

Clinical Study

The Efficacy of Short-Term Psycho-Oncological Interventions for Women with Gynaecological Cancer: A Randomized Study

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Key Words

Distress in cancer · Psycho-oncological intervention · Anxiety and depression · Supportive interventions

Abstract

Objectives: We aimed to examine the efficacy of two psycho-oncological interventions in anxiety, depression, and self-perceived as well as physiological stress in inpatients with gynaecological cancer. **Methods:** Forty-five women were included in the trial. Thirty-five were categorized as being at high risk of anxiety and depression, and were randomized to either a single psycho-oncological therapy session or a single-session relaxation intervention. **Results:** A significant decrease in anxiety [mean (t_0) = 12, mean (t_1) = 7.47, $p = 0.001$] and depression [mean (t_0) = 9.71, mean (t_1) = 6.35, $p < 0.001$] was observed in the psycho-oncological intervention group. In the relaxation group, anxiety also significantly decreased [mean (t_0) = 11.67, mean (t_1) = 8.22, $p = 0.003$], whereas depression did not. A comparative analysis of both interventions showed a trend in favour of psycho-oncological therapy for the treatment of depression ($F = 3.3$, $p = 0.078$). However, self-reported stress ($p = 0.031$) and different objective stress parameters only significantly decreased in the relaxation group. **Conclusions:** Psycho-oncological interventions should represent an essential part of interdisciplinary care for gynaecological cancer patients. Both types of intervention may reduce anxiety. However, the single psycho-oncological therapy session might be slightly more effective in treating depression, whereas the single-session relaxation intervention seems to have a stronger effect on physiological stress parameters.

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Introduction

A diagnosis of cancer can lead to severe psychological distress. Regardless of the prognosis, patients suffer from the threat of pain and the uncertainty [1]. In oncological and haematological settings, the prevalence of combination diagnoses was 20.7% for any type of depression (major, minor, or dysthymia), 31.6% for depression (according to the DSM or ICD) or adjustment disorder, and 38.2% for depression (according to the DSM or ICD), adjustment disorder, or anxiety [2]. No differences were found between palliative and non-palliative situations. The authors of another review suggest that one third of cancer patients in acute care hospitals suffer from mental health disorders [3]. It has been reported that higher stress before surgery is associated with increased pain in women undergoing major abdominal surgery, which in turn means that they need more morphine [4]. Furthermore, not only in cancer patients do psychiatric comorbidities contribute to prolonged hospital stays and more frequent hospital admissions [5]. Treatment costs have been shown to be higher for depressive cancer inpatients [6]. Moreover, depression significantly influences the severity and frequency of side effects [7] as well as adjustment to and compliance with oncological therapies [8].

Psychiatric comorbidities are most frequently found in women with gynaecological cancer [9]: 43.9% suffered from various mental disorders. However, until today, findings of psycho-oncological distress in women with gynaecological cancer are sparse. In line with other studies [10–12], Singer and Schwarz [13] report that 78% of women would like to have psycho-oncological support already during their inpatient stay.

An earlier analysis by our research group showed an indication for professional psycho-oncological support in 41% of the inpatients diagnosed with cancer [14]. Additionally, in a random sample study, we analysed the treatment effect of a psycho-oncological intervention versus a non-intervention in 131 inpatients at a hospital specialized in surgical oncology [15]. According to their score on the Hospital Anxiety and Depression Scale (HADS), the patients were either classified as 'at low risk' (<12) or 'at high risk of anxiety and depression' (≥ 12). A significant decrease in anxiety and depression was found in the high-risk patients undergoing the psycho-oncological intervention. No statistically significant changes could be found in the high-risk group without the psycho-oncological intervention as well as in the low-risk groups with or without the psycho-oncological intervention.

The rationale of the present study is based on Lazarus's stress and coping paradigm [16, 17]. In our case, managing stress is coping with the diagnosis of cancer [18]. Many theories consider the activity of the autonomic nervous system as an essential component of emotion [19], making the assessment of physiological parameters appear to be a useful complement to self-reports in assessing stress reactions. In research regarding anxiety, common indicators of an activation of the sympathetic nervous system are breathing rate measured per minute, skin conductance measured in microsiemens, heart rate measured per minute, amplitude for blood volume pulse measured in microvolts, and muscle activity (electromyogram) measured in microvolts. Anxiety leads to an increase in breathing rate, skin conductance, heart rate, and electromyogram while the amplitude for blood volume pulse decreases [20]. To our knowledge, until now, physiological parameters have not been used to evaluate changes in stress during psychological interventions in cancer patients.

In contrast to our prior study [15] which examined the treatment effect of several psycho-oncological therapy sessions on anxiety and depression, the current study used only one session. One-time psychosocial interventions have been shown to be effective in a study by Powell et al. [21]. Guidelines for our single psycho-oncological therapy session were developed based on the content-analytical evaluation of our prior study. The originally planned control group design was rejected by the local ethics committee for patients at high risk of anxiety and depression. Therefore, we chose to analyse whether there are differences in efficacy of a

single psycho-oncological therapy session versus a single-session relaxation intervention in reducing anxiety, depression, and stress in women with gynaecological cancer. Different studies have shown that relaxation training reduces side effects of chemotherapy in cancer patients [22–24]. However, we did not find any study on the treatment effect of single-session relaxation interventions. With psycho-oncological therapy being a targeted intervention, we assumed the single psycho-oncological therapy session to decrease anxiety and depression more strongly than the single-session relaxation intervention. Furthermore, we expected the single psycho-oncological therapy session to reduce self-reported stress more efficiently. This should also be reflected in physiological stress parameters.

Patients and Methods

Study Design

The study has a randomized and prospective design and was approved by the Ethics Board of Charité University Hospital (application No. EA01/028/09). It is subject to the Helsinki Declaration as well as the terms of data protection and privacy laws. Women with a diagnosis of gynaecological cancer were informed about the content and the aims of the study. After declaring their written informed consent, the participants were presented the German version of the HADS and the Perceived Stress Questionnaire (PSQ; t_0). The HADS [25] is a questionnaire for adults suffering from somatic complaints to self-assess anxiety and depression levels. Both subscales contain 7 items. All 14 multiple-choice items have a 4-point Likert response scale. The questionnaire yields raw values for each anxiety and depression on a scale from 0 to 21. According to the results of other studies [26, 27], a sum of 12 of both scales was used as a cutoff score to classify the women as at high (≥ 12) or at low risk of anxiety and depression (< 12). In the high-risk group, the women were assigned to either a single psycho-oncological therapy session or a single-session relaxation intervention by a randomization list (fig. 1).

The PSQ [28] is a self-rating instrument for measuring perceived stressful situations during the last month on a 4-point Likert scale. It consists of 4 subscales: worries, tension, joy, and demands. High scores on the PSQ are associated with a high level of perceived stress.

The two types of intervention (see below) took place between the third and sixth postoperative days and were conducted by specially trained staff. During both interventions, we measured the physiological stress parameters by using a portable NeXus-10 device (Mind Media, Herten, The Netherlands) [29]. At the end of their inpatient stay (t_1), the women completed the HADS and PSQ again.

Single Psycho-Oncological Therapy Session

In our prior study [15], we identified three essential issues which were important for patients during their inpatient stay: (1) information about the inpatient stay, (2) questions regarding communication with relatives or friends, and (3) questions regarding their future perspective.

Thus, the consultations, which lasted at least 30 min, focused on these three issues. Furthermore, the women had the opportunity to ask one individual question at the end of the session. No relaxation techniques were applied during these consultations.

Single-Session Relaxation Intervention

Progressive muscle relaxation according to Jacobson [30] is one of the most commonly applied relaxation methods and is often used in cancer care. Changes between tension and relaxation have been shown to reduce anxiety [31]. We used the modification by Bernstein and Borkevec [32]. It is a short intervention and includes 16 muscle groups. Following abdominal surgery, abdominal exercises were omitted. We applied a standardized procedure which lasted 30 min.

Participants

From April to December 2009, 76 women with gynaecological cancer from the Department of Gynaecology at Charité University Hospital were informed about the study. Since 31 women declined to participate, 45 were enrolled in the study. Reasons for non-participation were, for example, an involvement in other clinical trials or reservations about psychological support. The mean age of the attending women was 49.4 years, ranging from 23 to 79 years. Thirty-five women were considered at high risk (≥ 12) and 10 at low risk

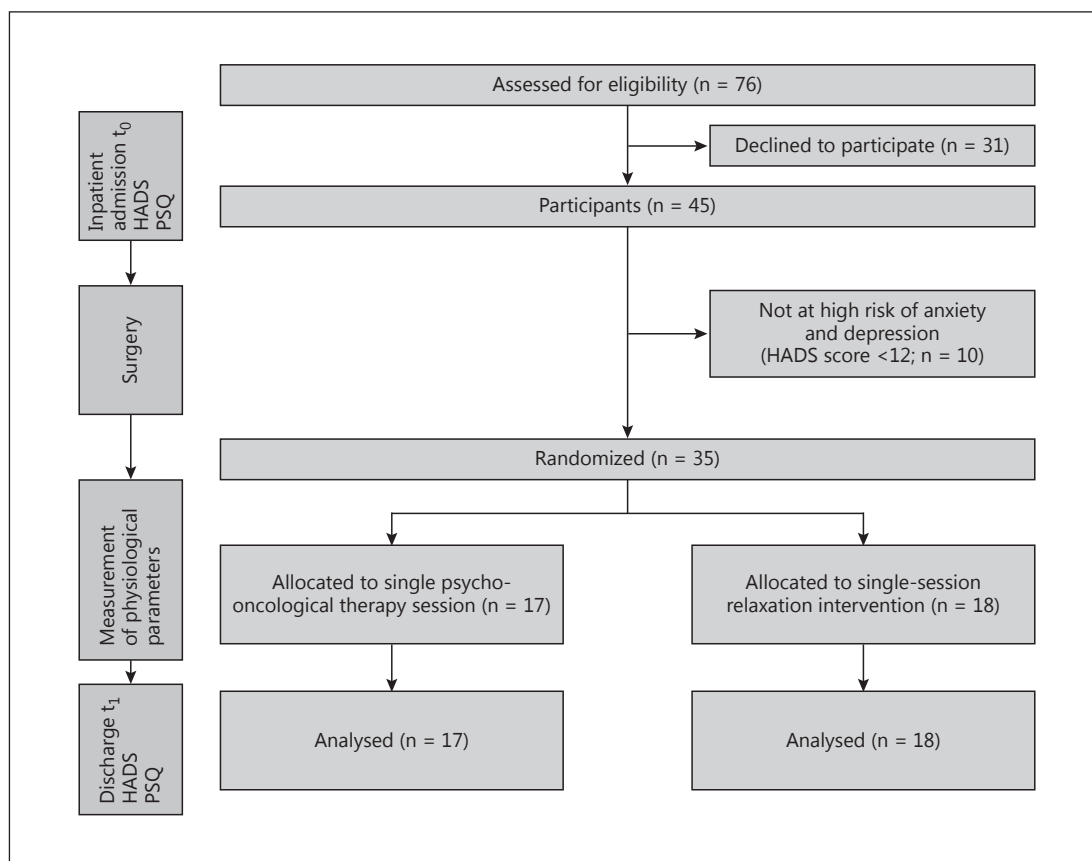


Fig. 1. Study design.

of anxiety and depression (<12) at the beginning of the study (t_0). The women randomized to the single psycho-oncological therapy session ($n = 17$) had higher depression scores at baseline ($p = 0.015$) than the women randomized to the single-session relaxation intervention ($n = 18$). This difference between the groups concerning depression was taken into account by including a priori depression as a covariate. Our sample did not have any prior knowledge about relaxation at baseline. The characteristics of the sample are shown in table 1.

Statistical Analyses

We analysed the data with an intention-to-treat rationale. The scoring of the questionnaires was performed according to the test manuals. To compare the groups considering anxiety, depression, and stress at baseline, the non-parametric Mann-Whitney test was applied. Results were expressed as arithmetic means with standard deviations (SD) or frequencies with percentages. Changes over time in each intervention group were ascertained by multivariate ANOVA with repeated measures. For the comparison between both interventions, we used ANCOVA models with the baseline characteristics as covariates.

The physiological stress parameters were measured during the intervention. For analysis, we defined 3 time points. The first 30 s before the intervention were taken as the baseline. Furthermore, we calculated arithmetic means for the first minute and the last minute of the intervention. This procedure was based on methodological considerations such as about the time it takes to adapt to the NeXus-10 device and to compensate for measurement variations.

A p value <0.05 was considered statistically significant. Numerical calculations were performed with SPSS version 18 (SPSS Inc., Chicago, Ill., USA).

Table 1. Characteristics of the sample

	High risk (n = 35)		Single psycho- oncological intervention (n = 17)		Single-session relaxation intervention (n = 18)	
	n	%	n	%	n	%
<i>Diagnosis</i>						
Endometrial cancer	2	5.71	1	5.9	1	5.6
Ovarian carcinoma	9	25.71	4	23.5	5	27.8
Vaginal cancer	1	2.86	0	0	1	5.6
Vulva cancer	2	5.71	1	5.9	1	5.6
Cervical carcinoma	21	60.00	11	64.7	10	55.6
<i>Tumor</i>						
T0	1	2.86	0	0	1	5.6
T1	15	42.86	8	47.1	7	38.9
T2	7	20.00	3	17.6	4	22.2
T3	7	20.00	4	23.5	3	16.7
T4	1	2.86	0	0	1	5.6
Unknown ¹	4	11.43	2	11.8	2	11.1
<i>Involvement of lymph nodes</i>						
N0	20	57.14	9	52.9	11	61.1
N1	4	11.43	2	11.8	2	11.1
N2	1	2.86	1	5.9	0	0
Unknown ¹	10	28.57	5	29.4	5	27.8
<i>Grading</i>						
G1	3	8.57	2	11.8	1	5.6
G2	16	45.71	7	41.2	9	50.0
G3	6	17.14	3	17.6	3	16.7
Unknown ¹	10	28.57	5	29.4	5	27.8
<i>Residual tumor</i>						
R0	15	42.86	8	47.1	7	38.9
R1	1	2.86	0	0	1	5.6
R2	1	2.86	1	5.1	0	0
Unknown ¹	18	51.43	8	47.1	10	55.6
<i>Stage</i>						
Primary	23	65.71	10	58.8	13	72.2
Relapse	8	22.86	5	29.4	3	16.7
Secondary	4	11.43	2	11.8	2	11.1
<i>Metastasis</i>						
Yes	9	25.71	4	23.5	5	27.8
No	26	74.29	13	76.5	13	72.2

¹ Since the histological statement was not yet available at the time of discharge, the number of ‘unknowns’ is high.

Results

Anxiety and Depression

We analysed the treatment effect on anxiety and depression (t_1 vs. t_0) separately for each intervention group. The means and SD for anxiety and depression at the beginning and at the end of the hospital stay are shown in table 2. A significant decrease in anxiety was found both in women undergoing the single psycho-oncological therapy session ($F = 41.57$, $p < 0.001$, η^2

Table 2. Changes in anxiety and depression scores in each intervention group

	t ₀ (admission to the hospital)	t ₁ (discharge from the hospital)	p value
Single psycho-oncological intervention			
Anxiety	12 ± 2.85	7.47 ± 2.78	<i><0.001</i>
Depression	9.71 ± 3.42	6.35 ± 3.39	<i><0.001</i>
Single-session relaxation intervention			
Anxiety	11.67 ± 2.78	8.22 ± 3.02	<i><0.003</i>
Depression	6.78 ± 3.3	5.72 ± 4.05	0.231

Values denote means ± SD unless specified otherwise. Significant results are set in italics.

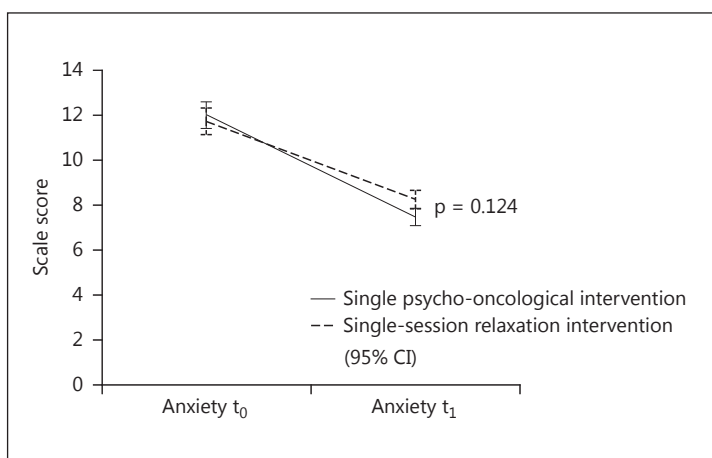


Fig. 2. Effect of treatment on anxiety.

= 0.72) and in those undergoing the single-session relaxation intervention (F = 12.5, p = 0.003, $\eta^2 = 0.42$). In women who had the single psycho-oncological therapy session, a significant decrease was also found for depression (F = 27.82, p < 0.001, $\eta^2 = 0.63$). However, the levels of depression did not change in women who had the single-session relaxation intervention (F = 1.54, p = 0.231, $\eta^2 = 0.08$).

A comparative analysis of both interventions showed no differences in treatment effects on anxiety (F = 2.5, p = 0.124; fig. 2). However, considering depression, we found a trend in favour of the single psycho-oncological therapy session (F = 3.3, p = 0.078; fig. 3).

Self-Reported Stress

Analogously, we analysed the treatment effect of each of the two interventions on self-reported stress (t₁ vs. t₀). For the patients who had the single psycho-oncological therapy session, the scores for worries (F = 2.7, p = 0.12, $\eta^2 = 0.14$), tension (F = 0.007, p = 0.93, $\eta^2 < 0.001$), joy (F = 2.4, p = 0.14, $\eta^2 = 0.13$), demands (F < 0.001, p = 1, $\eta^2 < 0.001$), and total self-reported stress (F = 0.95, p = 0.34, $\eta^2 = 0.06$) did not change significantly; the same was true for the patients who had the single-session relaxation intervention (worries: F = 1.15, p = 0.29, $\eta^2 = 0.07$; tension: F = 1.35, p = 0.26, $\eta^2 = 0.08$; joy: F = 0.7, p = 0.41, $\eta^2 = 0.04$; demands: F = 3.35, p = 0.08, $\eta^2 = 0.17$; total self-reported stress: F = 2.56, p = 0.11, $\eta^2 = 0.15$).

The comparison of the two types of intervention did not show any significant difference in self-reported stress scores between the two treatments regarding tension (F = 0.44, p = 0.25, $\eta^2 = 0.01$), joy (F = 2.76, p = 0.53, $\eta^2 = 0.80$), and demands (F = 2.85, p = 0.05, $\eta^2 = 0.82$).

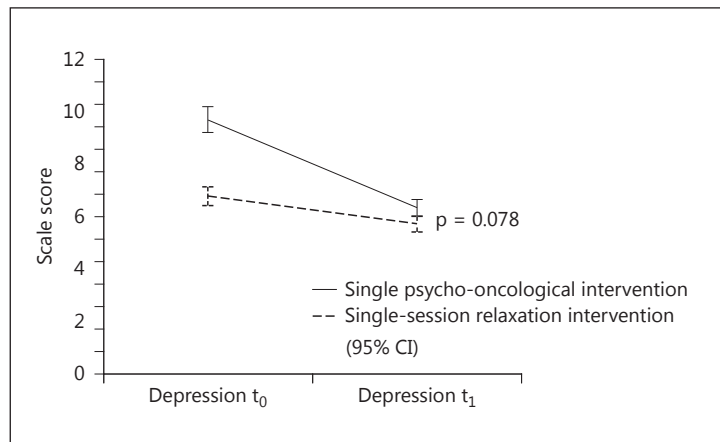


Fig. 3. Effect of treatment on depression.

Table 3. Changes in self-reported stress and objective stress parameters between both intervention groups
a Physiological parameters

	Single psycho-oncological therapy	Single-session relaxation intervention	p value
Worries t ₀	29.80±20.01	37.25±20.42	<i>0.044</i>
Worries t ₁	32.94±15.36	33.73±17.86	
Tension t ₀	49.80±20.83	48.24±17.08	0.255
Tension t ₁	49.41±16.34	43.92±17.96	
Joy t ₀	53.33±21.73	56.47±17.33	0.053
Joy t ₁	47.45±15.07	60.00±18.85	
Demands t ₀	36.86±25.83	54.12±28.46	0.053
Demands t ₁	36.86±22.74	47.06±25.10	
Total score t ₀	40.78±16.38	45.78±17.29	<i>0.031</i>
Total score t ₁	42.94±12.91	41.18±16.82	

b Physiological parameters

Breathing rate, breaths/min			
Baseline	25.62±2.83	25.67±4.43	<i>0.014</i>
First minute	27.07±4.42	21.29±4.19	
Last minute	27.30±4.43	20.22±7.09	
Skin conductance, µS			
Baseline	2.553±1.05	1.261±0.34	0.362
First minute	2.263±0.99	1.034±0.36	
Last minute	2.684±1.42	0.932±0.54	
Heart rate, beats/min			
Baseline	82.36±14.17	89.59±17.55	0.578
First minute	81.68±16.06	90.29±19.95	
Last minute	81.58±16.68	90.57±18.47	
Amplitude for blood volume pulse, µV			
Baseline	50.79±23.53	47.38±26.58	0.077
First minute	53.74±24.92	43.97±21.26	
Last minute	43.45±20.95	30.62±11.68	
Electromyogram, µV			
Baseline	20.76±10.59	19.09±9.91	0.169
First minute	14.95±2.67	17.52±9.80	
Last minute	18.72±7.33	13.46±8.27	

Values denote means ± SD unless specified otherwise. Significant results are set in italics.

In contrast, changes in worries ($F = 3.07$, $p = 0.044$, $\eta^2 = 0.088$) and total self-reported stress ($F = 3.71$, $p = 0.03$, $\eta^2 = 0.11$) significantly differed between the two groups. Worries and total self-reported stress tended to increase in the psycho-oncological therapy group, whereas a decrease was observed in the single-session relaxation group (table 3a).

Physiological Parameters

In addition, we analysed objective stress parameters (table 3b). During the single psycho-oncological therapy session, the breathing rate ($F = 0.36$, $p = 0.71$, $\eta^2 = 0.09$), the skin conductance ($F = 4.56$, $p = 0.06$, $\eta^2 = 0.57$), the heart rate ($F = 0.07$, $p = 0.93$, $\eta^2 = 0.02$), the amplitude for blood volume pulse ($F = 3.49$, $p = 0.09$, $\eta^2 = 0.49$), and the electromyogram ($F = 1.56$, $p = 0.29$, $\eta^2 = 0.38$) did not change significantly. In contrast, during the single-session relaxation intervention, the breathing rate ($F = 5.28$, $p = 0.03$, $\eta^2 = 0.51$), the skin conductance ($F = 10.44$, $p = 0.004$, $\eta^2 = 0.67$), and the electromyogram ($F = 4.84$, $p = 0.03$, $\eta^2 = 0.49$) significantly decreased. No significant changes were found for blood volume pulse ($F = 2.08$, $p = 0.17$, $\eta^2 = 0.29$) and heart rate ($F = 0.26$, $p = 0.77$, $\eta^2 = 0.05$).

The intervention groups differed in skin conductance already at baseline. The value for this parameter was significantly higher in women expecting the single psycho-oncological therapy session than in women anticipating the single-session relaxation intervention ($F = 17.39$, $p = 0.001$, $\eta^2 = 0.48$). This also held for the first ($F = 19.0$, $p < 0.001$, $\eta^2 = 0.48$) and the last minute of the intervention ($F = 20.23$, $p < 0.001$, $\eta^2 = 0.52$). In addition, the breathing rate was significantly higher in the psycho-oncological therapy group than in the single-session relaxation group in the first and the last minute of the intervention (first: $F = 6.47$, $p = 0.02$, $\eta^2 = 0.25$; last: $F = 5.83$, $p = 0.02$, $\eta^2 = 0.23$). Finally, a significantly higher blood volume pulse in the last intervention minute was found in the psycho-oncological therapy group compared with the single-session relaxation group ($F = 5.44$, $p = 0.03$, $\eta^2 = 0.22$). The comparison of both interventions over time shows a significantly larger decrease in breathing rate in the single-session relaxation intervention than in the psycho-oncological therapy session ($F = 7.46$, $p = 0.01$, $\eta^2 = 0.29$). All other physiological stress parameters did not reach statistical significance (table 3b).

Discussion

The aim of our study was to examine the treatment effect of two different psycho-oncological interventions on anxiety, depression, and self-perceived as well as physiological stress in women with gynaecological cancer in an inpatient setting. A high percentage of our sample of women with gynaecological cancer was identified as being at high risk of anxiety and depression (78%). This finding clearly points to psycho-oncological distress in the majority of female inpatients diagnosed with cancer.

Our prior results provide evidence for the efficacy of psycho-oncological interventions in reducing anxiety and depression compared with a non-intervention [15]. In the current study, our first hypothesis was that anxiety and depression can be reduced more efficiently by a single psycho-oncological therapy session than by a single-session relaxation intervention. Our findings show a significant decrease in anxiety for both intervention groups, whereas depression significantly decreased in the single psycho-oncological therapy group only. However, between-group analyses showed merely a small tendency in favour of the psycho-oncological therapy session versus the relaxation intervention in reducing depression. In line with our prior study [15], these results indicate that psycho-oncological interventions might reduce psychological distress during an inpatient stay. However, we could not find clear evidence supporting the stronger treatment effect of the targeted single psycho-oncological therapy session as compared with the single-session relaxation intervention.

Further, we assumed the single psycho-oncological therapy session to reduce self-reported stress more efficiently than the single-session relaxation intervention. In our mixed gynaecological cancer sample, self-reported stress was high compared with a sample of women with breast cancer [33]. However, we did not find a positive treatment effect on self-reported stress with either type of intervention. Moreover, comparing the two groups, worries and total self-reported stress tended to increase in the psycho-oncological therapy group. In contrast, at the same time, depression tended to decrease only after the psycho-oncological therapy session. One explanation might be that the HADS depression scale and the PSQ scales differ in content. Whereas the depression scale (HADS) focuses on a loss of interest and pleasure, the PSQ assesses the subjective perception, evaluation, and further processing of stressors on different scales, such as 'worries'. In the psycho-oncological therapy session, women are confronted with their current situation. This confrontation may have triggered more worries in patients, but nonetheless it may have been more effective in treating the principal symptoms of depression.

Finally, we expected changes in self-reported stress to be reflected in the objective stress parameters. In accordance with the results concerning self-reported stress, no decreases were found in the psycho-oncological therapy group. However, the relaxation intervention group showed a significant decrease in breathing rate, skin conductance, and electromyogram. Interestingly, the single-session relaxation group already had a lower skin conductance at baseline as well as a lower breathing rate and blood volume pulse throughout the session than the single psycho-oncological therapy group. Furthermore, the relaxation group showed a larger decrease in breathing rate.

Thus, the physiological data indicate that there was less stress in the single-session relaxation group. We assume the anticipation of relaxation and its effects on patients caused these results. From a clinical point of view, this finding suggests that anticipated relaxation might be a useful intervention mechanism, too. Further research is needed to analyse this aspect in more detail. Nevertheless, objective stress parameters appear to provide additional information that is not taken into account by self-assessment tools. Thus, the consideration of objective stress parameters might be a promising way of achieving a better understanding of the differential treatment effects of different interventions.

A similar study by Powell et al. [21] in women attending a gynaecological cancer clinic focused on the effect of a 1-hour psychosocial intervention on specific psychosocial outcomes including anxiety and depression. The authors reported decreased anxiety and depression scores in the intervention group and decreased anxiety, but increased depression scores in the control group without the intervention. In this study, all patients were included independent of their anxiety and depression scores. However, the results of our first study [15] highlight the necessity of seriously considering the level of psycho-oncological distress in patients: in contrast to the high-risk group, we could not find a treatment effect of the intervention compared with the non-intervention (observation) on anxiety and depression in the low-risk group. Furthermore, considering the limited psycho-oncological resources, it is important to focus on patients with high scores of anxiety and depression.

A limitation of our study is the reduced external validity due to its rather small sample size. Thus, final conclusions cannot be drawn. In our study, the rate of refusal was high (40%), but it corresponds to other studies [34]. At university hospitals, a variety of clinical studies are offered to patients. Aschenbrenner et al. [35] noted that patients with a great psychological burden often drop out of psychological studies.

For clinical trials, a randomized study design is considered the gold standard. However, it is not clear whether a preference for a specific type of intervention might influence the motivation of participants [36]. To analyse this question, a study design should be used which allows patients to select the type of intervention. On the other hand, considering our previous

result that the levels of anxiety and depression do not change without psycho-oncological intervention [15] and the current results that different types of interventions positively influence different aspects of psychological distress, future studies should also consider investigating the effects of interventions combining both psycho-oncological and relaxation sessions.

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Disclosure Statement

The authors have no conflicts of interest to declare.

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