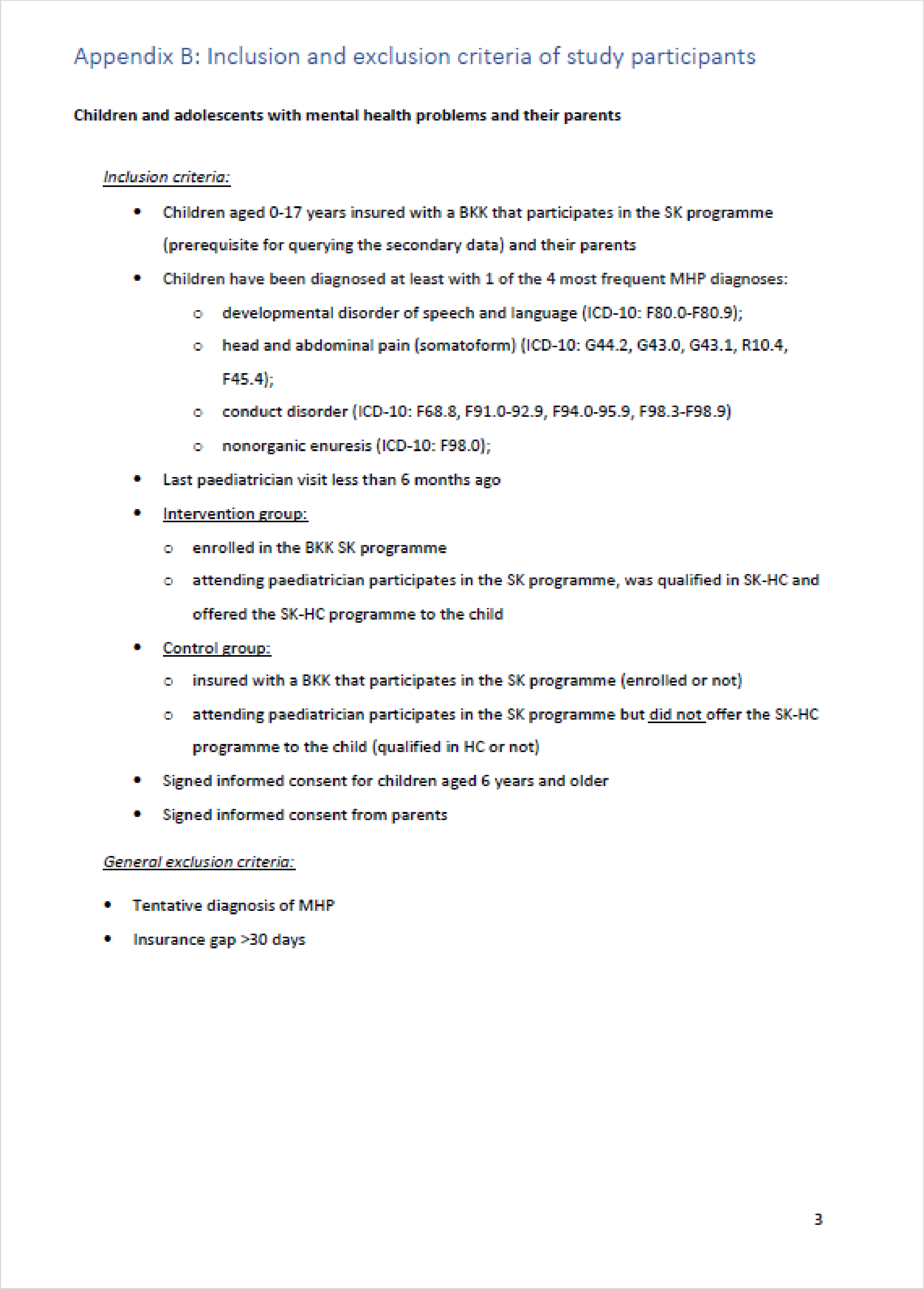
disorder of speech and language, enuresis, head and abdominal pain) and additional fees for paediatricians who undergo this specific training and demonstrably act according to the guidelines [1]. With the HC, 15 euros per 10 minutes up to a cap of 180 minutes per child in addition to the statutory standard care are billable. The basic programme's principles are participation, patient orientation and strengthening of existing resources. The social-paediatric diagnostic is divided into 3 steps as shown in Supplementary Figure 2.



Supplementary Figure 2: 3 steps model of social-paediatric diagnostics

Typically, abnormalities are noticed at the developmental check-ups, by the parents themselves or at kindergarten/school. In a second step, the paediatrician carries out a detailed examination. Usually, a therapy alliance for 6 months is arranged with the parents, assessing the family's resources.

If the problems are too serious or the HC programme does not work, a referral to specialised care takes place. In this sense, children with minor problems can remain in the care of the paediatrician while resources are available for others who need immediate referral to specialised care (e.g., therapists, social paediatric centre). To implement the programme, it is necessary that the paediatrician participates in the SK programme and has completed the HC training participation and the child is enrolled in the SK programme so that HC services are billable.



Appendix B: Inclusion and exclusion criteria of study participants

Children and adolescents with mental health problems and their parents

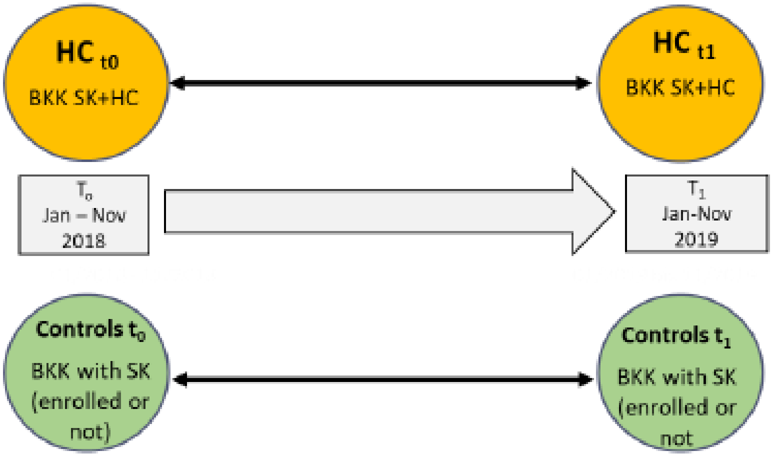
Inclusion criteria:

- Children aged 0-17 years insured with a BKK that participates in the SK programme (prerequisite for querying the secondary data) and their parents
- Children have been diagnosed at least with 1 of the 4 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 6 months ago
- Intervention group:
    - enrolled in the BKK SK programme
    - attending paediatrician participates in the SK programme, was qualified in SK-HC and offered the SK-HC programme to the child
- Control group:
    - insured with a BKK that participates in the SK programme (enrolled or not)
    - attending paediatrician participates in the SK programme but did not offer the SK-HC programme to the child (qualified in HC or not)
- Signed informed consent for children aged 6 years and older
- Signed informed consent from parents

General exclusion criteria:

- Tentative diagnosis of MHP
- Insurance gap >30 days

In the Supplementary Figure 3 the intervention group and control group corresponding to the group definition above are illustrated.



Supplementary Figure 3: Intervention (HC) and control group assessed at baseline (t0) and follow-up (t1) 1 year later.

SK="STARKE KIDS" programme, HC=Health Coaching programme
t0=Baseline assessment, t1=Follow-up assessment 1 year later

Appendix C: Strengths and Difficulties Questionnaire (SDQ)

1. Overview SDQ

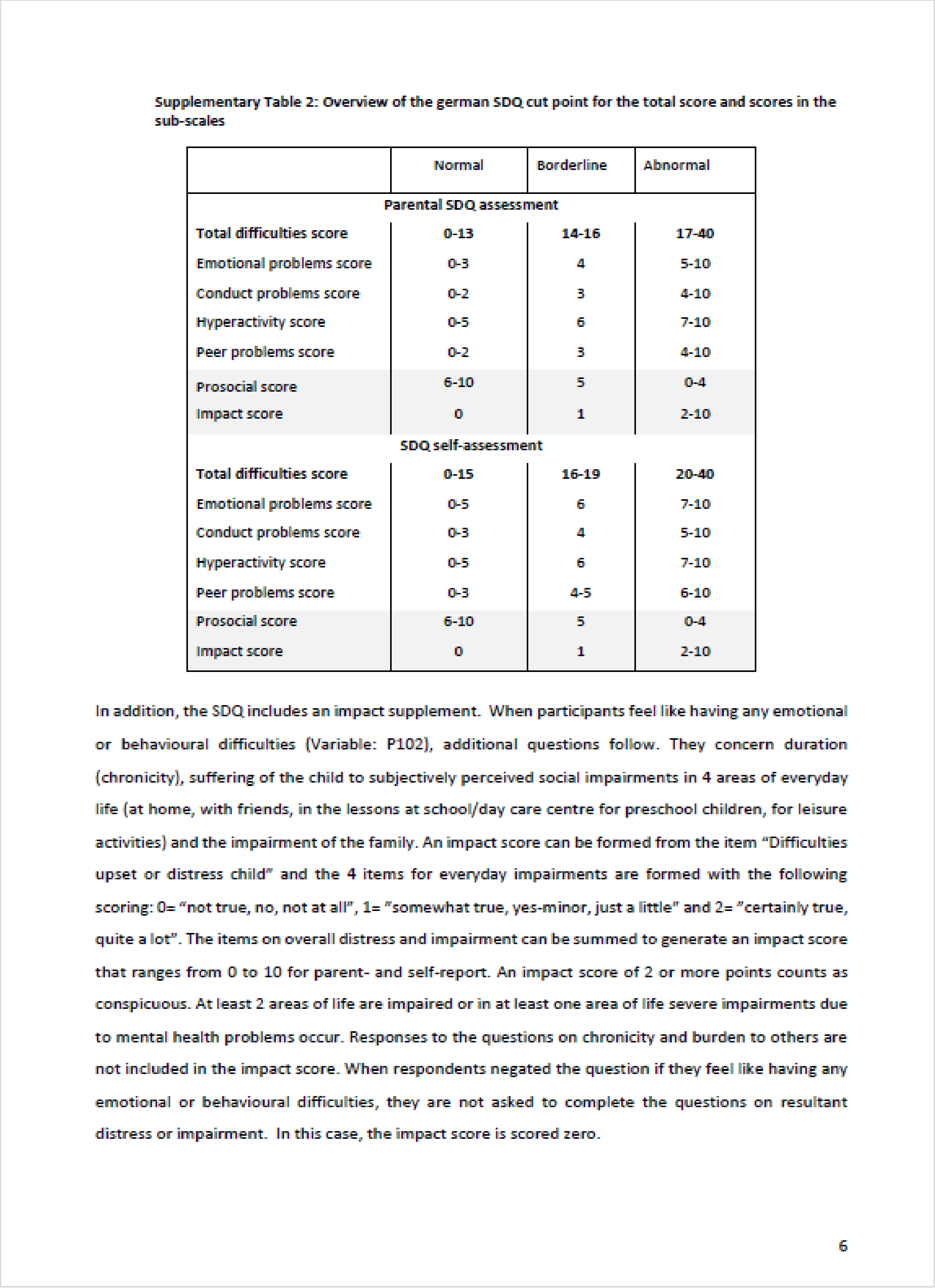
Children's mental health was assessed at baseline and follow-up using the German version of the Strengths and Difficulties Questionnaire (SDQ) [2,3]. The child and adolescent self-assessment version is used for children aged 11 years or older. A parental report is available for younger children. The SDQ comprises 25 items that contains 5 different sub-scales measuring (Supplementary Table 1):

Supplementary Table 1: Overview of the 5 SDQ sub-scales

SDQ Total Score	
1) emotional symptoms (5 items)	1) to 4) added together to generate a total difficulties score (based on 20 items)
2) conduct problems (5 items)	
3) hyperactivity/inattention (5 items)	
4) peer relationship problems (5 items)	
5) prosocial behaviour (5 items)	

Each of the SDQ items is scored on a 3-point scale with 0 = not true, 1 = somewhat true and 2 = certainly true, giving a maximum score of 10 for each sub-scale. Higher scores indicate more serious problems, except for prosocial behaviour, where higher scores indicate more positive behaviour. Following the SDQ scoring guide, these scores have been scaled up pro-rata if at least 3 items were completed for the sub-scale. If 2 or less items were completed, the sub-scale (and hence, the total SDQ) was treated as missing or incomplete. The questions for each sub-scale are the same at each age, with exception of 2 questions: The conduct disorder sub-scale varies slightly for 3-year-olds, as 2 items on antisocial behaviour are replaced by items on oppositionality.

The total difficulties score (range 0-40) is a sum of scores on 20 items (omitting prosocial items), with higher scores representing poorer psychosocial functioning. According to the German norms, a total parental assessment score ≤ 13 points is considered as "normal", a score of 14 up to 16 points as "borderline" and of 17 up to 40 points as "abnormal" (table 1). Congruently, in the self-assessment questionnaire the cut-offs are 0-15 ("normal"), 16-19 ("borderline") and 20-40 ("abnormal"). We used the more neutral terms "not at risk" (SDQ-P/SDQ-S: 0-13/0-15) and "at risk" (≥14/≥16). The German cut points for the SDQ total score and SDQ sub-scales are listed in Supplementary Table 2.



Supplementary Table 2: Overview of the german SDQ cut point for the total score and scores in the sub-scales

	Normal	Borderline	Abnormal
Parental SDQ assessment			
Total difficulties score	**0-13**	**14-16**	**17-40**
Emotional problems score	0-3	4	5-10
Conduct problems score	0-2	3	4-10
Hyperactivity score	0-5	6	7-10
Peer problems score	0-2	3	4-10
Prosocial score	6-10	5	0-4
Impact score	0	1	2-10
SDQ self-assessment			
Total difficulties score	**0-15**	**16-19**	**20-40**
Emotional problems score	0-5	6	7-10
Conduct problems score	0-3	4	5-10
Hyperactivity score	0-5	6	7-10
Peer problems score	0-3	4-5	6-10
Prosocial score	6-10	5	0-4
Impact score	0	1	2-10

In addition, the SDQ includes an impact supplement. When participants feel like having any emotional or behavioural difficulties (Variable: P102), additional questions follow. They concern duration (chronicity), suffering of the child to subjectively perceived social impairments in 4 areas of everyday life (at home, with friends, in the lessons at school/day care centre for preschool children, for leisure activities) and the impairment of the family. An impact score can be formed from the item "Difficulties upset or distress child" and the 4 items for everyday impairments are formed with the following scoring: 0= "not true, no, not at all", 1= "somewhat true, yes-minor, just a little" and 2= "certainly true, quite a lot". The items on overall distress and impairment can be summed to generate an impact score that ranges from 0 to 10 for parent- and self-report. An impact score of 2 or more points counts as conspicuous. At least 2 areas of life are impaired or in at least one area of life severe impairments due to mental health problems occur. Responses to the questions on chronicity and burden to others are not included in the impact score. When respondents negated the question if they feel like having any emotional or behavioural difficulties, they are not asked to complete the questions on resultant distress or impairment. In this case, the impact score is scored zero.

The SDQ follow-up versions include the 25 basic items and the impact question, but also 2 additional follow-up questions for use after an intervention (Has the intervention reduced any problems? Has the intervention helped in other ways, e.g. making the problems more bearable?).

2. SDQ: Generating scores in SAS

The SDQ scoring algorithm is based on 25 variables plus impact items for each questionnaire. The first letter of each variable name is 'p' for the parental SDQ version and 's' for the self-report SDQ assessment. After this first letter ('p' or 's'), the variable names are named as follows in the original scoring syntax e.g., "consid" is named as "psconsid" in the parental scores and "Sconsid" in the self-assessment scores.

consid = Item 1 : considerate
restles = Item 2 : restless
somatic = Item 3 : somatic symptoms
shares = Item 4 : shares readily
tantrum = Item 5 : tempers
loner = Item 6 : solitary
obeys = Item 7 : obedient
worries = Item 8 : worries
caring = Item 9 : helpful if someone hurt
fidgety = Item 10 : fidgety
friend = Item 11 : has good friend
fights = Item 12 : fights or bullies
unhappy = Item 13 : unhappy
popular = Item 14 : generally liked
distrac = Item 15 : easily distracted
clingy = Item 16 : nervous in new situations
kind = Item 17 : kind to younger children
lies = Item 18 : lies or cheats *[for the SDQ for 2-4 year olds, replace 'lies' with 'argues']*
bullied = Item 19 : picked on or bullied
helpout = Item 20 : often volunteers
reflect = Item 21 : thinks before acting
steals = Item 22 : steals *[for the SDQ for 2-4 year olds, replace 'steals' with 'spite']*
oldbest = Item 23 : better with adults than with children
afraid = Item 24 : many fears
attends = Item 25 : good attention
ebddiff = Impact question: overall difficulties in at least one area
distres = Impact question: upset or distressed
imphome = Impact question: interferes with home life
impfrie = Impact question: interferes with friendships
impclas = Impact question: interferes with learning
impleis = Impact question: interferes with leisure

If the first response category (not true, no, not at all) has been selected, this is coded as “0”, the next response category (somewhat true, yes-minor, just a little) is coded as “1” and the last category is coded as “2” (certainly true, quite a lot). The impact assessment has another category “3” (a great deal, yes-severe difficulties”).

The algorithm generates 6 scores.

emotion = emotional symptoms (e.g. pemotion)
conduct = conduct problems
hyper = hyperactivity/inattention
peer = peer problems
prosoc = prosocial

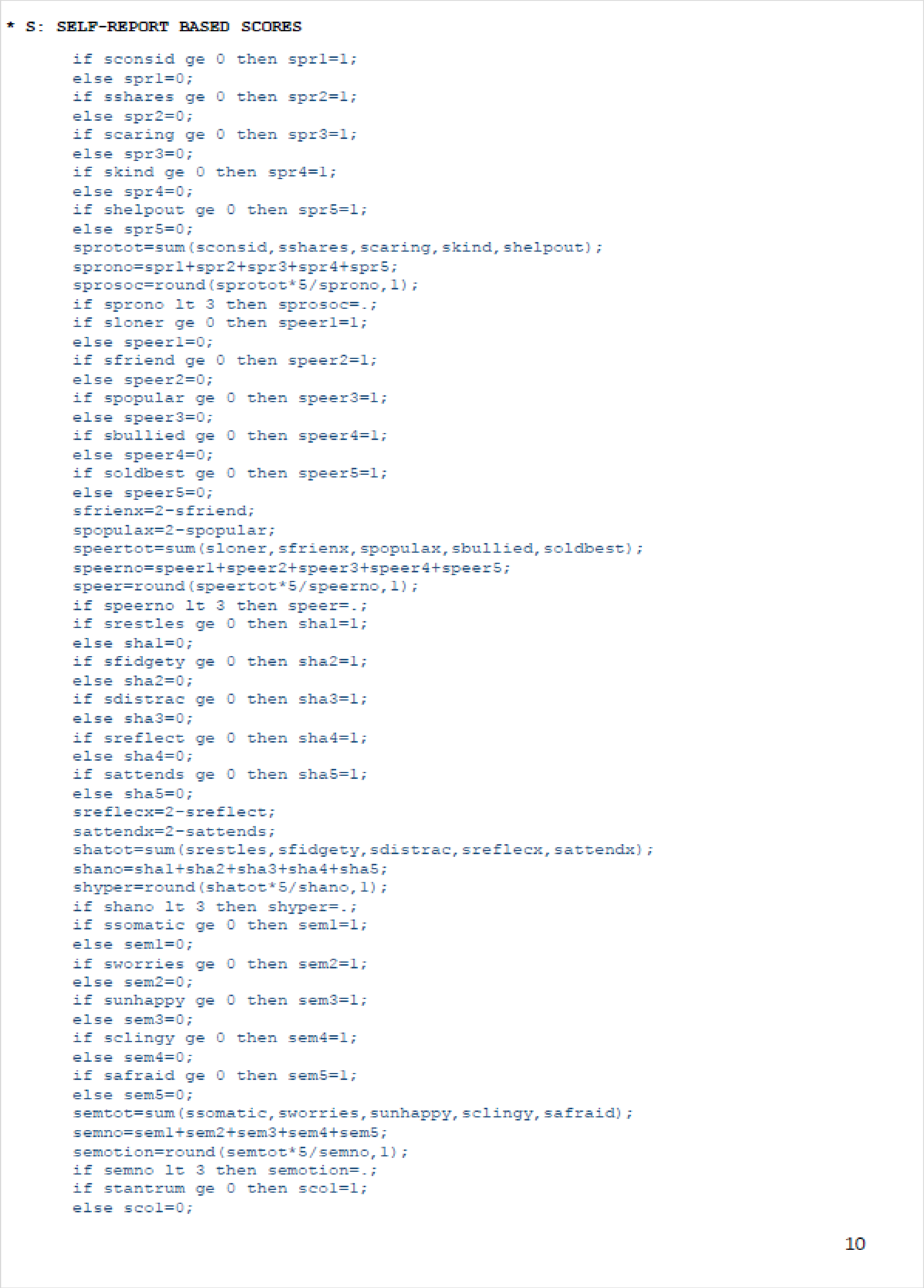
ebdtot = total difficulties
impact = impact

Again, the first letter of each derived variable is ‘p’ for parent-based scores and ‘s’ for self-report-based scores e.g., “emotion” is named as “pemotion” in the parental syntax and “semotion” in the self-assessment.

```
* P: PARENTAL SCORES

      if pconsid ge 0 then ppr1=1;
      else ppr1=0;
      if pshares ge 0 then ppr2=1;
      else ppr2=0;
      if pcaring ge 0 then ppr3=1;
      else ppr3=0;
      if pkind ge 0 then ppr4=1;
      else ppr4=0;
      if phelpout ge 0 then ppr5=1;
      else ppr5=0;
      pprotot=sum(pconsid,pshares,pcaring,pkind,phelpout);
      pprono=ppr1+ppr2+ppr3+ppr4+ppr5;
      pprosoc=round(pprotot*5/pprono,1);
      if pprono lt 3 then pprosoc=.;
      if ploner ge 0 then ppeer1=1;
      else ppeer1=0;
      if pfriend ge 0 then ppeer2=1;
      else ppeer2=0;
      if ppopular ge 0 then ppeer3=1;
      else ppeer3=0;
      if pbullied ge 0 then ppeer4=1;
      else ppeer4=0;
      if poldbest ge 0 then ppeer5=1;
      else ppeer5=0;
      pfrienx=2-pfriend;
      ppopulax=2-ppopular;
      ppeertot=sum(ploner,pfrienx,ppopulax,pbullied,poldbest);
      ppeerno=ppeer1+ppeer2+ppeer3+ppeer4+ppeer5;
      ppeer=round(ppeertot*5/ppeerno,1);
      if ppeerno lt 3 then ppeer=.;
      if prestles ge 0 then phal=1;
      else phal=0;
```

```
if pfidgety ge 0 then pha2=1;
else pha2=0;
if pdistrac ge 0 then pha3=1;
else pha3=0;
if preflect ge 0 then pha4=1;
else pha4=0;
if pattends ge 0 then pha5=1;
else pha5=0;
preflecx=2-preflect;
pattendx=2-pattends;
phatot=sum(prestles,pfidgety,pdistrac,preflecx,pattendx);
phano=pha1+pha2+pha3+pha4+pha5;
phyper=round(phatot*5/phano,1);
if phano lt 3 then phyper=.;
if psomatic ge 0 then pem1=1;
else pem1=0;
if pworries ge 0 then pem2=1;
else pem2=0;
if punhappy ge 0 then pem3=1;
else pem3=0;
if pclingy ge 0 then pem4=1;
else pem4=0;
if pafraid ge 0 then pem5=1;
else pem5=0;
pemtot=sum(psomatic,pworries,punhappy,pclingy,pafraid);
pemno=pem1+pem2+pem3+pem4+pem5;
pemotion=round(pemtot*5/pemno,1);
if pemno lt 3 then pemotion=.;
if ptantrum ge 0 then pco1=1;
else pco1=0;
if pobeys ge 0 then pco2=1;
else pco2=0;
if pfights ge 0 then pco3=1;
else pco3=0;
if plies ge 0 then pco4=1;
else pco4=0;
if psteals ge 0 then pco5=1;
else pco5=0;
pobeyx=2-pobeys;
pcotot=sum(ptantrum,pobeyx,pfights,plies,psteals);
pcono=pco1+pco2+pco3+pco4+pco5;
pconduct=round(pcotot*5/pcono,1);
if pcono lt 3 then pconduct=.;
pebdtot=pemotion+pconduct+phyper+ppeer;
pdistrez=pdistres-1 ;
if pdistres=0 then pdistrez=0;
pimphomz=pimphome-1 ;
if pimphome=0 then pimphomz=0;
pimpfriz=pimpfrie-1 ;
if pimpfrie=0 then pimpfriz=0;
pimpclaz=pimpclas-1 ;
if pimpclas=0 then pimpclaz=0;
pimpleiz=pimpleis-1 ;
if pimpleis=0 then pimpleiz=0;
pimpact=sum(pdistrez,pimphomz,pimpfriz,pimpclaz,pimpleiz);
if pimpact lt 0 and pebddiff=0 then pimpact=0;
drop ppr1 ppr2 ppr3 ppr4 ppr5 pprotot pprono
ppeer1 ppeer2 ppeer3 ppeer4 ppeer5 pfrienx ppopulax ppeertot ppeerno
pha1 pha2 pha3 pha4 pha5 preflecx pattendx phatot phano
pem1 pem2 pem3 pem4 pem5 pemtot pemno
pco1 pco2 pco3 pco4 pco5 sobeyx pcotot pcono;
```

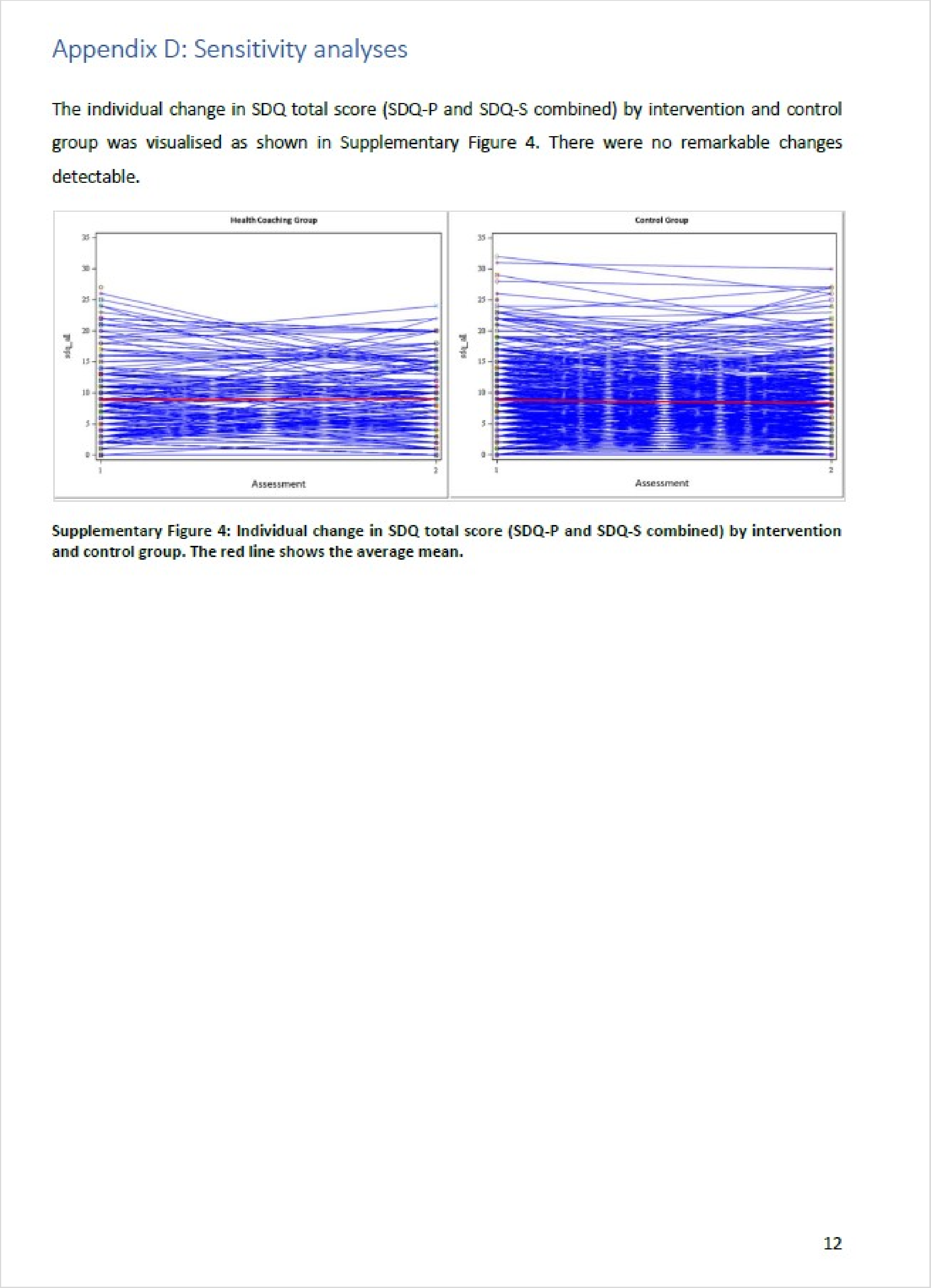


```
* S: SELF-REPORT BASED SCORES

       if sconsid ge 0 then spr1=1;
       else spr1=0;
       if sshares ge 0 then spr2=1;
       else spr2=0;
       if scaring ge 0 then spr3=1;
       else spr3=0;
       if skind ge 0 then spr4=1;
       else spr4=0;
       if shelpout ge 0 then spr5=1;
       else spr5=0;
       sprotot=sum(sconsid,sshares,scaring,skind,shelpout);
       sprono=spr1+spr2+spr3+spr4+spr5;
       sprosoc=round(sprotot*5/sprono,1);
       if sprono lt 3 then sprosoc=.;
       if sloner ge 0 then speer1=1;
       else speer1=0;
       if sfriend ge 0 then speer2=1;
       else speer2=0;
       if spopular ge 0 then speer3=1;
       else speer3=0;
       if sbullied ge 0 then speer4=1;
       else speer4=0;
       if soldbest ge 0 then speer5=1;
       else speer5=0;
       sfrienx=2-sfriend;
       spopulax=2-spopular;
       speertot=sum(sloner,sfrienx,spopulax,sbullied,soldbest);
       speerno=speer1+speer2+speer3+speer4+speer5;
       speer=round(speertot*5/speerno,1);
       if speerno lt 3 then speer=.;
       if srestles ge 0 then sha1=1;
       else sha1=0;
       if sfidgety ge 0 then sha2=1;
       else sha2=0;
       if sdistrac ge 0 then sha3=1;
       else sha3=0;
       if sreflect ge 0 then sha4=1;
       else sha4=0;
       if sattends ge 0 then sha5=1;
       else sha5=0;
       sreflecx=2-sreflect;
       sattendx=2-sattends;
       shatot=sum(srestles,sfidgety,sdistrac,sreflecx,sattendx);
       shano=sha1+sha2+sha3+sha4+sha5;
       shyper=round(shatot*5/shano,1);
       if shano lt 3 then shyper=.;
       if ssomatic ge 0 then sem1=1;
       else sem1=0;
       if sworries ge 0 then sem2=1;
       else sem2=0;
       if sunhappy ge 0 then sem3=1;
       else sem3=0;
       if sclingy ge 0 then sem4=1;
       else sem4=0;
       if safraid ge 0 then sem5=1;
       else sem5=0;
       semtot=sum(ssomatic,sworries,sunhappy,sclingy,safraid);
       semno=sem1+sem2+sem3+sem4+sem5;
       semotion=round(semtot*5/semno,1);
       if semno lt 3 then semotion=.;
       if stantrum ge 0 then scol=1;
       else scol=0;
```

```
if sobeys ge 0 then sco2=1;
else sco2=0;
if sfights ge 0 then sco3=1;
else sco3=0;
if slies ge 0 then sco4=1;
else sco4=0;
if ssteals ge 0 then sco5=1;
else sco5=0;
sobeyx=2-sobeys;
scotot=sum(stantrum,sobeyx,sfights,slies,ssteals);
scono=sco1+sco2+sco3+sco4+sco5;
sconduct=round(scotot*5/scono,1);
if scono lt 3 then sconduct=.;
sebdtot=semotion+sconduct+shyper+speer;
sdistrez=sdistres-1 ;
if sdistres=0 then sdistrez=0;
simphomz=simphome-1 ;
if simphome=0 then simphomz=0;
simpfriz=simpfrie-1 ;
if simpfrie=0 then simpfriz=0;
simpclaz=simpclas-1 ;
if simpclas=0 then simpclaz=0;
simpleiz=simpleis-1 ;
if simpleis=0 then simpleiz=0;
simpact=sum(sdistrez,simphomz,simpfriz,simpclaz,simpleiz);
if simpact lt 0 and sebddiff=0 then simpact=0;
drop spr1 spr2 spr3 spr4 spr5 sprotot sprono
speer1 speer2 speer3 speer4 speer5 sfrienx spopulax speertot speerno
sha1 sha2 sha3 sha4 sha5 sreflecx sattendx shatot shano
sem1 sem2 sem3 sem4 sem5 semtot semno
sco1 sco2 sco3 sco4 sco5 sobeyx scotot scono;
```

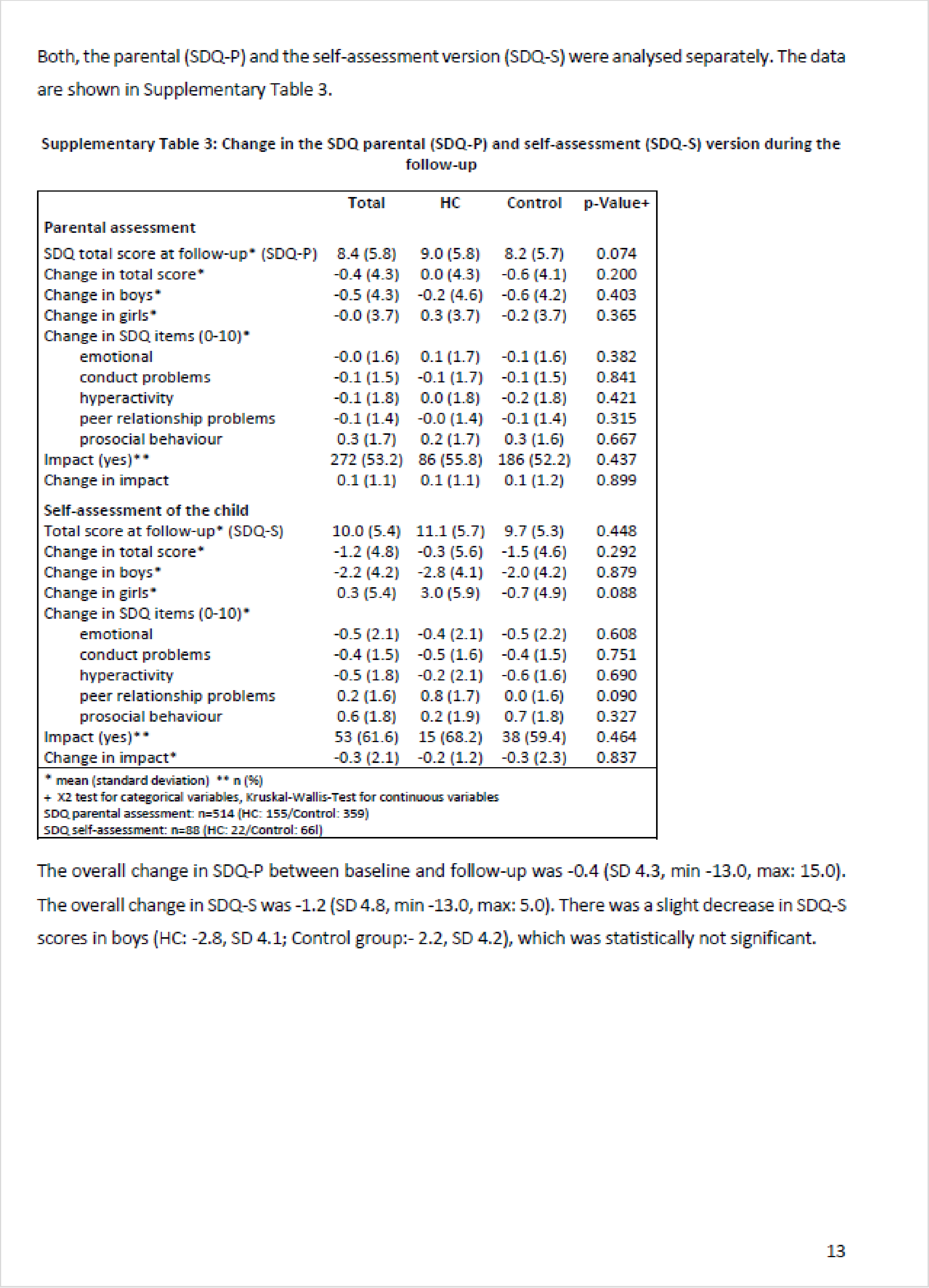
END OF SCORING SYNTAX



Appendix D: Sensitivity analyses

The individual change in SDQ total score (SDQ-P and SDQ-S combined) by intervention and control group was visualised as shown in Supplementary Figure 4. There were no remarkable changes detectable.

Supplementary Figure 4: Individual change in SDQ total score (SDQ-P and SDQ-S combined) by intervention and control group. The red line shows the average mean.



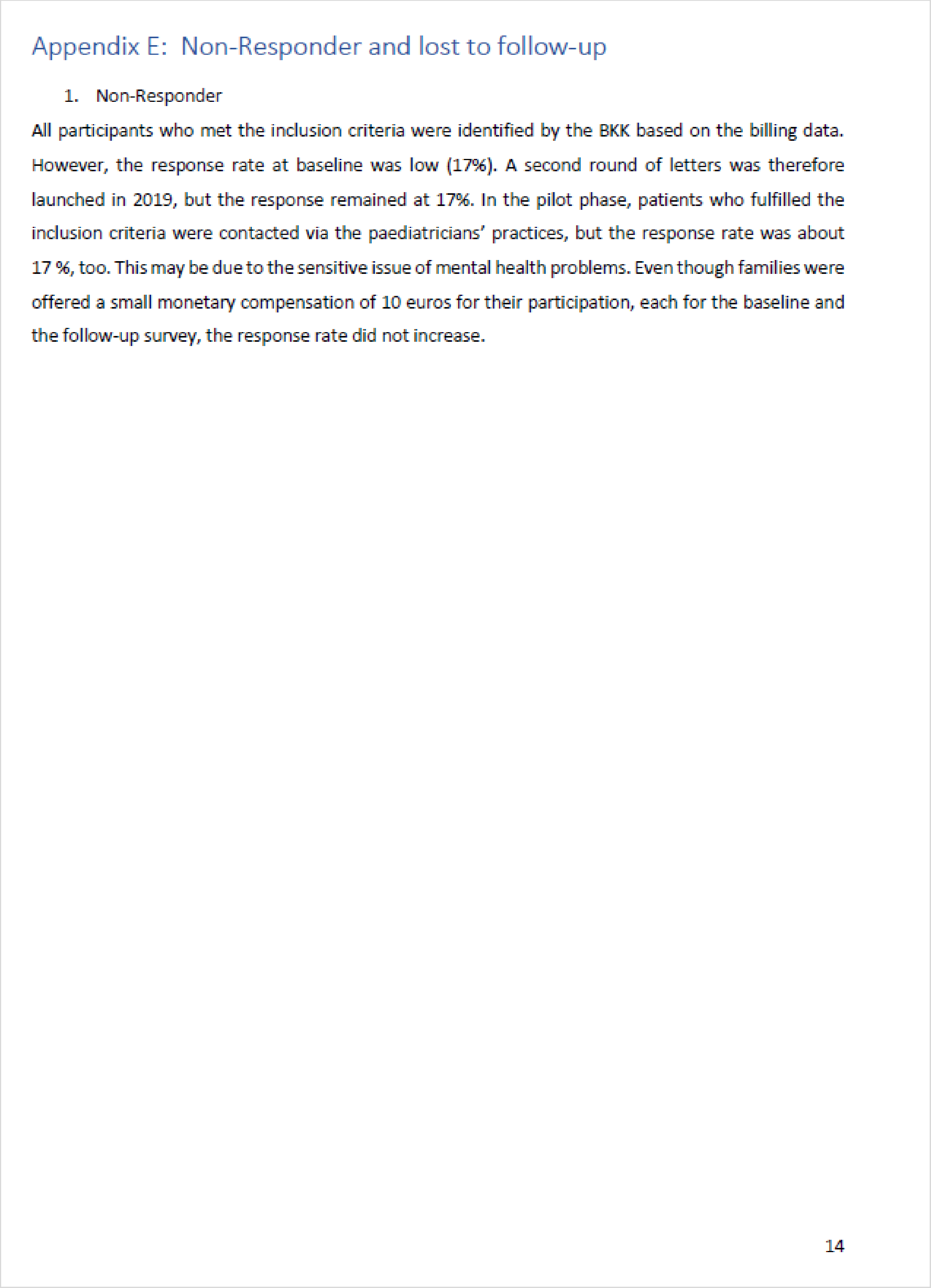
Both, the parental (SDQ-P) and the self-assessment version (SDQ-S) were analysed separately. The data are shown in Supplementary Table 3.

Supplementary Table 3: Change in the SDQ parental (SDQ-P) and self-assessment (SDQ-S) version during the follow-up

	Total	HC	Control	p-Value+
Parental assessment				
SDQ total score at follow-up* (SDQ-P)	8.4 (5.8)	9.0 (5.8)	8.2 (5.7)	0.074
Change in total score*	-0.4 (4.3)	0.0 (4.3)	-0.6 (4.1)	0.200
Change in boys*	-0.5 (4.3)	-0.2 (4.6)	-0.6 (4.2)	0.403
Change in girls*	-0.0 (3.7)	0.3 (3.7)	-0.2 (3.7)	0.365
Change in SDQ items (0-10)*				
emotional	-0.0 (1.6)	0.1 (1.7)	-0.1 (1.6)	0.382
conduct problems	-0.1 (1.5)	-0.1 (1.7)	-0.1 (1.5)	0.841
hyperactivity	-0.1 (1.8)	0.0 (1.8)	-0.2 (1.8)	0.421
peer relationship problems	-0.1 (1.4)	-0.0 (1.4)	-0.1 (1.4)	0.315
prosocial behaviour	0.3 (1.7)	0.2 (1.7)	0.3 (1.6)	0.667
Impact (yes)**	272 (53.2)	86 (55.8)	186 (52.2)	0.437
Change in impact	0.1 (1.1)	0.1 (1.1)	0.1 (1.2)	0.899
Self-assessment of the child				
Total score at follow-up* (SDQ-S)	10.0 (5.4)	11.1 (5.7)	9.7 (5.3)	0.448
Change in total score*	-1.2 (4.8)	-0.3 (5.6)	-1.5 (4.6)	0.292
Change in boys*	-2.2 (4.2)	-2.8 (4.1)	-2.0 (4.2)	0.879
Change in girls*	0.3 (5.4)	3.0 (5.9)	-0.7 (4.9)	0.088
Change in SDQ items (0-10)*				
emotional	-0.5 (2.1)	-0.4 (2.1)	-0.5 (2.2)	0.608
conduct problems	-0.4 (1.5)	-0.5 (1.6)	-0.4 (1.5)	0.751
hyperactivity	-0.5 (1.8)	-0.2 (2.1)	-0.6 (1.6)	0.690
peer relationship problems	0.2 (1.6)	0.8 (1.7)	0.0 (1.6)	0.090
prosocial behaviour	0.6 (1.8)	0.2 (1.9)	0.7 (1.8)	0.327
Impact (yes)**	53 (61.6)	15 (68.2)	38 (59.4)	0.464
Change in impact*	-0.3 (2.1)	-0.2 (1.2)	-0.3 (2.3)	0.837

* mean (standard deviation) ** n (%)
\+ X2 test for categorical variables, Kruskal-Wallis-Test for continuous variables
SDQ parental assessment: n=514 (HC: 155/Control: 359)
SDQ self-assessment: n=88 (HC: 22/Control: 66l)

The overall change in SDQ-P between baseline and follow-up was -0.4 (SD 4.3, min -13.0, max: 15.0). The overall change in SDQ-S was -1.2 (SD 4.8, min -13.0, max: 5.0). There was a slight decrease in SDQ-S scores in boys (HC: -2.8, SD 4.1; Control group:- 2.2, SD 4.2), which was statistically not significant.



Appendix E: Non-Responder and lost to follow-up

1. Non-Responder

All participants who met the inclusion criteria were identified by the BKK based on the billing data. However, the response rate at baseline was low (17%). A second round of letters was therefore launched in 2019, but the response remained at 17%. In the pilot phase, patients who fulfilled the inclusion criteria were contacted via the paediatricians' practices, but the response rate was about 17 %, too. This may be due to the sensitive issue of mental health problems. Even though families were offered a small monetary compensation of 10 euros for their participation, each for the baseline and the follow-up survey, the response rate did not increase.

2. Lost to follow-up

491 (45 %) participants were lost to follow-up. Characteristics of participants with missing follow-up are shown in Supplementary Table 4.

Supplementary Table 4: Characteristics of participants with missing follow-up

	Total (n=1090)	With FU (n=599)	Lost to FU (n=491)	p-Value+
Responder (mother)	875 (87.9)	488 (87.6)	387 (88.4)	0.721
Children per family (n=430)				
1 child	73 (17.0)	34 (15.0)	39 (19.2)	0.499
2 children	267 (62.1)	145 (63.9)	122 (60.1)	
3 or more	90 (20.9)	48 (21.2)	42 (20.7)	
Age of the child in years*	6.9 (3.3)	6.7 (3.2)	7.1 (3.5)	0.038
Boys**	656 (60.2)	370 (61.8)	268 (58.3)	0.237
Age of the mother in years*	38.1 (5.2)	38.1 (5.0)	38.0 (5.4)	0.723
Age of the father in years*	41.0 (6.1)	41.0 (5.8)	41.1 (6.4)	0.888
Health of the parents (EQ5D)	0.9 (0.1)	0.9 (0.1)	0.9 (0.1)	0.590
VAS	84.6 (14.1)	84.9 (13.9)	84.2 (14.4)	0.520
Migrant background	175 (16.1)	90 (15.0)	85 (17.3)	0.306
Educational level of parents**				
high	562 (51.6)	341 (56.9)	221 (45.1)	<.0001
middle	424 (38.9)	227 (37.9)	197 (40.2)	
low	103 (9.5)	31 (5.2)	72 (14.7)	
Diagnosis of the child is known				
MHP diagnosis**				
head/abdominal pain	223 (20.5)	104 (17.4)	119 (24.2)	0.005
speech disorder	571 (52.4)	330 (55.1)	241 (49.1)	0.048
conduct disorder	262 (24.0)	145 (24.2)	117 (23.4)	0.884
enuresis	92 (8.4)	51 (8.5)	41 (8.4)	0.923
Parental assessment (n=922)				
SDQ score (0-40)*	8.4 (5.7)	8.7 (5.9)	8.1 (5.4)	0.189
SDQ score "at risk"**	214 (23.3)	127 (24.7)	87 (21.4)	0.241
Impact (yes)	411 (44.7)	242 (47.0)	169 (41.7)	0.111
Impact score (0-10)*	0.6 (1.3)	0.6 (1.4)	0.5 (1.2)	0.005
Self-assessment of the child (n=168)				
SDQ score (0-40)*	11.1 (6.4)	11.4 (6.3)	10.7 (6.5)	0.509
SDQ score “at risk”**	42 (25.0)	20 (23.8)	22 (26.2)	0.722
Impact (yes)	93 (55.4)	51 (60.7)	42 (50.0)	0.164
Impact score (0-10)*	1.2 (2.0)	1.2 (2.1)	1.2 (2.0)	0.775
Self-efficacy*(10-40)	27.8 (6.0)	27.7 (6.4)	27.9 (5.6)	0.855

* mean (standard deviation) ** n (%)
+ X2 test for categorical variables, Kruskal-Wallis-Test for continuous variables
n: Total= 1.090 (with FU= 599/ Lost to FU=491)
SDQ parental assessment: n=922 (with FU=515/ Lost to FU=407)
SDQ self-assessment: n=168 (with FU=84/ Lost to FU=84)

There were no significant health-related or demographic differences as compared to participants with complete follow-up (FU) that could explain the drop-out from the study. However, participants with 2 data collection points had slightly younger children on average (6.7 vs. 7.1 (p=0.038)), were more likely to belong to a higher educational level (56.9 vs. 45.1) and less likely to belong to a low educational level (5.2 vs. 14.7). Children with head and abdominal were more likely to drop out. No significant differences were found for the other diagnoses. This would indicate a short-lived diagnosis that possibly did not require further treatment. No differences were found between intervention and control group with regard to dropping out of the study.

In a next step, individual items from the family stress questionnaire (FABEL) and patient satisfaction (PACIC) were examined more closely. There was no indication that dissatisfaction or high satisfaction with medical care or high stress due to the child's diagnosis were reasons for dropping out either. A lost-to-follow-up questionnaire was provided. Main stated reason for non-participation was a lack of time.

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Appendix: Unpublished manuscript

Title: “A new approach in paediatric primary care – Theoretical considerations and targets of a health coaching programme for paediatricians. An expert interview with the programme developer (PrimA-QuO).”

Aim

The unpublished manuscript is an additional contribution to generate a better understanding of the background of the programme development. The theoretical background of the programme was not published by decision of the Thesis Advisory Committee in October 2019.

Methods

Three programme developers were named by PaedNetz and invited by the study team for an interview. The expert interview was conducted via telephone and took place in May 2017. The interview lasted 25 minutes. The interview was audio-recorded via F4 (version 2012. Dresing & Pehl GmbH, Marburg, Germany) and then transcribed verbatim.

Following questions were addressed:

1) What were the anticipated aims of the programme development?
2) Which health models and theories have been incorporated into the HC development?
3) What is particularly important for the programme to stand the test of time?

Analyses

MAXQDA 18 (VERBI Software; Consult, Sozialforschung GmbH, Berlin, Germany) was used for coding and analysis.

Results

Anticipated aims of the programme development

According to the experts, new morbidities – defined as paediatric indications with a multilevel and social background – arose as an important topic in paediatric practices. However, there was a lack of response to these conditions including a lack of training for paediatricians. As a consequence, children with (suspected) MHP were referred to specialised care too soon. With the aim of offering in-depth clarification of the child’s MHP and improved integrated care, a group of paediatricians decided to address this subject and wanted to make the field of social paediatrics more manageable for paediatricians.

Incorporated health models and theories

The programme developers were oriented towards established test procedures and quality standard of multidisciplinary diagnostics as applied in social paediatric centers. In a workshop taking place in 2010, a lot of theory was compiled in the form of modules called basis diagnostic. The modules turned out to be too extensive and unwieldy in practice and were therefore replaced by the current checklist form. In a continuous process, the modules were jointly developed and revised by the programme developers until a final version was available. The HC is now designed as a three steps model following social-paediatric diagnostics (see **Publication II, Figure 1**). When MHP are suspected, a detailed examination takes place (step 1 and 2). In the next step, a therapy alliance (typically for six months) is arranged with the parents including an assessment of patient's and family's resources. If the problems are too serious or the HC programme does not work, a referral to specialised care takes place. As a result, children with minor problems can remain in the care of the paediatrician while resources are available for children with MHP who need immediate specialised care. In this sense, the basic principles of the programme, namely patient orientation, participation and strengthening of existing resources, were met quite well, according to the experts.

Needed conditions to stand the test of time

With the aim of enabling a long-term implementation of the programme, the developers tried to create a practical structure that enables the programme right from the start to be used effectively and flexibly in practice. Whether and to what extent the programme is implemented is up to the doctor. A realistic resource estimate by the doctor as to whether he/she can implement the HC programme and whether it can be effective is a central link before its implementation.

Conclusion and contribution to the PhD thesis

The expert interview provided important information on the background of the programme and its underlying objectives. Based on this knowledge, the interview guides were refined for paediatricians and families. In particular, the interviews with HC qualified paediatricians therefore addressed the question to what extent the programme's goals and its basic principles can be fulfilled in practice. The process of data triangulation is shown in **Publication I (Figure 1).**

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Scientific publications

Peer reviewed publications

Decke S, Hamacher K (neé Deckert), Lang M, Laub O, Schwettmann L, Strobl R, Grill E. Longitudinal changes of mental health problems in children and adolescents treated in a primary care-based health-coaching programme – results of the PrimA-QuO cohort study. BMC Primary Care 23, 211 (2022). https://doi.org/10.1186/s12875-022-01780-1.

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Conference contributions

Decke S, Loidl V, Deckert K, Laub O, Lang M, Schwettmann L, Grill E. Wir sind da in guten Händen“ - Akzeptanz, Barrieren und Förderfaktoren eines Gesundheitscoaching Programmes aus der Sicht von Pädiatern, Kinder und Jugendlichen mit psychischen Auffälligkeiten & Störungen und ihren Eltern. Ergebnisse der PrimA-QuO-Interviewstudie (Innovationsfondsprojekt). Oral presentation at DGEpi 2019. 14th annual conference of the German Society for Epidemiology. 2019 September 11-13, Ulm, Germany.

Loidl V, **Decke S**, Deckert K, Schwettmann L, Grill E. Health-Related Quality of Life among children and adolescents with Mental Health Problems and their guardians: Baseline results of the PrimA-QuO cohort study. DGEpi 2019. 14th annual conference of the German Society for Epidemiology. 2019 September 11-13, Ulm, Germany.

Decke S, Radevic-Pahl N, Bauer Ines, Laub O, Lang M, Teuner C, Holle Rolf, Schwettmann L, Grill E. Optimierte primärärztliche Versorgung von Kindern und Jugendlichen mit psychischen Auffälligkeiten und Störungen – Evaluation von Qualität und Outcomes (PrimA-QuO). Poster presented at: DKVF 2017. 16. Deutscher Kongress für Versorgungsforschung. 2017 October 4-6, Berlin, Germany.

Decke S, Radevic-Pahl N, Bauer Ines, Laub O, Lang M, Teuner C, Holle Rolf, Schwettmann L, Grill E. Projekt Präsentation zu Optimierte primärärztliche Versorgung von Kindern und Jugendlichen mit psychischen Auffälligkeiten und Störungen- Evaluation von Qualität und Outcomes. Oral presentation at BVKJ Herbstsymposium 2017. September 23, Munich, Germany.