S H A R K – Study

Study of the Havelhöhe Community Hospital on interventions for irritable bowel syndrome in the context of short term therapy

Requested by

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1. **Introduction and research question**

The following is an overview of the components and procedures of the planned intervention study on irritable bowel syndrome at the Havelhöhe Community Hospital in cooperation with the Max Lüscher Foundation (Switzerland) and the Steinbeis University of Applied Sciences Berlin.

The aim is to investigate the effects (in particular the improvement of physical and mental well-being) of an integrative short-term therapy approach with multimodal therapy elements based on anthroposophic medicine in the treatment of irritable bowel syndrome. For this purpose, different therapy modules and their effects on a cohort of irritable bowel patients will be analysed (1st study hypothesis: therapy effect versus waiting group).

Various survey instruments will be used within the study (see point 4.3.). It is to be investigated whether and which schema disorders predispose the irritable bowel syndrome. Here, the Lüscher colour test as a non-verbal personality test is to be compared with validated psychometric tests (2nd study hypothesis: participant collective shows specific uniform patterns / 3rd study hypothesis: survey differences between non-verbal and verbal survey instruments).

2. **Presentation of the clinical picture of irritable bowel syndrome**

In gastroenterology, irritable bowel syndrome is one of the functional gastrointestinal diseases that are often characterised by typical constellations of symptoms. The following typical symptoms can be present in patients together, individually or in any combination.

- Abdominal pain (abdominal cramps, malaise, flatulence)
- Change in stool behaviour or stool consistency,
- often alternating between constipation and diarrhoea,
- Mucus on the stool,
- Feeling of incomplete bowel emptying (Layer et al., 2011).

Combinations of complaints and symptoms are quite common. In addition to the typical symptoms, there may be

- mental and physical exhaustion as well as
- other psychological symptoms (ibid.).
**Epidemiology**

The prevalence and incidence of IBS patients depend on the definitions used (Manning, Kruis, Rome I, II, III). According to current studies, the prevalence ranges from 2.5 to 25% (Manning), 5.5 to 13.6% (Rome I) and 2.5 to 19.1% (Rome II). These show a higher prevalence and variability according to Manning compared to Rome I and II criteria. Here, the number of Manning criteria used influences the prevalence from 2.5 - 37%; when 3 Manning criteria are used, the prevalence is about 10%. The pooled prevalence is 7% (Leyer et al., 2011).

**Course of the disease**

Irritable bowel syndrome regresses spontaneously in some patients, but is often chronic. There is no increased co-prevalence with other serious diseases of the gastrointestinal tract, but certainly with serious other diseases, such as depression, anxiety disorders, somatoform disorders and rigid personality accentuation.

The prognosis of IBS depends on the length of the medical history. Patients with a long medical history are less likely to improve. In this case, permanent life stress is relevant to the prognosis. Irritable bowel syndrome is not associated with the development of other gastrointestinal or other serious diseases and does not have an increased mortality. Irritable bowel patients have a higher risk of surgery (hysterectomy, cholecystectomy) than non-irritable bowel patients.

**Diagnostics**

According to the currently valid German medical guidelines, irritable bowel syndrome exists if all of the following three conditions are fulfilled. 1:

1. there are chronic complaints, i.e. lasting longer than 3 months (e.g. abdominal pain, flatulence), which are referred to the intestine by the patient and doctor and are usually accompanied by changes in bowel movements.
2. the complaints should justify the patient seeking help and/or worrying about it, and be so severe that the quality of life isrelevantly impaired by it.
3. it is a prerequisite that there are no changes characteristic of other clinical pictures which could probably be responsible for these symptoms.
3. **Presentation of the short-term therapy approach**

**Therapy elements / modules**

3.1.1. **Psychoeducation**
Psychoeducation serves to inform patients about the disease and its course as well as a healing way of dealing with it. In particular, the following goals are pursued through the structured communication of information:
- Promotion of the understanding of the disease and the self-responsible handling of it
- Support in coping with the disease
- Reduction of fears, feelings of guilt and shame.

3.1.2. **Artistic therapies (sculpting, painting)**
Within the art therapy, tried and tested methods are used by experienced therapists from the Havelhöhe Clinic. As "non-verbal psychotherapy", these are particularly effective on the psychological level of the patients and promote introspective self-regulation processes and are also intended to serve as an exercise of will in the study setting.

3.1.3. **Movement therapy (eurythmy therapy)**
Eurythmy therapy as a special movement therapy is intended to mediate the patient's balance between tension and relaxation and to be activated by rhythmic exercises with the body. Within movement therapy, patients learn to better perceive and evaluate their own bodily processes and to enter into their own process of change.

3.1.4. **External application**
Within this module, different wraps and their indications are introduced and tried out, which the patients can then apply on their own, easily and inexpensively, if necessary.

3.1.5. **Healing Imagination**
In the context of healing imagination, an evidence-based, specially developed intestinal hypnosis is used, which is intended to give the patients peace and relaxation and relief from their complaints.
3.1.6. **Nutritional counselling**

This is to advise patients on specifics of their diet and eating habits. Individual questions, food intolerances and allergies should also be addressed.

3.1.7. **Cognitive training group**

Within the cognitive training group, the contents of the specific treatment day are reflected on, among other things, with the help of structuring work materials. This is to ensure that the patients deal with the therapy elements in the long term and can also apply individual elements in everyday life.

**Target group and study participants**

| Target group/Requirements | Requirements | Participants who meet the diagnostic criteria according to 2.3. |
|---------------------------|--------------|---------------------------------------------------------------|
| Group size                | A group size of 12-15 participants is planned. This means that with 4 planned groups, a total number of 60 participants is planned. |
| Contra-indications        | Suicidality, psychotic experience, other study participation |
| Recruitment of participants| Press, waiting list, Internet, GPs, MVZs |

**Treatment period – weekly schedule**

- Within the first four weeks, two treatment days per week and within the second four weeks, one treatment day per week (12 treatment days in total).
- 2 groups per week: Mon / Wed; Tue / Thu (16.30 to 18.30 hrs and 19.00 to 21.00 hrs respectively)

| 1. Day | 2. Day | 3. Day | 4. Day | 5. Day | 6. Day |
|--------|--------|--------|--------|--------|--------|
| Psychoeducation | Movement therapy | Psychoeducation | Movement therapy | Psychoeducation | Movement therapy |
| Painting | External Application | Painting | External Application | Painting | External Application |
| Healing Imagination | Nutritional counseling | Healing Imagination | Nutritional counseling | Healing Imagination | Nutritional counseling |
| Cognitive training group | Cognitive training group | Cognitive training group | Cognitive training group | Cognitive training group | Cognitive training group |
| 7. Day | 8. Day | 9. Day | 10. Day | 11. Day | 12. Day |
Psychoeducation | Movement therapy | Psychoeducation | Movement therapy | Psychoeducation | Movement therapy
---|---|---|---|---|---
Sculpting | External Application | Sculpting | External Application | Sculpting | External Application
Healing Imagination | Nutritional counseling | Healing Imagination | Nutritional counseling | Healing Imagination | Nutritional counseling
Cognitive training group | Cognitive training group | Cognitive training group | Cognitive training group | Cognitive training group | Cognitive training group

**Figure 1 Plan of therapy elements – overview**

**Therapy manual / patient literature / worksheets**
In order to ensure an equivalent, standardised implementation of the individual therapy elements, the following therapy manuals are to be created:
- Psychoeducation
- External application
- Healing imagination
- Cognitive training group

The contents of the mentioned therapy elements will be planned for the study and documented within the manuals. Furthermore, the patients will receive information material in the form of flyers at the beginning of the therapy on the following modules:
- Psychoeducation
- External application

Within the cognitive training group, work materials will be used to incorporate exercise elements into the therapy. For each of the 12 therapy days, a worksheet is designed to reflect the contents of the day. In addition, patients are given a booklet for self-documentation during and after the 12 days of treatment.

4. **Project design**

**Project implementation**
The project is to be carried out by an assembled project team. The following persons are planned for the project team:
- Patient acquisition: Gastroenterology / Psychosomatics secretariat
- Information meeting (preliminary talk)
- Anamnesis interview
- Psychoeducation
- Painting
- Sculpting
- Imaginations
- Nutritional counselling
- Body therapy
- Cognitive training group
- External application

Management and supervision: H. Matthes, S. Dörner (Havelhöhe), Maria Sepke, W. Albert (Steinbeis University Berlin), M. Hinse (Charité).

Follow-up study: student

Timetable and study design

With a planned number of 4 groups and a duration of 8 weeks per group, this results in a pure survey period of 12 weeks (from mid-January 2018 to mid-April 2018). The two waiting groups start the intervention from the 5th week. Patients will be randomly assigned to the groups. Treatment groups 1 and 2 will receive treatment on Mondays and Wednesdays, while waiting groups 3 and 4 will receive treatment on Tuesdays and Thursdays, thus guaranteeing that treatment and waiting groups cannot meet.

| Nov 2017 | Dez 2017 | Jan 2018 | Feb 2018 | March 2018 | April 2018 | May 2018 | May 2019 |
|----------|----------|----------|----------|------------|------------|----------|----------|
|          |          |          |          |            |            |          |          |
| Preparations | Treatment Group 1 | Treatment Group 2 | Waiting List 3 | Waiting List 4 | Follow-Up | Evaluations |

Abbildung 1 Zeitplan des Projektes

Instruments / Test diagnostics

Three survey dates are planned within the framework of a pretest-posttest design with a final follow-up. This is to ensure that differences between pre- and posttest measurements can be collected. A follow-up survey after 12 months will examine the long-term effect of the intervention. Furthermore, two survey dates are planned as part of the comparison between treatment and waiting list group. Care should be taken during the survey to ensure that the duration of the tests is reasonable. For this reason, all questionnaires will be sent to the patients...
in advance so that they are already pre-filled at the survey dates. During the surveys, only the Lüscher colour test and the SKID-II are then carried out on site. The posttest questionnaires were distributed at the last appointment and completed directly by some patients. The follow-up questionnaires for the 12-month evaluation of the intervention will be sent to patients by post. The follow-up includes two new questionnaires to assess the patients' independent implementation of the exercises and supports learned in the intervention within the last 12 months after the end of the intervention.

Survey time point 1 Screening & pre-test (Dec 2017):
- General anamnesis sheet
- Irritable Bowel Syndrome - Symptom Severity Scale (IBS-SSS)
- Patient Health Questionaires (PHQ-9)
- General Anxiety Disorder (GAD-7)
- Schema Mode Inventory (SMI)
- Lüscher colour test
- Structured Clinical Interview for Personality Disorders (SCID-II)

Survey Timepoint 2 (Prätest Treatment Warteliste; Februar 2018)
- Irritable Bowel Syndrome – Symptom Severity Scale (IBS-SSS)
- Patient Health Questionaires (PHQ-9)
- General Anxiety Disorder (GAD-7)

Survey period 3 (posttest treatment; March 2018)
- Irritable Bowel Syndrome - Symptom Severity Scale (IBS-SSS)
- Patient Health Questionaires (PHQ-9)
- General Anxiety Disorder (GAD-7)
- Schema Mode Inventory (SMI)
- Questionnaire for the Evaluation of Anthroposophic Therapies (EVAL26)

Erhebungszeitraum 4 (Posttest Warteliste 2018):
- Irritable Bowel Syndrome – Symptom Severity Scale (IBS-SSS)
- Patient Health Questionaires (PHQ-9)
- General Anxiety Disorder (GAD-7)
- Schema Mode Inventory (SMI)
- Fragebogen zur Evaluation der anthroposophischen Therapien (EVAL26)

Survey period 5 - (12 months follow-up May 2019)
• General medical history Follow-up
• Irritable Bowel Syndrome - Symptom Severity Scale (IBS-SSS)
• Patient Health Questionaires (PHQ-9)
• General Anxiety Disorder (GAD-7)
• Questionnaire for independent application of anthroposophic therapies

Location
Psychosomatische Tagesklinik GKH / Haus 23 / Kladower Damm 221; 14089 Berlin

5. Literature

Häuser, W. (2008). *Hypnose beim Reizdarm*. In: Revenstorf D. Peter B (Hrsg.): Hypnose in Psychotherapie, Psychosomatik und Medizin. Springer Verlag. 555-568.

Layer, P. et al. (2011). *S3-Leitlinie Reizdarmsyndrom*. AWMF-Registriernummer: 021/016. Z Gastroenterol, Georg Thieme Verlag KG Stuttgart, 237 – 293.

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