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Permalink

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Journal

Journal of Consulting and Clinical Psychology, 86(4)

ISSN

0022-006X

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Publication Date

2018-04-01

DOI

10.1037/ccp0000294

Peer reviewed



Published in final edited form as:

J Consult Clin Psychol. 2018 April ; 86(4): 367–371. doi:10.1037/ccp0000294.

Treatment Expectancy and Working Alliance in Pharmacotherapy as Predictors of Outcomes in Complicated Grief

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Abstract

Objective—Nonspecific factors such as treatment outcome expectancy and working alliance can influence treatment outcome. No studies to date have examined the role of expectancy and alliance on pharmacotherapy outcomes in individuals with complicated grief (CG).

Method—This secondary analysis of a larger RCT examined the relationship between pharmacotherapy expectancy and alliance on treatment outcome in adults with CG who were participating in a multi-site, double-blind, randomized controlled trial examining the efficacy of citalopram and complicated grief treatment (CGT). Participants ($n = 202$) were randomized to one of four treatment conditions: citalopram (CIT), placebo (PBO), CGT + citalopram (CGT+CIT), or CGT + placebo (CGT+PBO).

Results—Pharmacotherapy outcome expectancy and working alliance were higher among individuals randomized to CGT + CIT and CGT + PBO compared to CIT or PBO without CGT. Pharmacotherapy outcome expectancy was higher at Week 2 among individuals who ultimately responded to treatment compared to those who did not, and among those who remained in

treatment compared to those who dropped out. In contrast, working alliance did not correlate with dropout or treatment outcomes in pharmacotherapy.

Conclusions—Expectancy for medication was higher among individuals randomized to receive CGT. Clinicians should assess symptoms and expectancies in the first weeks of treatment, as these could be early markers of drop out and treatment response.

Keywords

complicated grief; outcome expectancy; working alliance; treatment outcome; randomized controlled trial

Nonspecific treatment factors, including outcome expectancy (Greenberg, Constantino, & Bruce, 2006) and working alliance (Lambert & Barley, 2001), are associated with improved treatment outcomes. Nonspecific factors, which can be integrated into evidence-based practice (see Barth et al., 2012 for a review), are estimated to account for a larger portion of variance than treatment-specific factors and placebo effects, which account for similar proportions of variance in psychotherapy outcomes (Asay & Lambert, 1999).

Outcome expectancy, or a patient's expectation for improvement as a result of participating in treatment (Constantino, Arnkoff, Glass, Ametrano, & Smith, 2011), facilitates outcomes in psychotherapy (Constantino et al., 2011) and pharmacotherapy (Rutherford, Wager, & Roose, 2010). Response rates are higher in open-label pharmacotherapy studies (Kim & Halloway, 2003) than placebo-controlled studies, presumably because patients know they are receiving active medication (Rutherford et al., 2016). One theory of placebo effect, the expectancy theory, states that the expectation for an experience leads to that experience (Kirsch, 1997). In fact, expectancy may mediate the placebo effect (Rutherford et al., 2016).

Working alliance refers to the quality of the therapist-patient relationship, usually measured in a way which encompasses the personal bond along with the mutual agreement about treatment goals and how best to achieve them (Tracey & Kokotovic, 1989). Alliance is consistently associated with psychotherapy outcome (Baldwin, Wampold, & Imel, 2007). A less-developed but initially promising literature suggests that there may be a relationship between alliance and outcomes in pharmacotherapy as well (Barber et al., 2014). The precise mechanism is unclear, but positive appraisals of the working alliance may increase a patient's confidence in the treatment thereby enhancing outcome expectancies.

The impact of expectancy and working alliance on pharmacotherapy treatment outcomes in individuals with complicated grief (CG) has not been previously examined. Initial studies suggested that pharmacological interventions, specifically antidepressant medications, had promise in treating CG (Hensley, Slonimski, Uhlenhuth, & Clayton, 2009). However, the randomized controlled clinical trial from which data in the current study were obtained failed to demonstrate a difference in post-treatment CG symptoms between the antidepressant medication citalopram and pill placebo (Shear et al., 2016).

The present study was a secondary analysis of a multi-site, double-blind, randomized controlled trial examining the efficacy of an antidepressant medication, the serotonin selective reuptake inhibitor (SSRI) citalopram, alone or in combination with CGT for adults

with CG. We were interested in examining the relationship between both pretreatment pharmacotherapy expectancy and working alliance with the pharmacotherapist on CG symptom improvement and dropout from treatment. Participants were recruited at four academic medical centers and randomized to one of four treatment conditions: citalopram (CIT), pill placebo (PBO), CGT + citalopram (CGT+CIT), or CGT + placebo (CGT+PBO). In the original study, controlling for site variation, response rates were higher for CGT+PBO (83%) than PBO (55%) and CGT+CIT (84%) than CIT (69%), and showed equivalent results for CGT+CIT and CGT+PBO. The purpose of this secondary analysis was to determine whether treatment expectancies and the therapeutic alliance might account for pharmacotherapy not being as effective as it was when delivered in combination with CGT. We were interested in whether adding CGT to medication or placebo was associated with higher expectancies for pharmacotherapy and higher alliance scores with pharmacotherapists, perhaps because participants viewed stand-alone medication treatment for grief as less effective than medication delivered in combination with psychotherapy. We hypothesized that (a) participants receiving medication without CGT would report lower expectancies for medication treatment response than participants assigned to CGT, (b) participants who endorsed greater expectancy and working alliance would demonstrate lower dropout rates and (c) participants who endorsed higher expectancy and alliance would demonstrate greater treatment response later regardless of treatment assignment. As an exploratory analysis, we were interested in examining whether CGT assignment status moderated the relationship between treatment expectancy and working alliance and outcome.

Methods

Participants

Full details regarding the methodology can be found in the report of primary outcomes (Shear et al., 2016). Briefly, following informed consent obtained in accordance with institutional Internal Review Board standards, individuals ($N = 395$) who scored ≥ 30 on the Inventory of Complicated Grief underwent a baseline assessment with an independent evaluator (IE) blind to treatment condition. Those with primary CG were eligible for randomization. Current substance use disorder, lifetime psychotic or bipolar I disorder, suicidality requiring hospitalization, cognitive impairment, pending legal issue related to the death, and concurrent treatment were exclusionary. Data from one of the four sites ($n = 111$) were not eligible for inclusion because of a procedural error that resulted in the majority (88.29%) of participants not completing expectancy or working alliance forms. Of eligible participants ($n = 284$), 202 participants who attended session 1 and completed expectancy and working alliance forms were included for this secondary analysis. An additional 82 individuals were not included in this analysis as a result of not having completed measures of expectancy and alliance.

Procedure

After baseline assessment, participants were assigned to protocolized pharmacotherapy with flexible dosing. The pharmacotherapists ($n = 19$) were primarily psychiatrists (89%) with one Pharm.D. and one R.N. who were knowledgeable about CG. Pharmacotherapy included

emphasis on a clear rationale for treatment using antidepressant medication, building a strong therapeutic alliance, psychoeducation about CG and medication use, and provision of support. Those randomized to CGT were also assigned a psychotherapist. Participants completed follow-up assessments at 4, 8, 12, 16, and 20 weeks after the first treatment visit and 6 months after study termination. All measures were completed at each assessment period, with the exception of the outcome expectancy and working alliance measures which were completed at the second treatment visit in Week 2. Outcomes were examined at Week 12 as this time was the primary pharmacotherapy outcome assessment in the parent study.

Measures

Clinician Global Impressions – Improvement and Severity of Illness (CGI-I, CGI-S)—Treatment response was defined as a rating of 1 (“very much”) or 2 (“much”) improved on the CGI-I. The CGI-I and CGI-S (Guy, 1970) is a 7-point scale widely used in clinical trials to measure symptom improvement and severity, respectively. Each point represents a distinct characterization of wellness and overall improvement since baseline. A full description of the CGI-S and CGI-I adapted in relation to grief symptoms is provided in the primary outcome paper (Shear et al., 2016). A rater blind to treatment assignment and trained to reliability on the CGI-I completed assessments that were audio recorded. To remain consistent with the parent study, our primary outcome was pre-specified as a binary version of the CGI-I, with responder defined as much or very much improved and non-responder defined as any other category. Inter-rater agreement on IE CGI-I ratings used to determine treatment response was good ($Kappa = 0.89$).

Inventory of Complicated Grief (ICG)—The ICG (Prigerson et al., 1995) is a reliable and valid 19-item self-report used to assesses CG symptoms severity. Items are rated on a 0 – 4 Likert scale. Total scores range from 0 – 76, and higher scores indicate greater severity.

Treatment Outcome Expectancy—This is a widely adapted measure designed to assess the patient’s perceived credibility of the treatment (Borkovec & Nau, 1972; Holt & Heimberg, 1990). We used the first three items to assess pharmacotherapy outcome expectations. Participants were asked to rate how logical the treatment seemed, how successful they thought it would be in reducing grief symptoms, and how likely they would be to recommend the treatment to a friend. Total scores ranged from 3 – 27 with higher scores indicating higher expectancy. This measure is widely used in clinical outcome studies (e.g., Rodebaugh, Holaway, & Heimberg, 2004) and has good internal reliability (Devilley & Borkovec, 2000). Internal consistency in the current sample was good (Cronbach’s $\alpha = .89$).

Working Alliance Inventory-Short Form—The WAI-SF (Tracey & Kokotovic, 1989) is a 12-item self-report measure commonly used as a measure of therapeutic alliance. Three subscales measure agreement on goals for treatment, agreement on therapeutic tasks, and perception of therapeutic bond. Participants completed this with regard to their relationship with their pharmacotherapist. Ratings are given on a 7-point Likert scale. Total scores range from 12 – 84 with higher scores reflecting a stronger working alliance. Consistent with its use in other studies (e.g., Arnow et al., 2013) and to reduce risk for Type I error, working alliance was measured as an aggregate score rather than by its three subscales. The WAI-S

has good internal reliability for the composite score (Cronbach's $\alpha = .91$) (Busseri & Tyler, 2003). Internal consistency in the current sample was good (Cronbach's $\alpha = .87$).

Data Analysis

Descriptive statistics for continuous variables are reported as means and standard deviations. Categorical variables are reported as frequencies and distributions. Demographic and clinical variables at baseline were compared between patients who completed measures of expectancy and working alliance and patients who did not, using chi-squared tests for categorical variables and two-sample t-tests for continuous variables. Consistent with the parent study, the same statistical approaches were used to compare treatment expectancy and working alliance between treatment responders (CGI-I = "much" or "very much improved") and non-responders (all other CGI-I ratings), as well as between medication treatment completers and those who dropped before week 12. To assess whether the relationships between expectancy and outcome and alliance on outcome varied by CGT status, stratified analyses were performed. Statistical significance was defined using a two-tailed alpha = 0.05. Data were analyzed using SAS 9.3.

Results

Participants were mostly female (75%), white (81%), and had completed college (57%). The mean age was 51.51 ($SD = 13.59$). Relation to the deceased varied and included partner (36%), parent (34%), child (16%), and friend or other relative (14%). Average time since loss was 4.77 years ($SD = 6.47$). There were no differences between the study sample and those who were excluded in age ($p = .98$), gender ($p = .47$), race ($p = .65$), education ($p = .18$), marital status ($p = .61$), relationship to the deceased ($p = .21$), time since loss ($p = .49$), or CG symptom severity ($p = .77$). Those not included in this analysis because they did not complete the expectancy and alliance forms were more likely to drop out (63% vs. 24%, $\chi^2 = 39.02$, $p < .001$).

Descriptive statistics for outcomes, expectancy, and working alliance are presented in Table 1. Outcome expectancy was correlated with working alliance ($r = .59$, $p < .0001$). Baseline CG severity as measured by the ICG score was not correlated with either outcome expectancy ($r = .05$, $p = .46$) or working alliance ($r = .09$, $p = .20$). Evidence supported our first hypothesis, that expectancy was higher at Week 2 among participants receiving CGT +CIT ($M = 21.89$, $SD = 4.10$) compared to CIT (16.30, $SD = 6.84$), $p < .0001$ and those receiving CGT+PBO ($M = 20.91$, $SD = 5.10$) compared to PBO ($M = 15.74$, $SD = 5.69$), $p < .0001$. Working alliance was higher at Week 2 among participants receiving CGT+CIT ($M = 68.25$, $SD = 9.95$) compared to CIT (61.58, $SD = 13.75$), $p < .0001$ and those receiving CGT+PBO ($M = 68.67$, $SD = 10.28$) compared to PBO ($M = 56.55$, $SD = 14.73$), $p < .0001$. There were no differences between the two pharmacotherapy conditions or the two CGT conditions, p 's $> .05$ (see Table 1).

Evidence was mixed with respect to our second hypothesis. Expectancy was lower among those who dropped out of pharmacotherapy ($n = 49$: $M = 15.41$, $SD = 6.60$) compared to those who were still in treatment ($n = 153$: $M = 20.10$, $SD = 5.43$), $t(200) = 4.99$, $p < .0001$, *Cohen's d* = 0.82. However, there was no evidence of a difference in working alliance

between those who dropped out of pharmacotherapy ($n = 49$: $M = 61.65$, $SD = 13.28$) and those who did not drop out ($n = 153$: $M = 65.12$, $SD = 12.85$), $t(200) = 1.63$, $p = .105$, *Cohen's d* = 0.27.

Evidence was mixed with respect to our third hypothesis. Expectancy was higher among those who responded to treatment ($n = 94$: $M = 20.79$, $SD = 5.15$) compared to those who did not ($n = 76$: $M = 17.47$, $SD = 6.26$), $t(168) = 3.79$, $p < .001$, *Cohen's d* = 0.58. Contrary to expectation, there was no evidence of a difference in working alliance for those who responded to treatment ($n = 94$: $M = 65.38$, $SD = 12.31$) and those who did not ($n = 76$: $M = 62.57$, $SD = 14.40$), $t(168) = 1.37$, $p = .17$, *Cohen's d* = 0.21.

The results of our exploratory hypothesis suggested that assignment to CGT did not modify the relationship between expectancy or alliance on any of the outcomes examined with one exception. Among participants receiving CGT, working alliance was significantly lower among those who dropped out of pharmacotherapy ($n = 25$: $M = 64.68$, $SD = 11.08$) compared to those who did not ($n = 85$: $M = 69.56$, $SD = 9.54$), $t(108) = 2.17$, $p < .05$, *Cohen's d* = 0.49.

Discussion

In this secondary analysis of a multisite RCT, randomization to concurrent CGT, a targeted psychotherapy for CG, was associated with higher expectations for medication treatment and higher working alliance with the pharmacotherapist. Consistent with our hypothesis, higher outcome expectancy early in treatment was associated with better outcomes and lower dropout from pharmacotherapy. In contrast, working alliance was not associated with treatment outcomes regardless of treatment assignment, with the exception of those receiving CGT and medication for whom lower alliance was associated with higher pharmacotherapy drop out. These findings, which suggest that grief symptom reductions are more likely to occur in the context of positive expectations for treatment than positive regard for the pharmacotherapist, support the expectancy theory, which may explain the placebo effect (Kirsch, 1997). Belief in the treatment may be more important for symptom improvement than belief in the provider of that treatment.

Randomization to CGT further enhanced positive expectations about medication effectiveness, underscoring the importance of psychosocial treatments in the intervention of CG. Participants' expectations were perhaps bolstered by having multiple providers, exposure to multiple interventions, or because of a belief that medication outcomes will be better when given the opportunity to address grief in psychotherapy. Patients may prefer a structured-grief-focused psychotherapy over medication alone, even if the latter is delivered with extra support from the prescriber (as was the case in this study). Although treatment preference was not systematically assessed in the current study, anecdotally we observed that many participants had preferences for CGT. Having preference for therapy, and then being randomly assigned to a pharmacotherapy only arm of treatment, may have attenuated outcome expectations for this subsample and may explain the relationship between dropout and noncompletion of alliance and expectancy measures. Although preference is distinct from treatment expectancy, preference is known to influence both expectancy and alliance

(Mergl et al., 2011) and may affect willingness to receive treatment and moderate outcomes in randomized controlled trials (Le, Doctor, Zoeller, & Feeny, 2014).

There are several limitations. First, our sample was limited to individuals participating in a RCT, which limits generalizability to adults seeking treatment for CG in real-world settings. Second, we did not measure symptom change between baseline and Week 2 of the study. An alternative explanation of our findings is that early symptom change led to differences in outcome expectancy and alliance at Week 2. Third, neither expectancy and working alliance nor CG severity were measured in an ongoing manner (session-by-session) throughout treatment. Evidence suggests that working alliance strengthens as treatment progresses (Arnow et al., 2013). Similarly, if patients became aware of the ineffectiveness of medication over time they may have disengaged from treatment. We cannot comment on how the development of expectancy and alliance or patient perceptions of symptom improvement impacted CG treatment outcomes and dropout. Lastly, missing data was a significant limitation. We did not have treatment response data on all of the participants. Importantly, we did not have expectancy and alliance measures for a subset of the sample that was ultimately excluded. Their non-completion could be related to low expectancy and alliance ratings or treatment assignment dissatisfaction.

Conclusions

In working with patients with CG, pharmacotherapists are encouraged to make explicit efforts to increase outcome expectancy and provide opportunity for involvement in evidence-based, grief-focused psychotherapy.

Acknowledgments

Grant sponsor information: This work was supported by a grant from the National Institute of Mental Health: R01MH085297; and a grant from the American Foundation for Suicide Prevention: LSRG-S-172-12. Naomi M. Simon has received research support from the American Foundation for Suicide Prevention, Department of Defense, Highland Street Foundation, and NIH. Her spouse has equity in G1 Therapeutics.

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Public health significance statement

Complicated grief is a distressing, impairing and understudied condition; identifying predictors of treatment response, such as expectancies and working alliance, could improve interventions and patient outcomes.

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Table 1

Descriptive statistics for outcome measures.

	Baseline <i>M</i> (<i>SD</i>)	Week 12 <i>M</i> (<i>SD</i>)
CIT		
ICG	41.9 (7.4)	24 (12)
CGI-S	4.90 (0.71)	3.41 (1.26)
Expectancy	16.30 (6.84)	–
WAI-SF	61.58 (13.75)	–
Responder Status (%)		69%
PBO		
ICG	42.8 (9.6)	25.9 (12.3)
CGI-S	4.83 (0.70)	3.86 (1.07)
Expectancy	15.74 (5.69)	–
WAI-SF	56.55 (14.73)	–
Responder Status (%)		55%
CGT+CIT		
ICG	43.6 (10.1)	23.6 (12.3)
CGI-S	4.86 (0.72)	3.28 (1.34)
Expectancy	21.89 (4.10)	–
WAI-SF	68.25 (9.95)	–
Responder Status (%)		84%
CGT+PBO		
ICG	42.1 (7.6)	25.3 (10.7)
CGI-S	4.80 (0.63)	3.45 (1.28)
Expectancy	20.91 (5.10)	–
WAI-SF	68.67 (10.28)	–
Responder Status (%)		83%

Note. CIT = citalopram. ICG = Inventory of Complicated Grief. CGI-I = Clinical Global Impressions – Improvement. CGI-S = Clinical Global Impressions – Severity. WAI-SF = Working Alliance Inventory – Short Form. PBO = placebo. CGT = Complicated Grief Therapy. Baseline WAI-SF and Expectancy assessment occurred at 2 weeks.