A psycho-oncological online intervention supporting partners of patients with cancer (PartnerCARE): Results from a randomized controlled feasibility trial

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Abstract
Objective: Partners of cancer patients are the primary supporters and burdened at the same time. Support for partners is hitherto scarce and existing offers are rarely used. The PartnerCARE online intervention was specifically developed to address the caregiving partners’ needs. This two-arm parallel randomized controlled trial (RCT) evaluates the feasibility, acceptability, and potential efficacy of PartnerCARE.

Methods: Sixty German-speaking partners of patients with various cancer entities were randomized into two conditions: intervention group (IG) with PartnerCARE (N = 30) or waitlist-control group (N = 30). Participants completed online questionnaires at baseline (T0), post-treatment (T1) and 4-months follow-up (T2). Feasibility and acceptability outcomes included dropout rates, use and acceptance of PartnerCARE, individual user/e-coach feedback as well as negative effects. Relevant efficacy outcomes were assessed to test for potential intervention effects.

Results: Recruitment success illustrates demand for and acceptability of PartnerCARE. Satisfaction with the intervention was high (Client Satisfaction Questionnaire adapted to Internet-based interventions, T1: M = 24.66, SD = 6.42) and 73.3% of participants completed the intervention. Study dropout rate was low (T1: 17%, T2: 29%). More positive than negative side effects of the intervention were identified, and negative ones were mainly related to “intrapersonal change”. For efficacy outcomes we found effects over time, with strongest effects within the IG from T0 to T1 in psychological distress (d = 0.73, 95%-CI: [0.34; 1.12]) and anxiety (0.66, [0.26; 1.04]), but no group effects were significant at T1 and T2.

Conclusions: PartnerCARE is feasible, acceptable and potentially efficacious. Based on received feedback, PartnerCARE is currently undergoing further development and subsequently efficacy will be investigated in a RCT.

Trial Registration: German Clinical Trial Registration: DRKS00017019. Registered on 08 April 2019.
1 | INTRODUCTION

It is well known that a cancer diagnosis also places a heavy burden on partners of cancer patients.1 Partners not only often take over the patients’ household tasks and provide financial and emotional support, they also share the anxieties associated with the diagnosis.2,3 The increased household responsibilities, the personal emotional burden, the existential uncertainty due to a life-threatening disease exhibit a substantial impact on social activities as well as relationships. This may increase the risk for depression, anxiety and various somatic symptoms in partners.4,5 Despite these conditions, partners are often unaware of their own needs and prioritize the patients’ needs.6,7 Therefore, partners rarely seek support for themselves. Furthermore, healthcare systems often neglect the burden of caregiving partners because focus is on the patients.

Low threshold support, such as online interventions may overcome this barrier and help to introduce partners to support offers.6 Additionally, online interventions are advantageous in being much more flexible in time and location, easily and quickly accessible and anonymous if preferred.5,7 So far, online support offers especially for caregiving partners are rare8 and the field of research associated with it is still in its infancy.9 Existing online offers for partners include interventions addressing couples10 or spouses,11–13 a smartphone app14 and a self-management application.15 None of them are available in German. Statements about the efficacy of these offers are difficult because they are largely in the development or feasibility testing stage.11,13–15 Likewise the comparison of these studies is difficult as they targeted different outcomes like quality of life,12 psychological distress,12 emotional well-being13 and caregiver burden.15

The PartnerCARE online intervention has been the first online intervention in Germany, which was especially developed to address the support needs of partners of cancer patients. PartnerCARE includes psychoeducational information, practical exercises like other interventions.12,14 This is additionally combined with exemplary partners (via image and text) who accompany the participants through the intervention and relaxing guided imagery exercises with the intention to increase well-being and improve selfcare in partners (cf. for a detailed description of development process and content of PartnerCARE in the corresponding study protocol). The herein presented development and feasibility study of PartnerCARE is only the first step of a consecutive development and evaluation process. One important aspect of our study is, that it observes both possible positive and possible negative effects of PartnerCARE. This follows the CONSORT-Guidelines17 as well as recommendations from Rozental and Colleagues.18

The present study aims to explore the feasibility and acceptance of the newly developed online intervention PartnerCARE. It specifically focusses on recruitment, dropout, adherence, and satisfaction with PartnerCARE. Moreover, possible negative effects of the online training are examined. In addition, first findings on the potential efficacy of the intervention are discussed. With this feasibility study a consecutive development and evaluation process was initiated to provide a reliable support offer for partners.

2 | METHODS

This randomized controlled trial with a two-arm parallel design compares an intervention group (IG) receiving the guided online intervention PartnerCARE with a waitlist control group (CG). Intervention description and results of this clinical trial are reported according to the CONSORT-Statement for feasibility RCTs17 and the template for intervention description and replication.19 The study design is described in detail in the corresponding study protocol.16 The study was approved by the Ethics Committee of Ulm University (No. 390/18) and registered in the German clinical trial register (DRKS00017019).

2.1 | Study population and recruitment

To overcome the challenging recruitment of partners of patients with cancer,20 a wide variety of recruitment routes was used, both online (e.g. social media groups, online support groups, links on clinic homepages) and offline (e.g. flyers, cancer counseling centers). Participants were recruited in German-speaking countries from April 2019 to March 2020. Interested partners registered for the study via a contact form on the PartnerCARE study homepage (https://esano.klips-ulm.de/de/trainings/tumor/partnercare/) and subsequently received an email with detailed study information and a detailed consent form. After providing written informed consent, participants were invited to the online baseline assessment (T0). Before questionnaires started, the following inclusion criteria were checked via self-report: (1) age 18 years and older, (2) being in a relationship and (3) the partner is diagnosed with cancer (any type, any disease stage, any treatment stage). Additional inclusion criteria (4) having Internet access and a corresponding terminal device, (5) providing an email address for contact and (6) giving a signed informed consent) were checked through the previous study process. If inclusion criteria were not fulfilled, baseline assessment was canceled and the participant received an automated email with recommendations for already available support.

Since this was a feasibility study, a formal sample size calculation was not performed. A sample size of 60 participants (30 per group)
was the predefined target, based on recommendations for sample sizes in feasibility studies.\(^{21}\)

### 2.2 | Randomization

After completing baseline assessment, participants were randomly allocated to the study conditions IG and CG (1:1). For this, a permuted block randomization with randomly arranged block sizes of two and four was used. An independent researcher (TD) conducted the randomization using an automated generated randomization list via an online program (www.sealedenvelope.com). Therefore, allocation of participants was not able to be forecasted by any other member of the study team. After randomization, all participants received an email including information about group allocation and the resulting study procedure.

### 2.3 | Intervention

PartnerCARE is a guided individually psycho-oncological online intervention delivered on the online platform minddistrict (www.minddistrict.com). It aims to improve quality of life, self-efficacy, and caregiver burden in partners of patients with cancer by creating awareness of one's own needs and learning to meet them. The intervention is based on psychoeducation, cognitive behavioral therapy, supportive therapy and guided imagery elements, which have previously been proven to be beneficial concepts for cancer caregivers.\(^{22}\) PartnerCARE consist of an introductory session, six weekly main sessions (topics: specific burdens, inner drivers, partnership communication, handling negative feelings, control and acceptance, path and goals), four optional additional sessions (topics: support of own children, healthy sleep, closeness and sexuality, existential burdens) and one booster session (2 weeks after the last main session). Detailed information about structure and content of the intervention is provided in Table S7 and in the corresponding study protocol.\(^{16}\) Sessions were multimodally and interactively conceptualized through text, visual and auditory material, practical exercises, and homework assignments, as well as three exemplary partners. Each session has a duration of 30–60 min. In addition to the intervention, participants had the option of choosing an automated Short Message Service- (SMS) Coach, who sent two motivational text messages per week.

All participants of the IG received a personal account for the online platform minddistrict and were assigned to an e-coach (trained and supervised postgraduate psychology student and psychologists). After initial login, participants were able to start with the introductory session of the PartnerCARE intervention. Each completed session had to be sent to the e-coach who replied within two weekdays after session completion by a partly standardized and partly individualized feedback for the respective session. Additionally, participants had the possibility to message the e-coach via minddistrict, for example, to report technical problems or to inform the e-coach in case they were not able to work on the session at the agreed time. The e-coach also reminded the participants when they missed a session (three times in intervals of two weekdays). All communication and feedback between participant and e-coach was asynchronous.

Participants of the CG received access to the unguided PartnerCARE intervention after completion of the follow-up questionnaire (4 months after randomization). All participants had unrestricted access to standard care treatments.

### 2.4 | Outcomes

Self-report measurements took place at baseline (T0), post treatment (T1, 2 months after randomization) and at follow-up (T2, 4 months after randomization) via an online-based assessment platform (www.unipark.de). Sociodemographic variables and clinical characteristics of the diseased partner were assessed at baseline via self-report by the partner. Use of psychotherapy by partners as well as their level of information about help services was recorded at all assessment time points. Participants were reminded to complete assessments up to five times in interval of two weekdays, to reduce dropouts.

### 2.4.1 | Feasibility and acceptability outcome

Feasibility and acceptability of the PartnerCARE online intervention was assessed using various questionnaires to display the different aspects of this outcome.

The Client Satisfaction Questionnaire adapted to Internet-based interventions (CSQ-I) measured satisfaction with the online intervention in the IG.\(^{23}\) Sum score of the eight items ranged from eight to 32 and reliability was excellent (T1: \(\omega = 0.96\), T2: \(\omega = 0.98\)), with values >23 are being defined as good treatment satisfaction.\(^{24}\) Side effects of the online intervention were assessed with a 22 item-version of the Inventory for the Assessment of Negative Effects in Psychotherapy (INEP) adapted to online intervention (INEP-ON).\(^{25}\) Additionally, an abridged and adjusted version of the INEP (14 items) measured negative effects about participating in the study in the CG (INEP-CG). Both INEP questionnaires (IG: INEP-ON, CG: INEP-CG) included a question about suicidal thoughts. To provide adequate support in case a participant scored on this item, a stepped emergency plan was implemented.\(^{16}\) The Attitudes towards Psychological Online Interventions Questionnaire (APOI) consists of 16 items with a total sum score between 16 and 80.\(^{26}\) Reliability of the total scale can be considered acceptable to good (T0: \(\omega = 0.72\), T1: \(\omega = 0.86\), T2: \(\omega = 0.88\)). Median score can be used to classify the sum score (median of total scale = 56). Satisfaction with the SMS Coach was assessed with three self-compiled questions about helpfulness, motivation, and comfort of the message content. In addition to the questionnaire assessments, participants were able to give a short voluntary feedback after each finished PartnerCARE
session. They were asked on a scale from one (not at all) to 10 (very good), to rate the length of the session and how they liked the session. Furthermore, four open questions measured, what the most helpful and positive exercise was, what may be improved and what the required processing time of the session was.

2.4.2 | Efficacy outcomes

The Distress Thermometer (DT) measured psychological distress with a scale from 0 to 10.27 A score of five or higher indicated an increased level of distress. The Patient Health Questionnaire-8 (PHQ-8) was applied to measure current depression symptoms.28 The total score ranged from 0 to 24 and the scale achieved good reliability (T0: ω = 0.80, T1: ω = 0.87, T2: ω = 0.88). With the Generalised Anxiety Disorder-7 Questionnaire (GAD-7) current symptoms of the generalized anxiety disorder were assessed (total score 0–21).29 Reliability was good (T0: ω = 0.86, T1: ω = 0.88, T2: ω = 0.89). The Veterans RAND 12-Item Health Survey (VR-12) assessed quality of life regarding physical and mental health.30 The scale reached good reliability (T0: ω = 0.86, T1: ω = 0.89, T2: ω = 0.91). The amount of burden was measured with the Short Version of the Burden Scale for Family Caregivers (BSFC-s).31 The scale consists of 10 items (sum score ranges from 0 to 30) and showed excellent reliability (T0: ω = 0.87, T1: ω = 0.91, T2: ω = 0.93). The Questionnaire Fear of Progression in Partners of Chronically Ill Patients (FoP-Q-SF/P) assessed fear of progression specifically in partners based on 12 items (sum score range: 12–60).32 Reliability was good (T0: ω = 0.84, T1: ω = 0.88, T2: ω = 0.89). Perceived social support was assessed with the ENRICHD Social Support Inventory with five items and a scale range from five to 25.33 Reliability of the scale was excellent (T0: ω = 0.91, T1: ω = 0.95, T2: ω = 0.97). Received social support was measured with the Oslo Social Support scale.34 Reliability of the 3-item scale (range: 3–14) was acceptable (T0: ω = 0.72, T1: ω = 0.76, T2: ω = 0.76). Loneliness experienced by partners was measured with a single self-formulated question: “How lonely do you feel at the moment?” (five-point scale from one “not at all” to five “very much”). Perceived self-efficacy was rated on the Generalised Self-Efficacy scale.35 The total score of the 10 items ranged from 4 to 40 and the scale reached excellent reliability (T0: ω = 0.91, T1: ω = 0.92, T2: ω = 0.92). The BriefCOPE (Brief Coping Orientation to Problems Experienced) Inventory was used to measure coping.36 The three subscales achieved up to acceptable reliability (emotion T0: ω = 0.66, T1: ω = 0.78, T2: ω = 0.74; problem T0: ω = 0.72, T1: ω = 0.80, T2: ω = 0.76; dysfunction T0: ω = 0.46, T1: ω = 0.54, T2: ω = 0.68).

2.5 | Data analyses

All statistical analyses were performed using SPSS 26 (IBM SPSS Statistics). All tests were two-tailed with a significance level of p ≤ 0.05. McDonald’s omega (ω) was calculated to estimate the reliability of outcome scales.37 To investigate significant differences at baseline between IG and CG as well as differences between intervention completers and non-completers, t-tests, Mann-Whitney-tests and χ² tests were conducted.

All statistical analyses were conducted following the intention-to-treat principle (ITT). Additionally, per-protocol analyses were conducted based on participants who adhered to treatment protocol (=completers; completing at least 80% of the intervention, five out of six main sessions). Multivariate imputation was performed by fully conditional specification with Markov Chain Monte Carlo algorithm.38 Missing data was assumed to be missing at random.39 Predictive mean matching was applied as imputation method.40 Based on recommendations m = 20 data sets were imputed.41 The imputed data sets were each analyzed and results were pooled using Rubin’s Rule.41

Feasibility and acceptability outcomes were analyzed descriptively (participants’ adherence, feedback from participants and e-coaches, side effects, attitude towards online interventions) and with t-test (satisfaction). Efficacy outcomes for testing a potential intervention effect were analyzed using repeated measures analyses of variance (ANOVA; factor one: group [IG, CG], factor two: time [T0, T1, T2]). Since SPSS 26 does not run this analysis on Multivariate imputation data, a SPSS macro was used.42,43 Significant results were reported using Cohen’s d along with the corresponding 95% CI.44

3 | RESULTS

3.1 | Participants

A total of 94 potential participants expressed their interest in the study. Based on inclusion criteria 33 applicants were excluded. The most common reason for exclusion was the absence of a written informed consent (after two reminders). Hence, 61 of the applicants received an invitation for baseline assessment. Through the proceeded screening of inclusion criteria, one participant was excluded. Thus 60 participants completed baseline assessment and were randomized afterward to IG (n = 30) and CG (n = 30). Post-assessment was completed by n = 49 (81.7%) with a higher proportion of completers in CG (n = 27, 93%) than in IG (n = 22, 73%). Follow-up was completed by n = 42 (70%) participants, likewise more completers in CG (n = 22, 76%) than in IG (n = 20, 67%) (Figure 1).

Participants had a mean age of 47 years (SD = 9.62, range = 28–71). The majority was female (69.5%), married (88.1%) and had children (69.5%). Other personal characteristics as well as patients’ cancer related characteristics are displayed in Table 1. At baseline, one third of participating partners rated themselves as well informed (33.9%) and one third as poorly informed (35.6%). Over time, the proportion of well-informed participants increased (T1: 34.7%, T2: 52.4%), while the proportion of poorly informed decreased (T1:
26.5%, T2: 16.7%). Looking at the IG separately, the proportion of well-informed participants is already highly increased at T1 (T1: 54.5%, T2: 55.0%).

On average, participants are burdened at baseline: they reported a clinically significant level of distress (DT: $M = 6.39$, $SD = 2.61$), mild depression and anxiety symptoms ($PHQ-8$: $M = 8.54$, $SD = 4.61$; $GAD-7$: $M = 7.68$, $SD = 4.57$), low mental health ($VR-12$ mental: $M = 34.99$, $SD = 11.34$), moderate caregiver burden ($BSFC-s$: $M = 12.42$, $SD = 6.74$) and a dysfunctional fear of progression ($FoP-Q-SF/P$: $M = 37.39$, $SD = 9.02$) (see separate results for IG and CG in Table 2).

3.2 | Feasibility of PartnerCARE

3.2.1 | Recruitment

Recruitment started in April 2019 and concluded in March 2020 when the target sample size of 60 participants was reached. The most successful recruitment route was via online platforms (online forum, social media, clinic homepages, search engine, etc.) where 61% of participants became aware of the study. 18.6% were informed through cancer counseling centers, 8.5% through the diseased partner and 3.4% through doctor consultation. Other access routes were reported by 8.5%.

3.2.2 | Use of and adherence to the online intervention

All except one participant of the IG have logged in and completed at least the introductory session (Figure 2). Twenty-two out of 30 participants (73.3%), who were randomized to the IG, were classified as intervention completers by adhering to treatment protocol. With this subsample, PP-Analyses were conducted. All intervention completers finished all six main sessions within 2 months after randomization. The average intervention duration was 7 weeks ($SD = 1.93$) for intervention completers. On average 9.79 days ($SD = 4.85$) were between two completed main sessions. The booster session was completed by 46.6% of participants. Over all six main sessions, participants spent 64.5 min ($SD = 37.02$) at one session on average (Table S1). Twenty-two participants of the IG completed at least one
# TABLE 1  Baseline partners’ characteristics and patients’ cancer related characteristics

| Characteristic | Total sample (n = 59) | Intervention group (n = 30) | Waitlist control group (n = 29) | p^a |
|----------------|-----------------------|-----------------------------|---------------------------------|-----|
| **Partners’ characteristics** | | | | |
| Age (M±SD [range]) | 47.17 ± 9.62 [28–71] | 47.67 ± 8.86 [30–61] | 46.66 ± 10.48 [28–71] | 0.690 |
| Gender | | | | 0.223 |
| Male | 18 (30.5%) | 7 (23.3%) | 11 (37.9%) | |
| Female | 41 (69.5%) | 23 (76.7%) | 18 (62.1%) | |
| Relationship | | | | 0.723 |
| In partnership | 7 (11.9%) | 4 (13.3%) | 3 (10.3%) | |
| Married | 52 (88.1%) | 26 (86.7%) | 26 (89.7%) | |
| Duration of relationship in years (M±SD [range]) | 18.35 ± 11.32 [0.67–50] | 17.73 ± 11.29 [1–47] | 18.99 ± 11.50 [0.67–50] | 0.644 |
| Children | | | | 0.296 |
| Yes | 41 (69.5%) | 19 (63.3%) | 22 (75.9%) | |
| No | 18 (30.5%) | 11 (36.7%) | 7 (24.1%) | |
| Nationality | | | | 0.321 |
| German | 58 (98.3%) | 29 (96.7%) | 29 (100%) | |
| Other | 1 (1.7%) | 1 (3.3%) | 0 | |
| Level of education | | | | 0.799 |
| < 10 years | 3 (5.1%) | 1 (3.3%) | 2 (6.9%) | |
| 10 years | 9 (15.3%) | 5 (16.7%) | 4 (13.8%) | |
| > 10 years | 47 (79.7%) | 24 (80.0%) | 23 (79.3%) | |
| Employment status | | | | 0.122 |
| Employed (full time) | 26 (44.1%) | 17 (56.7%) | 9 (31.0%) | |
| Employed (part time) | 21 (35.6%) | 9 (30.0%) | 12 (41.4%) | |
| Unemployed | 12 (20.3%) | 4 (13.3%) | 8 (27.6%) | |
| Psychotherapy (current or last 8 weeks) | | | | 0.942 |
| Yes | 14 (23.7%) | 7 (23.3%) | 7 (24.1%) | |
| No | 45 (76.3%) | 23 (76.7%) | 22 (75.9%) | |
| **Patients’ characteristics** | | | | |
| Cancer diagnosis | | | | 0.375 |
| Breast cancer | 9 (15.3%) | 3 (10.0%) | 6 (20.7%) | |
| Prostate cancer | 2 (3.4%) | 1 (3.3%) | 1 (3.4%) | |
| Colon cancer | 6 (10.2%) | 3 (10.0%) | 3 (10.3%) | |
| Lung cancer | 4 (6.8%) | 3 (10.0%) | 1 (3.4%) | |
| Pancreatic cancer | 4 (6.8%) | 0 | 4 (13.8%) | |
| Brain tumor | 6 (10.2%) | 4 (13.3%) | 2 (6.9%) | |
| Hematological tumor | 18 (30.5%) | 11 (36.7%) | 7 (24.1%) | |
| Other | 10 (16.9%) | 5 (16.7%) | 5 (17.2%) | |
| Time since diagnosis | | | | 0.512 |
| ≤ 1 year | 24 (40.7%) | 11 (36.7%) | 13 (44.8%) | |
| 1–2 years | 14 (23.7%) | 9 (30.0%) | 5 (17.2%) | |
| > 2 years | 21 (35.6%) | 10 (33.3%) | 11 (37.9%) | |

*Continues*
of the optional additional sessions. Most of them worked on the additional session "Healthy sleep" (n = 17, 77.3%). Eleven participants completed "Closeness and sexuality" (50%), 10 completed "Existential burdens" (45.5%) and five completed "Support of own children" (22.7%). In addition, 20 participants of the IG used the automated SMS coach (66.6%).

3.2.3 | Feedback from e-coaches

The e-coaches spend an average of 14.34 min (SD = 5.89, range = 4–27) reading the entries of the participant and writing feedback for a session (Table S2). Time for feedback continuously decreased from 17.54 min (average with SD = 6.09, range = 4–27) for session 1 to 7.27 min (average with SD = 2.99, range = 4–16) for session 6. In total, the e-coaches sent 74 reminders resulting to a mean of 2.47 reminders per participant (SD = 2.32, range = 0–7).

3.3 | Acceptability of PartnerCARE

3.3.1 | Attitude towards online interventions and satisfaction with PartnerCARE

Overall, participants of the study displayed a positive attitude towards online interventions. Attitudes towards Psychological Online Interventions Questionnaire median scores from IG remained stable over time (T0: Mdn = 56.0, T1: Mdn = 56.1, T2: Mdn = 54.3), while median scores from CG participants decrease after baseline (T0: Mdn = 56.0, T1: Mdn = 51.0, T2: Mdn = 51.1). One participant of the IG had prior experience with online interventions. In PP-analyses, APOI median scores from IG increased lightly (T0: Mdn = 54.5, T1: Mdn = 57.6, T2: Mdn = 55.6) (Table S3).

Participants’ satisfaction with PartnerCARE according the CSQ-I was high at both timepoints, post-treatment and follow-up (T1: M = 24.66, SD = 6.42; T2: M = 22.97, SD = 7.27). Difference in intervention satisfaction was not statistically significant (t[29] = 1.69, p = 0.09). PP-Analysis also showed no significant difference.

3.3.2 | Individual user feedback

Across all main sessions we received written feedback 145 times (range per session: 22–27 feedback statements) from IG participants. 82.7% (n = 120) of these rated the length of the sessions as just right (Figure S1). Overall, participants rated the sessions as quite good (M = 8.15, SD = 2.0, scale range 1–10, Table S4). Open questions indicate that the following elements of the intervention were perceived as positive and most helpful: respective practical session exercises (n = 62), guided imagery exercises (n = 33), basic information (n = 27), and the possibility to write openly (n = 20). Some participants reported also improvables: more information and assistance at session five (session topic: "Control and Acceptance") and six ("Paths and Goals") (n = 7), technical difficulties in saving or final sending of sessions to the e-coaches at session one ("Specific Burdens") and two ("Inner Drivers") (n = 5) and distracting noises at the guided imagery exercises (n = 6). Fifteen of 20 SMS Coach users provided feedback at T1. 53.4% (n = 8) of them rated the SMS Coach as helpful, 73.4% (n = 11) as motivational and 73.4% (n = 11) rated the content of the SMS as comfortable.

3.3.3 | Side effects

Overall, participants of the IG reported 51 negative, 339 neutral, and 94 positive side effects at T1 (based on observed data from n = 22). Of these, participants attributed 13 (25.5%) negative, 30 (8.9%) neutral and 76 (80.9%) positive side effects to the online intervention. Four (18.2%) participants of the IG reported at least one negative side effect which was attributed to the online intervention. Participants of the CG reported overall 74 negative, 290 neutral and

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**TABLE 1 (Continued)**

| Characteristic                  | Total sample (n = 59) | Intervention group (n = 30) | Waitlist control group (n = 29) | p*     |
|---------------------------------|----------------------|-----------------------------|-------------------------------|--------|
| **Disease stage (UICC)**        |                      |                             |                               |        |
| I–II                           | 16 (27.1%)           | 7 (23.3%)                   | 9 (31.0%)                     | 0.817  |
| III–IV                         | 30 (50.8%)           | 15 (50.0%)                  | 15 (51.7%)                    |        |
| Remission                      | 5 (8.5%)             | 3 (10.0%)                   | 2 (6.9%)                      |        |
| Not known                      | 8 (13.6%)            | 5 (16.7%)                   | 3 (10.3%)                     |        |
| **Treatment status**           |                      |                             |                               | 0.714  |
| Currently in treatment         | 40 (67.8%)           | 21 (70.0%)                  | 19 (65.5%)                    |        |
| Completed                      | 11 (18.6%)           | 6 (20.0%)                   | 5 (17.2%)                     |        |
| Pausing                        | 8 (13.6%)            | 3 (10.0%)                   | 5 (17.2%)                     |        |

Abbreviation: UICC, union for international cancer control.

*p-test for independent sample for age, Mann-Whitney test for duration of relationship and χ² tests for the remaining variables.
## TABLE 2
Acceptability and efficacy outcomes pre, post and follow-up and results of t-test and repeated measures ANOVA and effect sizes of significant within group effects (ITT analyses)

| TABLE 2 | Acceptability and efficacy outcomes pre, post and follow-up and results of t-test and repeated measures ANOVA and effect sizes of significant within group effects (ITT analyses) |
|---------|--------------------------------------------------------------------------------------------------|
| CSQ-I*  |                                                                                                   |
| IG      | 30 - 24.66 ± 6.42 22.99 ± 7.27 1.69                                                              |
| DT      |                                                                                                   |
| IG      | 30 6.67 ± 2.60 4.93 ± 2.12 4.69 ± 2.25 9.80***                                                   |
| CG      | 29 6.10 ± 2.62 5.68 ± 2.89 4.81 ± 3.00 0.15 [-0.22; 0.52] 0.46 [0.04; 0.87]                   |
| PHQ-8   |                                                                                                   |
| IG      | 30 8.90 ± 4.77 7.43 ± 4.39 6.56 ± 4.18 6.81**                                                    |
| CG      | 29 8.17 ± 4.50 8.41 ± 5.19 6.61 ± 4.11 -0.05 [-0.38; 0.28] 0.36 [-0.03; 0.74]                 |
| GAD-7   |                                                                                                   |
| IG      | 30 8.30 ± 4.63 5.62 ± 3.46 5.74 ± 3.86 7.49***                                                   |
| CG      | 29 7.03 ± 4.50 6.77 ± 4.79 5.87 ± 3.32 0.06 [-0.28; 0.39] 0.29 [-0.09; 0.68]                 |
| VR-12 physical |                                                                                               |
| IG      | 30 48.03 ± 8.70 49.84 ± 6.86 47.18 ± 8.90 2.30                                                   |
| CG      | 29 50.27 ± 6.45 51.24 ± 6.73 49.53 ± 4.88 -                                                    |
| VR-12 mental |                                                                                             |
| IG      | 30 34.63 ± 10.59 39.20 ± 10.88 40.53 ± 10.15 -11.45***                                           |
| CG      | 29 35.37 ± 12.25 35.65 ± 11.65 41.83 ± 10.57 -0.02 [-0.35; 0.30] -0.56 [-1.03; -0.09]         |
| BSFC-s  |                                                                                                   |
| IG      | 30 12.97 ± 6.44 11.33 ± 6.89 10.42 ± 6.70 2.48                                                   |
| CG      | 29 11.86 ± 7.10 12.31 ± 7.06 10.59 ± 6.67 -                                                    |
| FoP-Q-SF/P |                                                                                             |
| IG      | 30 37.83 ± 9.26 35.07 ± 8.47 32.94 ± 8.56 -12.96***                                              |
| CG      | 29 36.93 ± 8.90 36.57 ± 9.40 31.95 ± 9.13 0.04 [-0.23; 0.30] 0.55 [0.16; 0.93]                |
| ESSI    |                                                                                                   |
| IG      | 30 16.60 ± 5.85 18.39 ± 6.10 18.30 ± 6.55 1.73                                                   |
| CG      | 29 17.97 ± 5.02 17.69 ± 5.10 18.35 ± 5.58 -                                                    |
| OSS-3   |                                                                                                   |
| IG      | 30 9.20 ± 2.78 9.66 ± 2.95 9.62 ± 2.75 0.78                                                   |
| CG      | 29 8.93 ± 2.53 9.02 ± 2.23 9.28 ± 2.55 -                                                    |
| GSE     |                                                                                                   |
| IG      | 30 27.23 ± 5.14 29.47 ± 5.17 28.36 ± 5.52 -4.06*                                               |
| CG      | 29 28.93 ± 4.58 29.85 ± 4.44 30.35 ± 3.55 -0.20 [-0.44; 0.03] -0.35 [-0.66; -0.03]         |
| BriefCOPE emotion |                                                                                           |
| IG      | 30 20.53 ± 5.20 22.15 ± 5.65 22.13 ± 4.76 1.59                                                   |
| CG      | 29 21.10 ± 3.62 20.67 ± 4.04 21.43 ± 4.14 -                                                    |

(Continues)
14 positive side effects at T1 (based on observed data from \( n = 27 \)). Of these, 0 (0%) negative, 7 (2.4%) neutral and 1 (7.1%) positive side effects were attributed to study participation.

Participants of the IG reported overall 52 negative, 320 neutral and 68 positive side effects (based on observed data from \( n = 20 \)) at T2. Three (5.8%) of the negative, 29 (9.1%) of the neutral and 54 (79.4%) of the positive side effects were attributed to the online intervention. Three (15%) participants of the IG each reported one negative side effect attributed to the online intervention. Participants of the CG reported overall 64 negative, 213 neutral and 33 positive side effects (based on observed data of \( n = 22 \)). Of these, four (6.5%) negative, 21 (9.9%) neutral and 11 (33.3%) positive side effects were attributed to study participation. Two (0.9%) participants reported the four negative side effects which were attributed to study participation. A detailed overview of side effects is displayed in Table S5.1–S5.4.

### 3.4 Potential intervention effect on efficacy outcomes

The main effect of time was significant for some outcomes (Table 2). Distress decreased significantly over time (\( F[2106.48] = 9.80, p < 0.001 \)), as well as depression (\( F[2106.66] = 6.81, p = 0.002 \)), anxiety (\( F[2109.75] = 7.49, p < 0.001 \)), and fear of progression (\( F[2110.60] = 12.96, p < 0.001 \)). Both, the mental component of quality

| TABLE 2 (Continued) |
|-----------------------|
| BriefCOPE problem     |
| \( n \) Pre-assessment (T0) | Post-assessment (T1) | Follow-up (T2) | ANOVA: F Main effect (time) | Pre-post Within-group d (95% CI) | Pre-follow up Within-group d (95% CI) |
| IG 30 15.17 ± 3.45 | 16.07 ± 3.79 | 15.80 ± 3.48 | 0.22 | - |
| CG 29 15.79 ± 3.12 | 15.29 ± 3.09 | 15.67 ± 3.46 | - | - |
| BriefCOPE dysfunction |
| \( n \) Pre-assessment (T0) | Post-assessment (T1) | Follow-up (T2) | ANOVA: F Main effect (time) | Pre-post Within-group d (95% CI) | Pre-follow up Within-group d (95% CI) |
| IG 30 20.97 ± 3.35 | 21.05 ± 3.42 | 20.13 ± 3.13 | - | - |
| CG 29 20.38 ± 3.75 | 20.98 ± 3.40 | 20.87 ± 4.41 | - | - |
| Loneliness |
| \( n \) Pre-assessment (T0) | Post-assessment (T1) | Follow-up (T2) | ANOVA: F Main effect (time) | Pre-post Within-group d (95% CI) | Pre-follow up Within-group d (95% CI) |
| IG 30 2.60 ± 1.20 | 2.36 ± 1.26 | 2.37 ± 1.25 | 1.15 | - |
| CG 29 2.48 ± 0.87 | 2.51 ± 1.00 | 2.21 ± 1.02 | - | - |

Note: Data is imputed and analyses are based on ITT. Reported are mean ± SD.

Abbreviations: ANOVA, analyses of variance; BriefCOPE, brief coping orientation to problems experienced inventory; BSFC-s, short version of the burden scale for family caregivers; CG, control group; CSQ-I, client satisfaction questionnaire adapted to Internet-based interventions; DT, distress thermometer; ESSI, ENRICHED social support inventory; FoP-Q-SF/P, fear of progression in partners of chronically ill patients; GAD-7, generalised anxiety disorder-7 questionnaire; GSE, generalised self-efficacy scale; IG, intervention group; ITT, intention to treat; OSS-3, Oslo social support scale; PHQ-8, patient health questionnaire-8; VR-12, veterans RAND 12-item health survey–physical and mental health scale.

*Recorded in intervention group and at T1 and T2 only, paired t-test was calculated.

*a \( p < 0.05 \). ** \( p < 0.01 \). *** \( p < 0.001 \).

FIGURE 2 Number of completed sessions of the guided PartnerCARE intervention until 2 months after randomization (T1) per intervention group participants (\( n = 30 \))

Number of participants
of life ($F_{2111.51} = 11.45, p < 0.001$) and general self-efficacy ($F_{2106.90} = 4.06, p = 0.02$) increased significantly over time. For all these outcomes, changes between T0 and T1, represented by effect size d, are higher for IG than for CG. For IG these effects remain stable over time or even increase (e.g., PHQ-8: T0 and T1: $d = 0.32$, [95% CI: 0.01–0.62]; T0–T2: $d = 0.52$, [95% CI: 0.21–0.83]). For CG, effect sizes are small or even zero when comparing T0 and T1, whereas effect sizes are higher when comparing T0–T2 (e.g., PHQ-8: T0 and T1: $d = −0.05$, [95% CI: −0.38 to 0.28]; T0–T2: $d = 0.36$, [95% CI: −0.03–0.74]). A detailed description of the proportion of participants in the clinical categories can be found in Table S6. In contrast, there was no statistically significant main effect of group (IG vs. CG) and no significant interaction for all efficacy outcomes. In PP analyses similar effects were found with slight differences in effect sizes (Table S3).

### 4 | DISCUSSION

Findings from this feasibility trial indicate that the newly developed psycho-oncological online intervention PartnerCARE is both feasible and acceptable. Feasibility was particularly evident in high intervention completion rate, less drop out and choice of recruitment strategy. The high intervention completion rate (73.3%) indicates that once participants begin the intervention, they are likely to finish it. This treatment adherence is comparable to other online intervention studies with caregivers, but substantially higher than average intervention adherence in online intervention studies with patients. This rather high intervention adherence rate might result from the intervention being guided by e-coaches, provided as internet-based intervention with mobile app features instead of a mobile application only, developed using persuasive design principles and used by more female, middle aged, educated participants. The overall study procedure can be classified as feasible since the study dropout rate was low (T1: 17%, T2: 29%) compared to other online caregiver studies (14%–77%). Furthermore, the challenging recruitment due to time limitations and logistic constraints of partners was overcome with a wide recruitment strategy with the most successful recruitment route being online recruitment (61%). As proportion of male participants was similarly low to other online partner interventions (approximately 30%), recruitment strategies need to be explored that reach male caregivers better.

In terms of acceptability outcomes, attitudes towards online interventions are positive across the whole sample and satisfaction with PartnerCARE is high and stable over time. Assessments in this area are necessary to adequately evaluate the intervention as participant satisfaction and positive attitude may increase adherence and intervention efficacy. However, some technical difficulties such as saving and sending of sessions must be solved in the optimization process of PartnerCARE. Likewise, the text messages from the SMS Coach need to be revised to increase their helpfulness (e.g., improve content more towards daily and practicable exercises).

As highly recommended, our study assess possible negative side effects. The advantage of this assessment is that one can only react to negative side effects when aware of them. Participants of PartnerCARE attributed a small number of the negative side effects to the intervention, which were mainly related to the category “intrapersonal change”, for example, by reporting “feeling dependent on the online program” or “having longer periods of feeling bad”. As the intervention encouraged participants to reflect on personal problems and conflicts, negative feelings can commonly increase initially with an increase of self-awareness. This common fluctuation of symptoms is also indicated by the decrease of these negative side effects again from T1 to T2. All reports of suicidal ideation could be clarified by using our emergency plan (including telephone interviews to guarantee credible distancing from suicidal thoughts). Although caregivers are not at high risk for suicide (they want to take care of the patient and not leave him or her alone), the occurred cases highlight the need for an emergency plan. In contrast to the negative side effects, it needs to be pointed out that about 80% of the positive side effects were attributed to the intervention at T1 and T2.

There are first insights in potential post-intervention effects of PartnerCARE on the efficacy outcomes. The potential post-intervention effect is reflected in the higher effect sizes for IG than for CG in the pre-post comparison regarding distress, depression, anxiety, mental quality of life, fear of progression and general self-efficacy. These preliminary findings are consistent with the aim of PartnerCARE making partners aware of their own needs and feelings and showing them that they can effectively help themselves. For the IG these effects seem to be stable or even increase over time (like for distress, depression, mental quality of life, fear of progression), which may reflect a potentially delayed effect of the intervention. In the pre-follow up comparison, also participants of the CG experienced some improvements over time. Since that effect only occurs at follow up, it may be, that through their repeated involvement with the topics of the questionnaires, they were encouraged to reflect and changed their behavior in the meantime. It should be emphasized, that all these results are only interpretable to a limited extent and a larger study sample is needed to make reliable statements about group differences as well as to verify the potential intervention effects.

### 4.1 | Study limitations

The first limitation of our study concerns the sample population. As has been seen in comparable other studies the majority was female and highly educated, which does not reflect the population of partners in real-life. In addition, generalizability of the results is limited, because it can be assumed that only partners with an existing affinity for online tools have expressed their interest in the study via homepage. A reason for non-significant group effects may be the small sample size, which was however appropriate for the feasibility study. A further limitation of the present online assessment is the uncertainty regarding the diagnosis of the ill spouse as this was recorded via self-report. The additional collection of medical data
Therefore, it is necessary to provide support offers for partners as an integral part of the healthcare routine. Online interventions may be a suitable offer to support partners in a flexible way.\(^5\) But there are two barriers that must be overcome before partners use such support offers: partners’ lack of awareness of their own needs\(^6\) and how to reach burdened partners.\(^2\) Providing informational material about the potential impact of cancer to caregiving partners and an accompanying distress screening of partners in clinical routine could help to increase the partners’ awareness of their own burden and thereby their own needs. Such screenings could be easily conducted via mobile app and additionally linked with PartnerCARE, to provide support instantly in case of increased burden. Since the current study demonstrated online recruitment as an effective way to reach partners and, as previous studies showed, partners are comfortable in using the Internet to search for information and help,\(^8\) reach of partners via Internet should be focused. In addition, despite limited time resources of healthcare professionals, they should also pay attention to the partner by handing out relevant support information during visit hours. As PartnerCARE itself increase the proportion of participants who rate themselves as well informed about help services for caregivers in general, such online-interventions might have the potential to be a low threshold entry into the psycho-social support system for caregivers.

\[\]

5 | CONCLUSION

The present study demonstrated feasibility and acceptance of the online intervention PartnerCARE and the corresponding study process. Online interventions can overcome barriers regarding the use of psychosocial health care offers and improve the care for partners of patients with cancer.\(^2\) Based on the received feedback, PartnerCARE is currently being further developed to improve content, modify how content is displayed (in form of short videos), solve technical problems and enhance the audio quality of the guided imagery exercises. Subsequently, the promising preliminary results and implementation of PartnerCARE into standard care will be further investigated in a randomized controlled efficacy evaluation trial. The process was initiated to provide a reliable, long-lasting support offer for partners.

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CONFLICT OF INTEREST

Harald Baumeister received consultancy fees, reimbursement of congress attendance and travel costs as well as payments for lectures from Psychotherapy and Psychiatry Associations as well as Psychotherapy Training Institutes in the context of E-Mental-Health topics. He has been the beneficiary of study support (third-party funding) from several public funding organizations. All other authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

Daniela Bodschwinna, Natalie Bauereiß, Harald Gündel, Harald Baumeister and Klaus Höning contributed to the conception and design of this study. Daniela Bodschwinna and Inga Lorenz collected the content of the intervention sessions. The online design and structure of the intervention was carried out from Daniela Bodschwinna building on prior online interventions of the department of Clinical Psychology and Psychotherapy (Harald Baumeister). Intervention development was supervised by Natalie Bauereiß, Harald Gündel, Harald Baumeister and Klaus Höning. Daniela Bodschwinna was responsible for recruitment, coordination of the study and data analyses. Daniela Bodschwinna drafted the manuscript. All authors provided critical revision and approved the final manuscript.
DATA AVAILABILITY STATEMENT
The data that support the findings of this study are available from the corresponding author upon reasonable request.

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