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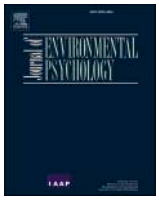

A mindfulness- and relaxation-based nature intervention improves mood in depressed patients in psychosomatic rehabilitation: Results from the GREENCARE non-randomized controlled clinical trial

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ABSTRACT

Introduction: Guided contact with nature has positive effects on well-being. Little is known about the effectiveness of adding nature-based interventions to inpatient treatment for depression. Therefore, we evaluated a mindfulness- and relaxation-based nature intervention for depressed patients in psychosomatic rehabilitation treatment.

Method: Psychosomatic rehabilitation inpatients with depression were allocated to either a Greencare mindfulness- and relaxation-based nature intervention (n = 116) or to treatment as usual plus waitlist control group (TAU + WL) (n = 111) in two centres. All patients received questionnaires on admission (T1) and discharge (T2). Greencare patients received follow-up questionnaires three months after the intervention (T3). Main outcome was mood, assessed by the Positive and Negative Affect Schedule (PANAS). Secondary outcomes were depression, mindfulness, state self-compassion, and contact with nature. Data were analysed as intent-to-treat using mixed models for repeated measures, adjusted for propensity score and centre. Patients' ratings of the effectiveness of the sessions and their well-being, and situational aspects of each session, were recorded.

Results: We found significant interactions of time*group for PANAS, showing greater positive affect (Cohen's *d* at T2 = 0.48) and lower negative affect (Cohen's *d* at T2 = 0.52) in the Greencare group compared to the TAU + WL group at T2. At follow-up (T3), the effects in the Greencare group decreased, but remained significant compared to T1. Significant results for self-compassion and non-significant effects for depression and mindfulness were found. The groups did not differ in the amount of contact with nature. Sensitivity analyses revealed more favourable follow-up effects for patients with higher levels of depression. Patients reported high ratings of effectiveness and well-being for each session, and these ratings were not related to the weather conditions. No adverse events were reported.

Discussion: Depressed inpatients benefitted from a Greencare mindfulness- and relaxation-based nature intervention by improving positive and negative affect. The effects were slightly reduced after three months, but less in patients with higher levels of depression on admission. Results show that the intervention is feasible and effective even for patients with higher symptom burden.

Trial registration: German Clinical Trials Register (trial registration number: DRKS00023369, universal trial registration number: U1111-1260-7305).

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1. Introduction

Mental disorders are a major challenge for health systems worldwide (World Health Organization, 2021). In Germany, the prevalence of at least one mental disorder among adults is 27%, with anxiety disorders (15.3%) and mood disorders (9.3%) being the most common diagnoses (Jacobi et al., 2014). Despite a dense network of treatment options for mental illnesses, patients wait an average of 20.3 weeks for a therapy spot (Bundespsychotherapeutenkammer, 2022). This results in a significant individual burden and high socio-economic costs due to absenteeism and reduced productivity. Existing treatment options, such as psychotropic medication or psychotherapy, consistently show promising effectiveness (Leucht et al., 2012; Munder et al., 2019). However, many questions remain unanswered. Some patients do not respond to treatment options, and in the case of depression, for example, relapse can occur again in the long term despite successful short-term treatment (Burcusa & Iacono, 2007). Therefore, research into alternative and extended treatments for mental disorders is highly relevant. Nature-based interventions have been increasingly proposed as possible elements of therapies for mental disorders, with promising initial results (Gonzalez et al., 2011; Pálsdóttir et al., 2014; Währborg et al., 2014). Therefore, we studied the effects of a nature-based intervention for depressed inpatients in German psychosomatic rehabilitation clinics as an innovative addition to existing treatment approaches.

1.1. Nature and well-being

Nature experiences have received growing attention for their potential to enhance human well-being, building on the concept of biophilia - the human affinity for nature (Kellert & Wilson, 1993; Wilson, 1984). Various theoretical frameworks have emerged to describe and explain the relationship between nature and well-being. Traditional theories such as attention restoration theory (Kaplan & Kaplan, 1989) and stress reduction theory (Ulrich et al., 1991) have provided foundational understanding of how nature experiences can positively impact mental health and cognitive functioning. Expanding on these foundations, the concept of emotional affinity towards nature (Kals et al., 1999) suggests that positive emotional connections with nature can contribute to mental well-being, aligning with our intervention's focus on mindfulness and relaxation in natural settings. This perspective has been further developed in research on increasing pro-environmental attitudes and behaviors (Kals & Müller, 2012).

Recent theoretical developments offer more nuanced and comprehensive perspectives. Work on salutogenic environments emphasizes how urban green spaces can function as health-promoting settings, adding depth to our understanding of how nature-based interventions might benefit depressed patients (Ward Thompson, 2011). Empirical support for the stress-reducing effects of nature exposure, particularly relevant for clinical populations facing multiple stressors, has also been provided (Ward Thompson et al., 2012). The relationship between nature experiences and well-being has been further elucidated by Nisbet and Zelenski (2022). Additionally, the biodiversity-health framework (Marselle et al., 2021) proposes multiple pathways through which biodiversity can influence health, including psychological restoration and stress reduction. This multi-pathway approach is particularly relevant to our study as we examine the effects of nature-based interventions on mood in depressed patients. Most recently, frameworks such as that developed by Dan-Rakedzon et al., 2024, describe what constitutes experiencing nature, providing valuable insights into the design of effective nature-based interventions. These recent developments offer a more comprehensive understanding of how nature-based interventions might benefit depressed patients in clinical settings.

Empirical evidence supports the idea that positive experiences with nature have both preventive and rehabilitative effects (Abraham et al., 2010; Bowler et al., 2010; Hossain et al., 2020) on physical and mental health (Kals & Nisbet, 2023). Overall, research suggests a high potential for healing, particularly for mental health (Cox et al., 2017). Studies have shown that nature experiences can reduce the incidence of mental illness (Beyer et al., 2014; Cervinka et al., 2012; Cox et al., 2017). Nature experiences can also promote psychological well-being by reducing mental fatigue (Berman et al., 2008; Berto, 2005), improving concentration (Bratman et al., 2015; Hartig et al., 2014), and increasing frustration tolerance (Cackowski & Nasar, 2003; Kuo & Sullivan, 2001). In addition, contact with nature can build positive emotions and reduce negative emotions (Ballew & Omoto, 2018; McMahan & Estes, 2015; Russell et al., 2013).

1.2. Nature-based interventions

Nature-based interventions (NBIs), also referred to as Greencare, represent an approach that integrates the positive effects of nature experiences into a broader framework (Annerstedt & Währborg, 2011). These interventions involve structured activities in natural settings to improve physical and mental health, such as green exercise, nature-based arts and crafts activities, and nature-based therapies. NBIs target three key factors for promoting well-being through experiencing nature: nature connectedness, time spent in nature, and active engagement with the natural environment (Richardson et al., 2021).

NBIs have attracted considerable interdisciplinary interest, particularly in recent years, for their potential to promote and improve health and well-being (Shrestha et al., 2023). While empirical research on the effectiveness of nature-based interventions and the underlying processes is still at an early stage, initial meta-analyses suggest that NBIs significantly improve well-being (Coventry et al., 2021; Soga et al., 2017; Zhang et al., 2022). Effectiveness appears to be more pronounced in natural environments such as forests than in gardens and parks (Djernis et al., 2019). Although there is evidence that even a single session in nature (Muro et al., 2023; Shanahan et al., 2019) lasting as little as 10 minutes (Meredith et al., 2019) can significantly affect well-being, structured, longer interventions lasting 8–12 weeks, with sessions of 20–90 minutes each, appear to be most effective (Coventry et al., 2021).

In particular, the combination of mindfulness practice and nature experiences seems to have positive effects on well-being, such as on positive affect and state mindfulness (Muro et al., 2022, 2023), see (Djernis et al., 2019) for a review of nature-based mindfulness interventions.

1.3. Nature-based interventions in clinically relevant populations

More recently, scientific interest has broadened to focus on the impact of nature experiences on clinically relevant disorders. Here, structured and guided NBIs are typically studied as an effective adjunct to usual care for various conditions in need of treatment, including chronic pain (Choi et al., 2021; Han et al., 2016), binge eating disorder (Corazon et al., 2018), and chronic stroke (Chun et al., 2017). Given the impact of nature on mental health, there is a particular focus on the incorporation of NBIs into existing treatments for affective and/or psychosomatic disorders. Several (non-)randomized controlled trials indicate that patients receiving treatment for depression who participate in NBIs show greater improvements in several areas of mental health compared to a control group (Joschko et al., 2023), such as increased connectedness to nature and positive affect, and decreased negative affect (Keenan et al., 2021), as well as increased restorative experiences and decreased psychological distress (Hyvönen et al., 2023). Meta-analyses also point in this direction with moderate effects of NBIs on reducing depressive and anxiety symptoms (Bettmann et al., 2016; Coventry et al., 2021; Grassini, 2022). The effects of NBIs on positive and negative affect as measured by the PANAS (Watson et al., 1988) are still unclear, with results ranging from non-significant effects (Oh et al., 2018) to small effects (Iwata et al., 2016).

1.4. Research gap and study objectives

There is strong evidence for the positive impact of nature on well-being. Nevertheless, several questions remain unanswered. So far, some studies have found inconclusive evidence or included pre-post designs without control groups or follow-up assessments (Bettmann et al., 2016), calling for more rigorous designs to confirm statistically significant relationships between NBIs and well-being (Jimenez et al., 2021). Meta-analyses often included different types of NBIs or participants with varying degrees of mental health problems in their analyses. Moreover, it is unclear whether to ideal program duration, as stated by Coventry et al. (2021), applies to all groups of NBI participants and how the severity of symptoms affects this issue.

We used a multi-centre study design to examine the effects of a NBI on mood, our primary outcome variable, and on depression, trait mindfulness, state self-compassion, and time spent in nature as secondary outcomes in inpatients clinically diagnosed with depression. Our study compared participants who received the NBI in addition to their treatment as usual (TAU) (arm 1; Greencare) with those who received only the TAU (arm 2; TAU + WL). Patients in arm 1 continued their TAU alongside the intervention, patients in arm 2 received only the TAU and a brief intervention after the second survey. We assessed the effectiveness of the NBI on mood and secondary outcomes over a period of 3- to 4-weeks and included a 3-month follow-up to assess the long-term effects of the NBI. The present study has two primary research questions:

(1) Are changes in positive and negative affect (Positive and Negative Affect Schedule Short Form; PANAS-SF) different in patients who participate in the NBI with treatment as usual (arm 1; Greencare) compared to those patients who receive only treatment as usual (arm 2; TAU + WL)?
(2) Are the changes in positive and negative affect in arm 1 stable after three months?

Further exploratory research questions examine changes in the secondary outcomes:

(3) Are changes in depression (Patient Health Questionnaire; PHQ-9), trait mindfulness (Mindfulness and Awareness Scale; MAAS), state self-compassion (State Self-Compassion Scale Short Form; SSCS-S), and time spent in nature different in patients participating in the NBI with treatment as usual (arm 1) compared to those receiving only treatment as usual (arm 2)?
(4) Are the changes in depression, trait mindfulness, state self-compassion, and time spent in nature arm 1 stable after three months?

Based on the theoretical background and previous findings, we expect a greater improvement in the primary outcome mood in arm 1 than in arm 2 immediately after treatment (H1). We also hypothesise that the effects in arm 1 on the primary outcome will remain stable three months after treatment (H2). For the secondary outcomes, we likewise expect greater changes in arm 1 than in arm 2 immediately after treatment (H3), and again, that these changes will remain stable three months after treatment (H4).

2. Materials and methods

2.1. Study design

This study included inpatients from two psychosomatic rehabilitation clinics in Germany, one in the UNESCO Biosphere Reserve Rhön and on in the UNESCO Biosphere Region Berchtesgadener Land. Both clinics provide an environment with access to nature, such as parks and forests. Patients routinely spend time outdoors during their inpatient stays. The clinics seemed particularly well suited for the study because patients have ample opportunity to spend time in nature, even without guided programs. We expected the patients in the TAU + WL group to regularly spend time in nature during their treatment. In the Greencare group, the participants were expected to spend an overall similar amount of time in nature as in the TAU + WL group, but with guided mindfulness and relaxation trainings. Therefore, we hypothesized that any differences in the outcomes between the two groups would be attributable to differences in the quality, and not the quantity of contact with nature.

In fact, nature experiences are already part of the treatment as usual at these clinics, as patients have ample opportunity to spend time in nature even without guided programmes. By offering our NBI as a guided and structured nature experience, the effects of the intervention were not based on contact with nature alone.

The intervention was integrated into the usual treatment programme (treatment as usual, TAU) of the clinics: Multimodal inpatient psychosomatic treatment programmes, which included group and individual psychotherapy, mindfulness and relaxation practices. For this reason, a randomised study design was not feasible, as patients were in contact with each other, and a constant exchange of treatment experiences could not be avoided. Therefore, groups for arm 1 and arm 2 were recruited in two separate study phases.

The study was registered with the German Clinical Trials Register (trial registration number: DRKS00023369, universal trial registration number: U1111-1260-7305).

2.2. Participants

Patients were screened for inclusion and exclusion criteria by the authors and chief physicians of the clinics, FK and AG, and, if appropriate, were invited to participate in the study.

2.2.1. Inclusion criteria

The inclusion criteria were originally set at a maximum age of 59 years. However, due to the conditions in the clinics and the high interest in the intervention, 44 patients aged between 60 and 65 years were included. The individual and final decision on inclusion in the study was the responsibility of the clinicians. Participants of both sexes were eligible for inclusion. Other inclusion criteria were depressive illness (as determined by the initial medical diagnosis on admission to the clinic), adequate tetanus vaccination status, possession of sturdy footwear and weatherproof clothing, and knowledge of the German language.

2.2.2. Exclusion criteria

Exclusion criteria were manic episodes, delusional and other severe psychiatric comorbidities, physical impairments that limited mobility in the field, and inability to consent. The selection of eligible patients for the offer was made by the admitting senior physicians and reference nurses (UNESCO Biosphere Reserve Rhön) or the head physician, senior physicians and/or reference therapists (UNESCO Biosphere Region Berchtesgadener Land).

2.3. Treatments

The study was divided into two arms and was conducted in both locations. Treatments in arm 1 were carried out from September 2020 to February 2022 in the UNESCO Biosphere Reserve Rhön, during all seasons. In the UNESCO Biosphere Region Berchtesgadener Land, the study period was from June 2021 to November 2021, as the treatments could not be offered in the winter because excessive snowfall prevented access to the forest where the sessions took place. The one-day interventions in arm 2 were offered from February to June 2022.

Both interventions were based on the experience of nature as a therapeutic factor and developed in close cooperation with experts such as psychosomatic medicine, psychotherapy and behavioural therapy specialists. They were delivered by trained staff (a psychologist and wilderness educator, and an educator, ethnologist and environmental

manager, respectively). They were accompanied by a trained health professional (psychologist or psychotherapist) and a trained forest and nature educator or nature coach.

2.3.1. Arm 1 (Greencare)

The Greencare programme consisted of two NBIs for patients, one in each location. Both interventions were based on the experience of nature as a therapeutic factor, but had slightly different emphases in their implementation. These structural differences were due to the different circumstances of the cooperating clinics. The NBIs were designed for small groups with a maximum of seven participants (min = 2, max = 7, median = 5).

In the UNESCO Biosphere Reserve Rhön, a more relaxation-based NBI was offered once a week for 4 h in closed groups over a period of four weeks. The intervention included exercises borrowed from wilderness education and also used in cognitive behavioural therapy (CBT) and mindfulness-based cognitive therapy (MBCT).[1]

In the UNESCO Biosphere Region Berchtesgadener Land a more mindfulness-based NBI was also offered once a week for 4 h, but over a period of three weeks and using open groups. In this intervention, exercises used in MBSR (Mindfulness-Based Stress Reduction) and MBCT (Mindfulness-Based Cognitive Therapy) such as breathing meditation, body scan, and mindfulness in performing everyday activities were combined with methods from nature education (e.g. exercises on sensory perception, changing perspectives, and experiencing nature).[2]

2.3.2. Arm 2 (TAU + WL)

Arm 2 was designed as a treatment as usual plus waitlist (TAU + WL) group. Participants received the usual treatment programme of the clinics consisting of multimodal inpatient psychosomatic treatment programmes as described above. After the second survey, patients in both clinics were offered a 4-h NBI once or twice based on the corresponding NBI in arm 1.

2.4. Outcome measures

2.4.1. Pretest

To test the quality criteria of the questionnaire instruments in advance, they were tested in a preliminary study. For this purpose, an ad hoc sample of $N = 205$ participants was obtained from the general population who completed an online questionnaire between February 26 and April 4, 2020. Data were subsequently analysed using factor analyses, reliability analyses, correlations, multiple regression analyses, and mean comparisons using *t*-test. SPSS Statistics 29 (IBM Corp., Armonk, NY, USA) was used for statistical analyses. The findings confirmed the suitability of most scales for the project. For compassion, due to insufficient results, it was decided to use a well-validated scale, namely the State Self-Compassion Scale Short Form (SSCS-S; Neff et al., 2021), using the German items of the Self-Compassion Scale (Hupfeld & Ruffieux, 2011). As validity data are already available, no further validation was conducted in the project. Furthermore, the project group decided to use a measure of depression in the sample (Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001), German version (Löwe et al., 2002).

2.4.2. Primary outcome

The primary outcome was mood as assessed by the Positive and Negative Affect Schedule Short Form (PANAS-SF; Mackinnon et al., 1999; Watson et al., 1988). Participants were asked to rate their current mood for five positive and five negative adjectives on a five-point Likert scale ranging from 1 (very little or not at all) to 5 (extremely). Mean scores of each of the two subscales were then used as variables in the outcome analyses.

2.4.3. Secondary outcomes

Depression was measured using the nine-item depression module of the Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001). Each item is assessed on a four-point Likert scale ranging from 0 (not at all) to 3 (almost every day). The sum score was used as a continuous variable in outcome analyses. In addition, the cut-offs of 0–9 (no or mild depression) and 10 to 27 (probable major depressive disorder, MDD) were used to create diagnostic categories.

Self-compassion was measured as a momentary state using the State Self-Compassion Scale Short Form (SSCS-S; Neff et al., 2021). The Short Form consists of six items (sample item: "I give myself the care and empathy I need"). Responses were rated on a scale from 1 (does not apply to me at all) to 5 (pretty much applies to me). The total score was calculated as the mean of all items.

Mindfulness was measured using the Mindfulness and Awareness Scale (MAAS; Brown & Ryan, 2003). It consists of 15 items rated on a scale from 1 (almost never) to 5 (almost always; example item: "I could have a feeling and not be aware of it until later"). For further analyses, an overall mean score was calculated from all items.

Additionally, recent contact with nature was measured with one item ("I currently spend a lot of time in nature") using a six-point Likert scale (1 = does not apply at all to 6 = is completely true).

2.4.4. Additional variables

In addition to the aforementioned primary and secondary outcome variables, other variables were assessed in the project.

Social support was measured using the ENRICHD Social Support Inventory (ESSI; (Cordes et al., 2009), which consists of six items (example item: 'Is there someone available to whom you can talk about your problems?'). These are rated on a five-point scale from 1 ("none of the time") to 5 ("all of the time").

Nature-related mindfulness was assessed using five items (example item: 'In nature, I pay attention to sensations such as sunshine on my face or wind in my hair'; (Wastlhuber, 2019). These and all subsequent items were measured on a six-point scale from 1 ("strongly disagree") to 6 ("strongly agree").

2.4.5. Sociodemographic data

For sociodemographic data, participants' gender and age was collected. Also, they were asked whether or not they were parents, if they had previous experiences with mindfulness trainings and whether they grew up in a more urban or more rural environment.

2.4.6. Additional data

For each session of the NBI, data were gathered on situational aspects of the sessions and on patients' experiences during the sessions. Situational aspects of the session included location (name of place and description of natural environment), time (date and time), group size, weather, and temperature. Specifics of the session could also be noted. For participants' subjective experience of the session, they were asked to indicate their well-being during the session on a four-point Likert scale (1 = I did not feel comfortable to 4 = I felt very comfortable). Similarly, they were asked to rate the extent to which they perceived the intervention session to be effective (1 = I did not find it effective to 4 = I found it very effective).

2.5. Participant safety

Prior to inclusion, patients were assessed for inclusion criteria and possible risk factors (physical ability, psychological stability). The trainers of the interventions were especially schooled for risks that can

[1] For more information of the NBI developed in the UNESCO Biosphere Reserve Rhön see https://www.biosphaerenreservat-rhoen.de/green-care.

[2] For more information of the NBI developed in the UNESCO Biosphere Region Berchtesgadener Land see https://brbgl.de/bereiche-aufgaben/forschung-und-monitoring/gesundheit-erholung-green-care/.

occur when working with groups in the field (breaking branches, ticks, etc.). Moreover, all sessions were attended by trained medical staff, who could intervene if necessary. No adverse events with an apparent causal connection to the intervention were recorded. In one session, a participant dropped out of the intervention because of an incident unrelated to the intervention. The main reasons for non-participation in individual sessions were general health issues (e.g., COVID-19 infection).

2.6. Statistical analysis

Statistical analyses were performed using SPSS Statistics 29 (IBM Corp., Armonk, NY, USA) and R (R Core Team, 2020).

Linear mixed models for repeated measures (MMRM) were used to compare the trajectories of the dependent variables based on the factors time (T1 and T2) and group (Greencare vs. TAU + WL). Additionally, centre (UNESCO Biosphere Region Berchtesgadener Land vs. UNESCO Biosphere Reserve Rhön) was used as a factor to control for possible differences between the two clinics. Significance levels were set to $p = .05$ and adjusted using the Bonferroni correction for multiple testing.

Since follow-up data were only available for the experimental group, MMRM analyses were performed with the dependent variables using the Greencare group and the factor time (T1, T2, and T3), again controlling for centre.

All MMRM analyses used were performed with fixed effects and a random intercept. Model estimation was based on full information maximum likelihood.

Propensity Score. To reduce bias, an important point in non-randomized controlled studies is to adjust the results for potential confounders by the use of covariates. The exact method was not detailed in the pre-registration of our study. Therefore, before data analysis, we introduced the use of propensity scores. To balance the two groups and to compensate for the potential bias implicit in a non-randomized sample, a propensity score was calculated for each participant. This score was calculated as the predicted probability of choosing the Greencare treatment using the available sociodemographic and psychometric assessments, with the use of logistic regression analyses. As a result, each participant obtained a score that could vary between 0 (TAU + WL group) and 1 (Greencare group). This score was then used as a covariate in the MMRM analyses, with the intention to obtain results adjusted for propensity score (Rosenbaum & Rubin, 1983).[3] Traditionally, in non-randomized controlled studies, several possible confounders are used as covariates in the analyses. However, selecting covariates based on their statistical significance at baseline can introduce bias. This approach may overlook important confounders that are not statistically significant due to sample size limitations or measurement variability; also, including a large number of covariates can negatively affect model convergence and interpretability. On the other hand, when not adjusting for confounders, the model does not control for confounders that might influence both the group assignment and the outcome. This could lead to biased estimates of the treatment effect. Overall, the propensity score summarizes multiple confounding variables into a single scalar value representing the probability of group assignment given those covariates. This allowed us to adjust for all observed confounders simultaneously, reducing the risk of omitted variable bias.

Effect sizes were calculated as Cohen's d for repeated measures (Cohen, 1988) for comparisons within groups at different points in time. For comparisons between groups at T2, Cohen's d was calculated based on the estimates from MMRM analyses.

In sensitivity analyses, the following variables were added to the models: depression (low vs. high), childhood residence (more urban environment vs. more rural environment), gender, prior experience, age, and children. Additionally, the analyses were also performed without the propensity scores as covariates.

To analyse the additional information on the single sessions, means and standard deviations were calculated for the items of subjective well-being and subjective effectiveness items. Bivariate correlations were calculated to test whether situational characteristics of the sessions were related to the subjective assessment.

2.7. Sample size

At the time the study was planned, there were still too few comparable studies available to be able to make a precise estimate of the expected effects. We therefore planned the group size of the interventions in such a way as to be able to determine a medium effect on the main outcome variable, the PANAS, with a power of 80% and an alpha error of 5%. Based on this reasoning, a sample size of at least $N = 48$ test subjects would be required for each group at each location, which resulted in an overall sample size of $N = 192$. Concerning possible dropouts, in inpatient psychosomatic settings, attrition rates are generally lower (around 7%–15%) compared to outpatient settings (which can reach up to 30%), primarily due to the more intensive and supportive nature of inpatient care (Reuter & Scheidt, 2014). If, on the basis of these data, a possible rate of 15% attrition is considered, a total of at least 220 people should be included in the study.

3. Results

3.1. Study participants

In both centres, a total of 251 patients were approached to participate in the study (see Fig. 1). Of these, 21 (8%) declined to participate and three individuals did not meet the inclusion criteria. There were 116 patients in the Greencare group and 111 patients in the TAU + WL group. These patients are included in the further analyses on an intent-to-treat basis, even if incomplete data are available. Finally, 13 individuals in the Greencare group did not receive the intervention, representing a dropout rate of 11%. In the TAU + WL group, the dropout rate was 8 patients (7%).

Finally, 103 patients in both the Greencare group and the TAU + WL group received the intervention. For these patients, completed questionnaires are also available at T2.

For the follow-up three months after the intervention, only the 103 participants in the Greencare group who also completed the training were contacted. Of these, 92 returned complete questionnaires. This corresponds to a response rate of 89%.

Demographic and clinical data at baseline (T1) are shown in Table 1.

3.2. Outcomes

Mixed models for repeated measures (MMRM) were calculated for the main analyses of the data. Measurement time, group, and centre, as well as their interactions, were included as fixed factors in the analyses. In addition, a random intercept was included in the analyses. Propensity score was used as a covariate to account for differences between groups due to non-randomized grouping. According to the research questions, it was expected that there would be significant interactions between time point and group in each case, but not between time point, group, and centre.

3.2.1. Primary outcomes: positive and negative affect

Comparing the two groups at time points T1 and T2 (Fig. 2), there were significant effects of time point*group for the two subscales of the PANAS, positive and negative affect ($F_{\text{positive Affect}} = 7.15$, df = 1/207.148, $p = .008$; $F_{\text{negative Affect}} = 10.52$, $df = 1/211.83$, $p = .001$). Pre-post effect sizes showed that there were large effects in the Greencare groups ($d_{\text{positive Affect}} = 1.13$, $d_{\text{negative Affect}} = 1.04$), while the TAU + WL also showed significant effects, but more in the range of medium effect

[3] A detailed description of the rationale for the calculation can be found in the supplementary material.

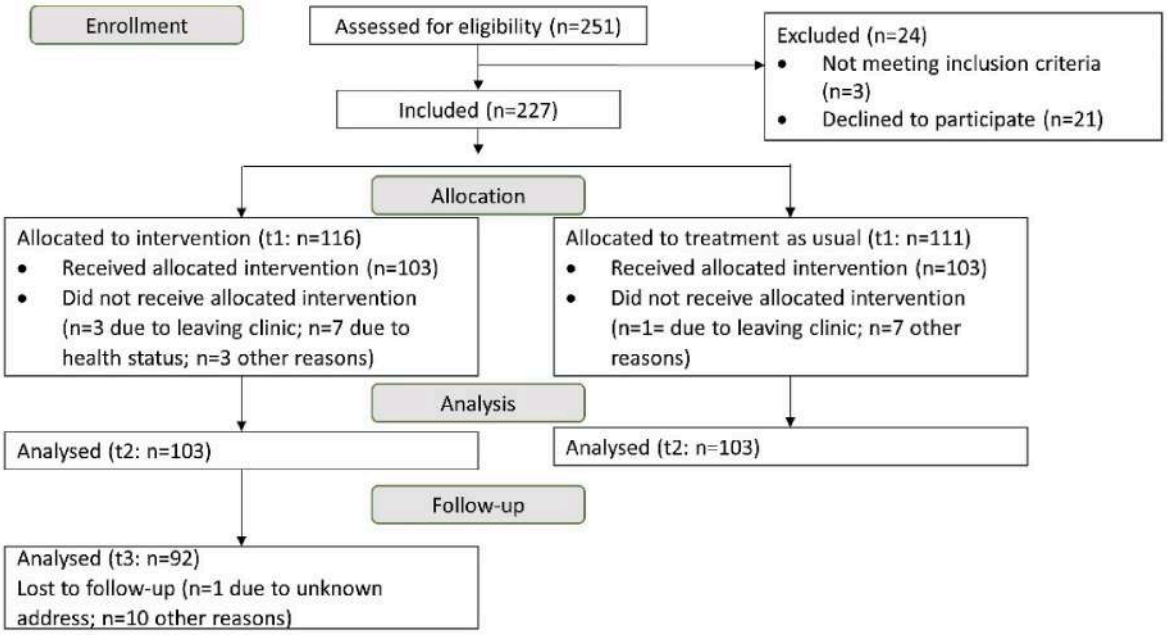

Fig. 1. Participants flow chart.

Table 1
Sociodemographic and psychometric baseline data of the sample (N = 227) with percentages or means (95% confidence intervals).

	Greencare (N = 116)	TAU + WL (N = 111)
Gender	61 % f, 39 % m	55 % f, 44 % m, 1 % N.A.
Age (in years)	52.3 (50.7–53.8; MIN = 29; MAX = 65)	51.0 (49.0–52.9; MIN = 19; MAX = 64)
Children	69 % yes, 31 % no	67 % yes, 32 % no
Previous Experiences with Mindfulness Training	17 % yes, 81 % no, 2 % N.A.	21 % yes, 78 % no, 1 % N.A.
Positive Affect	2.40 (2.26–2.53)	2.59 (2.42–2.76)
Negative Affect	3.07 (2.90–3.24)	2.78 (2.59–2.96)
Depression	12.5 (11.4–13.5)	12.1 (11.0–13.2)
Self-Compassion	2.66 (2.55–2.78)	2.82 (2.71–2.94)
Mindfulness	3.49 (3.33–3.65)	3.68 (3.50–3.86)
Recent Contact with Nature	4.43 (4.24–4.63)	4.33 (4.13–4.54)

Note. Positive Affect and Negative Affect were measured on a 5-point scale (1 = very little or not at all, 5 = extremely). Depression was measured on a 4-point scale (0 = not at all, 3 = almost every day). Self-compassion was measured on a 5-point scale (1 = does not apply to me at all, 5 = pretty much applies to me). Mindfulness was measured on a 5-point scale (1 = almost never, 5 (almost always). Recent Contact with Nature was measured on a 6-point scale (1 = does not apply at all, 6 = is completely true).

sizes ($d_{\text{positive Affect}} = 0.76$, $d_{\text{negative Affect}} = 0.59$). Comparing the groups at T2, we found medium effect sizes ($d_{\text{between(positive affect)}} = 0.48$; $d_{\text{between (negative affect)}} = 0.53$).

For both positive and negative affect, the interaction time-*group*centre was not significant, indicating that the interventions were equally effective in both centres. These results confirmed H1.

Looking at the longitudinal section of the Greencare group (Fig. 3), there was also a significant effect after three months (T3) compared to the first time point (T1). However, the effects decreased slightly compared to the second time point directly after treatment (decrease in positive affect: small effect with $d = 0.23$, in negative affect: small effect with $d = 0.21$). Again, we found no significant interaction of the effects with centre. This confirmed H2.

3.2.2. Secondary outcomes

A significant interaction was found for the secondary outcome variable of self-compassion. A significantly larger effect was found in the Greencare group compared to TAU + WL, and at T2, the group difference was $d = 0.70$. Medium effects also persisted at the tree-month follow-up.

Non-significant interactions were found for depression, mindfulness, and current contact with nature. Effect sizes for group differences at T2 were small, and pre-post effects were similar for mindfulness and contact with nature, indicating that both groups increased similarly in their mindfulness and thei contact with nature. Pre-post differences for depression were somewhat in the Greencare group, but the difference was not significant ($d_{\text{Greencare}} = 1.02$ compared to $d_{\text{TAU + WL}} = 0.79$).

The effects for all analyses were independent of centre, i.e., interactions of time*group*centre or time*centre were not significant for the follow-up analyses. In conclusion, H3 und H4 were partly confirmed.

Detailed tables showing the results of the primary and secondary outcome measures are provided in Tables 2 and 3.

3.2.3. Sensitivity analyses

To check the validity of the results for different subgroups, it is necessary to consider them in subgroup analyses. Methodologically, however, the problem arises that on the one hand, the power to detect effects is reduced, and on the other hand, there is the risk of accumulation of errors. The latter can lead to effects that are not actually present becoming significant only by chance. Two measures were taken to prevent this error: First, the analyses were restricted to the main target variables of the PANAS, and second, the accepted significance level was corrected to $p = .008$ (Bonferroni correction for seven subgroup analyses: 0.05/7 = 0.008; Victor et al., 2010).

Depression. The PHQ 9 scale was scored according to the recommendations of Manea et al. (2012) using a cut-off score of 10. Individuals with scores less than 10 were categorized as "no or mild depression", and individuals with scores greater than or equal to 10 were categorized as "possible major depression". The resulting binary variable was used as a predictor in the analyses.

Group comparisons of Greencare vs. TAU + WL showed no significant interactions for the primary outcome measures (positive and negative affect): low and highly depressed patients benefited equally from the interventions ($F_{\text{positive Affect}} = 0.25$, $df = 2/209.71$, $p = .782$; $F_{\text{negative Affect}} = 0.05$, $df = 2/222.13$, $p = .960$).

Longitudinally, for the Greencare group, significant interactions were found for the primary outcome measures ($F_{\text{positive Affect}} = 17.22$, *df*

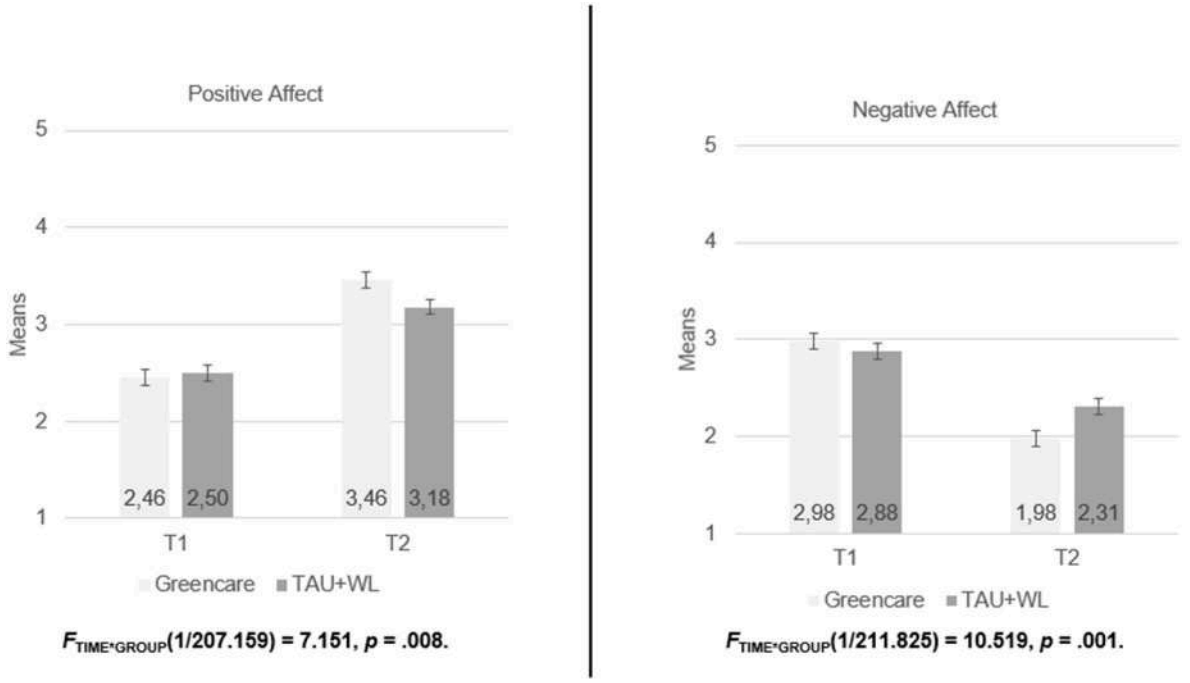

Fig. 2. Means of Positive and Negative Affect for the Greencare and Treatment As Usual Plus Waitlist (TAU + WL) Groups From Admission (T1) to Discharge (T2).
Note. Results are parameter estimates from mixed models for repeated measures adjusted for propensity score.

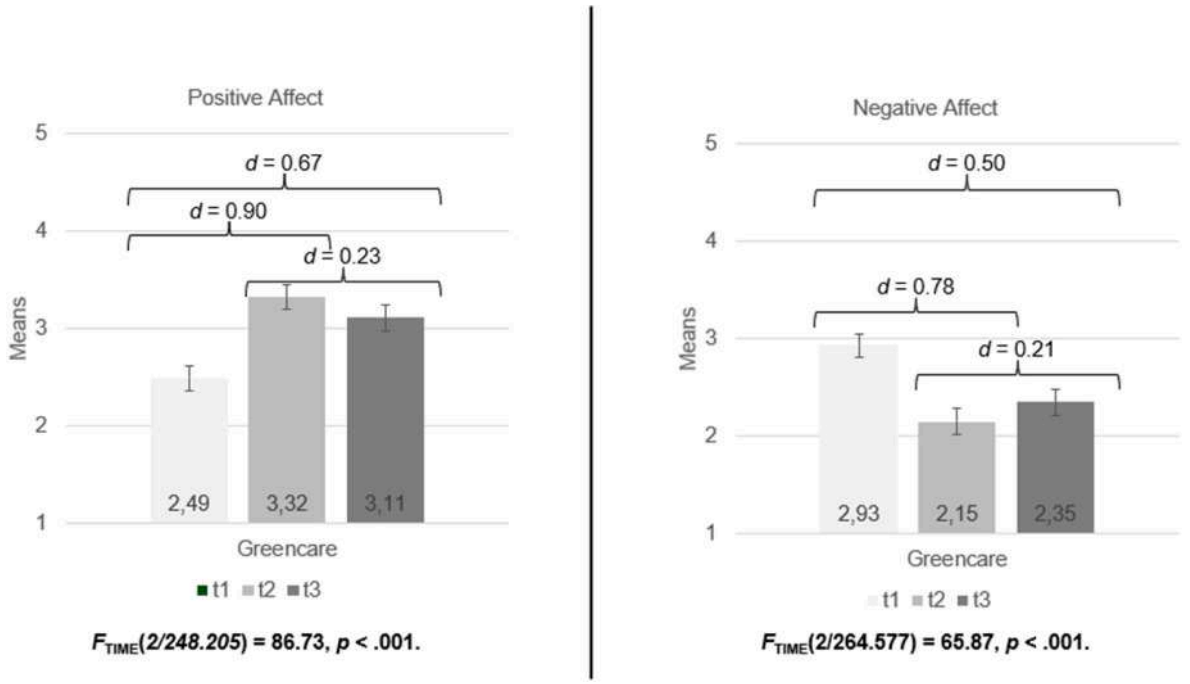

Fig. 3. Changes in Positive and Negative Affect from Admission (T1) and Discharge (T2) to Follow-Up 3 Months After Discharge (T3) for the Greencare Group.
Note. Results are parameter estimates from mixed models for repeated measures adjusted for propensity score.

= 3/324.76, $p < .001$; $F_{\text{negative Affect}} = 30.34$, $df = 3/340.64$, $p < .001$). The results arise from two facts: First, patients that are more depressed had significantly less favourable scores on the clinically relevant variables at T1, resulting in improvement that is even more significant. Second, the results indicate that the effects are more stable in patients that are more depressed, since the scores between T2 and T3 were not significantly different for this group, whereas in the group of less depressed patients these values slightly decreased or, in the case of negative affect, slightly increased again. In summary, it can be said that the more highly stressed patients benefited most from the program.

Childhood residence. Childhood residence was used as a binary variable (more urban environment vs. more rural environment) in the analyses. In the Greencare vs. TAU + WL group comparison, no significant differences were found on the primary outcome measures ($F_{\text{positive Affect}} = 1.81$, $df = 1/202.46$, $p = .180$; $F_{\text{negative Affect}} = 0.02$, $df = 1/203.99$, $p = .892$).

Table 2
Changes in primary and secondary outcomes from T1 to T2 for both arms (Greencare vs. TAU + WL), with effect sizes[1].

	Greencare (n = 116)				TAU + WL (n = 111)				$d_{between}$ (T2)	p
	T1	T2	d_{within}	p	T1	T2	d_{within}	p		
	m (95%CI)	m (95%CI)			m (95%CI)	m (95%CI)				
Primary Outcomes										
Positive Affect	2.46 (2.31–2.61)	3.46 (3.31–3.62)	1.13	<0.001	2.50 (2.35–2.66)	3.18 (3.02–3.33)	0.76	<0.001	0.48	0.013
Negative Affect	2.98 (2.83–3.13)	1.98 (1.82–2.14)	1.04	<0.001	2.88 (2.72–3.04)	2.31 (2.15–2.47)	0.59	<0.001	0.53	0.005
Secondary Outcomes										
Depression	12.32 (11.33–13.30)	7.38 (6.35–8.41)	1.02	<0.001	12.31 (11.30–13.32)	8.46 (7.43–9.49)	0.79	<0.001	0.30	0.150
State-Self-Compassion	2.74 (2.63–2.84)	3.25 (3.14–3.36)	1.04	<0.001	2.74 (2.63–2.86)	3.01 (2.90–3.12)	0.59	<0.001	0.70	0.004
Mindfulness	3.57 (3.41–3.73)	4.29 (4.12–4.46)	0.83	<0.001	3.60 (3.43–3.77)	4.11 (3.94–4.28)	0.79	<0.001	0.29	0.154
Recent Contact with Nature	4.28 (4.03–4.52)	4.73 (4.47–4.98)	0.35	<0.001	3.97 (3.72–4.22)	4.42 (4.16–4.67)	0.35	<0.001	0.33	0.101

Abbreviations: T1 = Admission, T2 = Discharge, TAU = treatment as usual, WL = waitlist.
The values are parameter estimates from linear mixed models with repeated measures. The mean values were adjusted for propensity score as a covariate.
[1]Standardized mean differences at T1 can be found in the supplementary material.

Table 3
Changes in primary and secondary outcomes from T1, T2, and T3 for the Greencare arm, with effect sizes.

	T1	T2	T3	$d^{(T1T2)}$	p	$d^{(T1T3)}$	p
	m (95%CI)	m (95%CI)	m (95%CI)				
Primary Outcomes							
Positive Affect	2.49 (2.37–2.60)	3.32 (3.20–3.44)	3.11 (2.94–3.27)	0.90	<0.001	0.67	<0.001
Negative Affect	2.93 (2.81–3.05)	2.15 (2.02–2.,27)	2.35 (2.18–2.53)	0.78	<0.001	0.50	<0.001
Secondary Outcomes							
Depression	12.31 (11.61–13.02)	7.92 (7.19–8.65)	8.95 (7.98–9.92)	0.91	<0.001	0.64	<0.001
State-Self-Compassion	2.74 (2.66–3.83)	3.13 (3.04–3.22)	3.08 (2.96–3.19)	0.64	<0.001	0.48	<0.001
Mindfulness	3.59 (3.46–3.71)	4.20 (4.07–4.33)	4.20 (4.03–4.38)	0.71	<0.001	0.58	<0.001
Contact with Nature	4.13 (3.95–4.30)	4.58 (4.40–4.76)	4.37 (4.13–4.62)	0.41	<0.001	0.21	0.038

Note. T1 = Admission, T2 = Discharge, T3 = Follow-Up three months after discharge.
The values are parameter estimates from linear mixed models with repeated measures. The mean values were adjusted for propensity score as a covariate.

In longitudinal analyses including the follow-up, a significant interaction was detected only for negative affect ($F_{positive\ Affect} = 0.36$, $df = 3/286.49$, $p = .781$; $F_{negative\ Affect} = 3.54$, $df = 3/284.59$, $p = .015$). Here, more stable effects were found for people from urban environments at T3, meaning that for this group the values did not differ significantly between the discharge time point and three months after treatment.

Gender. The variable gender was asked in the study in three categories (female, diverse, male). As none of the subjects classified themselves as "diverse" in the questionnaire, this category was not further considered in the analyses. The results showed that for the gender variable, no significant differences were found in the primary outcome measures, nor in the group comparisons ($F_{positive\ Affect} = 2.69$, $df = 1/205.42$, $p = .103$; $F_{negative\ Affect} = 2.80$, $df = 1/209.92$, $p = .096$) and in the longitudinal analyses ($F_{positive\ Affect} = 1.82$, $df = 3/318.89$, $p = .143$; $F_{negative\ Affect} = 3.41$, $df = 3/322.77$, $p = .018$).

Concerning previous experiences with mindfulness training, age, and whether the participants were parents or not, no significant effects were detected, neither in the group comparison of Greencare cs. TAU + WL nor in the longitudinal analyses.[4]

Finally, the primary and secondary outcome analyses were performed without adjusting for propensity score. The analysis resulted in a similar pattern to the main outcome analyses, with the exception of the positive affect subscale of the PANAS. Here, the p value of 0.010 scored above the threshold of $p = .008$ adjusted for multiple comparisons. This means that only by accounting for the propensity scores is the effect significant by our pre-selected threshold.[5]

3.3. Situational aspects and patients' experiences

Overall, the sessions took place throughout the year; in the UNESCO Biosphere Region Berchtesgadener Land, the period was limited to the months of June to November due to weather conditions. Interventions were conducted at different times (between 8 a.m. and 5:30 p.m.). The average session size was 6 people, with a range of 2–12 participants. Interventions were conducted in temperatures ranging from −13 °C to 32 °C, and weather conditions included sunshine, fog, clouds, wind to storms, rain showers, thunderstorms, and snowfall.

96 % of patients in the Greencare groups reported feeling comfortable during the sessions ($AM = 3.68$; $SD = 0.55$). Across all sessions, 94 % of the patients rated the interventions as effective ($AM = 3.55$; $SD = 0.63$).

Finally, we examined the role of the weather during the sessions on patients' subjective ratings. Two factors were considered: First, whether the sun was shining most of the time during the intervention (dichotomous variable), and second, the temperature during the intervention (the highest temperature during each intervention was chosen). These

[4] The detailed results can be found in the supplementary material.

[5] More detailed information on these results is provided in the supplementary material.

variables were then correlated with the results of the subjective experience of the participants (well-being and effectiveness). Only very small and non-significant correlations were found ($r_{sunshine/well\text{-}being} = 0.11$, $p = .41$; $r_{sunshine/effectiveness} = 0.08$, $p = .55$; $r_{temperature/well\text{-}being} = -0.13$, $p = .37$; $r_{temperature/effectiveness} = -0.06$, $p = .68$).

4. Discussion

The Greencare study of a mindfulness- and relaxation-based nature intervention for depressed inpatients in psychosomatic rehabilitation centres set out to compare the effects of a three-to four-session nature-based intervention (NBI) with treatment as usual. Treatment groups were divided into two arms, a Greencare arm, which received the interventions in addition to their treatment as usual, and a treatment-as-usual plus waitlist control group, which did not receive the intervention during their inpatient stay but was offered a brief one-to two-day intervention after completion of the second assessment at discharge. The two participating centres were in UNESCO biosphere regions, offering all patients access to nature in the form of parks and forests. This allowed the study to ensure that the effects were not attributable to differences in mere exposure to nature, but rather to the effects of the mindfulness- and relaxation-based guided nature experience.

Comparing the groups at admission (T1) and discharge (T2), the results show that the Greencare intervention improved patients' mood more than treatment as usual, with medium sized effects in the overall effect size analyses. These effects were found on the main outcome measure, the positive and the negative affect subscales of the PANAS, when controlled for possible covariates using the propensity scores. Those effects were independent of study centre. Sensitivity analyses revealed that these effects were not dependent on patients' level of depression, gender, age, prior experience with mindfulness training, whether they grew up in a more rural or more urban environment, or whether they had children. Further sensitivity analyses revealed that after removing the propensity score covariate from the models, the results for the positive affect subscale scored slightly above the adjusted p threshold level. In our understanding, this can be interpreted in three ways: First, that the effects of the intervention on negative mood are more stable than on positive mood; second, that adjusting for propensity score has increased the precision of the estimate by reducing unexplained variability; and third, that while controlling the results using a propensity score may compensate for some of the disadvantages of a non-randomised controlled trial, a fully randomised study seems warranted.

These findings support results from current research on the effects of NBIs for patients with affective disorders (e.g., Hyvönen et al., 2023) and psychosomatic disorders (Joschko et al., 2023). These studies reported effects on psychological distress and well-being that were similar to our findings on positive and negative affect. Also, similar effects were found in healthy participants concerning positive affect (Muro et al., 2022, 2023).

Looking at secondary outcomes, state self-compassion revealed a significant effect similar to the PANAS. To our knowledge, state self-compassion (Neff et al., 2021) has not been used as an outcome measure for nature-based interventions in clinical settings, although both have been combined in theory and practice (Loy et al., 2022). Research has repeatedly shown that self-compassion can be an important predictor of well-being (Zessin et al., 2015) and a significant factor in the effectiveness of psychotherapy (Neff, 2023). Therefore, it seems worthwhile to further explore the role of self-compassion in nature interventions.

Depression and mindfulness did not change significantly between the two groups. The results for mindfulness could possibly be due to the fact that we chose a trait mindfulness scale, which is less sensitive to change than a state scale. In the mentioned forest bathing study with healthy individuals (Muro et al., 2022, 2023), a difference in state mindfulness was found. The results for depression were comparable to those of Hyvönen and colleagues (2023), who found no differences between the nature intervention group and the treatment as usual control group (participants were included if they were in treatment for depression). Our results show that the treatment as usual, in our case psychosomatic inpatient rehabilitation, was effective in treating depression in both Greencare and TAU + WL patients. The treatments in the clinics are specifically tailored to psychosomatic patients, often with comorbid affective disorders, and include multimodal treatment including mindfulness training. Therefore, large differences between the groups were not expected. However, the direction of the effects was similar to the main outcomes, i.e., there was a tendency for the Greencare group to show greater treatment effects than the TAU + WL group. Further research is needed to better understand the size of the effects in larger samples.

Contact with nature did not change significantly between the groups. This further underlines the suitability of the two chosen clinics. Both are located in UNESCO biosphere regions, which offer a vast amount of contact with nature. Therefore, this is an important finding, as it shows that contact with nature alone, for example using the nearby parks and gardens without a purposely and guided intent, did not make a difference. The observed effects on affect and self-compassion are likely due to the specifics of the interventions and their professional design and guidance. This is consistent with the findings of Joschko and colleagues (2023). It can be concluded that contact with nature alone cannot explain the observed changes in the Greencare group. However, the guided use of nature as the setting and instrument of the intervention can be considered a contributing factor.

Patients in the Greencare arm were contacted for a follow-up measurement three months after the intervention. The low attrition rate of 11 %–92 out of 103 patients responded - indicates the high level of patient interest in the Greencare program. The data show that effects were reduced compared to discharge at T2, but remained high compared to admission (T1). Sensitivity analyses revealed that patients with higher levels of depression did not show significant differences in affect from T2 to T3, indicating that this group of patients continued to benefit from the Greencare intervention even after three months. A second variable that moderated the longitudinal findings was childhood residence (urban vs. rural). Here, patients who had spent their childhood in an urban environment did not show a significant increase in negative affect three months after discharge (T3) compared to discharge (T2), which means that for these patients the effects could be sustained in the follow-up. The results indicate that the intervention is particularly suitable for people from urban environments. Previous research has shown that a childhood spent in a more rural environment has an impact on emotional affinity towards nature in adolescence (Müller et al., 2009), which in turn is related to happiness and well-being later in life (Capaldi et al., 2015). The present research suggests that interventions such as Greencare may be helpful for the well-being of patients who had less access to nature in their childhood and adolescence. However, further studies are required to substantiate this claim.

The additional data from the sessions corroborate the results of the outcome evaluations. The effectiveness assessed by the quantitative data from the questionnaires is also confirmed by the patients' experiences. Furthermore, the weather (i.e., sunshine and temperature) was not related to patients' subjective ratings of well-being and effectiveness. It should be noted that our data are only a first step towards a more comprehensive understanding of how specific characteristics of NBI sessions influence the overall outcome. Consequently, the use of process evaluations in conjunction with a summative assessment of the effectiveness of NBI is an area of research that warrants further scientific attention and should be a focus of future studies.

Another area of research interest could be the interventions themselves. Here, the NBIs were delivered once a week for 4 h over three or four weeks and were found to be effective. Future studies could investigate whether extending the intervention over a longer period (8–12 weeks) or shortening the sessions to a maximum of 90 minutes each (as

suggested by Coventry et al., 2021) would lead to more sustained or enhanced effects. Based on our findings, it should also be considered whether the inclusion of more explicit activities or exercises aimed at promoting self-compassion might be beneficial. Exploring the optimal level of guidance or facilitation required for the NBI is another potential area for future research. Comparing the effects of highly structured sessions with minimally facilitated sessions could provide valuable insights. In addition, the potential benefits of tailoring the content or delivery of the intervention to specific subgroups of patients, such as those with different levels of depression or different childhood experiences of nature, may also be worth investigating.

The results suggest several potential implications for clinical practice in psychosomatic rehabilitation. Integrating NBIs like Greencare could optimize treatment outcomes by effectively improving mood and well-being in depressed patients. These approaches could be meaningfully incorporated as complementary therapy components to enhance the overall effects of rehabilitation. Centres should aim to provide low-barrier access to guided nature experiences, especially for patients from urban backgrounds who may have had less exposure to natural environments during childhood and adolescence. In addition, a focus on fostering self-compassion in combination with guided nature exposure could promote mental health benefits. For patients with higher depression severity, the intervention showed sustained positive effects even three months after completion, suggesting that it is particularly suitable for those with a higher symptom burden. The results underscore the value of integrating NBIs into multimodal treatment concepts within psychosomatic rehabilitation to further improve treatment quality.

4.1. Limitations

Although the best efforts were made to realize a feasible and attractive treatment for patients in psychosomatic rehabilitation, the study bears some limitations. First, it was not a randomized, albeit controlled, clinical trial. Because all patients interacted and shared information during treatment in the clinic, individual randomization would not have been possible. We believe that by choosing this method we were able to ensure greater external validity of the study, as the intervention could be integrated directly into the naturalistic setting of a psychosomatic rehabilitation clinic (see e.g. Rothwell, 2005, for a discussion of external validity in healthcare studies). Moreover, we chose to adjust our analyses for propensity score, a method developed specifically for balancing groups in non-randomized studies. Because the propensitiy score was not explicitly specified in the study's pre-registration, we also performed sensitivity analyses without this factor. The fact that comparable results were found in the analyses with and without a propensity score indicates that the groups in the clinics were actually very similar to each other.

Second, the two Greencare treatment programs differed slightly in that they focused more on relaxation and mindfulness, respectively, and used slightly different techniques in each session. In addition, the circumstances of the clinics at both centres had to be considered (closed vs. open groups, four vs. three treatment sessions). However, no meaningful differences between the centres were found in the analyses, confirming the effectiveness of both programs. Third, no follow-up data could be obtained for the TAU + WL group. These groups were realized after the Greencare interventions, so a follow-up study would have been possible only after the end of the project. Furthermore, in the case of a follow-up measure, the waiting list offer would have to be realized later - after the follow-up measurement - which would not have been realistic as many patients lived further away.

This study leaves some important questions unanswered. For example, the work focused on the outcomes of the interventions. As it became clear, there was a difference between the groups, even though both spent the same amount of time in nature. Moreover, mindfulness and relaxation were essential parts of the treatment-as-usual in both groups. This raises the question of the explicit effective factors of the interventions. These could be investigated in further dismantling studies. In addition, no bio-psychological correlates of the outcomes could be recorded in the study. These should be investigated in future studies. Furthermore, the age distribution of the sample was skewed towards older adults, so the generalizability of the findings to younger populations needs to be explored in future research.

5. Conclusions

The results provide evidence that depressed inpatients in psychosomatic rehabilitation benefit from a Greencare mindfulness- and relaxation-based nature intervention by improving positive and negative affect. The effects were slightly reduced after three months, but less for patients with higher levels of depression on admission. Results show that the intervention is feasible and effective even for patients with higher symptom burden. In summary, by creating opportunities for nature experiences, not just mental well-being can be promoted but well-being in all its dimensions and thus biopsychosocial health (Kals and Nisbet, 2023).

CRediT authorship contribution statement

Markus M. Müller: Writing – review & editing, Writing – original draft, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Patricia Zieris:** Writing – review & editing, Visualization, Validation, Project administration, Data curation, Conceptualization. **Meike Krebs-Fehrmann:** Investigation. **Katharina Thümer:** Investigation. **Peter Loreth:** Supervision. **Doris Pokorny:** Supervision. **Florian Katzlberger:** Supervision. **Arpad Grec:** Supervision. **Elisabeth Kals:** Writing – review & editing, Project administration, Methodology, Funding acquisition, Conceptualization.

Availability of data

The dataset for the current study is available from the corresponding author upon reasonable request.

Ethics statement

This study was carried out in accordance with the recommendations of the Ethics Committee Catholic University Eichstätt-Ingolstadt with written informed consent from all subjects. All subjects gave written informed consent in accordance with the Declaration of Helsinki. The protocol was approved by the Medical Ethics Committee of Catholic University Eichstätt-Ingolstadt (# 029–2020).

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Declarations of interest statement

None.

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Appendix A. Supplementary data

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