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Incorporation of Fasting Therapy in an Integrative Medicine Ward: Evaluation of Outcome, Safety, and Effects on Lifestyle Adherence in a Large Prospective Cohort Study

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ABSTRACT

Objectives: The aim of this study was to implement fasting therapy in an inpatient integrative medicine ward and to evaluate safety, acceptance, and effects on health-related outcomes and lifestyle adherence.

Design: This was a prospective observational study with consecutive inpatients over 13 years. Inclusion and exclusion criteria for fasting therapy were checked by treating physicians and recommendations given. After receiving full information patients decided whether they would participate in fasting. Outcomes were assessed on admission, at discharge, and 3 and 6 months after discharge.

Setting: The study took place in an integrative medicine department of an academic teaching hospital.

Subjects: Subjects were newly admitted inpatients with chronic internal diseases and chronic pain syndromes, with lengths of hospital stay of >3 days.

Interventions: All patients received intensive integrative treatments including Mind/Body Medicine, acupuncture, nutritional/lifestyle education, and hydrotherapy. Fasting patients participated in a 7-day juice fast (intake <350 kcal/day) with accompanying bowel cleansing, 2 prefasting relief days, and 3 days with stepwise reintroduction of food.

Outcome measures: Outcomes were assessed based on rate of participation in fasting, severity of main complaint, quality of life (QOL, MOS 36-Item Short-Form Health Survey), safety, lifestyle adherence to recommendations given (relaxation, diet, exercise).

Results: Of 2121 patients with complete discharge questionnaires, 952 patients participated in fasting, 873 had a normocaloric vegetarian diet, and 296 patients had other diets and were excluded. Response rates were 71% and 56% at 3- and 6-month follow-up. The main disease-related complaint at discharge was significantly greater improved in fasters versus nonfasters ($p < 0.01$). Patient QOL increased significantly and comparably from baseline to discharge in both groups. Fasting was well tolerated and no serious fasting-related adverse effects were reported. In all, 743 (78%) of fasting patients reported improvement of their health through fasting. Descriptors of lifestyle adherence showed higher levels of related activities in the 3 and 6 months of follow-up.

Conclusions: Fasting can safely and successfully be implemented in an inpatient integrative medicine concept and is perceived as a health-promoting method by the majority of patients. Potential effects on disease-related complaints and lifestyle adherence should be further evaluated in randomized trials.

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INTRODUCTION

Fasting as a medical treatment is claimed to be a valuable therapeutic method for chronic and acute diseases in most ethnomedical systems.[1,2] Historically, the reasons to fast involved both religious or spiritual and medical issues.[3] Many religions have a component of fasting involved. The common belief is that fasting reinforces spiritual performance and focuses the mind. In antiquity, fasting was an established treatment method since the time of Hippokrates and was thereafter recommended by most older European medical schools for the treatment of acute and chronic diseases,[4] after the empirical observation that infections are frequently followed by an anorectic response. More standardized methods of extended medical fasting were developed in the United States in the beginning of the 20th century by the physicians Tanner, Dewey, and Hazzard.[3,5] Their method of fasting consisted of water and tea fasting, supported by enemas and physical exercise. Thereafter, despite publication of beneficial health-related effects, little attention has been given to the value of medical fasting, and the method has almost disappeared in North America. In contrast, based on the works of the physicians Buchinger, Bircher-Benner, and Mayr, medical fasting attracted a growing number of patients from the 1950s on in Europe.[4] Buchinger's method of fasting included the free intake of mineral water and the limited intake of fruit juice (<350 kcal/day),[6] which substantially reduces the protein loss of gluconeogenesis.[7,8] The fasting cure is further accompanied by bowel cleansing, exercise, nutritional advice, and Mind/Body techniques. Recently, modified juice fasting has attracted a growing popularity in the German general public as a self-care method for health and particularly for initiating lifestyle modification.[9,10]

So far, the effects of therapeutic fasting have been studied only for a few indications. There is evidence that fasting followed by a vegetarian diet is beneficial in rheumatoid arthritis.[11,12] Some studies have further documented a relevant antihypertensive effect of fasting.[13,14] To date, no studies have investigated whether fasting is a feasible method within an integrative medicine approach, or whether fasting truly enhances adherence to lifestyle modification.

The Department of Integrative Medicine in Essen, Germany, was founded in 1999 at an Academic Teaching Hospital as a model institution of the State government. The hospital stay has a preplanned duration of 10–14 days, and treatment costs are covered by health insurance. On the background of the given experience with fasting, it was decided to establish fasting as one of the basic treatment methods. Therefore, within the medical concept that focuses on lifestyle modification and mind–body medicine and the treatment of chronic diseases, all patients were offered a modified 7-day fast as an adjunctive treatment method. In a first phase, to ensure the highest level of safety, the available techniques of modified fasting were adapted under the conditions of a fully medically supervised inpatient treatment. After establishment of the fasting technique and with enlargement of the department to 54 hospital beds in 2001, a prospective cohort study of all consecutive inpatients was started. The method of fasting, and the results of the outcome evaluation from 2001 to 2004, are reported here.

MATERIALS AND METHODS

Fasting: Indication and description of method

After performing an initial examination and taking a full medical history, the physician decided whether the patient would be offered fasting therapy under consideration of predefined exclusion and inclusion criteria. Predefined indications were as follows: rheumatoid arthritis, chronic pain syndromes of the locomotor system (osteoarthritis, fibromyalgia, back pain), stable inflammatory bowel disease and irritable bowel syndrome, chronic pulmonary disease, and migraine and chronic tension-type headache. Metabolic syndrome was not defined as an indication criterion because treatment costs for metabolic syndrome as the main admission diagnosis were not reimbursed by most health insurance companies at that time.

Exclusion criteria were as follows: eating disorders, body mass index <21 kg/m^2 or >40 kg/m^2, liver disease, renal failure, gastric ulcer, severe comorbidity including cancer and acquired immunodeficiency syndrome, premedication with immunosuppressive drugs (except corticosteroids) or coumarins, alcoholism, malnutrition, serious chronic infections, psychosis, epilepsy, type 1 diabetes mellitus, pregnancy, lactation, and weight loss of >3 kg during the previous 3 months.

After the physicians' recommendations to fast, the patients were fully informed about the course and effects of fasting, all accompanying procedures, and potential side-effects and were offered participation in the program. The patients then decided whether to participate and gave their written informed consent.

The method of fasting was adapted from the technique described by Buchinger.[1,2] A fasting period of 7 days was defined to achieve optimal feasibility. The fixed length of fasting allowed the continuous forming of small patient "fasting-groups." It was anticipated that sharing the fasting experience within small group would further support adherence to the program.

Fasting was preceded by two "relief" or prefasting days, using a 800 kcal/day monodiet of fruit, rice, or potatoes according to patients' choices. Fasting then began the following day with ingestion of an oral laxative, Natrium sulfat ("Glauber's salt" [Cesar & Loretz GmbH, Hilden, Germany], 20–40g). During fasting an enema or, if not wished by the patient, a mild laxative was administered every other day. The patients were recommended to drink 2–3 L of flu-

ids each day (mineral water, small quantities of juice, and herbal teas). Vegetable broth was taken at lunch. The daily energy intake during the fast amounted to 350 kcal/day.

For breaking the fast, an apple or cooked potato was offered. Patients were advised to chew slowly and to be mindful to enhance the perception and joy of the first solid food intake. This was followed by stepwise reintroduction of food with achievement of normocaloric intake by vegetarian meals on the postfasting day 4. In the postfasting days a focus was set on reintroducing mindfulness to eating.

Outcome evaluation

For the outcome study, all patients with a treatment period >3 days between January 1, 2001, and January 31, 2004, were included. Patients were asked to fill out detailed questionnaires on entry, at discharge, and at 3 and 6 months after discharge. The questionnaires included questions about demographic variables, health-related behavior, and severity of the main complaints. At discharge, patients were asked about participation in fasting. At each time point, quality-of-life (QOL) and lifestyle habits were assessed. At discharge and at the follow-ups, the courses of the main complaints compared to entry were asked. In addition, fasting patients were asked to evaluate the impact of fasting on their main complaints at the end of the treatment period. The QOL was assessed by the MOS 36-Item Short-Form Health Survey (SF-36).[15] Adherence to recommended lifestyle behaviors was assessed by numeric rating scales that asked for the self-practice of relaxation (four items), exercise (two items), and nutrition (eight items). Body weight was measured in all fasting patients and was documented in a sample of 120 patients by means of a calibrated scale with the patients wearing light clothing and no shoes. At discharge, the treating physicians reported the diagnoses and all side-effects by means of standardized questionnaires.

Besides nutritional therapy, all included patients received an identical treatment approach that included mind/body techniques, exercise, herbal medicine, acupuncture, yoga, hydrotherapy, and cupping. Fasting and nonfasting patients received the same amount of educational classes about nutritional therapy, stress reduction, and exercise.

Statistical analysis

Descriptive results are expressed as mean ± standard deviation or as mean with 95% confidence intervals (95% CI). Estimates of between-group differences in change are given as mean with 95% CI. Group comparisons for change of QOL and main complaints were performed using Wilcoxon-rank sum test or *t* test, as appropriate. Effect sizes were calculated for changes of QOL subscales. All data were analyzed with SAS version 8.2 statistical software (SAS Institutes, Cary, NC). No adjustments were made for multiplicity, as all tests were explorative. Results of lifestyle adherence were restricted to descriptive analysis.

RESULTS

Within the 3-year-period, 2787 patients were treated in the clinic for >3 days. The mean length of hospital stay was 13.5 days. Pre- and post-treatment questionnaires were filled out completely by 2121 patients (76%). Patients participating in the study differed from nonparticipants in that they were of slightly younger age and included a higher proportion of migraine patients (Table 1). Among the responders, 952 indicated that they participated in fasting; 873 patients did not participate in fasting and had normocaloric vegetarian diets; and 296 patients had other nutritional therapies (rice diet, elimination diets) or gave no information about applied nutritional therapy. Baseline characteristics of fasting and nonfasting patients were mainly balanced, with migraine and fibromyalgia being more predominant in the fasting group (Table 2). The response rates during the study follow-up were 71% ($n = 1497$) and 56% ($n = 1190$) at 3

Table 1. Response to Survey: Comparison of Responders and Nonresponders at Baseline

Characteristic	*Participants (N = 2121)*	*Nonparticipants (N = 666)*
Age, years, mean ± SD (range)	54.0 ± 14.1 (16–91)	57.6 ± 16.1 (17–93)
Male gender	417 (19.7%)	144 (21.6%)
Female gender	1704 (80.3%)	522 (78.4%)
Main diagnosis		
Headache/migraine	178 (8.4%)	27 (4.1%)
Inflammatory bowel disease	100 (4.7%)	26 (3.9%)
Rheumatoid arthritis	135 (6.4%)	27 (4.1%)
Osteoarthritis	201 (9.5%)	51 (7.7%)
COPD, bronchial asthma	109 (5.1%)	45 (6.8%)
Fibromyalgia	141 (6.7%)	48 (7.2%)
Chronic back pain, spondylarthrosis	380 (17.9%)	101 (15.2%)
Other	877 (41.4%)	341 (51.2%)

SD, standard deviation; COPD, chronic obstructive pulmonary disease.

Table 2. Baseline Characteristics and Demographic Data of Study Population

Characteristic	*Fasting patients (N = 952)*	*Nonfasting patients (N = 873)*
Age, years, mean ± SD (range)	53.5 ± 11.7 (19–82)	52.4 ± 15.9 (16–91)
Male gender	173 (18.2%)	198 (22.7%)
Female gender	779 (81.8%)	675 (77.3%)
Educational level		
Low	332 (41.7%)	270 (39.1%)
Middle	324 (41.0%)	291 (42.2%)
≥12 years	141 (17.7%)	129 (18.7%)
General perceived health		
Serious/poor	774 (81.6%)	712 (83.6%)
Good	174 (18.4%)	140 (16.4%)
Main diagnosis		
Headache/migraine	120 (12.65%)	44 (5.0%)
Inflammatory bowel disease	17 (1.8%)	76 (8.7%)
Rheumatoid arthritis	75 (7.9%)	43 (4.9%)
Osteoarthritis	94 (9.9%)	67 (7.7%)
COPD, bronchial asthma	47 (4.9%)	43 (4.9%)
Fibromyalgia	80 (8.4%)	46 (5.3%)
Chronic back pain, spondylarthrosis	149 (15.7%)	184 (21.1%)
Other	370 (38.9%)	370 (42.4%)

SD, standard deviation; COPD, chronic obstructive pulmonary disease.

and 6 months after discharge. At discharge, the main disease-related complaints had improved to significant greater extents in the fasting than in the nonfasting patients (Table 3). During the follow-up, physical and mental QOL improved in both groups significantly and to a comparable extent and continued to be significantly improved at the 6-month follow-up (Table 4). Effect sizes for change in physical and mental sum scores at 6 months were 0.33 and 0.40 in fasters and 0.49 and 0.28 in nonfasters (group difference, not significant). Within the QOL subscales, the largest effect sizes (> 0.5) at the 6-month follow-up were found for the dimensions of pain, vitality, and physical role in both groups (Table 5).

In the general evaluation of fasting therapy, 743 (78.0%) of the 952 fasting patients reported improvements in their health status through fasting at the time of discharge. Of the fasting patients, 176 (18.5%) reported no change and 33 (3.5%) a worsening of health.

Table 3. Intensity of the Main Disease-Related Complaint at Discharge Compared to Before Treatment for Fasting and Nonfasting Patients

Change in complaint	*Fasting patients* n *(%)*	*Nonfasting patients* n *(%)*
Much worse	8 (0.9)	13 (1.5)
Worse	29 (3.1)	24 (2.8)
Unchanged	135 (14.4)	161 (18.7)
Better	422 (45.0)	456 (52.8)
Much better	344 (36.7)	209 (24.2)

For difference between groups, $p < 0.01$ (Wilcoxon rank sum test).

Safety of fasting

There were no serious adverse effects reported during fasting. In all, 23 patients (2.3%) stopped fasting prematurely because of hunger, irritability, or general loss of motivation. In continuing fasters, these symptoms mostly subsided after fasting day 3. Two cases of uncomplicated hyponatremia occurred in the presence of continued diuretic medication use (Serum-Na:121/123 mmol/L). After discontinuation of diuretics, sodium levels normalized. One patient with gout experienced an symptomatic increase in uric acid levels to 11.2 mg/dL and was treated with allopurinol. Four patients experienced moderate gastric pain that subsided after the rebuilding days. Fasting induced a mean weight loss of -4.3 ± 0.7 kg, as assessed in the subsample.

Adherence to lifestyle recommendations

Relaxation was rarely practiced on entry and increased substantially in both groups at 3 and 6 months, with a more pronounced increase in fasting versus nonfasting patients. Accordingly, physical exercise increased in both groups and was slightly more pronounced in fasting compared to nonfasting patients (Table 6). Finally, both fasting and nonfasting patients improved their diets compared to baseline according to the given recommendations, with slightly better adherence patterns in fasters (Table 7).

Table 4. Physical and Mental Quality-of-Life (QOL) Sum Scores of the Short Form–36 QOL Questionnaire, Mean (95% Confidence Interval) for all Answers[a]

	Before admission		*3-months' follow-up*		*6-months' follow-up*	
	Fasting	*Nonfasting*	*Fasting*	*Nonfasting*	*Fasting*	*Nonfasting*
Physical QOL	33.1 (32.5; 33.7)	33.8 (33.1; 34.4)	37.6 (36.8; 38.4)	37.7 (36.8; 38.5)	36.9 (3.61; 37.8)	38.5 (37.7; 39.4)
Mental QOL	41.2 (40.5; 42)	39.2 (38.4; 39.9)	46.0 (45.2; 46.8)	44.1 (43.2; 45)	45.9 (45; 46.7)	43.4 (42.5; 44.3)

[a]Significant increase of QOL in each group from baseline to follow-ups ($p < 0.001$). No significant between-group differences.

DISCUSSION

This study evaluated the feasibility and effectiveness of incorporating fasting therapy for patients of an integrative medicine ward. The rationale to implement fasting as a basic treatment in this model institution was driven by the preexisting significant experience with fasting treatments for various chronic diseases and the inference that fasting may be a method to enhance lifestyle modification.[1,3,4,9] The results show that, when supported by a medical concept, a voluntary fast is chosen by up to one half of the patients in such a setting. Also, fasting was found to be safe and accompanied only by slight symptoms of discomfort for a few patients. In addition, fasting patients showed greater improvement in their disease-related complaints, which might point to specific treatment effects in the selected diagnostic groups. Finally, within the descriptive analysis, fasting patients showed somewhat better adherence to certain lifestyle recommendations.

For the whole study population, the results indicate that the integrative treatment generally was accompanied by a significant increase in QOL for at least 6 months after discharge. The persisting improvement in subjective health status corresponds to the results of two recent observational studies that evaluated an outpatient integrative medicine approach[16] and a 27-day stay in a residential hospital for TCM treatments.[17] In addition, fasting patients in our study showed better improvement of their main complaint. A similar method of fasting was also evaluated by an outcome documentation of 599 obese patients in a German rehabilitation facility. With response rates of 55%, the effect sizes for change of subjective health outcomes at 12 months after discharge were even greater,[18] and the patients showed lasting weight reduction. Although in the present study patients with primary metabolic syndrome were not included because of current reimbursement policies, these data indicate that medically supervised modified fasting may be a beneficial treatment for metabolic syndrome and merits further evaluation in randomized trials. This suggestion is supported by data from this study on health-related behaviors that indicate better adherence to nutritional recommendations, exercise, and relaxation practices, which may also have contributed to the clinical improvement. Principally, the experience of fasting may support motivation for lifestyle change. Most fasters experience clarity of mind and feel a "letting go" of past actions and experiences[19] and thus

Table 5. Short Form–36 Subscales Mean Scores with Effect Sizes (Baseline to 6 Months) for Patients who Returned the 6-Months' Follow-Up Questionnaire[a]

	Fasting (n = 494)			*Nonfasting (n = 422)*		
	Mean (Baseline)	*Mean (6 months)*	*Effect size (6 months)*	*Mean (Baseline)*	*Mean (6 months)*	*Effect size (6 months)*
Physical function	55.8	61.8	0.21	55.0	61.6	0.23
Physical role	23.0	40.4	0.52	21.7	41.1	0.59
Pain	29.9	43.5	0.62	34.4	48.0	0.53
General health Perception	36.4	45.9	0.41	42.1	49.2	0.41
Vitality	36.4	45.9	0.52	33.9	43.2	0.50
Social function	53.6	65.5	0.44	53.4	63.0	0.35
Emotional role	55.1	66.1	0.24	49.9	61.1	0.25
Mental health	53.6	62.0	0.33	52.3	59.3	0.36

[a]Significant increase of QOL in each group from baseline to follow-ups ($p < 0.001$). No significant between-group differences. QOL, quality of life.

Table 6. Self-Reported Practice of Relaxation (Meditation, Body Scan, Visualization, Deep Muscle Relaxation), Aerobic Exercise, and Gymnastics (Including *T'ai Chi*, Yoga, *Qigong*, and Feldenkrais)

	Before admission		*3-months' follow-up*		*6-months' follow-up*	
	Fasting	*Nonfasting*	*Fasting*	*Nonfasting*	*Fasting*	*Nonfasting*
Relaxation						
Never	379 (64.4%)	385 (64.7%)	116 (22.4%)	143 (29.2%)	129 (24.8%)	142 (30.1%)
1–2/week	148 (25.1%)	117 (19.7%)	185 (35.6%)	149 (30.5%)	194 (37.2%)	163 (34.6%)
>2/week	62 (10.5%)	93 (15.6%)	218 (42%)	197 (40.3%)	198 (38%)	166 (35.2%)
Aerobic exercise						
Never	252 (27%)	275 (33.2%)	123 (18.1%)	136 (22.7%)	111 (18.2%)	136 (25.9%)
1–2/week	396 (42.5%)	304 (36.7%)	270 (39.7%)	248 (41.3%)	271 (44.4%)	223 (42.5%)
>2/week	284 (30.5%)	250 (30.2%)	287 (42.2%)	216 (36%)	229 (37.5%)	166 (31.6%)
T'ai chi, Yoga, *Qigong*, and Feldenkrais						
Never	559 (61.6%)	544 (65.5%)	261 (38.7%)	273 (45.7%)	266 (44.1%)	248 (47.9%)
<1–2/week	199 (22%)	150 (18.1%)	153 (22.7%)	130 (21.7%)	149 (24.7%)	127 (24.5%)
≥2/week	149 (17%)	137 (16.5%)	261 (38.7%)	195 (32.6%)	188 (31.2%)	143 (27.6%)

may develop a more positive attitude toward the future. Specific fasting-induced neurendocrine responses[20] may also enhance motivation for behavioral change. It has previously been reported that the Integrative Medicine approach results in improved health-related lifestyle and increased internal control beliefs.[21] In this context, fasting seems to be a promising method to reinforce motivation for lifestyle change.

Some limitations apply to this study. Because of the nonrandomized treatment assignment, confounding by indication may have biased the results. However, demographic baseline data including educational data and response rates showed no differences between the groups. Also, the different diagnostic patterns may have biased the results; yet, an additional regression analysis (data not shown) did not reveal a significant effect of diagnosis on health-related outcomes. Therefore, no major bias of group comparison is apparent from these data. Another limitation relates to the loss of observations. Response rates at 3 and 6 months were satisfying; however it is likely that among patients who did not mail back the questionnaires, treatment success was less. Accordingly, nonadherent patients may have dropped out more frequently, whereas those remaining in the study may have increased their adherence. In consequence, the treatment effects may be overestimated for the whole study sample. However, this bias applies to both groups and should not have biased the group comparisons. That a significant superiority of fasting could not be demonstrated in the QOL outcomes may best be explained by the fact that in the study concept the individual treatment was tailored to the patients' disease states and constitutions. Therefore, under optimal conditions, both groups should have derived relevant benefits from the chosen integrative treatment. However, given the claims of the efficacy of fasting and the reduced complaints at discharge in the fasting group, the specific impact on clinical outcomes should be further tested in randomized trials.

Safety

In this study, fasting was reported to be safe and not accompanied by any serious side-effects. The 4% of patients who rated fasting as having worsened their health reported no specific adverse effects. Thus, it seems likely that this perception reflects the general course of disease which cannot be improved in all inpatients with chronic disease. In previous studies it was found that hunger is only moderate during fasting.[22] However, some discomfort may be experienced during fasting, especially on the fasting day 2 or 3, when metabolism is changing to lipolysis. Typical com-

Table 7. Reported Intake of Foods

	Before admission		*3-months' follow-up*		*6-months' follow-up*	
Food type	*Fasting*	*Nonfasting*	*Fasting*	*Nonfasting*	*Fasting*	*Nonfasting*
Fruits ≥1×/day	558 (59.6%)	485 (57%)	465 (71.8%)	382 (65.4%)	437 (71.4%)	349 (65.8%)
Vegetables ≥1×/day	524 (56.1%)	455 (53.7%)	414 (64%)	330 (56.6%)	384 (63%)	299 (56.3%)
Meat >3×/week	402 (43%)	360 (42.3%)	177 (27.4%)	182 (31.2%)	172 (28.2%)	183 (34.5%)
Sausage >3×/week	433 (46.3%)	423 (49.9%)	223 (34.5%)	241 (41.3%)	272 (44.6%)	223 (42%)
Sweets >3×/week	428 (45.9%)	390 (45.9%)	243 (37.8%)	252 (43.2%)	238 (38.9%)	232 (44%)

plaints in that context include tiredness, irritability, headache, nausea, and light-headedness.[6] These complaints, which were perceived as nonsevere by all study patients in the present and three previous studies,[20,22,23] can be successfully treated by self-help measures, which were included in the prefasting patient informations in the current study.

The concern over fasting-induced loss of protein reserves and related adverse effects is ever present in nutritional medicine. However, the overall experience in fasting therapy and the present results, which found supervised fasting to be a safe approach, are in contrast to these concerns.

CONCLUSIONS

Fasting can safely be implemented as a promising treatment method in an integrative medicine ward. For the vast majority of patients, fasting is experienced as beneficial for their chronic disease states. Potential specific treatment effects and the proposition that fasting is a useful tool to promote a health-related lifestyle or is a "missing link" in lifestyle modification adherence should be further adressed in randomized controlled trials.

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