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Hasya-Yoga for the improvement of quality of life in primary breast cancer patients: A single arm observational trial

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ABSTRACT

Background: So far scientific evidence on the effect of laughter yoga on prognosis and quality of life in primary breast cancer is limited. Few studies show positive effects on quality of life and stress. The aim of this trial is to investigate the effect of a structured laughter yoga program on individuals after initial treatment for primary breast cancer and to evaluate its effectiveness as a complementary medical treatment.

Subjects and methods: Forty women with primary breast cancer were included in a monocentric, prospective, single-arm intervention trial. Quality of life, spirituality, affectivity, life satisfaction, depression, and stress were measured before the intervention, after the intervention, and six months after the start of the intervention. Internationally validated questionnaires for global and breast cancer-specific quality of life were used (FACT-B, FACIT-SP, PANAS, SWLS, BDI, PSS-10, NCCN Distress Thermometer). For the statistical analysis, we used IBM SPSS, Version 25. Differences were determined using the Wilcoxon Test, with a p-value < 0.05 considered statistically significant.

Results: Our results show significant improvements in global (5.8%; p = 0.014) and breast cancer-specific quality of life (7%; p = 0.002). Significant improvements were also observed in spirituality (8.2%; p = 0.001), life satisfaction (13.1%; p = 0.001), depression (14.7%; p = 0.028), and stress (7.9%; p = 0.005). These improvements remained sustainable, as they were still detectable six months after the start of the intervention.

Conclusion: The present data support the potential efficacy of a structured laughter yoga program for individuals after initial treatment for primary breast cancer and suggest laughter yoga as an appropriate complementary approach. Future research on laughter yoga in oncology is needed.

1. Introduction

In 2022, breast cancer was the most common cancer among women, with approximately 74,500 incidences and 18,500 deaths [1]. At diagnosis, around 30 % of affected women were younger than 55 years. Diagnosis and treatment had a serious impact on quality of life [2–4]. Besides oncological safety and for an increasing number of patients in lifelong aftercare the importance of quality of life is attracting more notice [5]. Modern approaches recognize the significance of complementary medical measures and recommend physical activity for patients after breast cancer treatment [6]. Moderate exercise, including 150 min of physical activity per week, as well as yoga and Mindfulness-Based Stress Reduction (MBSR) techniques, showed a positive impact on quality of life and life expectancy [7–11]. However, laughter exercises have not yet been included in current recommendations. Nevertheless,

not all patients can benefit from exercise programs. Comorbidities, obesity and depression can negatively affect some individuals. The majority of patients has never participated in sports programs, and it is often difficult or even impossible to motivate them to change their behaviour. These circumstances can lead to further comorbidity and reduced quality of life. Against this background the study "Laughter Helps!" [12] investigates Hasya Yoga (laughter yoga) as a low-threshold, complementary medical program suitable for improving quality of life. Laughter yoga was introduced in 1995 by the Indian doctor Madan Kataria [13], who was also influenced by the gelotologists Cousins, Frey, and Berk [14–16]. Laughter yoga is a combination of classic hatha yoga, laughter, and relaxation exercises. It involves simulating laughter (laughing without reason) and is performed louder and longer than spontaneous laughter. When practised in a group, it has highly positive, self-energizing effects and interpersonal benefits. Some authors in

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reviews support laughter treatments as a complementary medical method (Bennett and Lengacher [17–20], Mora-Ripoll [21,22]). The current literature on medical applications reflects sparse but encouraging data (Shahidi [23], Morishima et al. [24], Lee et al. [25], Cho/Oh [36], Kim [37]): their investigation, overall, demonstrate existing evidence for potential benefits of laughter-based interventions on psychosocial outcomes. The oncological trials of them [24,25,36,37] illustrated significant improvements of either quality of life or anxiety, depression, pain and stress. The investigation by Shahidi [23] with members of a senior residence performed predominant results for quality of life and resilience (here: laughter yoga in comparison to physical training). It should be noted that these findings are heterogeneous and largely derived from small or methodologically diverse studies. Regarding the multidimensional burden experienced by breast cancer patients, global and breast cancer specific quality of life was chosen as the primary outcome to capture physical, emotional, functional and social domains beyond symptom-specific effects. Our secondary outcomes (spirituality, affectivity, life satisfaction, depression, and stress) were selected to reflect psychosocial and existential dimensions that are commonly affected during cancer survivorship and were assessed using internationally validated measurement instruments.

2. Material and method

The study "Laughter Helps!" [12] was designed as a prospective, single-arm, monocentric intervention study and was conducted between 2016 and 2017. It was approved by the ethics committee of the medical faculty prior to commencement. The study included 40 adult volunteers (Appendix shows "Patient Characteristics") who had completed primary treatment for invasive breast cancer, and their participation was independent of their physical constitution. There was no statistical calculation for necessity of the sample size. The sample size was determined by feasibility of intervention at a certain place by one trainer. Two groups with 20 individuals each were chosen. A certain control-group for having the chance of randomization was not chosen. Laughter yoga interventions were performed in an outpatient clinic by one investigator (senior author of this paper). The effectiveness of a structured laughter yoga exercise program was investigated using internationally validated questionnaires. The primary study objective was to assess quality of life measured by validated quality of life questionnaires (FACT [26] and FACT-B [27]). Secondly, we investigated spirituality, affectivity, life satisfaction, depression, and stress levels. Data were collected at three points in time: pre-measurement (T1), post-measurement (T2), and follow-up, 14 weeks after completion (six months after beginning) (T3). There was no scientific reason for a longer follow-up time since prognostic evaluation was not part of the trial. The primary study objective, "Quality of Life," was operationalized as the total score achieved on the FACT questionnaire [26] and, together with the additional breast cancer-specific questions, also on the FACT-B questionnaire [27]. The five dimensions of breast cancer-specific quality of life (physical well-being, emotional well-being, social well-being, functionality, and breast cancer-specific questions) depicted in the analysis questionnaire were first analysed separately, and afterwards, the total score was determined. The secondary study objectives were assessed using the following measurement instruments, operationalized as the total score achieved in each case: spirituality (FACIT-SP [28]), life satisfaction (SWLS [29]), positive and negative affectivity (PANAS [30]), depression (BDI [31]), and stress (PSS-10 [32], NCCN Distress Thermometer [33]). The interventions lasted 60 min, with ten sessions offered at weekly intervals. Test subjects were required to participate in at least eight out of the ten sessions. The interventions focused on stress reduction, relaxation, breathing techniques, communication, and social exchange. The statistical analysis was carried out using IBM SPSS, version 25. Data sets from 38 study participants (2 dropouts before starting the intervention) were analysed statistically, with 36 (two drop-outs during intervention) data sets being complete in all points of time.

3. Results

3.1. Primary study objective: quality of life

The primary study objective was global quality of life evaluated by the FACT questionnaire [26], which examines four dimensions: physical well-being, relationships with friends, mental well-being, and functionality. The total score from this questionnaire reflects global quality of life. When including the fifth dimension, which consists of breast cancer-specific questions, the result is referred to as breast cancer-specific quality of life, measured by the FACT-B questionnaire [27]. The differences in scores were measured from T1 to T2 and from T1 to T3. The Wilcoxon test was used for statistical analysis, with p -values < 0.05 considered significant (two-sided, asymptotic significance).

Physical well-being improved by 6.8% ($p = 0.003$) in the T1/T2 interval and by 7.6% ($p = 0.004$) in the T1/T3 interval. Both improvements are significant. There were no significant changes in the measurement times for either relationships with friends or mental well-being. Functionality did not change significantly in the first interval (T1/T2), with a change of 4.2% ($p = 0.176$). However, there was a significant improvement of 13% ($p = 0.000$) in the T1/T3 interval. For breast cancer-specific questions, a significant improvement of 9% ($p = 0.011$) was recorded in the T1/T2 interval, but no significant change was observed in the T1/T3 interval, where the change was 5.6% ($p = 0.114$). The total score for global quality of life (dimensions 1–4) improved significantly in both intervals, showing increases of 5.8% ($p = 0.014$) and 6.2% ($p = 0.005$). Additionally, the overall score of breast cancer-specific quality of life (dimensions 1–5) demonstrated significant improvements of 7% ($p = 0.002$) and 6% ($p = 0.006$) for both intervals.

(Appendix: Table 1 shows these results; Figures 1a to 1d illustrate the progression of changes for global quality of life, breast cancer-specific quality of life, physical well-being, and functionality)

3.2. Secondary study objectives: spirituality, affectivity, life satisfaction, depression, and stress

The secondary study objectives were analysed using the following questionnaires: spirituality (FACIT-SP [28]), life satisfaction (SWLS [29]), positive and negative affectivity (PANAS [30]), depression (BDI [31]), and stress (PSS-10 [32] and NCCN Distress Thermometer [33]). The NCCN Distress Thermometer was only used in the T1/T3 interval. The respective total scores were determined for each questionnaire. Differences in scores at the time points T1 to T2 and T1 to T3 were measured. The Wilcoxon test was used for statistical analysis, with p -values < 0.05 considered significant (two-sided, asymptotic significance).

Spirituality improved significantly in both intervals, first by 8.2% ($p = 0.001$) and second by 4.7% ($p = 0.011$). For positive affectivity, there were no significant improvements in either interval. Negative affectivity showed significant improvement in the first interval (T1/T2) by 8.2% ($p = 0.014$). In the T1/T3 interval, there was a non-significant improvement close to the significance level, with an increase of 5.6% ($p = 0.059$). Satisfaction with life also showed significant improvement in both intervals, with an increase of 13.1% ($p = 0.001$) in the first interval and 10.1% ($p = 0.008$) in the second. The results for depression in both intervals demonstrated significant improvements of 14.7% ($p = 0.028$) and 20.5% ($p = 0.003$), respectively. When examining stress using the PSS-10 measurement instrument, a 7.9% improvement was recorded in the first interval ($p = 0.005$) and an 8.7% improvement in the second interval ($p = 0.003$). The NCCN Distress Thermometer was only used in the T1/T3 interval, where the sub-item "physical problems" showed an 18.2% improvement ($p = 0.012$). All other sub-items for this measurement instrument showed no significant changes.

(Appendix: Table 2 shows these results)

4. Discussion

To our knowledge, this study is the first to investigate the influence of laughter yoga on quality of life and spirituality not only straight post-intervention but also after 6 months follow-up. The number of participants (40) is nearly twice as high as that in comparable international studies in the intervention arm [24,25,36,37]. The drop-out rate was 10 %. Internationally validated measurement instruments [26–33] were utilized in the study. Our data confirm a significant and sustainable improvement in quality of life, particularly in its physical and functional dimensions, similar to findings from sports programs (Zeng [34], Bing [35]). This emphasizes the low-threshold nature of the Hasya Yoga intervention. No positive changes were found for "relationships with friends" or "mental well-being." Morishima et al. [24], Lee et al. [25], Cho and Oh [36], and Kim et al. [37] corroborate the positive findings on quality of life in their studies. There were also sustainable (ongoing) positive changes in spirituality. Meraviglia [38] and Heather et al. [39] found a positive correlation between religion, spirituality, and physical health in cancer patients. However, Heather et al. [39] found no evidence for an inverse correlation (where positive well-being promotes spirituality), which our study may suggest. Negative affectivity showed significant improvement in the pre-post comparison but not in the follow-up, indicating a short-term reducing influence. For "positive affectivity," we found no significant changes. Ellis et al. [40] documented significant changes in residents of a nursing home for both positive and negative effects; however, their results are only comparably limited due to the different populations studied. Significant positive changes were also observed for life satisfaction at all measurement points. There is a lack of comparable international studies in oncology, but a significant effect on non-oncological patients is documented by Weinberg et al. [41]. We also found significant, sustainable improvements in depression, a conclusion that aligns with findings by Lee et al. [25]. Additionally, we observed a significant, sustainable reduction in subjectively perceived stress using the PSS-10 stress measurement method [32], though not using the NCCN Distress Thermometer [33]. This questionnaire only showed a significant positive effect in the "physical problems" sub-aspect. However, the stress-reducing effect is well documented in the literature and appears to be a specific strength of laughter treatments [21,22,25,43,44]. Non-oncological studies [23,42,45] also provide evidence for the positive effects of laughter treatments, indicating their potential for oncological applications. Current meta-analyses by Van der Wal and Kok [45] and Stiwi/Rosendahl [46] demonstrate positive physical and psychological effects for simulated laughter, particularly in oncological applications, which we were able to confirm in our study. Furthermore a recent scoping review of six randomized controlled trials by Giridharan and Ansari [47] reported improvements of QoL as well as emotional and physical functioning, and reduction in stress and depressive symptoms among cancer patients participating in laughter yoga interventions. Importantly, these authors also highlight the methodological limitations of the existing evidence. In line with these observations, we emphasize the benefits of Hasya Yoga as a complementary medical application and acknowledge that our study has some limitations. Despite the prospective approach, it was not randomized. Additionally, all patients were cared for by the same laughter yoga therapist, which, while favourable, may introduce bias due to the relationship some patients had with the therapist. We acknowledge that the sample of 40 preselected individuals is too small for generalisation and limits its representativeness. It is also challenging to find individuals willing to participate in laughter therapy, as well as qualified therapists. In this context, randomization was not feasible. Nevertheless, the population size of 40 is larger than that of comparable studies, placing it within a phase II scope. Future randomized studies with more laughter yoga trainers and larger patient populations could provide a more reliable statistical database.

5. Conclusion

Laughter yoga applications represent a complementary bio-psycho-social therapeutic approach (Mora-Ripoll [22]). This approach facilitates intrapsychic maturation and learning processes, which can lead to long-term behavioural changes and promote sustainability. In our study, 56 % of our participants continued to practice laughter yoga voluntarily after completing the intervention. This ongoing practice enables individuals to break free from negative spirals, thereby sustainably improving the quality of life for breast cancer patients.

The results of our study illustrate the significant complementary medical potential of laughter treatments. In times of scarce resources and under the pressure of a growing number of patients in aftercare, this form of therapy should be the focus of further research, and the results should be confirmed through a prospective multi-centre study.

Authors' contributions

Author A and Author B designed the study. Author A collected the data and performed the analysis. Author A drafted most of the manuscript. Author B a part of it. All authors critically reviewed, approved the final manuscript, and agree to be accountable for the accuracy and integrity of the work.

CRediT authorship contribution statement

Rüdiger Lewin: Writing – original draft, Visualization, Validation, Resources, Project administration, Investigation, Formal analysis, Data curation. **Eugen Ruckhäberle:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Tanja Fehm:** Writing – review & editing. **Svetlana Mohrmann:** Writing – review & editing. **Natalia Krawczyk:** Writing – review & editing. **Bernadette Jäger:** Writing – review & editing. **Verena Friebe:** Writing – review & editing.

Consent for publication

Consent for publication of anonymised data was obtained from all participants.

Ethics statement

This study was conducted in accordance with the Declaration of Helsinki and all applicable national and institutional ethical guidelines for research involving human participants.

Ethical approval was obtained from:

- Ethikkommission der medizinischen Fakultät der Heinrich-Heine-Universität, Moorenstraße 5, 40225 Düsseldorf

- Approval Number: Studiennummer 4165R/ Registrierungs-ID: 2010232250

- All participants provided written informed consent after receiving full information regarding the study objectives, procedures, potential benefits, and possible risks. Participation was voluntary, and participants were free to withdraw at any time without disadvantage.

All collected data were anonymized prior to analysis, and no identifying information will be released in any publication arising from this study.

The authors confirm that the manuscript is original, has not been published previously, and is not under consideration elsewhere. All authors have approved the final version and accept responsibility for the integrity and accuracy of the work. Potential conflicts of interest and funding sources are disclosed in the appropriate sections.

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Appendix

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Table 1

Primary study objective. The relative differences are shown in per cent and the corresponding P values in brackets (green=significant differences; orange=non-significant differences)

Quality of life dimension	Difference T1/T2 (significance level)	Difference T1/T3 (significance level)
1. physical well-being	6.8% (p=0.003)	7.6% (p=0.004)
2. relationship with friends	4,8% (p=0.142)	1,3% (p=0.272)
3. mental well-being	1.1% (p=0.282)	3.2% (p=0.182)
4. functionality	4.2% (p=0.176)	13.0% (p=0.000)
5. breast cancer specific questions	9.0% (p=0.011)	5.6% (p=0.114)
Global quality of life <i>(Dimension 1-4)</i>	5.8% (p=0.014)	6.2% (p=0.005)
Breast cancer-spec. quality of life. <i>(Dimension 1-5)</i>	7.0% (p=0.002)	6.0% (p=0.006)

Table 2

Secondary study objectives. The relative differences are shown in per cent and the corresponding P values in brackets (green=significant differences; orange=non-significant differences)

(continued on next page)

Table 2 (continued)

Secondary study objectives	Differences T1/T2 (significance level)	Difference T1/T3 (significance level)
Spirituality	8,2% (p=0.001)	4,7% (p=0.011)
Positive affects	-3,5% (p=0.320)	1,1% (p=0.616)
Negative affects	8,2% (p=0.014)	5,6% (p=0.059)
Satisfaction with life	13,1% (p=0.001)	10,1% (p=0.008)
Depression	14,7% (p=0.028)	20,5% (p=0.003)
Stress (PSS-10)	7,9% (p=0.005)	8,7% (p=0.003)
Stress (NCCN-Distress-Themometer-physical problems)	Not analysed	18,2% (p=0.012)

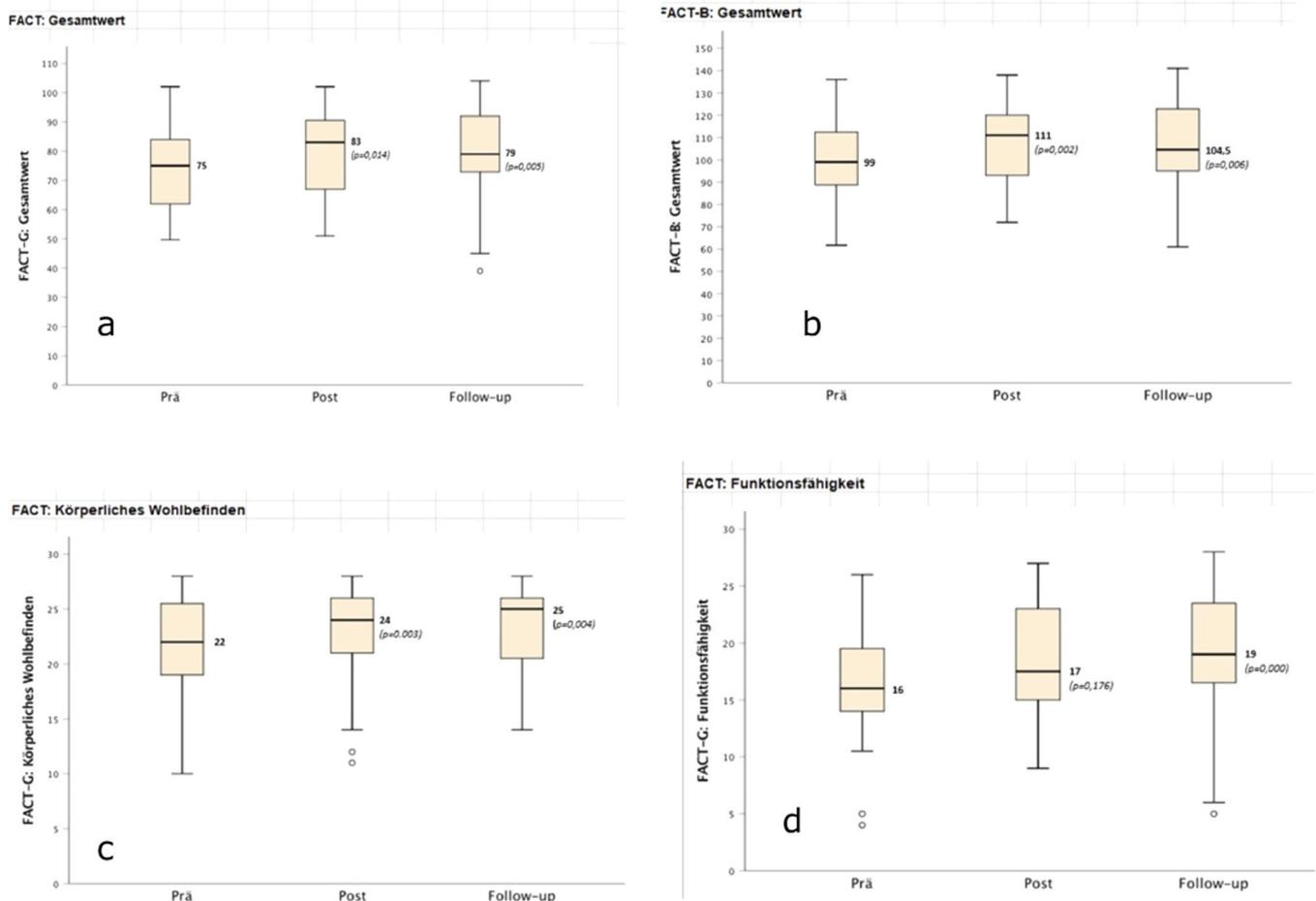


Fig. 1. Fig. 1 shows the development of a. global quality of life, b. breast cancer-specific quality of life, c. physical well-being and d. functionality at the points in time T1 (pre), T2 (post) and T3 (follow-up).

Patient Characteristics (participants n = 38 at T1)

<u>Age</u>	min	max	median
years	42	80	56

range from 42 years to 80 years; median 56 years

<u>Tumor-Status</u>	number of patients	percentage
TX	1	2,6
T1	14	36,8
T2	13	34,2
T4	1	2,6
DCIS	4	10,5
missing data sets	5	13,2

71% T1-T2; no T3; 2,6% T4; 10,5% DCIS, rest Tx or missing data sets

<u>Nodal-Status</u>	number of patients	percentage
N0	24	63,2
N1	4	10,5
N2	2	5,3
N3	4	10,5
missing data sets	4	10,5

63,2% N0; 15,8% N1-N2; 10,5% N3; rest missing data sets

<u>Metastasis</u>	number of patients	percentage
M0	29	76,3
M1	4	10,5
missing data sets	5	13,2

76,3% M0; 10,5% M1; rest missing data sets

<u>Number of CTX-Therapies</u>	number of patients	percentage
no CTX	3	7,9
1 CTX	21	55,3
2 CTX	3	7,9
missing data sets	11	28,9

no CTX 7,9%; 1 CTX 55,3%; 2 CTX 7,9%; rest missing data sets; (median: 1CTX)

<u>Number of RTX-Therapies</u>	number of patients	Percentage
no RTX	5	13,2
1 RTX	26	68,4
2 RTX	2	5,3
missing data sets	5	13,2

no RTX 13,2%; 1 RTX 68,4%; 2 RTX 5,3%; rest missing data sets (median: 1RTX)

<u>Number of Surgical Intervent.</u>	number of patients	percentage
no surgery	1	2,6
1 intervention	30	78,9
2 interventions	5	13,2
3 interventions	1	2,6
5 interventions	1	2,6

no Surgery 2,6%; 1 interv. 78,9%; 2 interv. 13,2%; 3–5 interv. 5,2%; (median: 1 intervention)

<u>Number of endocr. Therapies</u>	number of patients	percentage
no endocrine therapy	7	18,4
1 endocrine therapy	24	62,2
2 endocrine therapies	1	2,6
missing data sets	6	15,8

no end. Th. 18,4%; 1 end. Th. 62,2%; 2 end. Th. 2,6%; rest missing data sets, (median: 1 endocrine therapy)

Data availability

The datasets generated and analysed during the study are available from the corresponding author on reasonable request.

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