

# Inbalance® - Yoga Therapy in Breast Cancer Patients



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## Introduction

Today modern chemotherapy regimens in breast cancer therapy continue over a long time period. These therapies put high physical and psychological demands on the patients, which they normally have to sustain by themselves. Especially in case of neoadjuvant chemotherapy (a chemotherapy which takes place before surgery) high levels of psychological stress are expected, because surgery is going to be delayed for 6 months in order to complete chemotherapy first. It is postulated that accompanying Yoga exercise during neoadjuvant chemotherapy can ameliorate physical and psychological stress.

Kiecolt-Glaser et al. [1] investigated in 200 breast cancer survivors whether three months of Hatha Yoga improved parameters of chronic inflammation (IL-6, TNF $\alpha$ , IL-1 $\beta$ ), fatigue, vitality or depression. They found that immediately after Yoga therapy, levels of fatigue were not lower, but vitality was improved in patients who practiced Yoga as compared to controls. Three months after Yoga therapy also levels of fatigue were lower in Yoga patients. This study showed a positive effect of Yoga on fatigue, vitality and on parameters of chronic inflammation (decrease of IL-6, TNF $\alpha$  and IL-1 $\beta$ ).

Another study by Chandwani et al. [2,3] examined Yoga during radiation therapy. They randomized patients to a Yoga-group (n=53) versus a Stretching group (n=56) and a control group (n=54). Importantly, Yoga increased the physical functionality in the Yoga-group compared to the other two groups, while in both the Yoga and the Stretching group, a decrease of fatigue symptoms at the end of radiation therapy was observed along with a positive effect on the stress hormone Cortisol. Furthermore, Yoga seemed to reduce nausea symptoms [4], since a positive correlation between the Morrow Assessment of Nausea and Emesis Score and fear/depression was seen. Because of these findings, Yoga might decrease chemotherapy-induced nausea. A study by Buffart et al. [5] described a clear

stress reduction, less fear and depression and a moderate decrease in fatigue and an increase in general life quality.

In their totality, these studies demonstrate a positive effect of Yoga on quality of life in breast cancer patients, especially in the areas of fatigue and vitality. So far no data exist whether similar effects are also seen during neoadjuvant chemotherapy. This therapy is known as especially stressful, because the tumour will only be removed after several months of chemotherapy. Hence, we aimed to set up a study to provide first insights into whether Yoga is a reasonable and effective complementary therapy in breast cancer patients during neoadjuvant chemotherapy.

## Study Design

All female patients  $\geq 18$  years from a single tertiary care hospital with the new diagnosis of breast cancer are being asked to participate in the study. Inclusion criteria are first diagnosis of breast cancer, stage cT1-4, cN0-1, cM0, female, planned for neoadjuvant chemotherapy, ECOG 0-1. Exclusion criteria are severe physical impairment (ECOG $>1$ ) including immobile patients, severe psychological disorder (severe depression, psychosis, suicidal tendency), ongoing Yoga exercises (during the last 6 months), missing knowledge of German (to answer the questionnaires) and participation in other studies. If they agree, the study is explained and they have to sign an informed consent.

Included patients are being randomized in a 4:4 block randomization. Patients from the Yoga group (n=50) are having Yoga exercises (Viniyoga) once a week for 75 minutes for 6 months (for the total duration of the neoadjuvant chemotherapy). Exercises are chosen according to the specific cancer situation and are primarily derived from Viniyoga. One Yoga teacher was recruited for the project and developed a plan with suitable Yoga exercises, which are performed by the patients for 10-15 minutes at home every other day. The Yoga exercise group is limited to a maximum of 12 patients. The Yoga

teacher is certified (BDY/EYU) with multiple further trainings in ruminant Yoga and specifically recommended for cancer patients by the Bavarian Cancer Society.

The control group (n=50) receives two detailed consultations about complementary therapies in addition to the standard breast cancer treatment. One consultation takes place at the beginning of the neoadjuvant chemotherapy, the other at the end of chemotherapy. Psychological support is offered to all patients by professional counselling. There are three evaluations at three defined time points in the study: before the beginning of neoadjuvant chemotherapy, after the end of neoadjuvant chemotherapy and 6 months after the end of neoadjuvant chemotherapy. At each evaluation patients have to answer questionnaires, perform physical tests and they have a blood sample taken to determine laboratory parameters.

The psychosomatic evaluation is performed in collaboration with the Department of Psychosomatics and Psychotherapeutic Medicine. Quantitative-empirical as well as qualitative-empirical methods are being used. The qualitative analysis will be performed in structured interviews within focus groups. The evaluation is planned as qualitative content analysis (May ring method). The examination of the first effects of the treatment is performed with validated and standardized instruments. The primary study goal is the assessment of mental health from the SF 36 questionnaire. Furthermore, Hospital Anxiety and Depression Scale, LQ are used to evaluate secondary outcome-parameters. As intervention variables, clinical and socio demographic variables, social support, possible psychooncological measures and the pattern of coping with the disease, are investigated. The questionnaires are distributed by a study nurse, who is blinded to the randomization and the group affiliation. The results can be used to plan a larger, future randomized-controlled study.

Physical resilience is examined in collaboration with the department of Physical Therapy. The assessment consists of a 6-min. walking test to assess the physical efficiency and endurance, power measurement of upper extremities according to Janda,

Functional Reach Test to analyze balance and coordination, ROM (Range of motion) to examine the function of the shoulder on the affected side, visual scale (VAS) for pain evaluation, Shoulder Pain and Disability Index (SPADI) and Disabilities of the Arm, Shoulder, Hand (Quick DASH) to test pain and impairment in daily activities, FACT-G to describe quality of life. A secondary study goal in the area of physical parameters is to analyze the influence of Yoga exercises on side effects of chemotherapy such as nausea/emesis and poly neuropathy. Further items of interest are self-assessment of the measure by the patient, registration of self-perception and disease processing. In this study, laboratory parameters and medications will be documented, as well as the number and duration of doctor and/or hospital visits.

### Meaning

The meaning of the study is the controlled analysis of a potential positive effect of complementary Yoga therapy, with special emphasis on specific physical and psychological stress of breast cancer patients during neo adjuvant chemotherapy.

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