A Randomized Trial: The Blankenstein Healthcare Plan Improves Sustainability of Lifestyle Change After Inpatient Naturopathic Therapy for Chronic Back Pain

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ABSTRACT

Ordnungstherapie is the core of 5 areas of classical European naturopathy and focuses on salutogenesis and ways to deal and live with illness. The new tool Blankenstein healthcare plan (HCP) helps to integrate health-promoting activities into the daily routine. Using the Blankenstein questionnaire (BQ) this single-center randomized controlled trial examines whether HCP improves desired lifestyle changes in patients with chronic back pain. The main outcome measure is the difference between the weighted mean values of the BQ after 3 months and at the beginning. From 2011 to 2015, 600 female patients from the Department of Naturopathy were randomized whether or not to use the HCP in addition to in-patient naturopathic complex therapy. The BQ consists of visual analogue scales for the categories of "Ordnungstherapie": conscious nutrition, exercise and sports, stress and mental stress, naysaying ability, joy of being despite illness, and care of the soul. The importance of these areas is weighted and scored individually. The weighted mean values of the BQ improved significantly after 4 weeks and 3 months in both treatment groups, but significantly more in the group with a HCP (p<0.0001). No undesired effects were observed.

Abbreviations: BQ: Blankenstein Questionnaire   BMI: Body Mass Index; HCP: Healthcare Plan; VAS: Visual Analogue Scales; BDI: Beck Depression Inventory; WAVVAS: Weighted Mean Value of the VAS; CARE: Consultation and Relational Empathy; ITT: Intention to Treat; FFbH-R: Hannover Functional Ability Questionnaire Score; PP: Per Protocol; SD: Standard Deviation; LOCF: Last Observation Carried Forward; 95%-CI: 95%-Confidence-Interval; SLC: School Leaving Certificate; T0: At Enclosure; T1: After Inclusion in the Study; T2: At Discharge; T3: At 4 Weeks; T4: At 3 Months

Introduction

Classic European naturopathy has its place in therapy for chronic pain [1-3]. "Ordnungstherapie" (Ordnungstherapy) is the German naturopathic form of mind-body medicine. The term "Ordnungstherapie" was introduced by the Swiss physician Bircher-Benner (1867-1939) [4,5]. The focus is not on pathogenesis but is instead oriented around salutogenesis, which is an approach to human health that examines the factors contributing to the promotion and maintenance of physical and mental well-being rather than disease with particular emphasis on the coping mechanisms of the individual. Mind-body medicine works with objectively describable behavioral routines that influence spiritual and physical health. These include healthy eating and exercise routines, an appropriate lifestyle rhythm, the capability to reduce and to handle stress, successful processing of life crises and appropriate family and career structures [5]. Furthermore, the therapy includes psychosomatic, psychological, practical psychosocial and health-creating aspects and works using techniques such as autogenic training as described by Schultz [6], muscle relaxation as described by Jacobson [7], breath therapy and relaxation response.

Psychotherapeutical interventions include approaches from solution- and resource-oriented psychotherapy, behavioral therapy, short-term treatment, systemic therapy and health psychology. The resources required for the patient to manage their own illness and

lifestyle and the coping strategies applicable for these are learned. Mind-body medicine is characterized by the concept that the specialist knowledge of the experts in the relevant areas and the experience of the patient are both necessary to achieve the goals set. In many cases, patients lack the capacity to establish a routine, that is, to create a health-promoting lifestyle that they use in their day-to-day life. The long-term success of a treatment is dependent on this skill [8]. Studies on the effects of lifestyle modifications triggered by mind-body medicine generally document their effectiveness and sustainability [9-11]. Success in mind-body medicine has also been shown in cardiology, oncology and pain treatment [12]. In the USA around 18.9% of patients applied mind-body medicine, which is kin to "Ordnungstherapie" [13]. Spirituality is an important resource in handling illness [14].

The Department of True Naturopathy in Blankenstein (Hattingen) has been giving intensified multimodal inpatient naturopathic complex therapy with serial individually prescribed applications at a high density since 1999. The treatment team consists of physicians, nurses, physiotherapists, Ordnungstherapists (Psychologists with further special training), ecotrophologists/nutrition therapists and pastors. Outcomes were better for women in the naturopathy department than in an orthopedic department after 3 months. In rheumatology the results correspond with those from conventional therapies with classic disease- modifying anti-rheumatic drugs. Rehabilitation measures and treatments were performed more often following conventional orthopedic treatment. A clear additional value of naturopathy in terms of the clinical and financial aspects was seen for specific patient groups with multi-morbidities [1,15-20].

"Study findings (from exercise intervention studies) call for greater research and programmes efforts to maintain health, function, and physical activity behaviour after supports provided by research studies are removed" [21]. These observations and results from investigations on sustainability [22-24] led us to the development of a standardized form so that the process of mind-body medicine is rendered transparent and can be implemented by different therapists. To achieve this, two new therapy tools were created: the "Blankenstein questionnaire" (BQ) and the "Blankenstein healthcare plan" (HCP). Chronic back pain was selected as inclusion criterion as around 17% of the German population suffer from chronic pain, most of them are suffering from back pain - 85% at least once during their lifetime [25]. As the majority of patients treated in the Clinic for Naturopathy are women, the study is limited to female participants [26,27].

Methods

Investigation Design

1) This is a single-center randomized controlled trial with equal group size at the Clinic for Naturopathy in Blankenstein (Hattingen).

2) The patients did not receive any financial compensation.

3) The study was executed from November 2011 to August 2015.

4) Inclusion and exclusion criteria are shown in Table 1.

Table 1: Inclusion and exclusion criteria.

I nclusion Criteria	Exclusion Criteria
Female patients from the Department for Naturopathy at the Blankenstein Clinic	Participation in this study at an earlier point in time
Age ≤ 75 years	Cachexia (BMI ≤18.0)
FFbH-R ≤ 16 points (corresponding to < 70%)	Alcohol addiction
At least one of the following diagnoses: cervicocephalic syndrome or cervicalbrachial syndrome or chronic low back pain with or without radicular radiation	Chronic pain due to other illnesses which was the same as or more severe than the back pain, if it obliged the patient to take analgesics
Written consent following information	Clinical signs of or anamnestic clues to malignant conditions or metastases in the skeleton
Sufficient length of stay (expected ≥ 10 days)	Indications for surgery following a specialist orthopedic investigation
	Patients not capable of understanding the objective of the investigation
	Compliance not guaranteed

FFbH-R: Hannover Functional Ability Questionnaire Score

BMI: Body Mass Index

Objective Criteria

Main Outcome: Sustainability of the treatment success created by the lifestyle change, measured as difference between the WAVVAS (weighted average values of the visual analogue scales in the BQ: sum of the products from the relevant point number and the score on the visual analogue scale for the relevant behavior area divided by 10) after 3 months (Time T4) and the initial findings upon study inclusion (Time T1). A raise of the score is expected in both groups, more pronounced in the group with HCP.

Secondary Outcome: Sustainability of the treatment success created by the lifestyle change measured as difference between the WAVVAS after 4 weeks (Time T3) and the initial findings at Time T1. Sustainability of the treatment success produced by lifestyle changes measured using 5-step semi- quantitative scales (compare Table 8) for back pain and mental condition (subjective emotional status).

Questionnaires

Epidemiology Form: The physician documents on the epidemiology form whether the patient meets all inclusion criteria, has no exclusion criteria and whether she is participating in the study.

BQ: This questionnaire uses visual analogue scales (VAS; therefore shortened "Blankensteiner VAS"). It assesses current health-relevant behavior in 6 different lifestyle domains and the subjective importance of a change in the near future. Repetition allows evaluation of the goals achieved and measuring the sustainability of changes. An 11-stage number bar (from 0 [very bad] to 10 [excellent]) facilitates reliable telephone questioning and discussion (Figures 1 & 1a).

Figure 1: Blankenstein questionnaire (BQ).

Figure 1a: Blankenstein questionnaire (BQ; English Version).

The type and extent of the implementation of the following behaviors was queried:

- Conscious handling of nutrition

- Movement and sport

- Stress and psychological burden

- Ability to say no

- Ability to enjoy life

- Looking after the soul.

The patients worked with their therapists to establish where change was desired in each of the six areas for their individual case. A weighting of the individual significance of these areas was also carried out by allocating a total of 10 points to them. Based on this, the weighted mean value of the VAS (WAVVAS) was calculated (example: chosen areas "Ability to say no"/score 4/allocated points 7 and "Looking after the soul"/score 6/allocated points 3; WAVVAS=(4*7+6*3)/10=4,6). The minimum possible value is "0", the maximum "10", decimal places are allowed. The characteristics of the BQ were analyzed for the group of female in-patients (n=600) with chronic back pain (not published so far): the mean value of the WAVVAS of this group is 3.84, the standard deviation 1.47, the median 3.8. The result of the WAVVAS does not correlate with age, functional impairment (Hannover Functional Ability Questionnaire = FFbH-R) and body mass (BMI) (correlation coefficient < 0.3), only

with the score of the Beck Depression Inventory (BDI) it is weakly inversely correlated (correlation coefficient -0.39; slightly lower values in case of severe depression).

Graphically, there is no indication of a non-linear correlation in any case. Nor does the duration of the complaints, intensity of the complaints, marital status, schooling, vocational training, occupation, part-time or full-time work or retirement, unemployment, past or present psychotherapeutic treatment and religiosity have any discernible influence on the WAVVAS. Only earlier participation in a health program leads to a slightly higher (0.3) mean value.

Blankenstein HCP: The Blankenstein HCP is a written plan integrating measures that promote health-relevant behavior into daily life (Figures 2 & 2a).

Figure 2: Blankenstein healthcare plan (HCP).

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Memo sheet Healthcare Plan
Systematization of the conversation for the creation of a
health roadmap

Who: Ordnungstherapist
When: Final consultation on body mind therapy
Material: VAS from initial consultation (patient file), routing slip (brings patient with her)

Procedure:

Remove the Blankensteiner VAS from the patient file.

Preparation
After an appropriate introductory phase to get to know the patient, the "Healthcare Plan" concept is presented to the patient:

- The Healthcare Plan is an excellent help to successfully implement the findings and recommendations resulting from the stay in the clinic at home.
- The patient herself decides on the content of the Healthcare Plan.
- The Healthcare Plan includes everything that the patient plans to do at home with regard to a healthy lifestyle.
- The Blankensteiner VAS and the routing slip help to find and concretize the important areas of change.
- The Ordnungstherapist supports the patient in formulating the Healthcare Plan.
- The Healthcare Plan is an effective tool of scientific research and is used in our current investigation.

Creation of a Healthcare Plan

- Review the important areas of the VAS that the patient has marked. Include changes in importance in the Healthcare Plan.

Klinik Blankenstein

- For each important area that the patient wants to change, address the value on the scale again and ask the patient what she would have to do to improve the value on the scale by 0.5.
- Example "You ticked a 3 on the VAS scale for the area" Exercise and Sport ". What would it take for you to get a 3.5? "
- Record the patient's proposal and have it substantiated if necessary.
- Example: "I would have to move a little more." "How would that look in concrete terms if you moved a bit more?" "I walk with my girlfriend once a week for 30 minutes."
- Have the suggestion read by the "Inner Bastard".
- Example: "What does your Inner Bastard say about this project? What does your Inner Bastard need for you to succeed?"
- The patient's suggestion is transferred by hand or PC into the Healthcare Plan.
- The sample Healthcare Plan can be used as a template.
- Every other area in which the patient wants to change something is processed in the same way.
- For each important area of the patient there can be several change projects.
- Suggestions from the routing slip will also be concretized and transferred to the Healthcare Plan if the patient wants this.

The following applies to the formulation of the individual points of a health timetable:

- Always positive
- Always concrete
- Always realistic
- In case of doubt, better less than too much!

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Finalization

- The Healthcare Plan is read to the patient again in its entirety.
- The patient's explicit consent to her plan for home use is obtained. Changes will be incorporated if necessary.
- An **exact date and time** for the telephone interview will be agreed upon and written into the Healthcare Plan.
- The Healthcare Plan is signed by the patient and the Ordnungstherapist.
- The date for the telephone interview is noted in the desk calendar by the Ordnungstherapist with the abbreviation of the name.

The **meta question** is answered by the patient (mark with a cross in the sheet).

- Supporting question with regard to the meta question: "What can you do to make your Healthcare Plan even more successful?"

Copy the **Healthcare Plan**, the copy remains in the WB III folder, the original remains with the patient.

Saying goodbye to the patient with a view to the telephone interview.

The documents for the follow-up interview will be given to the patient:

2 Blankensteiner VAS (with instruction)
1 Hannover Functional Ability Questionnaire (FFbH-R)
2 Stamped envelopes

The Ordnungstherapist fills out the questionnaire for **external assessment** and files it together with the **Healthcare Plan** in the WB III folder.

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Sample Healthcare Plan

Area: Eating and drinking:

1. I cut in half piece of butter I use to smear my bread.
2. I eat meat-free 4 days a week.
3. I enjoy one day of sin a week.
4. After a day of sin I make a compensation day (as discussed with the nutritionist).

Area: Stress

1. I conduct resilience training at least 30 minutes per week.
2. I apply the "Columbo Technique" three times.

Area: Exercise and sport

1. I do 3 times 25 minutes light endurance sports per week.

Feedback on __.__.201_ at __:00 p.m. in the telephone interview

Blankenstein, __.__.201_

Signature of patient:

Signature of Ordnungstherapist:

Figure 2a: Blankenstein healthcare plan (HCP; English version).

These are created individually for each patient by the patient and therapist working together based on continuous notes made during the inpatient stay. Recommendations for health-promoting measures from the therapist (physician, Ordnungstherapist, physiotherapist, nutrition therapist, care staff and pastor) are written down in these continuous notes. The plan is limited to a maximum of five measures so that it can be integrated into the daily routine. The plan is as simple and direct as possible, with the elements broken down into small steps. It focuses on creating the synergistic effect so that small successes will create an internal feeling of control and the patient will thus follow a healthy lifestyle routine. Daily team meetings provide interdisciplinary coordination. The Ordnungstherapist supports the patient in formulating the HCP. Once the HCP has been created, it is signed by both the patient and therapist, which increases the probability that it will be implemented [23]. The creation of the HCP places great value on the individuality and multidisciplinary nature of the treating team. According to studies, this is far superior to monodisciplinary and generally formulated treatment concepts [28-31].

a)   The HCP is created by addressing the areas that the patient has indicated as important on the BQ and incorporating changes of importance into the HCP, querying for every area that a patient wants to effect change in and asking what the patient needs to do in order to improve the value on the scale by 0.5, adopting the patient's suggestions and rendering it concrete if necessary, checking suggestions by the "devil on your shoulder",

b)   Entering the patient's suggestions into the HCP, going through all other areas that the patient wants to effect change in, bearing in mind that all of the patient's important areas could have many plans for change in them,

c)   Specifying the suggestions from the continuous notes and placing them in the HCP if the patient desires this, finally.

d)   Reading out the complete HCP and collection explicit consent from the patient on her plans for when she returns home, incorporating changes where necessary, determining dates and times of the telephone interviews and recording them in the HCP, at last signing the HCP together with the patient.

e)   The individual points of a HCP must be always positive, always concrete, always realistic and in doubt restricted to the main points (less is more).

Hannover Functional Ability Questionnaire: The FFbH-R is a standardized questionnaire to measure the physical functional impairments that occur in conjunction with the back pain (scale from 0% to 100%, <70%: moderate restriction of the functional capacity). Unlike the BQ, the FFbH-R does not focus on the patient's estimations but instead seeks to reflect their physical condition as objectively as possible [32,33].

Beck Depression Inventory: The BDI has been used nationally [34] and internationally [35] for over 30 years. It is a psychological test that detects the severity of depressive symptoms in the clinical setting (21 questions with four possible answers each / 0-3 points; sum ≥29: severe depression). The reliability and validity are high [36] and are largely independent of age, sex and concomitant diagnoses.

Standardized Telephone Interview and Written Questionnaire: The follow-up investigations at four weeks and at three months after discharge record the implementation of the goals and measures set down in the HCP in a structured manner, based on a concrete schema (see supplementary material). The telephone interview is not carried out by the therapists themselves but by an Ordnungstherapist whom the patient does not know in order to prevent bias due to the tendency to provide a socially desirable response. The implementation of the measures in the 6 areas of the BQ is queried first, next to what percentage the goal set at discharge has been attained. Then the patient is asked how the implementation of the health-related behavior has gone overall and also whether anything else has changed in terms of the patient's well-being or general health. The BQ is filled out together.

Example: "Looking after the soul": VAS-value at the beginning: 4. Desired improvement: 2 points on the scale of 10. Achieved improvement: 50% of the desired change. Actual VAS-value: 4 plus 50% of 2, hence 4+0,5*2=5.

Medical History Questionnaire: The medical history questionnaire is used to record the age, height, weight, initiator of the instruction, job, working hours (part/full time), level of education and diagnoses and past diagnoses.

Empathy questionnaire (CARE Questionnaire): The CARE (Consultation and Relational Empathy) questionnaire measures the physician's communication style and the empathy experienced from the physician during the consultation [37]. It was translated and validated for implementation in German-speaking countries [38] (10 questions; 5-part Likert scale). The communicative behavior of the physician influences the treatment results and the patient´s satisfaction but does not significantly improve compliance [39,40].

Randomization

The patients were randomly allocated to the two treatment groups by an Ordnungstherapist using a program which generates pseudo-randomized numbers whose probability is adapted to the already existing distribution (programmed with turbo pascal 4.0 using the random-function to generate pseudo-randomized results), resulting in an at least nearly equal group size. The current randomization cannot be predicted, even with electronic data processing expertise, and each randomization is documented with the patients' name, surnames and birthday in a list which the user can only read.

Course of the Study

a)   The patients were selected by a physician or a research assistant using the FFbH-R and the epidemiology form and gave written informed consent.

b)   600 patients were randomized into two groups by a computer program into two equally-sized groups. One group of patients received a HCP in addition to the treatment, and the other group served as a control group.

c)   During the inclusion interview the treatment process was explained, the medical history form and the BDI were filled out and the treatment goals were compiled using the BQ. The patients weighted the six areas according to their individual relevance by allocation of 10 points to the chosen areas.

d)   Both groups received naturopathic complex treatment, lasting about two weeks [2,28]. Details of the naturopathic inpatient complex treatment were published before [15,16,20].

e)   In the HCP-group a continuous note form recorded the interdisciplinary recommendations of the therapists during the inpatient stay and served both as a guide and a foundation for the HCP.

f)   A CARE form was filled out upon discharge (after 2 to 3 weeks).

g)   At 4 weeks and 3 months after discharge, a telephone interview recorded the implementation of the BQ and the HCP and the BQ was sent to the clinic. The FFbH-R was only filled out at 3 months after discharge.

Statistics

After a pilot phase with 20 female subjects, the clinically relevant effect was defined as a change in the WAVVAS of 0.5 (mean change of 5% with reference to the whole scale -11 point/100mm) and the standard deviation was estimated. The necessary number of cases was calculated using the program G*Power 3.0.10 for a two-sided t-test for independent samples. At a desired power of 80% (type II error of 0.2) and a type I error of 0.05, at least 277 evaluable subjects are required for each group. 300 subjects were recruited for each group, based on a drop-out rate of 7% estimated by the pilot study. For the main objective parameter - difference in the WAVVAS at 3 months compared to initial findings - the differences in the WAVVAS at time T4 and at time T1 are calculated, tested for normal distribution (Shapiro-Wilk-Test) and tested between both treatment groups using the t-test for unpaired random samples. A probability of error of less than 5% ($p<0.05$) is considered significant. The secondary outcome "difference in the WAVVAS at Times T3 and T1" is compared between the two treatment groups in the same way.

As this constitutes descriptive information, no Bonferroni correction is applied. An intention to treat analysis (ITT analysis) according to the randomization and a per protocol analysis (PP analysis) according to the actual treatment are carried out. The missing data were estimated according to the LOCF method (last observation carried forward) for the ITT analysis. Weighting points with sums different from 10 (probably because the patient deemed it inadequate to attribute the missing point to or to remove the excess point from one of the chosen categories) were standardized to 10 total weighting points. This enables weighting according to the intention of the patient. The other parameters are described by giving the mean, the standard deviation, the number of cases, student tests, χ^2-tests and Cohens d for the effect size for mean differences between two groups.

Institutional Review Board Approval and Trial Registration

The study was carried out in accordance with the statements of the Declaration of Helsinki in the revised version of 1975 containing the amendments of 1983, 1989, 1996, 2000, 2004 and 2008. The version of the study as executed was approved by the Ethical Commission of the Medical Chambers of Westphalia-Lippe [Ethikkommission der Ärztekammer Westfalen-Lippe] and the Medical Faculty of the Westphalian Wilhelm University of Munster [Medizinische Fakultät der Westfälischen Wilhelms- Universität] on October 10, 2011 and November 26, 2011 (AZ 2011-222-f-S).

The study was registered in the German Clinical Trials Register (DRKS: WHO Primary Registry) (DRKS ID for the study: DRKS00003326).

Results

Recruitment and Study Workflow

The Flowchart of participant recruitment and study procedures is shown in Figure 3.

Anthropometric and Epidemiological Data

Demographic, physical and mental initial parameters for the patients are shown in Table 2. Additional anthropometric and epidemiological data are given in Tables 3-5. The level of confidence that change can be achieved is higher in the group with a HCP, both in terms of their own estimation and therapists' estimation.

Table 2: Demographic, physical and mental initial parameters.

HCP	56.69±10.05 (n=300)	164.92±7.10 (n=285)	78.56±18.03 (n=282)	28.92±6.59 (n=282)	11.47±3.52 (n=286)	15.72±8.65 (n=288)
p	0.657	0.954	0.449	0.545	0.497	0.721
Total	56.88±10.57 (n=600)	164.93±6.76 (n=575)	79.15±18.28 (n=569)	29.08±6.41 (n=569)	11.57±3.60 (n=576)	15.59±8.22 (n=575)

SD: Standard deviation; BMI: Body Mass Index [kg/m2]; FFbH-R: Hannover Functional Ability Score; BDI: Beck Depression Inventory; Control: Control group without healthcare plan; HCP: Group with Blankenstein healthcare plan (HCP); p: Student's t-test for difference between both treatment groups.

Table 3: Personal status, school leaving certificate and current job.

		Total	**Control**	**HCP**	**χ^2-Test (p)**
Personal Status	Single	49 (8%)	25 (9%)	24 (8%)	
	Married	333 (58%)	163 (57%)	170 (59%)	
	Separated	18(3%)	9 (3%)	9 (3%)	
	Divorced	116 (20%)	61 (21%)	55 (19%)	0,86
	Widowed	61 (11%)	29 (10%)	32 (11%)	
	Total	577	287	290	

		Total	Control	HCP	
School Leaving Certificate (SLC)	Still at school	1 (0,2%)	1 (%)	(%)	0,78
	No SLC	3 (0,5%)	2 (1%)	1 (%)	
	Special SLC	7 (1%)	6 (2%)	1 (%)	
	Vocational secondary school qualifications SLC	277 (48%)	141 (49%)	136 (47%)	
	German General Certificate of Secondary Education	182 (32%)	86 (30%)	96 (33%)	
	College or sixth form	64 (11%)	30 (10%)	34 (12%)	
	Degree	35 (6%)	17 (6%)	18 (6%)	
	Other	8 (1%)	4 (1%)	4 (1%)	
	Total	577	287	290	
Completed	Yes	507 (88%)	246 (86%)	261 (90%)	0,014
	No	68 (12%)	40 (14%)	28 (10%)	
	Total	575	286	289	
Current Job	Without work	88 (15%)	49 (17%)	39 (13%)	0,56
	Managerial position	18 (3%)	9 (3%)	9 (3%)	
	Permanent contract	221 (37%)	106 (37%)	115 (38%)	
	Temporary contract	21(4%)	10 (3%)	11 (4%)	
	Freelancer	18 (3%)	8 (3%)	10 (3%)	
	Pensioner	209 (35%)	100 (34%)	109 (36%)	
	Pension application	18 (3%)	8 (3%)	10 (3%)	
	Total	593	290	303	
Range of Occupation	Full-time	128 (21%)	63 (22%)	65 (22%)	0,93
	Part-time	148 (26%)	73 (25%)	75 (26%)	
	None	300 (53%)	151 (53%)	149 (52%)	
	Total	576	287	289	

SLC: school leaving certificate; HCP: Blankenstein healthcare plan

Table 4: Additional anthropometric and epidemiological data.,

Time T1		Total	Control	HCP	χ²-Test (p)
Participation in a health program	Yes	210 (36%)	101 (35%)	109 (38%)	0,41
	No	366 (64%)	185 (65%)	181 (62%)	
	Sum	576	286	290	
Current Psycho-Therapy	Yes	120 (21%)	59 (21%)	61 (21%)	0,77
	No	454 (79%)	226 (79%)	228 (79%)	
	Sum	574	285	289	
Previous Psycho-Therapy	Yes	317(56%)	155 (55%)	162 (56%)	0,56
	No	254 (44%)	128 (45%)	126 (44%)	
	Sum	571	283	288	
Religion Important	Yes	193 (34%)	93 (33%)	100 (35%)	0,45
	No	380 (66%)	192 (67%)	188 (65%)	
	Sum	573	285	288	

Duration of Pain	< 3 months	14 (2%)	8 (3%)	6 (2%)	0,63
	>3 <6 months	35 (6%)	18 (6%)	17 (6%)	
	> 6 months	527 (92%)	260 (91%)	267 (92%)	
	Sum	576	286	290	
Intensity of Pain	Low	10 (2%)	6 (2%)	4 (1%)	0,53
	Middle	228 (39%)	114 (40%)	114 (39%)	
	Very intense	337 (59%)	165 (58%)	172 (59%)	
	SUM	575	285	290	
Cause of Hospitalization (multiple answers allowed)	Own wish	124 (22%)	49 (17%)	75 (27%)	0,014
	Recommendation of physician	258 (46%)	132 (46%)	126 (45%)	
	Both	226 (40%)	112 (39%)	114 (40%)	
	Recommendation of a third party	84 (15%)	36 (13%)	48 (17%)	
	Press	34 (6%)	16 (6%)	18 (6%)	
	Sum	566	284	282	

HCP: Blankenstein healthcare plan

Table 5: Current self-assessment, desired changes across the six areas and weighting of the desired changes SD: Standard deviation;

			Movement and Sport Mean±SD	Stress and Psychological Burden Mean±SD	Ability to say No Mean±SD	Conscious Handling of Nutrition Mean±SD	Ability to Enjoy Life Mean±SD	Looking After the Soul Mean±SD
Current self-Assessment at Time t1	**Control**		5.227±2.509 (n=287)	4.548±2.127 (n=287)	4.379±2.474 (n=287)	5.738±2.354 (n=287)	5.246±2.235 (n=287)	4.888±2.525 (n=286)
	HCP		5.020±2.374 (n=289)	4.671±2.373 (n=289)	4.476±2.377 (n=289)	5.596±2.238 (n=289)	5.456±2.348 (n=289)	4.935±2.524 (n=289)
	p (t-test)		0.310	0.513	0.629	0.458	0.271	0.825
	Total		5.123±2.443 (n=576)	4.609±2.253 (n=576)	4.428±2.424 (n=576)	5.667±2.295 (n=576)	5.352±2.293 (n=576)	4.912±2.522 (n=576)
Desired Changes Across the Six Areas	**Control**	Yes	160	202	166	156	151	146
		No	125	84	119	129	134	138
		Total	285	286	285	285	285	284
	HCP	Yes	174	188	175	173	141	157
		No	113	99	112	114	146	130
		Total	287	287	287	287	287	287
	χ²-Test	p	0.121	0.069	0.343	0.056	0.193	0.261
	Total	Yes	334	390	341	329	292	303
		No	238	183	231	243	280	268
		Total	572	573	572	572	572	571
Weighting of the Desired Changes	**Control**		1.658±2.151 (n=287)	2.260±2.121 (n=286)	1.677±1.944 (n=286)	1.692±2.069 (n=286)	1.365±1.645 (n=287)	1.378±1.863 (n=285)
	HCP		1.598±1.881 (n=288)	2.043±2.021 (n=288)	1.669±1.827 (n=287)	2.011±2.538 (n=289)	1.259±1.605 (n=285)	1.467±1.753 (n=288)
	Total		1.628±2.019 (n=575)	2.151±2.072 (n=574)	1.673±1.884 (n=573)	1.852±2.320 (n=575)	1.312±1.624 (n=572)	1.423±1.807 (n=573)

HCP: Blankenstein healthcare plan

WAVVAS After 3 Months (Main Outcome)

In total, 26 patients from the group with the HCP and 34 patients from the control group could not be evaluated in the PP analysis due to missing data (the reasons are given in Figure 3). One patient with HCP could not be evaluated in the PP analysis due to mixed treatment. The result of the ITT analysis and of the PP analysis of the differences in the WAVVAS (at 3 months versus baseline) with comparison of the two treatment groups is shown in Table 6.
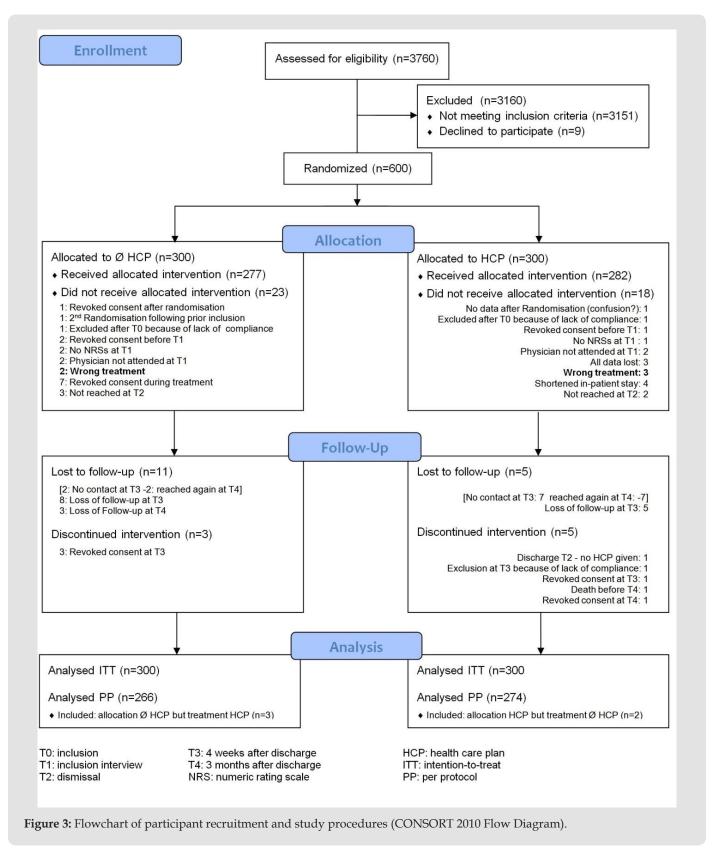

Figure 3: Flowchart of participant recruitment and study procedures (CONSORT 2010 Flow Diagram).

Table 6: Differences between the WAVVAS (main outcome) at times T4 (at 3 months) and T1 (after inclusion in the study) in ITT analysis and PP analysis.

WAVVAS T4-T1		Mean	SD	95%-CI	n	d (T4-T1)	p	d (±HCP)
ITT Analysis	**Control**	1.326	1.716	1.13-1.52	300	0.84	<0.0001	0.35
	HCP	1.924	1.686	1.73-2.11	300	1.18		
PP Analysis	**Control**	1.504	1.763	1.29-1.72	266	0.94	<0.0001	0.32
	HCP	2.048	1.644	1.85-2.24	274	1.27		

WAVVAS: weighted mean value of the visual analogue scales; SD: Standard deviation; 95%-CI: 95%-Confidence-Interval; ITT: Intention to treat; PP: Per Protocol; Control: Control group without healthcare plan; HCP: Group with Blankenstein healthcare plan (HCP); p: Student's t-test for difference between the two treatment groups; d: Cohens d (0.2 < d < 0.5: small effect; 0.5 < d < 0.8:medium effect; d > 0.8: strong effect).

A positive difference between the WAVVAS at 3 months and at baseline corresponds to an improvement (p<0,001 for both groups; ITT und PP analysis; paired t-test). The effect strength of the improvement of WAVVAS by the naturopathic complex therapy is strong in both groups. There is a small additional improvement effect in the group with HCP, which is significant (ITT: p=0.000019; PP: p=0.000225). The increase in the values of the WAVVAS at 3 months is greater by 45% respectively 36% with a HCP, compared to the group without HCP.

WAVVAS After 4 Weeks (Secondary Outcome)

The result of the ITT analysis and PP analysis of the differences in the WAVVAS (at 4 weeks versus baseline) with comparison of the two treatment groups is shown in Table 7.

Table 7: Differences between the WAVVAS (secondary outcome) at times T3 (at 4 weeks) and T1 (after inclusion in the study) in ITT analysis and PP analysis.

WAVVAS T3-T1		Mean	SD	95%-CI	n	d (T4-T1)	p	d (±HCP)
ITT Analysis	**Control**	1.179	1.395	1.02-1.34	300	0.78	0.0050	0.23
	HCP	1.512	1.499	1.34-1.68	300	0.97		
PP Analysis	**Control**	1.349	1.417	1.17-1.51	267	0.88	0.015	0.21
	HCP	1.655	1.491	1.47-1.82	269	1.06		

WAVVAS: weighted mean value of the visual analogue scales; SD: Standard deviation; 95%-CI: 95%-Confidence-Interval; ITT: Intention to treat; PP: Per Protocol; Control: Control group without healthcare plan; HCP: Group with Blankenstein healthcare plan (HCP); p: Student's t-test for difference between the two treatment groups; d: Cohens d (0.2 < d < 0.5: small effect; 0.5 < d < 0.8:medium effect; d > 0.8: strong effect).

The secondary outcome increase of WAVVAS at 4 weeks is also significant higher with HCP (ITT: p=0.0050; PP: p=0.015; increase ~28% respectively ~23%).

Other Secondary Outcomes

The further treatment and course results are presented for the PP analysis. The calculations were also carried out for the ITT groups, without producing significantly differing results. Change in back pain, mental well-being and FFbH-R is shown in Table 8. Change in back pain and change in mental well-being was not different between control und HCP-group at any point of time (p-values between 0.09 and 0.93; t-test) (Table 9). The FFbH-R improves significantly, with no significant difference between the treatment groups. The evaluation of the CARE form shows that the Ordnungstherapist in the group with the HCP was rated as significantly better (mean score control group 36.6, HCP-group 37.6; p=0.02; t-test). A comparable difference cannot be detected in the evaluation of the physician (mean score control group 36.1, HCP- group 36.5; p=0.36). Patients with a HCP found additional pastoral care beneficial (VAS, control group 6.7, HCP-group 8.3; p=0.007; t-test) and the discharge letter (control group yes:165/ no:94, HCP-group yes:189/no:77; p=0.009; χ^2-Test) more helpful (significant at 3 months). No undesired effects were observed.

Table 8: Change in back pain und mental well-being.

		Change in Back Pain							Change in Mental Well-being							
		Significantly Improved	Somewhat Better	Not Changed	Somewhat Worse	Significantly Worse	Total	1 = „Sign. improved" 5 = „Sign. worse"	Significantly Improved	Somewhat Better	Not Changed	Somewhat Worse	Significantly Worse	„Was not my Problem"	Total	1 = „Sign. improved" 5 = „Sign. worse"
At Discharge (T2)	Control	80	175	9	0	0	264	1,73	89	161	14	0	0	0	264	1.72
	HCP	97	162	12	1	0	272	1,69	101	161	6	0	1	3	272	1.66
	Total	177	337	21	1	0	536	1,71	190	322	20	0	1	3	536	1.69
After 4 Weeks (T3)	Control	67	95	58	19	15	254	2,29	71	103	58	17	7	0	256	2.16
	HCP	60	102	67	12	18	259	2,34	92	107	41	16	3	0	259	1.96
	Total	127	197	125	31	33	513	2,32	163	210	99	33	10	0	515	2.06
After 3 Months (T4)	Control	71	93	49	22	28	263	2,4	79	90	50	29	16	0	264	2.29
	HCP	68	87	66	31	17	269	2,41	94	95	45	21	13	0	268	2.12
	Total	139	180	115	53	45	532	2,4	173	185	95	50	29	0	532	2.20

Last row of each item:

Mean: 5-part Likert-scale: 1 = " Significantly improved"; 5 = „Significantly worse"

Note on the averages: 3 in the semiquantitative scale corresponds to "no change",

Values <3 correspond to an improvement over the previous query.

Table 9: Change in the FFbH-R.

FFbH-R	Total Mean±SD	Control Mean±SD 95%-CI	HCP Mean±SD 95%-CI	p (t-test: Con-trol-HCP)	d (Cohens d: Control-HCP)
At Enclosure T0	48.13±14.70 46.88-49.37 (n=536)	48.70±14.87 46.91-50.49 (n=266)	47.56±14.53 45.23-48.85 (n=270)	0.370	-0.077
After 3 Months (T4)	56.94±20.84 55.18-58.70 (n=538)	56.80±21.25 54.25-59.35 (n=266)	57.08±20.47 54.41-59.33 (n=272)	0.877	0.013
p (t-test: T0-T4)	<0.0001	<0.0001	<0.0001		
d (Cohens d: T0-T4)	0.49	0.44	0.54		

FFbH-R: Hannover Functional Ability Score; d: effect size (0.2 < d < 0.5: small effect; 0.5 < d < 0.8:medium effect; d > 0.8: strong effect); SD: Standard deviation; 95%-CI: 95%-Confidence-Interval.

Discussion

Randomization led to comparable treatment groups without relevant differences in the starting parameters for both groups. Limitations of the study and its statements result from the restriction to the female gender, so that a possible transferability to men remains unclear. It also remains unclear whether the HPC can also be used effectively in the outpatient area. The level of confidence that change can be achieved is higher in the group with a HCP, both in terms of the patients and the therapists' estimation.

It could be that bias has an effect here as the patients and the care providers knew about the group assignment at this point and potentially hoped that they would benefit from the HCP being tested. The better result of the Ordnungstherapist in the CARE form for the group with the HCP may be due to the increased intensity of care that the group with the HCP experienced. As we have seen from both previous scientific monitoring sessions, naturopathic complex therapy improves the functional impairments caused by back pain in both treatment groups, and therefore for the population as a

whole. This was measured with the FFbH-R over the course of the 3 month observation period and is significant.

No difference between the treatment groups could be evidenced here. Both treatment groups and therefore the entire study population had significant treatment success from the naturopathic complex therapy, as evidenced by the parameters measured by the BQ at all times. The effect size is strong. Whether the new use of the measuring instrument BQ itself is at least partly responsible for this cannot be decided with the current study design. The HCP leads to a significant and quantitatively meaningful increase in treatment success in both the PP analysis and the ITT analysis. Because the follow-up period was limited to 3 months, the long-term generalization of the results remains a task for future studies. It also remains to be seen whether the improvement in back pain with HCP lasts longer in the long term, so that the results of the Hannoveraner Bogen and measurements of the quality of life not directly and validated examined in this study also lead to demonstrable significant differences after a few years.

Conclusion

The HCP, used in conjunction with the BQ, is a valuable instrument in securing long-term success of mind- body medicine ("Ordnungstherapie"). Intended changes in Lifestyle are more intense and persisting. The HCP in conjunction with the BQ should be integrated into the routine care of naturopathic patients with chronic back pain, despite the significant increase in personal workload that this brings for the care provider. The question of whether these results could also be applied to naturopathic patients with other chronic diseases and to conventional medical departments, potentially in a form adapted specifically for the department, particularly if the departments are offering a form of complex therapy (such as pain therapy), should be explored in future studies.

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Informed Consent and Patient Details

We confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

Conflict of Interest

All authors declare that no conflicts of interest exist.

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