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Inpatient-based intensive interdisciplinary pain treatment for highly impaired children with severe chronic pain: Randomized controlled trial of efficacy and economic effects

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ABSTRACT

Pediatric chronic pain, which can result in deleterious effects for the child, bears the risk of aggravation into adulthood. Intensive interdisciplinary pain treatment (IIPT) might be an effective treatment, given the advantage of consulting with multiple professionals on a daily basis. Evidence for the effectiveness of IIPT is scarce. We investigated the efficacy of an IIPT within a randomized controlled trial by comparing an intervention group (IG) (n = 52) to a waiting-list control group (WCG) (n = 52). We made assessments before treatment (PRE), immediately after treatment (POST), as well as at short-term (POST6MONTHS) and long-term (POST12MONTHS) follow-up. We determined a combined endpoint, improvement (pain intensity, disability, school absence), and investigated 3 additional outcome domains (anxiety, depression, catastrophizing). We also investigated changes in economic parameters (health care use, parental work absenteeism, subjective financial burden) and their relationship to the child's improvement. Results at POST showed that significantly more children in the IG than in the WCG were assigned to improvement (55% compared to 14%; Fisher $P < .001$; 95% confidence interval for incidence difference: 0.21% to 0.60%). Although immediate effects were achieved for disability, school absence, depression, and catastrophizing, pain intensity and anxiety did not change until short-term follow-up. More than 60% of the children in both groups were improved long-term. The parents reported significant reductions in all economic parameters. The results from the present study support the efficacy of the IIPT. Future research is warranted to investigate differences in treatment response and to understand the changes in economic parameters in nonimproved children.

1. Introduction

Severe chronic pain with high impairment occurs in children, with an estimated prevalence of 3% to 5% [25]. These children are severely impaired in their daily activities; they are unable to attend school regularly, and suffer from severe emotional distress [46]. There is a high likelihood that the chronic pain might persist into adulthood [3]. Alarming data from the United States have recently shown that the costs of adult chronic pain exceed the costs of other diagnoses, such as cardiovascular diseases ($560 billion compared to $309 billion) [12]. The costs are also exorbitant in pediatric chronic pain [23]. These children access a variety of health care services, including primary care physicians, radiological examinations, and visits to the emergency department [23]. According to Sleed et al. [38], pediatric chronic pain incurred approximately £8000 per child per year in both direct and indirect costs in the United Kingdom.

Intensive interdisciplinary pain treatment (IIPT) might be advocated as an effective treatment [46]. This treatment addresses underlying pain mechanisms, adapts pain medication, treats specific symptoms, and teaches active coping skills [17,30]. IIPT as defined by the German Pain Society [1] is a treatment provided by a minimum of 3 health care disciplines, including medical, psychological, and physical therapy, which are provided concurrently. With only 9 publications [4,5,8,15,16,21,29,30,32], there is limited knowledge on the effectiveness of IIPTs for children compared to

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approximately 100 nonrandomized studies in adults [14]. The existing pediatric studies lack control groups and randomization. Additionally, there are only data from 1 single study suggesting that involvement in an outpatient interdisciplinary program for children may be associated with decreased health care use and decreased indirect costs [23].

There were 3 objectives in the present study: First, we aimed to evaluate the efficacy of an IIPT (inpatient-based) in a randomized controlled trial (RCT) by comparing treatment results of an intervention group (IG) to a waiting-list control group (WCG). The IG started the IIPT immediately after the initial session, whereas the WCG waited 3 weeks for treatment. We hypothesized that more children in the IG would show improvement at POST (3 to 4 weeks after randomization) compared to children in the WCG. Children were classified as showing improvement if they did not show deterioration in any pain-related variable (pain intensity, disability, school absence) and had clinically significant improvements in one or both disability-related variables [16,21]. At 6-month and 12-month follow-up, when both groups had completed treatment, we expected to observe declines in all outcome domains (pain intensity, disability, school absence, general anxiety, depression, pain catastrophizing). Second, we aimed to evaluate the economic effects of the IIPT by measuring 4 parameters: (1) utilization of health care services; (2) parental work absenteeism; (3) work days lost; (4) subjective financial burden. We determined the economic effects of the IIPT by computing changes in the 4 parameters at short-term and long-term follow-up. Third, we aimed to investigate whether there were any differences in the rate of change in the 4 economic parameters at the follow-up time points depending on the improvement of the children.

2. Methods

The study was approved by the Ethics Committee of the Witten/Herdecke University (Nr. 78/2007) and registered in the Deutsches Studienregister für Klinische Studien (trial number DRKS00000337) and the ISRCTN register (trial number ISRCTN91385238).

2.1. Sample size calculation

The à priori power analysis was based on the results of previous studies with regard to the composite endpoint improvement [16,21]. An assumption of improvement incidence of 60% in the IG versus 20% in the WCG, an assumed significance level of $\alpha = 5\%$ (2-tailed), and a power requirement of 90% resulted in a sample size of 35 patients per sample [11]. Assuming a dropout of approximately 40% over the entire 12-month study period, a total of 60 participants were enrolled for each study arm (in total, 120 subjects).

2.2. Participants, setting, and demographics at pretreatment assessment

Consecutive new referrals to the German Paediatric Pain Centre (patients aged 9 to 17 years) between November 2009 and July 2011 were included in the study. The patients were referred by primary care physicians due to previous unsatisfactory treatment results. All of the patients suffered severely from their pain conditions and fulfilled à priori-defined criteria for inpatient admission [16]. We excluded patients from the study if they were diagnosed with complex regional pain syndrome because of a different therapeutic concept, if they had undergone treatment at the trial site before the initial session, if they were younger than 9 years old, and if they did not demonstrate a comprehensive understanding of the German language.

Demographics and pain characteristics of the 2 groups are depicted in Table 1. Children in both groups were on average 14 years old ($SD_{IG} = 3.4$; $SD_{WCG} = 2.3$). They suffered from chronic pain for a median of 18 months and 13.5 months, respectively. The majority of children in both groups suffered from chronic headache (79% for the IG and 71% for the WCG). Both groups were severely impaired due to chronic pain, with high levels of school absence and significant pain-related disability. Statistical analyses at PRE (variables: age, sex, main pain location, pain diagnosis, school absence, pain intensity, pain-related disability, pain duration; tests: Fisher exact test, Wilcoxon signed-rank test) revealed no differences between the 2 groups.

2.3. Randomization and study participation

The flowchart is depicted in Fig. 1. A total of 322 children was assessed for eligibility during the recruitment period. Of these 322, we excluded 202 children from the trial. These 202 children were clinically comparable to the 120 randomized children with the exception that there were more boys in the excluded group than in the randomized group (37% compared to 22%, respectively).

A total of 120 children was randomized to either the IG (n = 61) or the WCG (n = 59). To minimize biased allocation to the 2 groups, the randomization list was programmed using SAS software (release 9.1) by an experienced holder of the certificate Biometry in Medicine. Randomization was conducted in blocks of 4 (probability of 0.6) and blocks of 6 (probability of 0.4) for both groups and was stratified for gender. The individual who carried out the randomization procedure was blinded to the treatment conditions. Blinding of the patients' allocation to the 2 study arms was not feasible. However, the participants and investigators could not foresee assignment because of central allocation to the 2 groups. The clinical staff was not informed about the group allocation.

The IG started the IIPT approximately 5 days after the initial appointment (PRE). The waiting time for the WCG was scheduled to be 3 weeks because the average waiting time to the inpatient unit was 3 to 6 weeks. There was no additional contact with our institute during the 3-week wait. After the 3-week wait, the WCG began treatment (POST). Only the children who completed the IIPT were included in the statistical analyses. Six children in the IG (3 girls and 3 boys) and 4 girls in the WCG (mean age = 14 - years, SD = 2.3) discontinued treatment (noncompleters). Their characteristics were comparable to the characteristics' of the study participants (Table 1). This dropout resulted in an effective sample for statistical analyses of 52 children in the IG and 52 children in the WCG. Over the follow-up time points, 7 children in the IG and 10 children in the WCG refused to resend the questionnaires (attrition rate: 13% for the IG and 19% for the WCG).

2.4. Study design of the RCT

The study was implemented as a 2-arm parallel sample RCT with a 1:1 randomization approach with 4 assessment points. These assessment points were as follows: pre-assessment at the first appointment (PRE); assessment post-treatment for the IG and at treatment commencement for the WCG (POST); and 2 follow-up assessments 6 (POST6MONTHS) and 12 months (POST12-MONTHS) after randomization.

2.5. Procedure

At the initial appointment (PRE), the child and his or her family completed the study questionnaires. If the inclusion criteria were met, the patient and his or her parents were informed about the trial, and written informed consent was obtained. Randomization was conducted by the research assistant. The inpatient team was not informed about the study participation and allocation of the patients to the 2 study arms. A total of 120 patients (60 + 60) were enrolled in this trial according to the à priori sample size