Complementary therapies in paediatric gastroenterology: prevalence, safety and efficacy studies
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Chapter 4

Hypnotherapy for children with functional abdominal pain or irritable bowel syndrome: a randomized controlled trial

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Abstract

**Background and aims** Functional abdominal pain (FAP) and irritable bowel syndrome (IBS) are highly prevalent in childhood. A substantial proportion of patients continue to experience long lasting symptoms. Gut-directed hypnotherapy (HT) has been shown highly effective in the treatment of adult IBS-patients. We undertook a randomized controlled trial and compared clinical effectiveness of HT with standard medical therapy (SMT) in children with FAP or IBS.

**Methods** 53 pediatric patients, age 8-18 years, with FAP (n=31) or IBS (n=22), were randomized to either HT or SMT. Hypnotherapy consisted of 6 sessions over a 3 month period. Patients in the SMT group received standard medical care and 6 sessions of supportive therapy. Pain intensity, pain frequency and associated symptoms were scored in weekly standardized abdominal pain diaries at baseline, during and 6 and 12 months after therapy.

**Results** Pain scores decreased significantly in both groups: pain intensity scores decreased in the HT group from 13.5 at baseline to 1.3 at one year follow-up and in the SMT group from 14.1 to 8.0. Pain frequency scores decreased from 13.5 to 1.1 in the HT group and from 14.4 to 9.3 in the SMT group. Hypnotherapy was highly superior with a significantly greater reduction in pain scores compared to SMT (p<0.001). At one year follow up, successful treatment was accomplished in 85% of the HT group and 25% of the SMT group (p <0.001).

**Conclusions** Gut-directed hypnotherapy is highly effective in the treatment of children with longstanding FAP or IBS.
Introduction

Functional abdominal pain (FAP) and irritable bowel syndrome (IBS) in childhood are pediatric functional gastrointestinal disorders (FGIDs) that are characterized by chronic or recurrent abdominal pain and in case of IBS with altered bowel movements and/or relief of pain after defecation. There is no objective evidence of an underlying organic disorder. FAP and IBS have reported prevalences of 1 to 19% and are among the most common reasons for consultation in pediatrics. Quality of life scores of children with functional abdominal pain are comparable to children with inflammatory bowel disease, highlighting the clinical significance of these functional disorders. Spontaneous remission is high, but long term follow-up studies have shown that a significant proportion of 25 to 66% continues to experience symptoms even in adulthood. For this group of patients with persisting abdominal complaints therapeutic options are limited.

Gut-directed hypnotherapy has been shown to be very effective in the treatment of adult patients with IBS, functional dyspepsia and non-cardiac chest pain, with the majority of patients showing long-term improvement in symptoms and quality of life. Several uncontrolled studies have shown the feasibility of the use of (self-) hypnosis in children with chronic abdominal pain, but so far no randomized controlled trials have been performed. We report the findings of a randomized controlled trial conducted in pediatric patients with long lasting complaints of IBS or FAP, recruited from a tertiary medical centre. We compared the effect of gut-directed hypnotherapy (HT) with that of standard medical therapy (SMT), consisting of education, dietary interventions and intervention on stress factors.

Methods

Study participants

Children were recruited from the department of pediatric gastroenterology of the academic medical centre Amsterdam, the Netherlands. All children between 8 and 18 years who were diagnosed with either functional abdominal pain or irritable bowel syndrome according to the Rome II criteria and with a history of abdominal complaints of at least 12 months were invited to participate. Exclusion criteria were the use of medication influencing gastrointestinal functions; a concomitant organic gastrointestinal disease; functional constipation; treatment by another health care professional for abdominal symptoms; mental retardation; neurological or psychiatric problems and insufficient knowledge of the Dutch language. All patients and/or parents gave written informed consent. The study protocol was approved by the medical ethics committee of the hospital.
Design

Patients were randomly allocated using a computerized random-number generator for concealment to either hypnotherapy or standard medical care. Hypnotherapy was carried out by C.M. and consisted of 6 sessions of 50 minutes over a 3 month period. C.M. is a registered nurse, with a four year training and 15 years of experience in hypnotherapy. The Manchester protocol of gut-directed hypnotherapy was used, adapted for children\(^{21}\). We used the same protocol in both children (<14 years) and adolescents; the only difference was the language used, adapted to the child’s developmental age. It is still unclear whether FAP and IBS are heterogeneous disorders with different pathological mechanisms or represent variable expressions of the same disorder. Therefore we decided to treat children with FAP and IBS using the same protocol.

Hypnotherapy consisted of general relaxation, control of abdominal pain and gut functions, and ego-strengthening suggestions. Hypnosis was not used to analyze the existence of causal or compounding psychological factors. The first session was always used to have the participant become familiar with hypnosis and the therapist. Furthermore, information was given on the “body-mind connection” and the mind’s ability to regulate bodily functions. Specific techniques were then introduced aiming at control of the abdominal pain and, if necessary, normalization of gut functions. For example, after a hypnotic induction the participant was invited to create visualizations of a normal working gut, using metaphors adapted to the child’s interests like a car running at a normal speed. In another session the participant was asked to place both hands on the belly with suggestions for positive effects on abdominal discomfort. No fixed hypnotic scripts were used, and subsequent sessions were often modified, based on the feedback of the participant. Apart from gut-directed suggestions, treatment also included a variety of non-analgesic suggestions for relaxation, sleep improvement and ego-strengthening suggestions to increase self-confidence and well-being. Every participant received a CD with a standardized hypnosis session and was encouraged to listen to it on a daily basis or to practice self-hypnosis.

Patients in the control group received standard care consisting of education, dietary advice, extra fibers and pain medication or proton-pump inhibitors if considered necessary. Moreover they received 6 half hour sessions of supportive therapy over a three month period with M.A.B or A.M.V. In these sessions symptoms of the previous weeks were discussed with an exploration of possible contributory triggers like dietary products, emotional problems and stressful events.

Outcomes were measured at baseline, 1, 4, 8 and 12 weeks after randomization and 6 and 12 months after therapy. Participants were asked to keep a 7-day pain diary card, on which they recorded daily the intensity and frequency of abdominal pain as well as associated symptoms (nausea, vomiting, loss of appetite, flatus, nocturnal pain, pain upon awakening and pain related to meals)\(^{11,22}\). Pain intensity was scored using an
affective facial pain scale with faces showing no pain at all (face A) to faces showing severe pain (face I)\(^2\). Afterwards, these scores were transposed to a daily score of 0 = no pain, 1 = faces A-C, 2= faces D-F and 3 = faces G-I. The data for 7 days were totaled, giving a maximum pain intensity score (PIS) of 21. Pain frequency was daily scored as follows: 0 = no pain, 1 = 1 to 30 minutes pain, 2 = 31 to 120 minutes of pain, 3 = > 120 minutes pain per day. Again, the data for 7 days were totaled giving a pain frequency score (PFS). Every associated gut symptom, as mentioned above, was given 1 point if it occurred at least twice a week and 0.5 point if it occurred only once. The total of the associated symptoms was the associated symptom score (ASS) with a maximum of 7. Furthermore, the existence of headache was scored separately. Pain diaries were analyzed by SW (medical student), who was blinded for the treatment arm. Primary outcomes were the percentages of patients with complete remission of their abdominal pain after the treatment phase and at one year follow-up. Clinical remission was defined as a decrease of the PIS and PFS of > 80%; significant improvement was defined as a decrease of PIS and PFS between 30 and 80% and treatment was considered unsuccessful if the scores improved < 30% or got worse. Secondary outcomes were the three different scores after treatment and at one year follow-up.

Statistical analysis

All analyses were performed using the intention to treat principle. Differences between the two therapy groups at baseline were analyzed by means of a \(\chi^2\) or t test. Missing data of the diary values were handled using replacing missing values with estimates computed with the linear interpolation method. The last valid value before the missing value and the first valid value after the missing value was used for interpolation. Predetermined end points for the study included results after the intervention period and at 6 and 12 months follow-up. For the analysis of differences of therapy effect within patients in time, a general linear model (repeated measures) was used. As mentioned above, three groups of treatment effects between baseline and end point values were determined: no effect, significant improved and a complete remission. \(\chi^2\) test was used to test groups of treatment effect between therapy effect. For each therapy group, analysis of repeated measures was used to examine the differences in treatment effects in time between patients with IBS and FAP and the differences of age and gender effects within patients in time. For all statistical analyses, statistical significance was set at the .05 level, and all tests were 2-tailed. Statistical analysis was performed using SPSS version 14.0. This trial is registered as an International Standard Randomized Clinical Trial, number ISRCTN 26628553. There was no external funding source.
Results

Between October 2002 and June 2005 a total of 55 children with functional abdominal pain fulfilling the Rome II criteria for FAP or IBS were referred by general pediatricians, pediatric gastroenterologists and psychiatrists to the outpatient clinic of our tertiary centre (figure 1). Of these patients 53 children agreed to participate in the study. Twenty-five patients were allocated to standard medical therapy and twenty-eight to hypnotherapy. Only one patient of the HT group did not provide baseline assessments and refused further therapy; therefore 27 patients in this group contributed to the data analysis. One patient, not responding to the standard medical therapy, was subsequently treated with hypnotherapy at the request of his parents. His pain scores at 6 and 12 months follow-up are lacking (Figure 1).

There were no differences between the two treatment groups with respect to demographic characteristics, clinical features and baseline measures of pain intensity, pain frequency and associated symptoms that could explain treatment effects (Table 1).

![Trial Profile](image)

**Pain intensity and frequency scores**

In both treatment groups the pain intensity scores decreased significantly during and after treatment. The pain intensity scores decreased from 13.5 to 1.3 at the final endpoint one year after therapy in the HT group (p<0.001) and from 14.1 to 8.0 in the SMT group (p=0.002). Hypnotherapy was however, highly superior with a significantly greater reduction in PIS compared to SMT (p<0.002; Figure 2). Also the pain frequency
scores decreased during and after therapy in both groups; the figures for the PFS were 13.5 to 1.1 in the HT group (p<0.001) and 14.4 to 9.3 in the SMT group (Figure 3; p = 0.007). Again, HT was significantly more effective in reducing the scores compared to SMT (p<0.001).

Associated symptoms

The associated symptom scores (ASS) decreased from 3.1 at the start to 1.2 at one year follow-up (p<0.001, Figure 4) and from 3.8 to 2.5 (p=0.002) in the HT and SMT group, respectively. There was no difference in treatment effect in time between the HT and SMT group (p=0.661). In both groups the percentage of patients with headaches increased slightly, but not significantly from 48 to 52% and from 60% to 67% at one year follow-up in the HT and SMT group, respectively.

Table 1: Baseline characteristics of participants, by treatment group.

<table>
<thead>
<tr>
<th></th>
<th>Hypnotherapy (n=27)</th>
<th>Standard Medical Therapy (n=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demography</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years) *</td>
<td>13.2 (2.5)</td>
<td>13.4 (2.9)</td>
</tr>
<tr>
<td>Girls (%)</td>
<td>67</td>
<td>84</td>
</tr>
<tr>
<td>Clinical features</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IBS* (%)</td>
<td>41</td>
<td>44</td>
</tr>
<tr>
<td>FAP* (%)</td>
<td>59</td>
<td>56</td>
</tr>
<tr>
<td>Duration of symptoms (years)</td>
<td>3.7 (2.5)</td>
<td>3.1 (2.4)</td>
</tr>
<tr>
<td>Associated symptoms (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>44</td>
<td>68</td>
</tr>
<tr>
<td>Nocturnal pain</td>
<td>70</td>
<td>76</td>
</tr>
<tr>
<td>Headache</td>
<td>48</td>
<td>60</td>
</tr>
<tr>
<td>School absenteeism (%)</td>
<td>78</td>
<td>68</td>
</tr>
<tr>
<td>Hospitalization (％)</td>
<td>14</td>
<td>23</td>
</tr>
<tr>
<td>for IBS/ FAP*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stress at school/home (%)</td>
<td>32</td>
<td>36</td>
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<tr>
<td>Previous psychological</td>
<td>33</td>
<td>24</td>
</tr>
<tr>
<td>treatment (％)</td>
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<tr>
<td>Family member with abdominal pain (％)</td>
<td>67</td>
<td>48</td>
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<tr>
<td>Abdominal pain scores</td>
<td></td>
<td></td>
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<tr>
<td>Pain intensity score</td>
<td>13.5 (3.9)</td>
<td>13.9 (4.1)</td>
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<tr>
<td>Pain frequency score</td>
<td>13.7 (5.9)</td>
<td>14.1 (4.7)</td>
</tr>
<tr>
<td>Associated symptom score</td>
<td>3.1 (1.4)</td>
<td>3.8 (1.5)</td>
</tr>
</tbody>
</table>

* Data are mean (SD). IBS = irritable bowel syndrome; FAP = functional abdominal pain.
Treatment success

At the end of the 3-month treatment period 16 of 27 patients (59%) in the HT group showed a clinical remission versus 3 of 25 (12%) in the SMT (table 2; p< 0.001). At 6 months follow up, 19 of 27 (71%) patients in the HT group were in clinical remission compared to only 4 of 24 (17%) in the SMT group. One year after the end of therapy a

Figure 2: Changes in pain intensity scores during and after treatment

Figure 3: Changes in pain frequency scores during and after treatment

Figure 4: Changes in associated symptoms score during and after treatment
further improvement had occurred in both groups with a remission in 22 of 26 patients (85%) in the HT group and 6 of 24 (25%) in the SMT group (table 2; p<0.001). After therapy only one child in clinical remission in the HT group had worsening of symptoms at 6 months. She was in clinical remission again 6 months later. All other children in the HT group remained in clinical remission during follow up.

The type of FGID (IBS or FAP) did not influence the response to therapy. Moreover no relation could be found between the pain severity and pain frequency pre-treatment and the effect of therapy, nor with gender and treatment effect. Age however, did effect treatment response: children < 14 years showed a significant better treatment response during treatment up until 6 months after therapy. No difference in therapeutic effect between the two age groups was found at one year follow up. The effect of age on treatment efficacy was similar in both treatment groups.

**Discussion**

This randomized controlled study is the first to demonstrate that gut-directed hypnotherapy is highly effective in the treatment of children with long lasting complaints of either IBS or FAP. Treatment was successful in 85% of the participants at one year follow-up, whereas only 25% of the children were in clinical remission after standard medical care, given by an experienced pediatric gastroenterologist and an experienced general pediatrician. This high success rate is remarkable since most children were referred by other hospitals after extensive other therapies such as treatment with proton-pump inhibitors or laxatives or psychotherapy without benefit.

Our results corroborate earlier data in 3 uncontrolled trials in children. Self hypnosis or a combination of guided imagery and relaxation, a technique almost identical to hypnosis, were successfully used in 90% of the children in these trials. The high success rate of our study is also in accordance with reports in adult IBS patients, where response rates to hypnotherapy of 61% to 100% have been reported. A difference though is the number of hypnotherapy sessions. In our study children underwent only 6 sessions of hypnotherapy, whereas 7 to 12 sessions were performed in studies in adult IBS patients.
Children are generally better hypnotizable than adults and our results seem to confirm our hypothesis that 6 sessions would be sufficient. Most children with IBS and FAP have other gut-related symptoms, like nausea, nocturnal pain, vomiting and loss of appetite. Also, these associated symptoms decreased significantly during therapy. Interestingly, the proportion of children with headaches did not decrease after hypnotherapy. An explanation might be that during hypnotherapy no specific suggestions were given for headache; during therapy the focus was on abdominal pain and gut function. We have now adapted our hypnotherapy protocol and also address headaches and other associated complaints, if considered necessary.

In accordance with the adult studies, therapeutic gains of HT were maintained for at least one year after treatment and some patients continued to experience further improvement in symptoms after ending therapy. This post-treatment effect could be caused by hypnotic suggestions that benefits of the treatment would persist and become even more effective over time or by the ongoing use of self-hypnosis by the participants. However, it might also be possible that further improvement was caused by either the natural course of the disease or an aspecific learning effect, since in the SMT group symptoms also further ameliorated after ending therapy, although less pronounced.

No predictors of treatment response could be identified such as the severity of the abdominal pain or the type of FGID. Gonsalkorale and colleagues reported in their analysis of 250 patients that males with a diarrhea-predominant bowel pattern had a statistically significantly lower response rate than other IBS patients. We could not observe such a difference since our study group was small and contained only a few patients with diarrhea predominant IBS. We did find, however that children below the age of 14 had a significantly greater response to both therapies compared to older children. These differences disappeared at one year follow up. Further studies are needed to examine whether this difference is caused by a higher suggestibility in younger children or by differences in motivation, expectation or symptom severity.

There are some limitations to this study. The study was only a single blind trial with all outcomes assessed by an investigator who was blinded for treatment allocation. It was inevitable though that the recipients were not blinded to their form of treatment. It is known that response expectancy is an important mechanism of hypnotic pain reduction, and it is therefore likely that expectancy, which was not recorded in this study, contributed to the treatment effect. However, we noticed that many patients, allocated to the HT group, were at first skeptical about hypnotherapy, suggesting that expectancy initially was low. Another limitation is the fact that the hypnotherapy was performed by only one therapist. Therefore, this study needs to be replicated with other therapists. Thirdly, in this study we focused mainly on abdominal pain and did not investigate the influence of HT on other important outcome factors like school absenteeism, sleeping problems and, more generally, quality of life.
One of the strengths of this study is the fact that we included only children with long-lasting complaints of at least one year, who had been treated previously with standard medical care or psychological therapies. This might explain the relative low percentage of patients that were cured in the SMT group (25%), which is considerably lower than the average placebo response rate in IBS trials (40%). Our strict use of Rome criteria for study entry might also account for the low response rate in the SMT group, since it has been shown that this is also associated with lower placebo responses.

Cognitive-behavioral therapy (CBT) has been shown to be an effective treatment option in children with recurrent abdominal pain with long lasting effects and for many pediatricians, CBT is the therapy of choice if standard medical care has failed. However, parents of children with FAP or IBS can be reluctant in accepting the existence of psychosocial influences on their child’s symptoms and often refuse to engage with psychological services. In our study, gut-directed hypnotherapy was introduced to parents and children as a method of influencing and reducing the pain through the brain and was therefore probably not perceived as a psychological treatment. This may be reflected by the fact that almost all of the invited patients agreed to participate in this study.

The mode of action of hypnotherapy is not completely understood yet. Some evidence exists that gut-directed hypnotherapy impacts IBS through a combination of effects on gastrointestinal motility, visceral sensitivity, psychological factors and/or effects within the central nervous system. Whorwell et al. demonstrated that hypnosis can have a relaxing effect on fasting colonic motility. The effect of hypnosis on visceral sensitivity is somewhat less clear, with two studies demonstrating a reduction in fasting rectal sensitivity after hypnosis, whereas two others failed to find such an effect. Evidence exists that an improvement in IBS symptoms after hypnotherapy parallels improvement in psychological symptoms, but whether this is a cause or a consequence of the treatment effect remains to be elucidated. Finally, brain imaging techniques have shown that the anterior cingular cortex (ACC) plays a key role in hypnotic pain modulation. This is an interesting finding since the ACC is one of the brain regions where IBS patients have been found to differ from healthy controls. However, so far no studies have been published evaluating the changes in ACC function after hypnotherapy in IBS patients. Not much is known yet on the pathophysiology of IBS and FAP in children, but there is no reason to believe it is much different from what is known on the pathophysiology of IBS in adults. It seems therefore plausible to assume that the mechanisms of the effects of gut-directed hypnotherapy on IBS and FAP in children as seen in our study are also a combination of the above described mechanisms, but further studies are needed to examine this.

In conclusion, this study clearly shows the efficacy of gut-directed hypnotherapy in the treatment of children with longstanding IBS and FAP. We advocate that hypnotherapy becomes the treatment of choice in children with persisting complaints of either FAP or
IBS in whom first line therapies like education and dietary advices have failed. Further studies are needed to confirm our findings and to investigate whether hypnotherapy might also be a treatment option for children with other functional gastrointestinal disorders.

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Reference List


