Evaluation of a Cognitive–Behavioral Pain Management Program for Children with Chronic Abdominal Pain: A Randomized Controlled Study

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Abstract

Background Chronic abdominal pain (CAP) in childhood is widely prevalent and has adverse effects on mental health and quality of life. Earlier research emphasized the positive effects of psychological intervention on pain symptoms. This study describes the results of a cognitive–behavioral pain management program for children with CAP. The newly developed cognitive–behavioral group program, "Stop the pain with Happy-Pingu," includes six sessions for the children and one meeting for the parents.

Purpose We hypothesized that the training would significantly reduce pain symptoms (frequency, duration, intensity, and pain-related impairment) and increase health-related quality of life compared to wait-list controls, with improvement seen both at the end of treatment and at a 3-month follow-up.

Method In all, 29 children were randomized into two groups: 15 in the intervention group (IG) and 14 as the wait-list controls (WLC). An intent-to-treat analysis was performed using two-factorial multivariate analyses of variance with repeated measures.

Results Children in the IG experienced both a reduction in pain (primary outcome) and an improvement in health-

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P. Warschburger Counseling Psychology, Karl-Liebknecht-Str. 24-25, 14476 Potsdam, Germany related quality of life (secondary outcome) as compared to the WLC. The effect sizes ranged from medium to high. *Conclusion* Cognitive–behavioral methods seem to be appropriate for treating children with CAP.

Keywords Chronic abdominal pain · Children · Cognitivebehavioral treatment

Introduction

Chronic abdominal pain (CAP) is very widespread and represents, besides headache, the most common pain syndrome in early childhood [2, 12, 28]. Prevalence rates range from 0.3% to 30.8% [5, 31], depending on the diagnostic criteria used. Girls are more likely to be affected by CAP than boys [31].

According to the international classification guidelines, CAP is characterized by chronic pain for at least 3 months, with pain occurring at least once a week, in the absence of serious physical disease [1, 22]. Nausea and vomiting are possible accompanying symptoms. Furthermore, pain has to be so severe that everyday activities are limited. CAP is accompanied by a reduction in health-related quality of life and psychosocial functioning [11, 20] as well as an increase in school absenteeism [20]. Additionally, parents often seek help from multiple healthcare providers, leading to high costs due to repeated medical examinations [2, 29]. The occurrence of CAP is associated with further pain diseases and psychological problems during adulthood [4, 16, 35, 38]. Emotional problems are frequently seen, especially anxiety and depressive symptoms that result from recurrent pain episodes. These data support the need for treatment programs that address this topic beginning in childhood [11]. Some studies demonstrate that pain can be reduced using cognitive-behavioral

intervention methods [11, 17, 23, 37], such as online treatment for families [15, 24] or as a treatment program either for parents or the whole family [10, 21, 26, 27]. Evidence-based programs using psychological treatment for chronic headaches and back pain are also available [9]. However, to date, standardized and evidence-based training programs that focus directly on children with CAP are lacking. Therefore, we designed a cognitive-behavioral program for children (called "Stop the pain with Happy-Pingu"). The program focuses on the children themselves and aims to enable children to cope autonomously with their pain experiences. The influence of the parents should be acknowledged as well because the parental response to the child's abdominal pain is essential [21]. For this reason, parents are informed during a psychoeducational session about the role of learning mechanisms, and they are encouraged to share their experiences with other parents. A first pilot study with 11 children showed promising results in terms of pain and quality of life. The acceptance of the program was very high [37]. However, the ability to interpret these data is limited because there was no untrained control group.

The present study aims to fill that gap by testing the efficacy of this training program in a randomized, controlled trial (RCT) and comparing the intervention group (IG) with wait-list controls (WLC). It was hypothesized that the pain-control training would significantly reduce pain symptoms (frequency, duration, intensity, and pain-related impairment) as well as increase health-related quality of life compared to the wait-list controls, both directly post-treatment and at the 3-month follow-up post-treatment.

Patients and Methods

Course of the Study

Figure 1 illustrates the course of the RCT. Patients were recruited consecutively from an ongoing epidemiological examination concerning learning disabilities in schoolchildren. An initial screening focusing on the frequency and trigger mechanisms of abdominal pain was performed to identify potentially affected children. The screening criteria (e.g., child suffered from abdominal pain at least once a week without organic findings) were fulfilled by 144 children between the ages of 7 and 12 years. In the next step, these potentially affected children, and their parents were invited to a comprehensive diagnostic assessment (T1) to validate the self-report data.

Inclusion and Exclusion Criteria

Physicians were asked to examine each child to exclude organic causes of the pain symptoms. A structured interview

by a psychologist (Kinder-DIPS) [30] was used to exclude mental disorders according to ICD-10. In addition, parents and children completed standardized questionnaires. The following inclusion and exclusion criteria had to be fulfilled (see Table 1).

In total, 36 children and their parents attended the diagnostic assessment procedure. Seven children were excluded from the study: One child had headache and earache exclusively, four children suffered from abdominal pain less than once a week, and two children fulfilled the criteria for a psychological disorder according to ICD-10 (depression and anxiety). These parents were advised to seek professional psychotherapeutic help. Parents and children fulfilling the diagnostic criteria of CAP were informed about the study and invited to participate.

Randomization

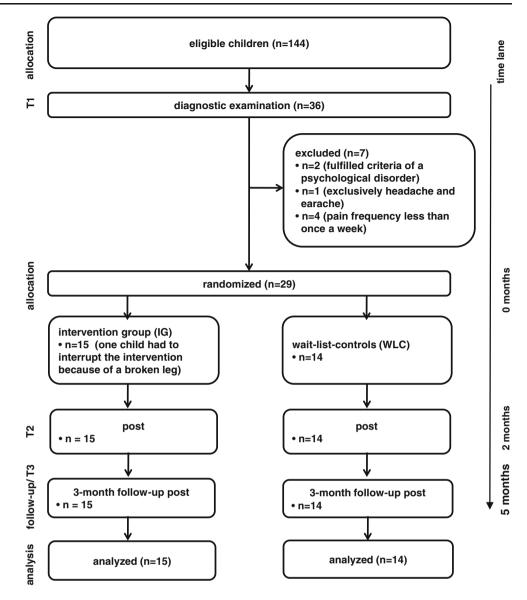
In all, 29 children fulfilled the inclusion and exclusion criteria and were randomly assigned to either the IG (n= 15) or the WLC (n=14). Computer-aided randomization was performed by a person who was not involved in the study. One child did not complete the training because of a broken leg. According to an intent-to-treat approach and because the number of participants was so small, the data for this child were included in the further analyses.

Power Calculation

Data from our previous study [37] were used as a basis for the power calculation. The intervention should achieve a medium interaction effect between the IG and the WLC for the three measurement times: before treatment (T1), after treatment (T2), and 3 months after the end of training of the IG (T3). To statistically ensure this effect with a probability of 80%, 14 participants should be included in each group [3]. Because dropouts are to be expected, especially in a study using a wait-list design, a dropout rate of 30% was estimated. This means that a minimum of 36 children should participate in the evaluation study.

Treatment

The pain management training, "Stop the pain with Happy-Pingu," consisted of six group meetings of 90 min and was conducted once a week by a psychologist. The sessions built on each other. An overview of the training sessions is displayed in Table 2. The sessions with children focused on increasing their self-management abilities. The following issues were addressed: imparting knowledge and teaching coping strategies, relaxation technique training, identification and change of negative pain-related thoughts and attention bias, as well as techniques for increasing self-esteem.



To help apply the training to everyday life, the children were given a CD with relaxation exercises (PMR) to do as homework assignments. Furthermore, the children were asked to keep a diary about the coping strategies they used when they had abdominal pain, and they were asked to record pain intensity and duration. Moreover, during a meeting, the parents received nutritional recommendations from a dietician and learned how operant mechanisms can exacerbate pain experiences. During this meeting, parents were encouraged to exchange their experiences with the pain management

| Table 1 | Inclusion a | and exclusion | criteria for | CAP ac | cording to | the Rome-III- | Criteria | [22] |
|---------|-------------|---------------|--------------|--------|------------|---------------|----------|------|
| | | | | | | | | |

| Symptomatology | Episodic or continuous abdominal pain |
|-----------------------|----------------------------------------------------------------------------------------------------|
| Duration | Abdominal pain for at least 3 months |
| Frequency | Pain occurs at least once a week |
| Associated criterions | Exclusion of an inflammatory, anatomic, metabolic or neoplastic process that explains the symptoms |
| | Episodes of pain are severe enough to affect the child's activities |
| | Additional somatic complaints (e.g., headache, limb pain or difficulty sleeping) |
| Exclusion criterions | Other childhood functional gastrointestinal disorder (Rome-III, e.g., functional dyspepsia) |
| | Psychological disorder (e.g., depression, anxiety disorder) |
| | |

 Table 2
 The contents and the main focus of the cognitive-behavioral program

| Session | Content | Main focus | | | | |
|---------|----------------------------------------------------------------|-------------------------------------------------------------------|--|--|--|--|
| 1 | | Identification of triggers | | | | |
| 2 | Imparting knowledge and teaching coping strategies | Relationship between stress and abdominal pain | | | | |
| 3 | | Training of relaxation techniques (progressive muscle relaxation) | | | | |
| 4 | Identification and change of negative pain-related thoughts | Cognitive restructuring | | | | |
| 5 | Direction of attention and support for | Distraction strategies | | | | |
| | positive experiences | Behaviors incompatible with pain for balance of stress | | | | |
| 6 | Implementation at home/transfer | Increasing self-esteem | | | | |
| | | Ressource enhancement ("first-aid-suitcase") | | | | |

within their family. The contents of the training program are summarized in a manual. In total, seven separate groups of three to six children were trained.

Design

A RCT with repeated measures (T1, T2, and T3) was conducted to evaluate the efficacy of the program. For ethical reasons, the participants of the WLC were provided with the opportunity to attend the training after an overall waiting period of 5 months. The ethics of the study were approved by the University of Potsdam.

Outcome Measures

Based on the Rome-III-Criteria [22] for CAP, the frequency, duration, and intensity of pain as well as pain-related impairment were recorded as primary outcomes. According to the actual guidelines [28] and international research literature [11], health-related quality of life was assessed as a secondary outcome.

In the 2 weeks prior to each time of measurement, the children kept a pain diary [37]. The main focus of this diary was to assess the duration of pain episodes throughout the day by describing the hours they were affected by pain (younger children received help from their parents). Using diaries is a reliable and valid method, which can be used from the age of five for pain assessment [7, 8]. The intensity of pain is measured using a visual analogue scale score (0= no pain, 10 = unbearable pain). Pain frequency, intensity, and duration were rated once a day. For each of these pain parameters, the mean per day was calculated. Additionally, pain-related impairment was recorded using the subscale "disease-specific module" of KINDL-R, which is reported to be reliable and valid [25]. In our sample, Cronbach's alpha reached poor internal consistency of $\alpha = 0.55$.

Heath-related quality of life was assessed using PedsQLTM, a reliable and valid questionnaire for children and adolescents

with chronic diseases [32–34]. PedsQLTM consists of four subscales that evaluate generic aspects of health-related quality of life. The raw values were transformed according to the procedure of Varni et al. [34], with values ranging from 0 to 100. Cronbach's alpha reached values between $\alpha = 0.68$ and $\alpha = 0.80$.

Pain-related cognitions were measured using a selfadministered questionnaire based on the Itch-questionnaire [36], which was adapted accordingly to match abdominal pain. This questionnaire was already tested successfully in our pilot study. It assesses positive cognitions (e.g., "When I have abdominal pain, then I tell myself to stay calm and relax") and negative cognitions (e.g., "...the pain makes me crazy"). Children rated the frequency of such cognitions on a 6-point Likert scale (from 1 = never to 6 = always). In the present set of data, Cronbach's alpha reached 0.71 (positive cognitions) and 0.69 (negative cognitions).

Statistical Analysis

Statistical analysis was performed with the software package SPSS 17. Changes from the initial assessment to the follow-up and differences between the groups were explored with two-factorial multivariate analyses of variance with repeated measures. All data were analyzed by intent-totreat methodology to compare the IG and WLC in terms of the treatment that the children were randomly allocated irrespective of the treatment they actually received. We hypothesized a reduction in abdominal pain (frequency, intensity, and duration) and pain-related impairment as well as an increase in health-related quality of life (interaction group \times time) would occur for the IG compared to the WLC. If sphericity (Mauchly test) was violated, a correction of the degrees of freedom, according to Greenhouse and Geisser [13, 14], was implemented and reported. Furthermore, the effect sizes for group differences following Cohen [6] and the effect of treatment were calculated [18]. The rates of success (defined as non-fulfillment of the diagnostic criteria

for CAP according to the Rome-III-Criteria; see Table 1) and failure (CAP criteria continued to be met) were calculated after the end of treatment for each group. These data were correlated with treatment arm to obtain information about the relative effects for the IG and WLC. Accordingly, the treatment effect describes the difference between the successes of the IG and the WLC in percent [18]. Additionally the number needed to treat (NNT) was calculated.

Results

Baseline values for IG and WLC did not differ in the sociodemographic parameters nor did they differ in the parameters connected with pain and quality of life. Table 3 summarizes the sociodemographic data of the study sample.

Pain

Table 4 illustrates the changes in pain parameters of the IG compared to the WLC. Significant interaction effects appeared for all pain parameters over the three measurements. A two-factorial analysis of variance with repeated measures showed significant interaction effects (group \times time) for pain intensity [F(2;54) = 8.39; p = 0.001], pain duration [F(1.21;32.62) = 8.43; p = 0.004], pain frequency [F(1.32;35.57) = 9.38; p = 0.002], and pain-related impairment [F(1.46;39.37) = 14.92; p < 0.001].

Post hoc tests demonstrated that improvements from T1 to T2 were significant for all scales, and changes in pain duration over time were significant from T2 to T3. Furthermore, a significant main effect by group emerged for pain intensity [F(1;27) = 16.16; p < 0.001], pain duration [F(1;27) = 8.27; p = 0.008], pain frequency [F(1;27) =

10.66; p = 0.003], and pain-related impairment [F(1;27) = 15.34; p = 0.001]. With respect to the changes from T1 to T2 and T1 to T3, group differences can assumed to be within the high range with effect sizes of d = 0.71 to d =2.21. As expected, effect sizes were lower concerning the changes from T2 to T3. The means of all pain parameters of the WLC did not change significantly over time.

Health-Related Quality of Life

In total, the results highlight that health-related quality of life in the IG improved more than in the WLC during the course of the study (see Table 5). A two-factorial analysis of variance with repeated measures showed significant interactions (group \times time) for physical functioning [F(2;54) = 14.88; p < 0.001], psychological functioning [F(2;54) = 6.37; p = 0.003], social functioning [F(1.62; 43.78) = 3.61; p = 0.044], and school functioning [F(1.45;39.01) = 5.77; p = 0.012]. Post hoc analyses showed that changes from T1 to T2 were significant for all scales. Furthermore, a significant main effect by group emerged for physical functioning [F(1;27) = 13.27; p = 0.001] and school functioning [F(1;27) = 4.51; p = 0.043]. Over time, no significant changes occurred in the WLC for any of the scales. With respect to the changes from T1 to T2 and T1 to T3, group differences can assumed to be within the high range with effect sizes of d = 0.69 to d = 2.17. As expected effect sizes were lower concerning the changes from T2 to T3. As expected effect sizes were lower concerning the changes from T2 to T3.

Pain-Related Cognition

The results demonstrate that pain-related cognitions in the IG improved more than in the WLC. A two-factorial

| Table 3 Baseline characteristicsof the study sample (IG andWLC) | | IG | WLC | Test statistic | Significance value |
|------------------------------------------------------------------------|----------------------------------------|----------------------------------|---------------------------------|-----------------|--------------------|
| | N | 15 | 14 | | |
| | Sex | | | $\chi^2 = 0.29$ | <i>p</i> =0.58 |
| | Age [mean (standard deviation), range] | 9.15 (1.54), Range 6,6–11,2 y | 10.1 (1.4), range 8,0–11,9 y | <i>U</i> =68.00 | <i>p</i> =0.11 |
| | Duration of CAP (in years) | 2.43 (1.32) | 3.1 (2.1) | U=89.50 | p = 0.49 |
| | Consultations of a physician beca | use of abdominal pain | within the last year | | |
| | on average (range) | 2.33 Range 0–10 | 4.8 Range 0–22 | <i>U</i> =87.00 | <i>p</i> =0.42 |
| | Consulted physicians (multiple en | | | | |
| | Pediatrician family physician | 6 (40.1%) | 7 (50%) | | |
| | Gastroenterologist | 4 (26.7%) | 3 (21.4%) | | |
| | No physician | 5 (33.2%) | 4 (28.6%) | | |

 Table 4
 Mean (standard deviation) scores of pain for the 2 weeks preceding each measurement time and pain-related impairment at baseline, post-treatment and at 3-month follow-up (IG and WLC)

| | | IG | SD | WLC | | p value ^b | d | Post hoc test ^c | |
|---|--------------------------------------------|-------|---------|-------|---------|----------------------|------------|----------------------------|--------------|
| | | Mean | | Mean | SD | | | F | p value |
| | Pain intensity (per day) ^a | | | | | 0.001 | | | |
| 1 | Baseline | 1.53 | (0.80) | 1.54 | (0.77) | | 1.51 (1-2) | 13.99 | 0.001 (1-2) |
| 2 | Post | 0.16 | (0.32) | 1.93 | (1.64) | | 0.13 (2-3) | 0.43 | 0.52 (2-3) |
| 3 | 3-month follow-up | 0.08 | (0.31) | 1.55 | (1.49) | | 1.37 (1–3) | | |
| | Pain duration (hours per day) ^a | | | | | 0.004 ^a | | | |
| 1 | Baseline | 0.73 | (0.64) | 0.80 | (0.86) | | 0.71 (1-2) | 11.14 | 0.002 (1-2) |
| 2 | Post | 0.31 | (0.68) | 0.83 | (0.60) | | 0.88 (2-3) | 6.89 | 0.014 (2-3) |
| 3 | 3-months follow-up | 0.02 | (0.06) | 0.61 | (0.50) | | 1.59 (1-3) | | |
| | Pain frequency (per day) ^a | | | | | 0.002^{a} | | | |
| 1 | Baseline | 0.62 | (0.54) | 0.65 | (0.37) | | 1.48 (1-2) | 10.77 | 0.003 (1-2) |
| 2 | Post | 0.05 | (0.09) | 0.68 | (0.58) | | 0.58 (2-3) | 0.33 | 0.54 (2-3) |
| 3 | 3-month follow-up | 0.24 | (0.09) | 0.62 | (0.56) | | 0.90 (1-3) | | |
| | Pain-related impairment | | | | | < 0.001 ^a | | | |
| 1 | Baseline | 27.33 | (14.21) | 24.29 | (10.25) | | 2.01 (1-2) | 21.73 | <0.001 (1-2) |
| 2 | Post | 5.33 | (6.64) | 24.52 | (14.06) | | 0.20 (2-3) | 0.16 | 0.69 (2-3) |
| 3 | 3-month follow-up | 4.22 | (5.26) | 24.76 | (14.00) | | 2.21 (1-3) | | |

^a Mean (standard deviation) scores of pain for the 2 weeks preceding each measurement time

^b For interaction; correction of degrees of freedom and significance (Greenhouse–Geisser)

^c Tests of within-subjects contrasts for interaction

analysis of variance with repeated measures demonstrated significant interactions (group × time) for positive cognitions [F(2;54) = 4.29; p = 0.019] and negative cognitions [F(2;54) = 24.59; p < 0.001]. Post hoc tests showed that changes from T1 to T2 were significant for all scales. A significant main effect by group emerged for negative cognitions [F(1;27) = 17.52; p < 0.001]. Over time, no significant changes occurred in the WLC. Group differences with effect sizes of d = 0.45 to d = 2.01 ranged from medium to high. Table 5 shows changes in health-related quality of life and pain-related cognitions for both groups.

Clinical Significance of the Results

To examine the effectiveness of the program, the treatment success was also determined. After treatment (at T2), only three children of the IG fulfilled the diagnostic criteria for CAP (according to the Rome-III-Criteria; see Table 1) compared to 14 children of the WLC. The success rate for the IG was 90.6, as opposed to 9.4 for the WLC, resulting in a treatment advantage of 81.2% for the IG. Thus, each child of the WLC increases its chances of having no abdominal pain by 81.2% by participating in the training. Additionally the NNT was calculated: 1.25 children needed to receive the treatment in order that one of them benefits from the intervention (= diagnostic criteria of CAP were no longer fulfilled).

Discussion

Chronic abdominal pain is associated with increased psychosocial strain for children and their families. Intervention should begin early because negative behavioral patterns can stabilize even at a very young age. Behavioral interventions are proposed as the treatment of choice for CAP in childhood [11, 23]. To date, treatment has mainly involved training parents in operant strategies. Training has not typically occurred in a group setting but rather separately within the families [10, 21, 26, 27] or as an online treatment [15, 24]. Until now, few programs have focused on the children directly. It is our opinion that the children themselves need to acquire positive strategies for dealing with chronic pain and need to increase their self-management abilities in everyday life, e.g., at school. These considerations were the foundation for developing a child-centered abdominal pain training program. In addition, parents need to receive information with regard to the triggering and exacerbation of pain experiences. Initial positive effects of this approach were demonstrated with an uncontrolled pilot study [37], and we intended to verify these effects in a RCT with a longer term follow-up.

In total, 29 children participated in this study; the children were randomly assigned to one of the treatment arms. Inquiries were made at baseline (T1), post-treatment (after

| Table 5 Mean (standard deviation) scores for health-related quality of life and pain-related cognitions at baseline, post-treatment and at 3-month |
|----------------------------------------------------------------------------------------------------------------------------------------------------|
| follow-up |

| | Health-related quality of Life | Mean | SD | Mean | SD | p value ^a | d | Post hoc test ^b | |
|---|--------------------------------|-------|---------|-------|---------|----------------------|------------|----------------------------|--------------|
| | | | | | | | | F | p value |
| | Physical functioning | | | | | < 0.001 | | | |
| 1 | Baseline | 61.67 | (21.44) | 68.53 | (17.35) | | 1.89 (1-2) | 19.39 | <0.001 (1-2) |
| 2 | Post | 90.21 | (7.91) | 61.61 | (25.37) | | 0.27 (2-3) | 0.93 | 0.34 (2–3) |
| 3 | 3-month follow-up | 93.33 | (6.01) | 57.37 | (27.78) | | 2.17 (1-3) | | |
| | Psychological functioning | | | | | 0.003 | | | |
| 1 | Baseline | 62.67 | (21.78) | 66.79 | (22.92) | | 1.25 (1-2) | 8.30 | 0.008 (1-2) |
| 2 | Post | 88.33 | (10.80) | 71.43 | (19.94) | | 0.08 (2-3) | 0.07 | 0.79 (2-3) |
| 3 | 3-month follow-up | 88.00 | (13.47) | 69.64 | (18.45) | | 1.22 (1-3) | | |
| | Social functioning | | | | | 0.044 ^a | | | |
| 1 | Baseline | 84.00 | (15.26) | 85.00 | (16.05) | | 0.85 (1-2) | 5.18 | 0.03 (1-2) |
| 2 | Post | 94.67 | (6.94) | 85.71 | (14.53) | | 0.17 (2-3) | 0.35 | 0.56 (2-3) |
| 3 | 3-month follow-up | 95.33 | (9.15) | 83.93 | (24.59) | | 0.69 (1-3) | | |
| | School functioning | | | | | 0.012 ^a | | | |
| 1 | Baseline | 70.33 | (17.88) | 72.50 | (14.90) | | 1.17 (1–2) | 6.19 | 0.02 (1-2) |
| 2 | Post | 87.33 | (9.04) | 72.14 | (18.88) | | 0.03 (2-3) | 0.37 | 0.55 (2-3) |
| 3 | 3-month follow-up | 88.33 | (12.05) | 70.71 | (22.00) | | 1.13 (1–3) | | |
| | Pain-related Cognitions | | | | | | | | |
| | Positive cognitions | | | | | 0.019 | | | |
| 1 | Baseline | 39.07 | (18.99) | 44.84 | (13.47) | | 1.34 (1–2) | 7.43 | 0.011 (1-2) |
| 2 | Post | 57.22 | (12.55) | 44.25 | (13.71) | | 0.77 (2-3) | 3.48 | 0.07 (2-3) |
| 3 | 3-months follow-up | 51.11 | (16.19) | 47.62 | (15.48) | | 0.57 (1-3) | | |
| | Negative cognitions | | | | | < 0.001 | | | |
| 1 | Baseline | 47.11 | (15.47) | 49.29 | (19.53) | | 0.62 (1-2) | 37.59 | <0.001 (1-2) |
| 2 | Post | 21.11 | (18.97) | 52.86 | (18.76) | | 0.45 (2-3) | 3.30 | 0.08 (2-3) |
| 3 | 3-month follow-up | 15.56 | (18.67) | 58.09 | (21.27) | | 2.01 (1-3) | | |

^a For interaction; correction of degrees of freedom and significance (Greenhouse-Geisser)

^b Tests of within-subjects contrasts for interaction

training of the IG; T2), and three-month follow-up (T3). With exception of the self-esteem scale from the KINDL, the medical and psychosocial outcomes were assessed by validated and reliable instruments. Randomization was successful, i.e., both groups were comparable in all relevant parameters.

The results show that attending the training, "Stop the pain with Happy-Pingu," is not only associated with a reduction in pain but also with an increase in healthrelated quality of life compared to the WLC. Except for the changes from T2 to T3 (which can be considered as the consolidation of the treatment effects), the majority of effect sizes were in the high range. These positive changes are apparent not only directly after the end of the intervention but also at the 3-month follow-up, which supports the intervention's long-term effects and its successful transfer to everyday life. It must be emphasized that during a 5-month waiting period, no significant changes in the WLC could be observed. This might be interpreted both as indirect support of the efficacy of the training and as a sign of the persistence of abdominal pain. A simple "waiting strategy," such as "the pain will vanish" or "this is just a temporary stress period," does not lead to improvements over time. On the contrary, children who were WLC did not change their coping strategies but continued to report that "lying down" or "sleeping" were their treatments of choice.

The effects on pain parameters in the IG demonstrate that it was possible for the children to cope with pain using the techniques imparted to them (such as relaxation or distraction) to permanently reduce their subjective pain sensations. There was no loss of data over the three measurements, especially when using diaries. The reasons for this could be that a reward contract included the regular completion of diary entries. Moreover, the trainer kept close, personal contact with the families, including repeated reminders of appointments. Our results are consistent with the results of previous intervention studies in which pain was successfully reduced with the help of cognitive-behavioral programs for children and adolescents with chronic abdominal pain [11, 21, 26, 27]. Similar to other evaluated programs for the psychological treatment of chronic illnesses (e.g., headaches and back pain), in the current study, children with CAP were able to significantly reduce their symptoms in a relative short treatment period [9].

Furthermore, treatment success was also measured by examining the percentage of children who, by attending the training, could reduce their symptoms to the point that the diagnostic criteria of CAP (see Table 1) were no longer fulfilled. This effect was observed for almost all children of the IG, whereas there was no success in the WLC. At 81.2%, the calculated treatment effect is very high and supports the efficacy of our training. In addition to the question of pain reduction, quality of life was the second focus. As is customary in intervention research on children and adolescents with chronic diseases [25, 28], we considered the subjective perspective of the children regarding the state of their health for relevant aspects of their everyday lives. Regarding quality of life, we were looking not only for a reduction in pain-related impairment in their daily lives but also an increase in physical, psychological, social, and school functioning for children in the IG compared to in the WLC. In prior studies, children with gastrointestinal conditions were reported to show lower quality-of-life scores compared to healthy children on the following scales [33]: physical functioning (mean = 80.80, SD = 13.84), psychological functioning (mean = 73.95, SD = 18.76), social functioning (mean = 84.33, SD = 15.77), and school functioning (mean = 70.29, SD = 18.56). High effect sizes were achieved in our study mostly with regard to pain symptoms, as already described. The effect size for social functioning was low at the follow-up, but it was still in the medium range. This is not surprising because the training was not aimed at increasing social competence. The positive effects can possibly be explained by the fact that all participants had been "pure" CAP children. Children with comorbid psychiatric disorders (e.g., depression) were excluded because these disorders require more intensive psychotherapeutic support. A cognitive-behavioral training that focused on how to cope autonomously with functional pain would demand too much from the children.

Similar to other studies [21, 23], pain-related cognitions in the IG improved more than in the WLC. Further studies are necessary to explain the concrete mechanism of change.

Limitations of the Study

Several limitations and areas in which further research is required should be highlighted. The sample size is small. The optimal sample size was determined according to Bortz and Döring [3]. Because this might be an underestimation, a post hoc effect-size calculation was performed for the interaction effect using G* power. Indeed, the power was not sufficient for an average effect. However, for a large effect, as was shown in our study, it was sufficient.

Patients were recruited consecutively from an ongoing epidemiological examination (that did not focus on CAP or clinical interventions) using an initial rough screening for pain symptoms. Then, 144 families were contacted for a detailed screening and informed of the possibility of training. Only 36 families consented to participate. The attrition rate in our study is high—but not exceptionally high when compared to other clinical studies. Karlson and Rapoff [19] reported a 37% (range 0-75%) average rate of enrollment refusal. We can only speculate on the reasons for non-participation, e.g., that the level of suffering was not great enough. However, data are lacking to support this interpretation.

Because follow-up surveys were obtained from all 28 children (+1 dropout), an additional recruitment period was waived. A possible explanation for observing no dropouts is that the trainer maintained close, personal contact with participating families, including repeated reminders of appointments. Furthermore, a reward contract included regular completion of the questionnaires and the diary. Thus, the possibility of a biased sample with highly motivated participants exists. However, to prove these interpretations, data are lacking.

Although the KINDL-R has low reliability, it is one of the few measures available for testing disease-specific limitations and was therefore used. Nevertheless, Cronbach's alpha values for some subscales were low to medium, highlighting the need for further research on psychometric evaluations and development of new instruments.

It must be kept in mind that the program was developed and evaluated in our own research group. It would be desirable if, as a next step, other research groups were to implement and evaluate this approach. To date, such an intervention has only been conducted in an outpatient setting, which could lead to a selection bias for families that are especially motivated. Because pain in children is a very common reason for inpatient rehabilitation, the training program should also be tested in this setting. Another limitation inherent in our study design is the short follow-up period. Because of ethical considerations, we decided to give children of the WLC group the chance to attend training after a waiting period of 5 months in total, thus limiting the duration of the follow-up period. A longer period did not seem justifiable in light of the large burden on families, and high refusal rates would have been the result.

In addition, it should be noted that those in the WLC group were aware that they were waiting for treatment, and it can be assumed that they were therefore making no effort to cope with the pain experiences. Because attention plays an important role in the pain experience, further studies should compare the effects of training with an attention control group to examine the specific effect of the intervention on the patients.

Summary and Future Prospects

The aim of this study was to evaluate a manualized, cognitive-behavioral group training program for children with CAP and their parents. Our results underscore that the training was not only very well accepted by both the affected children and their parents but also appears to successfully reduce pain and increase health-related quality of life. Furthermore, cognitive-behavioral treatments are shown to be important in teaching different ways of managing individual pain problems. However, the mechanisms of these changes must be analyzed in further studies to improve our understanding of how cognitive-behavioral treatments work. Future research should thoroughly examine which components of the program are essential for treatment success.

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