

ORIGINAL ARTICLE



Moderators and mediators of emotion regulation therapy for psychologically distressed caregivers of cancer patients: secondary analyses from a randomized controlled trial

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ABSTRACT

Background: Being an informal caregiver (IC) of a cancer patient is often associated with psychological distress. We have recently, in a randomized controlled trial (RCT), demonstrated efficacy of Emotion Regulation Therapy for ICs (ERT-C), evidenced as lower levels of psychological distress. Such efficacy demonstration is important, but a crucial step in improving treatments for the IC population is the identification of moderators (i.e., for whom the treatment works) and mediators (i.e., the drivers of the detected effect).

Material and methods: In a sample of 65 psychologically distressed ICs (combining participants who received immediate and delayed treatment in the RCT); we investigated age, gender, and homework completion as moderators of treatment outcome. Proposed mediators were derived from the ERT model and included mindfulness, emotion regulation dysfunction, decentering, and cognitive reappraisal.

Results and conclusions: The strongest moderation effect was found for homework completion, predicting improvements on psychological distress. Correlational mediation analyses generally supported the ERT model. However, temporal precedence was only established for the association between decentering and worry, where a bidirectional relation was revealed. Homework thus emerged as an important aspect of ERT-C and, albeit a bidirectional relationship, changes in decentering may precede changes in worry. Future trials should ensure the robustness of these results, hone the specificity of process measures, and further investigate the causal timeline of change.

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Background

Cancer rates are increasing globally [1], resulting not only in a higher number of patients but also a higher number of informal caregivers (ICs, e.g., family members or friends) involved in their care. Meta-analyses have documented elevated levels of psychological distress expressed as anxiety and depression in ICs [2,3], which has been associated with increased perceived burden, lower social functioning, more physical and emotional problems, lower mental health, less vitality, and poorer general health [4]. Distress levels may even exceed the level detected in patients [2,5,6] and are likely to persist into survivorship [e.g., 7]. In addition to psychological distress, caregiver burden is also associated with health complications, including sleep difficulties and fatigue [8,9], cardiovascular disease [10], and increased mortality [11]. Treatments effective in alleviating negative psychological and physical consequences of caregiving are crucial both for the individual IC and for securing their ability to perform the care needed for the patient.

In a recent randomized controlled trial [RCT; 12], we tested the efficacy of emotion regulation therapy adapted for the cancer caregiver population (i.e., ERT-C). ERT was originally developed to treat chronic anxiety with or without depression and has now gained empirical support [13–15]. It is a cognitive behavioral therapy (CBT), but compared to more traditional CBTs, ERT is more explicit in the delineation of the functional role of emotions and underlying motivational conflicts [16]. In the RCT, we randomized 81 psychologically distressed ICs to ERT-C or a waitlist. ICs in the ERT-C group experienced significant reductions in psychological distress, worry, and perceived caregiver burden (Hedges' g : 0.53–0.96) following the course of eight sessions [12]. With these results, we were able to replicate and extend findings from a previous open trial of ERT-C [17]. Such positive outcomes of ERT-C are very promising given previous disappointing meta-analytic results of other RCTs of CBTs within the context of informal caregiving ($g = 0.04$) [18].

Demonstrating efficacy is important, but an additional crucial step in improving and optimizing treatments is the

identification of moderators (i.e., for whom the treatment works) and mediators (i.e., treatment mechanisms accounting for the detected effect) [19]. In the meta-analysis mentioned above [18], age ($B = -0.02$, $p = .046$) and proportion of female participants ($B = 0.01$, $p = .001$) were significantly associated with the magnitude of the treatment effect. Specifically, younger samples and samples with a larger proportion of women obtained larger effects, thereby underscoring the importance of investigating age and gender as potential moderators in future trials. Homework during treatment may also be a potential moderator. Indeed, homework is an integral part of most contemporary CBTs, rooted in the premise that new skills are best acquired and consolidated through training in everyday life [20]. This supposition is supported by a recent empirical study showing that greater practice of regulatory skills following mindfulness treatment was associated with increases in decentering (i.e., observing items that arise in the mind with healthy psychological distance, which is a metacognitive capacity referring to higher-order cognition where one is becoming aware of one's awareness) [21,22], and by meta-analytic evidence showing that homework enhances overall treatment outcome in CBTs [23,24].

Concerning mediators, ERT/ERT-C is a mechanism-targeted treatment committed to the empirical identification of mediators [16]. To date, two studies have investigated the indirect effect (i.e., the proportion of the total effect of ERT that works through the proposed mediator) of the theoretically proposed mediators of ERT, including global indicators of mindful emotion regulation (i.e., trait mindfulness and emotion regulation) and specific indicators of metacognitive regulation (i.e., verbal manipulation of one's experience, including decentering as described above and cognitive reappraisal, referring to the ability to reinterpret an emotion-eliciting situation in a way that alters its meaning and changes its emotional impact [25]). In an RCT investigating the efficacy of 20 sessions of ERT compared with an attention control condition in the treatment of generalized anxiety disorder with and without depression, all four proposed mediators (mindfulness, emotion dysregulation, decentering, and cognitive reappraisal) showed an indirect effect on all primary outcomes [14]. In an open trial of ERT in a sample of young adults, changes in decentering and cognitive reappraisal were found to temporally precede changes in two and three measures of anxiety symptoms, respectively [26]. Taken together, findings support the mediational role of attention and metacognition in treatment gains following ERT.

The aims of this study were 1) to evaluate the potential moderators of age and gender as derived from past meta-analytic work [18] in addition to the extent to which the IC complied with planned homework related to skills consolidation and 2) to evaluate the indirect effect of the four proposed mediators as previously investigated [14] and as pre-registered on Clinicaltrials.gov (#NCT02322905). The indirect effect of these proposed mediators was explored for the three primary outcomes on which a significant effect was detected in the RCT [12].

Material and methods

The study was pre-registered at Clinicaltrials.gov (#NCT02322905).

Participants and procedures

Eighty-one ICs with elevated distress were recruited from university hospital oncology teams treating lung, gastrointestinal, and gynecological cancers. This number was determined based on power calculation for the randomized controlled study [12]. ICs could have any relationship with the patient (e.g., friend and spouse) but had to self-identify as being a caregiver of the patient. Elevated distress was operationalized as ≥ 4 on the Distress Thermometer [27] and elevated perseverative negative thinking (i.e., Brooding Subscale of the Rumination Response Scale [RRS-B] ≥ 12) or worry (Brief Penn State Worry Questionnaire [PSWQ] ≥ 15) [28,29]. Upon having provided written informed consent, ICs were randomly allocated to either the ERT-C or a waitlist condition as described in the previous publication establishing the efficacy of ERT-C [12].

Conditions

Emotion-Regulation Therapy for Cancer Caregivers (ERT-C). ERT-C is a manualized treatment for ICs and consists of eight weekly sessions [30]. The first half (sessions 1–4) of ERT-C focuses primarily on psychoeducation and the cultivation of attention regulation skills (i.e., shifting and sustaining attention on a difficult experience) and metacognitive regulation skills (i.e., decentering from and reappraisal of emotional experiences). The second half (sessions 5–8) helps ICs utilize their learned skills toward confronting motivational dilemmas (e.g., wanting to stay by the patient's side but needing a break, seeing that it is important to talk about the end of life but being scared of doing so). This objective is accomplished through exposure exercises. Twelve master's or doctorate level students delivered the treatment and showed good manual fidelity [12].

During the *waitlist condition* which also consisted of 8 weeks, participants were free to seek medical and psychological help as needed. Four participants (12%) in this condition sought psychological help during the waitlist period (1 encounter: $N = 2$, 3 encounters: $N = 1$, and 4 encounters: $N = 1$).

Instruments

All outcomes and proposed mediators were assessed before each of the eight sessions. Homework compliance, examined as a moderator, was only evaluated seven times as it could not meaningfully be recorded at the first session. Cronbach's alphas (α) refer to the first observation point (i.e., first session) [12].

Primary outcomes

Caregiver Burden was assessed by the *Caregiver Reaction Assessment* [CRA; 31], a 24-item self-report measure that assesses multiple dimensions of caregiver burden ($\alpha = 0.89$). Scores can range from 0 to 96, with higher scores indicating higher burden.

Psychological distress was evaluated using the *Hospital Anxiety and Depression Scale* [HADS; 32,33], which is a 14-item self-rated questionnaire (anxiety and depression subscales were combined for the evaluation of distress; $\alpha = 0.91$ [33]). Scores can range from 0 to 42, with higher scores indicating higher levels of distress.

Worry was measured with the brief PSWQ [29] which is a 5-item self-rated questionnaire ($\alpha = 0.87$). Scores can range from 5 to 25, with higher scores indicating higher levels of worry.

Proposed moderators and mediators

Age and gender were obtained at the assessment meeting.

Homework compliance was evaluated by the therapist using a Likert scale from 1 (completely non-compliant) to 5 (did more than agreed upon).

Mindfulness was assessed with The *Five Facet Mindfulness Questionnaire* [FFMQ; 34] which is a 39-item self-report measure comprised five factors (i.e., observing, describing, acting with awareness, non-judging of internal experience, and non-reactivity to internal experience) measuring trait mindfulness ($\alpha = 0.89$). Scores can range from 39 to 195, with higher scores indicating higher levels of mindfulness.

Difficulties with emotion regulation were assessed with The *Difficulties in Emotion Regulation Scale* [DERS; 35] which is a 36-item measure comprised six subscales (i.e., acceptance of emotions, ability to engage in goal-directed behavior when distressed, impulse control, awareness of emotions, access to strategies for regulation, and clarity of emotions) ($\alpha = 0.95$). Scores can range from 36 to 180, with higher scores indicating more emotion regulation difficulties.

Decentering represents a metacognitive capacity to observe items that arise in the mind (e.g., thoughts, feelings, and memories) with healthy psychological distance, greater self-awareness, and perspective-taking [22], and was assessed with The *Experiences Questionnaire* [EQ; 21], using five items from the decentering subscale [36] ($\alpha = 0.79$). Scores can range from 5 to 25, with higher scores indicating better decentering ability.

Cognitive Reappraisal was assessed with the six items comprising the reappraisal subscale of the Emotion Regulation Questionnaire [ERQ; 37] ($\alpha = 0.79$). Scores can range from 7 to 42, with higher scores indicating greater use of cognitive reappraisal.

Statistical methods

Analyses were conducted on the combined sample of ICs for the time period during which they each received ERT-C (i.e., immediate and delayed ERT-C). This combined sample was used for two reasons. First, efficacy concerning the primary

outcomes and proposed mediators has already been established using the controlled design [12], and second, only during the time period of active treatment did we obtain weekly measures. Using the combined sample thus means that analyses are based on eight data points rather than the three in the controlled portion of the trial (pre-, mid-, and post-treatment) which increases the statistical power.

Multilevel models (MLMs) were chosen both for the moderation and mediation analyses because they can handle observation dependency (i.e., multiple observations for the same individual) and allow for the modeling of continuous moderators. They furthermore tolerate missing observations across the study period so that the individual appears with their number of completed observations. This way of handling missing observations, without imputations, has been shown to be an appropriate strategy [38]. The data were hierarchically arranged in two levels, with time at level 1 nested within individuals at level 2. Specifically for the moderation analyses, time (1 through 8), the moderator (age, gender, or homework), and their interaction term served as predictors of the three outcomes (HADS, PSWQ, and CRA), investigated in three separate models. Homework, as opposed to age and gender, was a time-varying moderator. Age and homework were both entered as continuous variables. Effect sizes were expressed as Cohen's d , derived from the F -test and calculated as $d = 2 \times \sqrt{(F/df)}$ [39]. Values of 0.2, 0.5, and 0.8 were taken to denote small, medium, and large effects, respectively [40].

Analyses of indirect effects followed the principles of lower-level mediation [14,41] and were based on the product-of-coefficients approach using the Stata command *ml_mediation*. The independent variable was Time (i.e., 1 through 8), the explored mediators were the FFMQ total score, DERS total score, EQ decentering, and ERQ cognitive reappraisal, and the dependent variables were the three outcomes of HADS, PSWQ, and CRA, investigated in separate models. Results were bootstrapped with 5000 iterations to obtain both bootstrapped standard errors and bias-corrected confidence intervals. Significant mediators from the separate models were explored in a combined, multilevel multiple-mediator model [42]. We did this in order to evaluate the specificity of the significant associations obtained. Effect sizes for these models were expressed as correlation coefficients. Values of 0.1, 0.3, and 0.5 were taken to denote small, medium, and large effects, respectively [40]. To address the question of temporal precedence, significant mediators were investigated in multilevel time-lagged segment analyses. In these analyses, the mediator at session _{x} , controlled for session _{$x-1$} , predicted the outcome at session _{$x+1$} , and controlled for session _{x} [26]. Thus, there was no overlap in time between the segments.

Results

The mean age of the IC sample was 47.9 years. Most ICs were female (75%) caring for male patients (73%), primarily with stage IV cancer (58%), diagnosed primarily with colon cancer (25%). Twenty-nine ICs (36%) dropped out, 23 during

treatment. Treatment dropouts were statistically significantly older (mean age = 52.7 years) than completers (mean = 45.3 years; $p = .034$) and worried less at pretreatment ($p = .026$). See Figure 1 for participant flow. In total, 65 ICs had data from at least one session and analyses were based on this sample. During treatment, the average homework completion was 3.4 (scale from 1 to 5). Missing observations for each of the time points averaged to 11.5%: Session 1 = 0%, session 2 = 0%, session 3 = 11%, session 4 = 15%, session 5 = 17%, session 6 = 18%, session 7 = 20%, and session 8 = 11%. Other baseline characteristics can be found in the parent trial [12].

Moderation analyses

Female gender was associated with a larger reduction in worry, compared to the male gender, of a small magnitude ($F = 4.4$, $p = .037$, $d = 0.21$). This was not the case for psychological distress ($F = 2.1$, $p = .146$, $d = 0.15$) or perceived burden ($F = 2.0$, $p = .154$, $d = 0.15$). Concerning age, a significant interaction of a small magnitude was revealed for perceived burden ($F = 4.6$, $p = .032$, $d = 0.22$), such that younger participants experience a larger decline in burden. For psychological distress ($F = 0.1$, $p = .801$, $d = 0.03$), and worry ($F = 0.1$, $p = .810$, $d = 0.02$) the effects were non-significant. A higher degree of homework compliance was

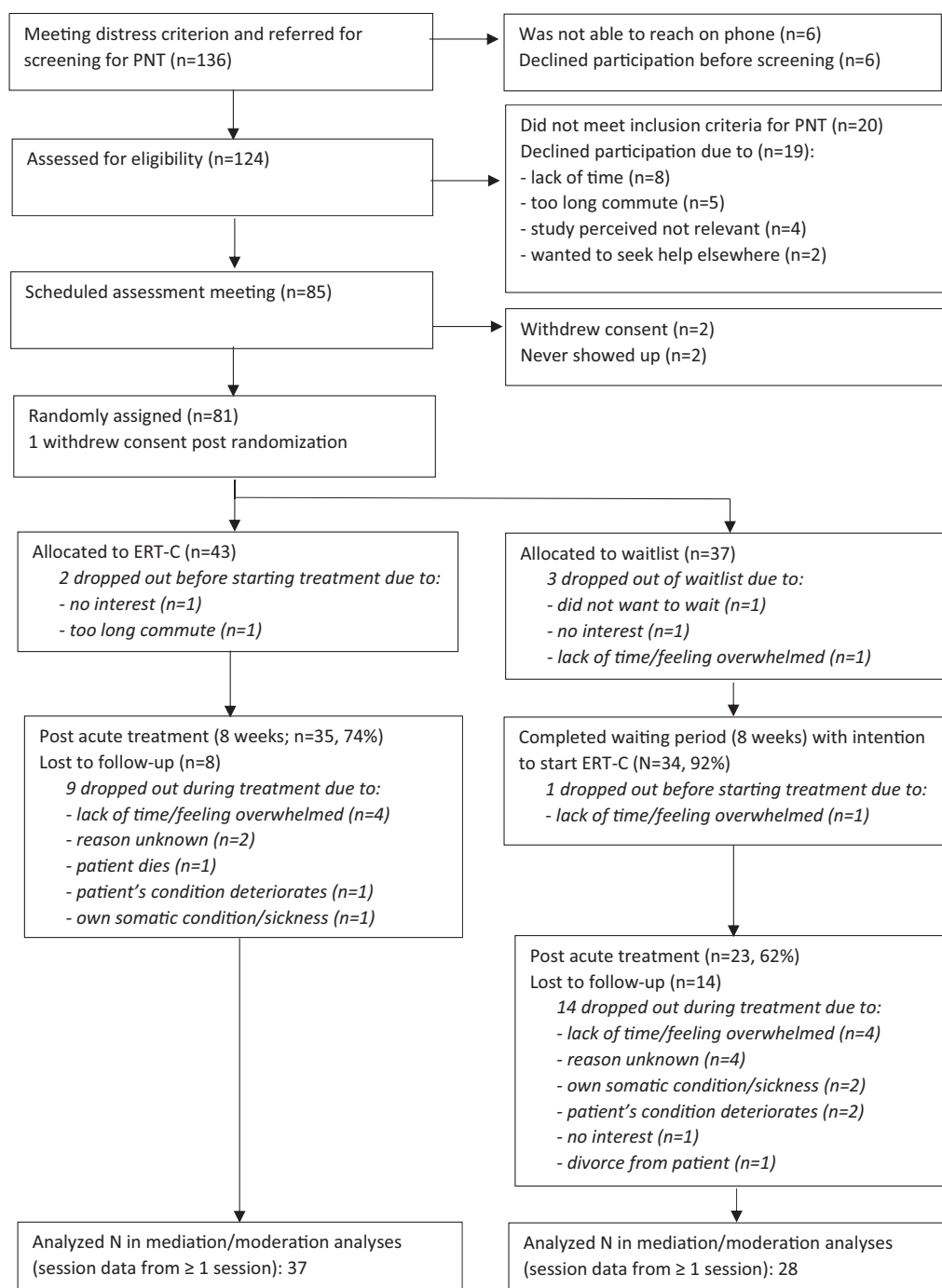


Figure 1. Participant flow diagram.

associated with lower psychological distress with an effect size approaching a medium magnitude ($F=10.5$, $p=.001$, $d=0.40$). This pattern of results was not detected for worry ($F=2.0$, $p=.164$, $d=0.17$) or perceived burden ($F=2.7$, $p=.099$, $d=0.21$), although both in the same direction and of a small magnitude. Due to recent empirical evidence showing that homework is important for skills consolidation [23], these analyses were followed up by moderation analyses with the four proposed mediators as outcomes. Greater homework compliance was associated with larger improvements in mindfulness ($F=6.8$, $p=.010$, $d=0.33$), emotion regulation ($F=5.1$, $p=.025$, $d=0.28$), and decentering ($F=6.3$, $p=.013$, $d=0.32$), but not cognitive reappraisal ($F=0.2$, $p=.681$, $d=0.06$).

Mediation analyses

The effect of time on outcomes (HADS, PSWQ, and CRA) and proposed mediators (FFMQ, DERS, EQ, and ERQ) was significant in all cases for the combined sample ($ps < .05$). Table 1 reveals zero-order correlations between outcomes and proposed mediators at baseline. With one exception (i.e., FFMQ), all four proposed mediators were associated with reductions in psychological distress and worry but not perceived burden. Over time, however, each of the proposed mediators was associated with each of the outcomes ($ps < .05$).

Concerning psychological distress, all four proposed mediators showed indirect effects when investigated separately as evidenced by confidence intervals not including 0¹ with effect sizes of a medium to large magnitude. See Table 2. In a combined model, mindfulness ($Z = -2.12$, $p = .034$, $r = 0.26$), emotion regulation ($Z = -2.92$, $p = .003$, $r = 0.37$), and decentering ($Z = -2.39$, $p = .017$, $r = 0.30$) continued to show significant indirect effects, which was not the case for cognitive reappraisal ($Z = -0.04$, $p = .969$, $r < 0.01$). Changes in psychological distress were not preceded by changes in any of the three variables (FFMQ: $Z = 0.23$, $p = .822$, $r = 0.03$; DERS: $Z = -0.81$, $p = .419$, $r = 0.10$; EQ: $Z = 0.35$, $p = .728$, $r = 0.04$).

All but cognitive reappraisal showed indirect effects on worry when investigated separately, with effect sizes of a medium to large magnitude. In a combined model, only decentering remained significant ($Z = -2.52$, $p = .012$, $r = 0.31$), not mindfulness ($Z = -1.27$, $p = .204$, $r = 0.16$) or emotion regulation ($Z = -0.87$, $p = .382$, $r = 0.11$). Changes in decentering, temporally preceded changes in worry ($Z =$

-2.77 , $p = .006$, $r = 0.34$), however, the reverse direction was also significant ($Z = 2.17$, $p = .030$, $r = 0.27$) and of a similar magnitude.

Finally, all but cognitive reappraisal showed indirect effects on perceived burden when investigated separately, with effect sizes of a medium to large magnitude. In a combined model, only emotion regulation remained significant ($Z = -2.72$, $p = .006$, $r = 0.34$), not mindfulness ($Z = -0.29$, $p = .863$, $r = 0.02$) or decentering ($Z = -0.67$, $p = .501$, $r = 0.08$). Changes in emotion regulation did not temporally precede changes in perceived burden ($Z = -1.20$, $p = .230$, $r = 0.15$).

Discussion

ICs of cancer patients often experience heightened levels of psychological distress. We have previously shown that it can be difficult to treat IC distress [18], but that ICs benefit from ERT-C and that patients, whose IC receives ERT-C, experience improved quality of life [12]. It is therefore important to deepen our understand of *why* and *for whom* ERT-C works. Such knowledge is important for healthcare professionals referring ICs to psychological treatment, choosing which psychotherapy to offer, and which treatment components to emphasize.

The strongest moderation effect was found for homework completion, predicting improvements on psychological distress. Since homework across CBTs is considered crucial for skills acquisition and consolidation, we further tested if homework completion in ERT-C predicted improvements in the four proposed mediators. This was the case for mindfulness, emotion regulation, and decentering. These findings underscore the important role of homework in ERT-C both for improvements on both regulatory skills and outcome. In general, homework completion was moderate to high as

Table 2. Indirect effects of proposed mediators on primary outcomes.

	<i>B</i>	BSSE	BCLL	BCUL	<i>r</i>
<i>HADS mediated by</i>					
FFMQ total score	-.03	.01	-.04	-.02	.54
DERS total score	-.03	.01	-.04	-.02	.55
EQ decentering	-.02	<.01	-.03	-.01	.48
ERQ reappraisal	-.01	<.01	-.02	-.01	.56
<i>PSWQ mediated by</i>					
FFMQ total score	-.04	.01	-.06	-.02	.46
DERS total score	-.04	<.01	-.06	-.03	.53
EQ decentering	-.04	.01	-.06	-.02	.49
ERQ reappraisal	-.01	<.01	-.02	<.01	.22
<i>CRA mediated by</i>					
FFMQ total score	-.01	<-.01	-.02	-.01	.44
DERS total score	-.02	<-.01	-.02	-.01	.46
EQ decentering	-.01	<-.01	-.01	<-.01	.31
ERQ reappraisal	<-.01	<-.01	-.01	<.01	.18

BSSE: bootstrapped standard error; BCLL: bias-corrected lower level of 95% confidence interval; BCUL: bias-corrected upper level of 95% confidence interval; DERS: difficulties in emotion regulation scale; ERQ-R: Emotion Regulation Questionnaire-Reappraisal; EQ: Experiences Questionnaire; FFMQ: Five Facet Mindfulness Questionnaire; HADS: Hospital Anxiety and Depression Scale; PSWQ: Penn State Worry Questionnaire.

Results refer to the indirect effect of the proposed mediators investigated separately. Results where the 95% CI does not include zero are in bold. Effect sizes (*r*) were approximated by transforming the observed coefficient for the indirect effect, given the bootstrapped standard error and *N*.

Table 1. Zero-order correlations between baseline measures.

	HADS	PSWQ	CRA	DERS	FFMQ	EQ
PSWQ	.55***					
CRA	.57***	.25*				
DERS	.39***	.58***	.17			
FFMQ	-.21	-.45***	-.05	-.66***		
EQ	-.44***	-.55***	-.22	-.70***	.58***	
ERQ-R	-.28*	-.28*	-.20	-.43***	.46***	.59***

* $p < .05$, *** $p < .001$.

DERS: difficulties in emotion regulation scale; ERQ-R: Emotion Regulation Questionnaire-Reappraisal; EQ: Experiences Questionnaire; FFMQ: Five Facet Mindfulness Questionnaire; HADS: Hospital Anxiety and Depression Scale; PSWQ: Penn State Worry Questionnaire.

rated by the therapist, which underscores that ICs are willing to complete homework.

The moderation analyses of age and gender revealed negligible to small effects, suggesting that females may experience a larger decrease in worry, and that younger participants may experience a larger decline in burden. However, the validity of the moderation analyses concerning age and gender may be threatened by the majority of participants included in this study being female and by dropouts being of older age. Nevertheless, these results combined with previous meta-analytic results [18] point to the importance of IC treatments ensuring their applicability to both genders and ICs of older age.

Mediators were first analyzed separately in correlation-based analyses. All but cognitive reappraisal consistently showed significant indirect effects on outcomes, thus being in support of the underlying ERT model [16]. The finding concerning skills improvement being associated with greater homework completion further provides support for the delivery format of ERT-C, where homework is stressed as a crucial treatment component. The inconsistent mediational findings concerning cognitive reappraisal, in addition to the finding that cognitive reappraisal did not improve with greater homework completion, cannot be explained by lack of treatment effect on this proposed mediator, although the effect was smaller for cognitive reappraisal ($g = 0.43$) than the other mediators [$g: 0.77\text{--}0.93$; 11]. The mediational role of cognitive reappraisal as measured with the ERQ-R [37] in treatment outcome for ICs is thus left with little empirical support. Future research should explore the role of other facets of cognitive reappraisal that more closely captures those stressed in ERT/ERT-C, namely reappraisals with respect to the individual's growing beliefs in self-focused courage and compassion [16].

The potential specificity of the proposed mediators was investigated in multiple-mediator models, where a more blurry picture emerged. These results should, however, be interpreted with caution. First, in this study, correlation coefficients between proposed mediators were relatively high (r s: $0.43\text{--}0.70$, see Table 1), which could point to between-measures overlap. Indeed, validation studies of the FFMQ for instance have shown that the various mindfulness facets correlate with specific metacognitive measures including acceptance and decentering [43,44]. Where such overlap could point to the measures' nonspecific overlap, it could, however, also point to what has been described as a dependency or order effect. Indeed, it has been theoretically argued and empirically documented, that attention regulation change precedes metacognitive regulation change because decentering, for instance, inherently relies on the individual paying attention to and being mindfully aware of their experience [22,45]. For now, the question of between-measure specificity in terms of their indirect effects remains largely unanswered.

We further tested the proposed mediators' temporal relation to the outcomes and found a bidirectional relation between decentering and worry. Changes in decentering preceded changes in worry and vice versa, thus partly replicating past ERT trial findings [26]. In the IC population, this

temporal relation between decentering and worry may or may not be specific to ERT-C, but the results are promising in that they elucidate a potential causal pathway to lowering worry. The lack of general demonstration of temporal precedence may be due to the lower number of sessions and a non-psychiatric population in this compared to past ERT trials (offering 16 and 20 sessions).

The present findings should be viewed in light of some limitations. First, most analyses were based on a correlational approach (i.e., products-of-coefficients) preventing causal interpretation, and only one significant finding was detected in analyses taking the timeline of change into account. Given the number of analyses conducted, thereby increasing the risk of a type-I error, these results should be replicated in future trials to ensure their robustness. Second, the relatively low number of participants poses a threat both to generalizability and to the statistical power. Our ability to detect effect sizes of small to medium magnitudes as statistically significant partly alleviates the latter concern. Third, without an active or competing treatment group, the specificity of the findings to ERT-C cannot be established. Third, the ICs included in this study were caring for patients with lung, gastrointestinal, and gynecological cancers, and were selected based on the presence of psychological distress (i.e., ≥ 4 on the distress thermometer and elevated perseverative negative thinking). Results can therefore only be generalized to this subgroup of ICs. Finally, a majority of females in the included sample, and an uneven dropout rate in terms of age, limit the moderation analyses concerning gender and age. Related to this finding, it cannot be ruled out that attrition may have been associated with the burden of homework completion.

Concerning clinical implications, the present findings underscore the important role of homework in ERT-C both in terms of improvements on the skills taught as well as outcome. Further understanding the role of homework, including identifying the type and dosage needed, is crucial in order to help strike the balance between amount of practice and resources available in this burdened population. Moreover, the data in past and the present trial concerning mediation provide support for the ERT model. In a recently funded trial (NIH; 1R01CA244185-01A1), we will further investigate mediators of the effect of ERT-C. Important future points of attention include honing the specificity of process measures as well as further investigating the causal timeline of change. Finally, our results underscore the benefits to cancer patients of addressing IC distress, and more broadly the necessity to consider caregivers as key members of treatment teams.

Conclusions

ERT-C has received empirical support for its efficacy in treating ICs of cancer patients. Its effects on skills taught during the course of treatment and psychological distress are associated with the degree of homework completion during treatment. Correlation-based mediation analyses provided general support for the ERT model. In terms of timeline of change,

changes in decentering preceded changes in worry and vice versa. This finding needs to be replicated but is an important step in understanding the causal pathway to lowering worry.

Note

1. The proportion of total effect mediated, which is often used as an effect size measure in this kind of analysis, in many cases exceed 1 because the indirect effect was larger than the direct effect.

Ethics approval

The study was approved by the local ethical committee (#1-10-72-430-14).

Disclosure statement

The authors have no conflicts of interest to declare.

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Data availability statement

The data that support the findings of this study are available upon request from the corresponding author.

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