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The Nature, Timing, and Symptom Trajectories of Dropout From Transdiagnostic and Single-Diagnosis Cognitive-Behavioral Therapy for Anxiety Disorders

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Dropout from psychotherapy is common and can have negative effects for patients, providers, and researchers. A better understanding of when and why patients stop treatment early, as well as actionable factors contributing to dropout, has the potential to prevent it. Here, we examined dropout from a large randomized controlled trial of transdiagnostic versus single-diagnosis cognitive-behavioral treatment (CBT) for patients with anxiety disorders (n = 179; Barlow

et al., 2017). We aimed to characterize the timing of and reasons for dropout and test whether participants who dropped out had different symptom trajectories than those who completed treatment. Results indicated that overall, the greatest risk of dropout was prior to the first treatment session. In single-diagnosis CBT, dropout risk was particularly elevated before the first session and after other early sessions, whereas in transdiagnostic CBT, dropout risk was low and stable before and during treatment. Participants most often dropped out due to failure to comply with study procedures or dissatisfaction with or desiring alternative treatment. Results from multilevel models showed that trajectories of anxiety symptoms did not significantly differ between dropouts and completers. These findings suggest that there may be specific time windows for targeted and timely interventions to prevent dropout from CBT.

Keywords: cognitive-behavioral therapy; CBT; transdiagnostic; dropout; attrition

THERE is a large literature supporting the efficacy of cognitive-behavioral therapy (CBT) for the treatment of anxiety and related disorders (see Hofmann & Smits, 2008). However, rates of attrition from CBT are considerable, with estimates ranging from 9 to 35% (Fernandez et al., 2015; Taylor et al., 2012). The variability in these estimates may in part be accounted for by discrepancies in how attrition has been defined (e.g., Keijsers et al., 2001; Salmoiraghi & Sambhi, 2010). The most common definitions of "attrition" (or "dropout," terms used interchangeably hereafter) in the psychotherapy literature include attending fewer than a specified number of sessions, not completing a protocol, or failure to attend a scheduled session without rescheduling or attending future sessions (e.g., Swift & Greenberg, 2012).

Dropout from CBT is problematic from clinical and research perspectives. Completing more sessions of CBT is associated with improved symptom and functional outcomes (Glenn et al., 2013). In contrast, premature termination reduces the likelihood that patients receive a sufficient dose of treatment (e.g., Barrett et al., 2008; Glenn et al., 2013) and has been linked to dissatisfaction with treatment, less robust symptom change, and failure to maintain gains over time (e.g., Issakidis & Andrews, 2004; Niles et al., 2017; Salmoiraghi & Sambhi, 2010; Swift & Greenberg, 2014). For researchers, cumulative dropout in clinical trials may result in large amounts of missing data, inadequate statistical power, and biased samples over time, rendering investigators unable to draw strong conclusions about treatment effects. Such consequences of dropout highlight the importance of improving our understanding of the nature and timing of dropout from CBT, as well as the factors that predict attrition, to improve the ability to prevent it.

Overall, little is known about the *temporal patterns* of dropout in CBT for anxiety disorders. There is some evidence to suggest that large proportions of patients drop out before the first appointment, with rates of pretreatment attrition ranging from 16 to up to 50% across studies (Barrett et al., 2008; Fernandez et al., 2015; Gutner et al., 2016; Issakidis & Andrews, 2004). Among those who begin treatment and subsequently drop out, the majority tend to terminate within early sessions or the first half of treatment (Ahmed & Lawn, 2012; Coles et al., 2004). In addition to dropout timing, considering individual-level reasons for dropout may be important. Whereas some patients drop out due to factors that prevent them from engaging with or successfully responding to treatment (e.g., ambivalence toward therapy, symptom severity and overall impairment, structural barriers [e.g., time, transportation]), others may decide they no longer need services after experiencing improvement in symptoms (e.g., Szafranski et al., 2017). Those who drop out because they are not seeing improvement and those who drop out due to determining they no longer need care likely represent distinct subpopulations warranting different responses aimed to prevent dropout.

In terms of factors associated with dropout, the majority of the CBT literature has focused on identifying *baseline* predictors, including fixed characteristics of both treatments and individual patients. In a meta-analysis of 115 studies, for example, Fernandez et al. (2015) reported that online CBT treatments were associated with the highest rates of dropout, followed by group and then individual CBT. Another study of attrition during CBT for posttraumatic stress disorder (PTSD) reported no differences in dropout rates between treatment protocols, which included prolonged exposure (PE), cognitive-processing therapy (CPT), and CPT–cognitive only (CPT-C; Gutner et al., 2016). Little research has directly compared attrition rates between newer transdiagnostic (i.e., designed to be applicable across a range of disorders) and single-diagnosis CBT protocols. Regarding patient-level predictors of attrition, findings have been inconsistent in the context of CBT for anxiety disorders (Taylor et al., 2012). Some data suggest that milder pretreatment symptom severity and higher levels of baseline motivation are associated with lower attrition, whereas baseline anxiety and depression comorbidity is associated with a

higher likelihood of dropout (Issakidis & Andrews, 2004; Keijsers et al., 2001; Taylor et al., 2012). Other studies, however, have not replicated these findings (e.g., Eskildsen et al., 2010; Hoyer et al., 2016; Keijsers et al., 2001). There is more consistent consensus that age and education level, as well as practical barriers (e.g., transportation, child care, cost), predict dropout (e.g., Keijsers et al., 2001; Santana et al., 2013; Taylor et al., 2012).

Whereas understanding fixed, baseline predictors of dropout can help identify who is most at risk for dropout, these "usual suspects" (e.g., demographic characteristics, baseline diagnoses) are not particularly actionable for providers. Thus, more recent work has focused on identifying *modifiable* or *time-varying* factors that contribute to dropout. Dynamic factors are promising candidates for interventions aimed to improve retention—for instance, by tailoring treatment if "red flag" patterns appear or informing the delivery of just-in-time interventions via mobile technologies (Nahum-Shani et al., 2016)—for example, individuals may receive app-based messages aimed to prevent dropout to their smartphone at the moments of elevated dropout risk.

Regarding dynamic and modifiable factors, there is evidence to suggest that greater motivation to engage in treatment, a stronger therapeutic alliance, and greater therapist adherence to CBT protocols are associated with less dropout from CBT for anxiety disorders (e.g., Haug et al., 2016; Keijsers et al., 2001). Findings are more mixed as to whether patients who experience less symptom change during treatment are more likely to drop out. A number of earlier studies have shown an association between poor outcome (especially early on) in CBT for anxiety or depression and dropout (e.g., Cahill et al., 2003; Lutz et al., 2014; Schindler et al., 2013). In a more recent study, however, Zieve et al. (2019) found that among adults in CBT (N = 1,092), rates of anxiety and depressive symptom change did not differ between dropouts and completers. Recent work has also used advanced modeling approaches to predict dropout using a combination of baseline and dynamic factors assessed over time, and suggested that variations in symptom trajectories, as well as the timing of therapeutic gains, may be associated with risk of dropout (e.g., Lutz et al., 2018). Given the inconsistent findings in this area (and surprisingly little research overall; e.g., Fernandez et al., 2015; Swift et al., 2017), more research is needed to better understand the relationship between symptom change during CBT and dropout. This line of work has the potential to identify optimal windows and targets for intervention.

The Present Study

This investigation is a secondary analysis of a recent randomized clinical equivalence trial of two CBT approaches for anxiety disorders (Barlow et al., 2017). The trial was designed to compare a transdiagnostic CBT protocol for emotional disorders (i.e., anxiety, depression, and related disorders), the Unified Protocol (UP) for Transdiagnostic Treatment of Emotional Disorders (Barlow et al., 2011, 2018), to gold-standard single-disorder CBT protocols (SDPs) for individual anxiety disorders. Participants with a principal diagnosis of social anxiety disorder (SOC), generalized anxiety disorder (GAD), panic disorder (PD), or obsessive-compulsive disorder (OCD) were randomized to the UP, the SDP corresponding to their principal diagnosis, or a wait-list control. Barlow et al. (2017) previously reported that participants who received the UP evidenced equivalent symptom reduction as those in the SDP condition, and were less likely to drop out from therapy (defined as completing less than 75% of the prescribed number of sessions). Here, we expand upon these findings by examining the timing of when participants dropped out from treatment, the reasons for treatment dropout, and symptom trajectories associated with treatment dropout. We hypothesized that most dropout would occur before or within the first few treatment sessions, but did not have hypotheses regarding reasons for dropout. We hypothesized that trajectories of anxiety symptoms would differ between dropouts and completers, with dropouts evidencing less change than completers.

Method

PARTICIPANTS

Participants were individuals seeking treatment at the Center for Anxiety and Related Disorders (CARD) at Boston University, either self-referred or through word-of-mouth referrals from former CARD patients, referrals from nearby medical and mental health professionals, local publicity about CARD or the study, and advertisements in local media. Advertisements, as well as the informed consent, described the study as comparing a new psychological treatment designed to apply to a variety of emotional disorders (UP) and other existing treatments for anxiety disorders (SDPs). The informed consent also summarized similarities (e.g., monitoring emotional patterns and learning strategies to manage anxiety, containing widely

used and effective CBT components) and differences between the treatment approaches (e.g., SDPs focusing primarily on symptoms of the primary disorder, UP focusing on core features cutting across disorders). The UP was explicitly framed as the "research treatment under investigation."

Study inclusion criteria were designed to be broadly inclusive; individuals were eligible for study participation if they were (a) assigned a principal (i.e., most interfering and severe) diagnosis of SOC, GAD, PD, or OCD; (b) fluent in English; and (c) 18 years or older. Consistent with longstanding procedures for clinical trials conducted at CARD, participants taking psychotropic medications were required to be stable for at least 6 weeks prior to study enrollment and were asked to not make any changes to their medications and dosages during treatment. Exclusion criteria consisted primarily of conditions where immediate or simultaneous treatment should be prioritized, including a diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder, or organic mental disorder. Patients with a current high risk of suicide (based on clinical judgment), recent (past 3 months) substance use disorder, and those who had received eight or more sessions of CBT in the past 5 years were also excluded.

The present study included data only from participants randomized to one of the two active treatment conditions (n = 179 of 223): 88 participants to the UP and 91 to the SDP condition. The sample was largely White (83.2%) and well educated (63.1% of participants had a college degree or higher), with an average age of 30.7 years (SD = 10.8). Approximately half of the participants (55.9%) were already taking psychotropic medication when they presented for treatment, and the majority (83.8%) met criteria for at least one comorbid diagnosis. There were no differences between UP and SDP conditions on demographic and clinical characteristics.

PROCEDURE

Participants randomized to the SDP condition received one of the following treatment protocols: *Managing Social Anxiety: A Cognitive-Behavioral Therapy Approach* (Hope et al., 2006, 2010), *Mastery of Your Anxiety and Panic*,(Craske & Barlow, 2007), *Mastery of Your Anxiety and Worry* (Zinbarg et al., 2006), and *Treating Your Obsessive-Compulsive Disorder With Exposure and Response (Ritual) Prevention Therapy* (Foa et al., 2012). The SDPs varied in content and number of sessions focused on a given therapeutic strategy, but each SDP included psychoeducation, exposure, and relapse prevention—with the exception of the OCD SDP—all SDPs also included cognitive restructuring. The GAD SDP also included problem solving, the GAD and PD SDPs included progressive muscle relaxation and diaphragmatic breathing exercises, respectively, and the SOC SDP included motivation enhancement.

Participants randomized to the UP condition were treated using the UP (Barlow et al., 2011, 2018) regardless of principal diagnosis. Although the UP utilizes similar strategies to the SDPs, such as cognitive reappraisal and exposure, it emphasizes reactions to the experience of emotion instead of situational factors. The UP comprises five core modules: (a) mindful emotion awareness, (b) cognitive flexibility, (c) identifying and countering patterns of emotion avoidance, (d) increasing awareness and tolerance of emotion-related physical sensations, and (e) emotion exposures. These five core modules are preceded by a motivation enhancement module and a module that provides psychoeducation on the adaptive nature of emotions.

In both conditions, in accordance with the treatment doses recommended by each treatment protocol, participants with a principal diagnosis of OCD, SOC, and GAD were offered 16 sessions of treatment, and participants with a principal diagnosis of PD were offered 12 treatment sessions. One participant was diagnosed with "coprincipal" (equally distressing and interfering) PD and SOC, and offered 16 (and received 15) UP sessions. The trial used a "treatment window," such that participants were required to complete the 12 (principal PD) or 16 (other principal diagnoses) sessions within a 16- or 21-week period, respectively. Across conditions, treatment sessions were approximately 50–60 minutes for participants with a principal diagnosis of SOC, GAD, and PD, and participants with a principal diagnosis of OCD received treatment sessions approximately 80–90 minutes in length.

Participants in both treatment conditions underwent study assessments (including clinician-rated and self-report measures) at each of the following time points: baseline, after Session 4, after Session 8, after Session 12 ("posttreatment" for PD participants), after Session 16 ("posttreatment" for non-PD participants), and at 6- and 12-month follow-up. Though participants with principal PD could only receive a maximum of 12 treatment sessions, they still underwent a "Session 16" assessment 4 weeks after their posttreatment assessment. Participants were paid $50 for each assessment.

Research assistants followed a standardized protocol for scheduling and following up with

participants who missed an assessment, which provided a specific schedule and number of outreach attempts, as well as phone scripts and unable-to-contact e-mail/letter templates. Study therapists, who were responsible for scheduling treatment sessions, adhered to routine clinic procedures to follow up about missed treatment sessions (e.g., two to three contact attempts after a missed visit, followed by a templated unable-to-contact letter), and ongoing study supervision included at least weekly reviews of participant flow through treatment with therapists.

Every effort was made by study staff to elicit a reason from participants about why they dropped out—as such, reasons such as "dissatisfaction with treatment," "felt they no longer needed treatment," and "clinical deterioration" were self-reported. For dropouts who could not be contacted, reasons such as "unable to comply with study procedures" were assigned by the study team only if there was a clear indication of why they dropped out (e.g., participants who canceled multiple visits in a row, citing scheduling conflicts, before dropping out were considered "unable to comply with study procedures"). Dropouts for whom "no reasons were available" did not respond to outreach and there was no clear indication why they dropped out.

MEASURES

Participants were evaluated for diagnoses by assessors blind to condition using a semistructured interview, the Anxiety Disorders Interview Schedule (ADIS; Brown & Barlow, 2014; Di Nardo et al., 1994).[1] Diagnoses are assigned a dimensional clinical severity rating on a scale from 0 (*no symptoms*) to 8 (*extremely severe symptoms*), with 4 or higher (*definitely disturbing or disabling*) representing the clinical threshold for a *Diagnostic and Statistical Manual of Mental Disorders* (DSM) diagnostic criteria. ADIS interrater agreement was 98% for principal diagnosis in this study (Barlow et al., 2017).

Participants in both treatment conditions completed the Overall Anxiety and Severity Impairment Scale (OASIS; Norman et al., 2006), a five-item self-report measure of symptom severity and related interference for anxiety during the past week, prior to each treatment session and at each of the assessment time points. Scores on the OASIS range from 0 to 20, with 8 or above representing scores in the clinical range. Reliability (Cronbach's alpha) for the OASIS in the current study ranged from .81 (Session 1) to .98 (Sessions 13–16).

DATA ANALYSIS

Operationalizing Treatment Dropout

We defined treatment dropout as completing less than 75% of the prescribed number of sessions (and not returning to treatment) to be consistent with commonly used definitions of treatment dropout (i.e., attending fewer than a specified number of sessions; Swift & Greenberg, 2012), as well as prior research on the UP (e.g., Barlow et al., 2017) and CBT for anxiety disorders more broadly (McGovern et al., 2009; Siqueland et al., 2005; Stangier et al., 2011). Importantly, participants could still receive all core components of each CBT protocol in 9 of 12 (for principal PD) or 12 of 16 (other diagnoses) treatment sessions.

Of the 179 participants randomized to active treatment, four were withdrawn by the study team due to psychiatric emergency (e.g., hospitalization due to suicide risk, emergence of psychosis) or severe failure to comply with study procedures (e.g., refusal to have sessions recorded, initiation of new nonstudy treatment and medication changes early in the trial; $n = 2$ in both conditions). The four individuals who were withdrawn by study staff are not considered dropouts in this paper and thus excluded from subsequent analyses and tables.

Description of Analyses

Analyses were conducted in R (R Core Team, 2016) and SPSS, Version 24 (IBM Corporation, 2016). First, we generated descriptive data on treatment attendance for all participants, including those who stopped attending treatment before 75% of sessions were completed ("dropouts") and those who completed at least 75% of sessions ("completers"). Second, we generated tables presenting the number of participants who remained in and stopped attending treatment, the proportion who ended treatment after each session (hazard), the proportion remaining in treatment (survival), and the cumulative proportion remaining in treatment from session to session, both across and within the treatment conditions. Next, we constructed figures presenting hazard proportions over time within the treatment conditions. Then, we used descriptive statistics to present reasons for dropping out from treatment before completing at least 75% of sessions across and within treatment conditions.

[1] The DSM-5 was introduced partway through the trial. Thus, approximately 75% of participants were assigned diagnoses based on DSM-IV and about 25% based on DSM-5. In order to standardize CSRs across these phases, an additional rating was given to overall PD and agoraphobia symptoms for participants diagnosed according to DSM-5, despite the fact that PD and agoraphobia were separated in DSM-5 (Barlow et al., 2017).

For analyses examining whether anxiety symptom trajectories were associated with dropout, we collapsed across the two treatment conditions due to a priori determination of insufficient power for within-condition models. We fit a series of multilevel models using hierarchical linear modeling (HLM) with the lme4 R package (Bates et al., 2015). Self-reported anxiety symptoms (OASIS scores; $N = 2{,}826$) were nested within individuals and used as the y (outcome) variable. Models were run using all available data and full information maximum likelihood estimation for missing data. Models were built with random slopes and intercepts (as best-practice likelihood ratio tests dropping random slopes and intercepts indicated that these should be retained; Singer et al., 2003). Consistent with best practices for HLM, we began by regressing OASIS scores onto participants (Level 2 units) in an unconditional means model, followed by an unconditional growth model that used time (i.e., session/assessment time point, centered at zero) as the (Level 1) predictor, and compared the fit (via -2log likelihood) of the unconditional growth model to the unconditional means model using the anova() function in R (Field et al., 2012). We then built and examined the fit (in comparison to the unconditional growth model) and fixed effects of a third model that included dropout status (1 = attended $\geq$ 75% of sessions, 0 = attended < 75% of sessions) as a Level 2 predictor.

Results

Describing Treatment Attendance Across Conditions

A total of 35 (of 175) participants (20%) dropped out before completing 75% of the prescribed number of sessions. Table 1 presents session-by-session treatment attendance data, collapsed across the two conditions and principal diagnoses (excluding the four withdrawn individuals). The greatest risk of treatment dropout before attending 75% of sessions occurred prior to the first session, with lower and relatively stable dropout rates thereafter until at least 75% of sessions were completed.

Being unable to comply with study procedures (e.g., schedule and consistently attend sessions within a 16- [principal PD] or 21-week [other principal diagnoses] treatment window) was the most common reason for dropout ($n = 11$; 31.4% of dropouts). Six (17.1%) participants reported dissatisfaction with or desiring alternative treatment, 5 (14.3%) logistical problems (e.g., moving from the area), 2 (5.7%) feeling they no longer needed treatment, 1 (2.9%) a life crisis, and 1 (2.9%) deterioration in clinical status. We were unable to obtain reasons for dropout for 9 (25.7%) participants.

Describing Dropout Within Treatment Conditions

Participants randomized to the UP were significantly more likely to complete treatment (i.e., attend at least 75.0% of sessions) than those in the SDP condition (OR = 3.11, 95% CI [1.44, 6.74]; Barlow et al., 2017). Regarding dropout, 9 (of 86 randomized) participants in the UP (10.5%) and 26 (of 89 randomized) participants in the SDP condition (29.2%) dropped out before completing at least 75.0% of the prescribed number of sessions. Session-by-session treatment attendance data for the UP and SDP conditions are presented in Tables 2 and 3, respectively. Dropout rates did not differ as a function of principal diagnosis, which determined the specific SDP provided.

Figure 1 presents hazard proportions across time, broken down by treatment condition. In the UP, the risk of dropout before attending 75% of sessions was low and stable from session to session. In the SDP condition, the greatest risk of dropout occurred prior to the first session, followed by Sessions 4, 8, 6, and 7. Of note, for participants who completed at least 75% of sessions, it was common to end treatment after the 14th or 15th session.

Regarding reasons for dropout in the UP, 3 participants (33.3% of those who dropped out) were unable to comply with study procedures, 2 (22.2%) reported dissatisfaction with treatment, 1 (11.1%) felt care was no longer needed, and 1 (11.1%) moved from the area; for the remaining 2 (22.2%) participants, we were unable to obtain reasons for dropout. In the SDP condition, 9 (34.6%) dropouts were unable to comply with study procedures, 4 (15.4%) cited a logistical problem, 2 (7.7%) desired alternative treatment, 1 (3.8%) reported a deterioration in clinical status, 1 (3.8%) a life crisis, and 1 (3.8%) felt care was no longer needed; for the remaining 8 (30.8%) participants, we were unable to obtain reasons for dropout.

Symptom Trajectories for Dropouts Versus Completers Across Conditions

Mean OASIS scores at each weekly assessment for participants who dropped out (completed less than 75% of sessions) and for completers (completed at least 75% of sessions), and corresponding effect sizes, are provided in Supplemental Table 1. When collapsing across the two conditions, mean weekly OASIS scores were consistently higher in terms of

Table 1
Number of Individuals Remaining in Treatment, Stopped Attending Treatment, Hazard, Survival, and Cumulative Survival Proportions Across the Two Treatment Conditions (Excluding Withdrawn Individuals)

Time	Session interval	Number of participants in tx	Number of participants stopped attending tx	Proportion stopped attending tx (hazard)	Proportion remaining in tx (survival)	Cumulative proportion remaining in tx
0	BL/randomization	175[a]	–	–	1.00	1.00
1	BL–S1	175	9	0.05	0.97	0.97
2	S1–S2	170	0	0.00	1.00	0.97
3	S2–S3	170	2	0.01	0.99	0.96
4	S3–S4	168	4	0.02	0.98	0.94
5	S4–S5	164	4	0.02	0.98	0.91
6	S5–S6	160	1	0.01	0.99	0.91
7	S6–S7	159	4	0.03	0.97	0.89
8	S7–S8	155	4	0.03	0.97	0.86
9	S8–S9	151	5	0.03	0.97	0.83
10	S9–S10	146	1	0.01	0.99	0.83
11	S10–S11	145	1	0.01	0.99	0.82
12	S11–S12	144	3	0.02	0.98	0.81
13	S12–S13	141	2	0.01	0.99	0.79
14	S13–S14	106	2	0.02	0.98	0.78
15	S14–S15	104	7	0.07	0.93	0.74
16	S15–S16	97	11	0.11	0.85	0.66

Note. tx = treatment; BL = baseline.
[a] 175 is the number of randomized participants minus the 4 withdrawn participants.

absolute values for participants who ultimately dropped out than for those who completed treatment. Mean OASIS scores were only significantly higher, however, for dropouts (across both conditions and within the SDP condition) at Sessions 8–10; dropouts had significantly higher OASIS scores at Session 7 in the SDP condition only.

Regarding results from HLM of anxiety symptom trajectories, the unconditional means model showed an intraclass correlation (ICC) of 0.55, indicating that just under half of variance in the outcome (OASIS scores) was attributable to within-person differences and thus that HLM was an appropriate analytic strategy. The unconditional growth model showed that time significantly predicted OASIS scores, $\beta = -.32$, $t(147) = -16.31$, $p < .001$, with OASIS scores decreasing over time in the sample as a whole. The unconditional growth model provided better fit to the data than the unconditional means model, deviance Δ ($\chi^2[3] = 1288.4$, $p < .001$). The third model, which included dropout status as a Level 2 predictor, did not indicate a significant effect of dropout status, $\beta = -.35$, $t(197) = -0.50$, $p = .62$, or an interaction of dropout and time, $\beta = -0.09$, $t(463) = -1.17$, $p = .24$, on anxiety symptoms, and failed to provide significantly better fit to the data than the unconditional growth model that did not account for dropout status, deviance Δ ($\chi^2[2] = 2.48$, $p = .29$). Results from the third model are shown in Figure 2.

We also ran this series of multilevel models only using weekly data collected before Session 13 (as missing data were common [though not universal, as some dropouts provided subsequent assessments] after treatment dropout). The same pattern of results held, indicating that the nonsignificant effect of dropout status on anxiety symptoms was *not* due primarily to uncertainty introduced by missing data later in the course of treatment for dropouts.

Discussion

Improved understanding of when and why patients drop out from CBT has the potential to identify novel windows and targets for intervention aimed to retain patients in evidence-based psychological treatments. Here, we characterized the nature, timing, and anxiety symptom trajectories of dropout from transdiagnostic and single-diagnosis CBT for anxiety disorders. Overall, the greatest risk of dropout was prior to the first treatment session—this was primarily driven by the single-diagnosis CBT condition. The risk of dropout was also elevated after specific early sessions in single-diagnosis CBT, whereas during transdiagnostic CBT, the risk of dropout before was low and stable. The most common reason for dropout was difficulty complying with study procedures, followed by dissatisfaction with or desiring alternative treatment. Results from multilevel models showed that anxiety symptom trajectories did

Table 2
Number of Individuals Remaining in Treatment, Stopped Attending Treatment, Survival, and Cumulative Survival Proportions in the Unified Protocol Condition (Excluding Withdrawn Individuals)

Time	Session interval	Number of participants in UP	Number of participants stopped attending UP	Proportion remaining in UP (survival)	Cumulative proportion remaining in UP
0	BL/randomization	86[a]	–	1.00	1.00
1	BL–S1	86	2	0.98	0.98
2	S1–S2	84	0	1.00	0.98
3	S2–S3	84	1	0.99	0.97
4	S3–S4	83	2	0.98	0.94
5	S4–S5	81	0	1.00	0.94
6	S5–S6	81	1	0.99	0.93
7	S6–S7	80	1	0.99	0.92
8	S7–S8	79	1	0.99	0.91
9	S8–S9	78	1	0.99	0.90
10	S9–S10	77	1	0.99	0.88
11	S10–S11	76	0	1.00	0.88
12	S11–S12	76	2	0.97	0.86
13	S12–S13	74	1	0.99	0.85
14	S13–S14	54	1	0.98	0.84
15	S14–S15	53	3	0.94	0.80
16	S15–S16	50	6	0.88	0.73

Note. UP = unified protocol; BL = baseline.
[a] 86 is the number of participants randomized to the UP minus the 2 withdrawn participants.

not significantly differ between dropouts and completers. These findings have implications for clinicians and researchers interested in improving retention from CBT for emotional disorders.

The fact that prior to the initial session had the highest risk of dropout overall is consistent with our hypothesis and other work showing that relatively large proportions of patients never attend the first session (e.g., Barrett et al., 2008; Fernandez et al., 2015; Gutner et al., 2016; Issakidis & Andrews, 2004). This suggests the potential importance of providers (or, in the context of studies, research staff) reaching out to patients proactively and consistently prior to the start of treatment to foster engagement, especially when there is a significant lapse of time between scheduling the first session and the last session. Brief contact (e.g., call, text message) interventions aimed to build motivation and ensure engagement that can be deployed before the initial session may be valuable especially for patients with preexisting risk factors for dropout.

Whereas there were no clear time points of elevated risk for dropout during transdiagnostic CBT, before the first session and during the first half of treatment (specifically, Sessions 4, 8, 6, and 7) were points of relatively elevated dropout risk for participants in single-diagnosis CBT. As each SDP comprised different therapeutic strategies at different times, we were unable to systematically evaluate whether the specific session content introduced during the aforementioned early sessions may have contributed to dropout risk at these time points. For example, although exposure was included in all SDPs, it was introduced at different points in the protocol (i.e., Session 3 in the OCD SDP, Sessions 7 or 8 in the SOC SDP, Session 5 in the PD SDP, and Session 8 in the GAD SDP) and varied in type of exposure (i.e., interoceptive, in vivo, imaginal). Additionally, the number of sessions spent focused on exposure varied among the SDP protocols (e.g., the OCD SDP included 13 sessions of exposure, whereas the PD SDP included 7). It is possible, however, that the delivery of explicit motivation enhancement strategies in the UP helped protect against early dropout as compared to SDP. Supporting this hypothesis, growing research suggests beginning therapy with motivation enhancement strategies may improve the likelihood that patients initiate and complete treatment (e.g., Buckner & Schmidt, 2009; Murphy et al., 2009). Future research aimed to rigorously evaluate the impact of explicit motivational strategies in transdiagnostic and single-diagnosis CBT on dropout is warranted.

Given that randomization (and an explanation of the protocol they would be receiving) occurred prior to Session 1, it is also possible that participants slated to receive an SDP were less enthusiastic about their treatment assignment, and thus more likely to never initiate therapy. This may have been in part due to how the UP was framed during the consent process (e.g., as described

Table 3
Number of Individuals Remaining in Treatment, Stopped Attending Treatment, Survival, and Cumulative Survival Proportions in the Single-Diagnosis Protocol Condition (Excluding Withdrawn Individuals)

Time	Session interval	Number of participants in SDP	Number of participants stopped attending SDP	Proportion remaining in SDP (survival)	Cumulative proportion remaining in SDP
0	BL/randomization	89[a]	–	1.00	1.00
1	BL–S1	89	7	0.92	0.92
2	S1–S2	82	0	1.00	0.92
3	S2–S3	82	1	0.99	0.91
4	S3–S4	81	2	0.98	0.89
5	S4–S5	79	4	0.95	0.84
6	S5–S6	75	0	1.00	0.84
7	S6–S7	75	3	0.96	0.81
8	S7–S8	72	3	0.96	0.78
9	S8–S9	69	4	0.94	0.73
10	S9–S10	65	0	1.00	0.73
11	S10–S11	65	1	0.98	0.72
12	S11–S12	64	1	0.98	0.71
13	S12–S13	63	1	0.98	0.70
14	S13–S14	48	1	0.98	0.69
15	S14–S15	47	4	0.91	0.64
16	S15-S16	43	5	0.88	0.58

Note. SDP = single-diagnosis protocol; BL = baseline.
[a] 89 is the number of participants randomized to SDP minus the 2 withdrawn participants.

above, the UP was framed as a treatment designed to address core features that cut across emotional disorders and SDPs as focusing primarily on symptoms of one disorder) or the research staff's implicit biases to favor the UP (see section discussing limitations, below). Studies that evaluate the impact of different ways to frame CBT from the outset of treatment on both dropout and efficacy may help shed light on these questions and inform best practices.

It is worth noting that for participants who did attend at least 75% of sessions (considered "completers" here), it was common to end treatment after Session 14 or 15 (of 16 total prescribed sessions for non-PD principal diagnoses). This is largely due to the fact that the trial used a treatment window that required participants to complete the 12 (principal PD) or 16 (other principal diagnoses) sessions within a 16- or 21-week period—this requirement of course would not apply in routine care. Indeed, the treatment window expired for 76% of participants whose last session was the 14th or 15th—as the window expiring is something the study therapist could plan for, these participants would still have received all core content from their assigned CBT protocol. This is another reason why we defined "dropout" as completing <75% (rather than <100%) of sessions for our analyses, as those completing <9 (PD) or <12 (other principal diagnoses) sessions would not have completed all protocol content.

The fact that most participants in both conditions dropped out due to difficulty complying with study procedures is not surprising, given the clinical trial context, which required individuals consistently schedule and attend weekly sessions (and complete repeated time-intensive assessments) within a designated window of time. This is in line with previous findings that practical barriers are consistently associated with dropout (e.g., Taylor et al., 2012). The fixed "treatment window" and time-intensive assessments in a clinical trial are less applicable to routine clinical care, but suggest the need for researchers to consider maximizing the flexibility of session and assessment scheduling/timing and formats (e.g., remote and in person), as well as reduce the burden and duration of assessments in clinical trials. Such flexibility, of course, must be balanced with the need for the standardization of variables that contribute to internal validity. It is also possible that being "unable to comply" in some cases reflects other factors driving termination, such as lack of satisfaction or motivation. Along these lines, it is noteworthy that the number of participants who dropped out in the SDP condition due to failure to comply was three times the UP ($n = 9$ vs. 3). Though these are small ns and speculations are tentative, systematically addressing motivation early on in the UP may have contributed to fewer participants dropping out due to inability to comply.

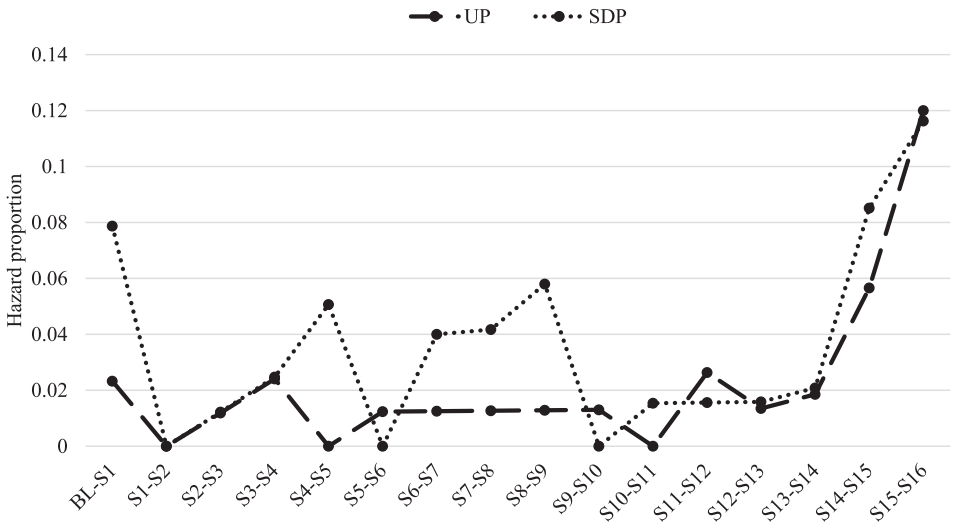

FIGURE 1 Hazard indicating the proportion of participants who stopped attending treatment after each session in the unified protocol and single-diagnosis protocol conditions. *Note*. UP = unified protocol; SDP = single-diagnosis protocol; BL = baseline; S1–S16 = Session 1–Session 16.

Multilevel models showed that the trajectories of weekly anxiety symptoms did not significantly differ between dropouts and completers—in other words, participants who dropped out of treatment did not necessarily have significantly different outcomes over time compared to those who did complete treatment. This was inconsistent with our hypothesis, but consistent with other recent studies on dropout (e.g., O'Keeffe et al., 2019; Zieve et al., 2019). Given that the most common reason for dropout was difficulty complying with study procedures, not for example deterioration or dissatisfaction with treatment, this result is perhaps unsurprising. Though the second most common reason was dissatisfaction with or desiring alternative treatment, reasons for dissatisfaction were not elaborated upon further and thus it is unclear whether dissatisfaction was related to symptom worsening or a preference for a different style of treatment. It is also important to note the models tested here only included time and dropout. Future research that includes baseline characteristics and other time-varying factors may result in better prediction.

Results of this study must be considered in the context of its limitations. First, reasons for dropout were not available for almost one third of those who dropped out. Second, although participants also completed a weekly depression scale, we were unable to generate stable models of these depression scores due to the lack of variability in depression over time. A limitation of the parent study from which these data were derived was that few participants had comorbid depression (Barlow et al., 2017). It is plausible, of course, that changes in other (nonanxiety) symptoms over time may also contribute to early termination. Third, the sample size was too small to model the interaction of dropout status and treatment condition on anxiety trajectories. Therefore, it is unknown whether the relationship between dropout status and symptoms differs in transdiagnostic versus single-diagnosis CBT. Fourth, like most research trials, paying participants to complete study assessments may limit generalizability of findings to purely clinical contexts. Finally, this trial was conducted by developers of the UP, which may have introduced bias in the study procedures (e.g., whether therapists made more effort in session to engage participants in UP than SDP content). As noted above, however, that research assistants used a standardized protocol and message scripts for participant outreach, the principal investigator (D.H. B) and colleagues also developed two of the four SDPs, and all sessions were coded for adherence by expert raters may have mitigated any bias.

Despite these limitations, this study adds important information to the growing literature on identification of modifiable risk factors for dropout from CBT. The results presented here could inform the development of brief, targeted interventions aimed to maximize the likelihood of patients initiating and remaining in treatment, thus enhancing the benefits they receive. Furthermore, research aimed to develop and evaluate briefer (and thus potentially more feasible to complete) versions of existing CBT protocols is a promising avenue for increasing access to (and the population health impact of) evidence-based mental health treatment on a large scale.

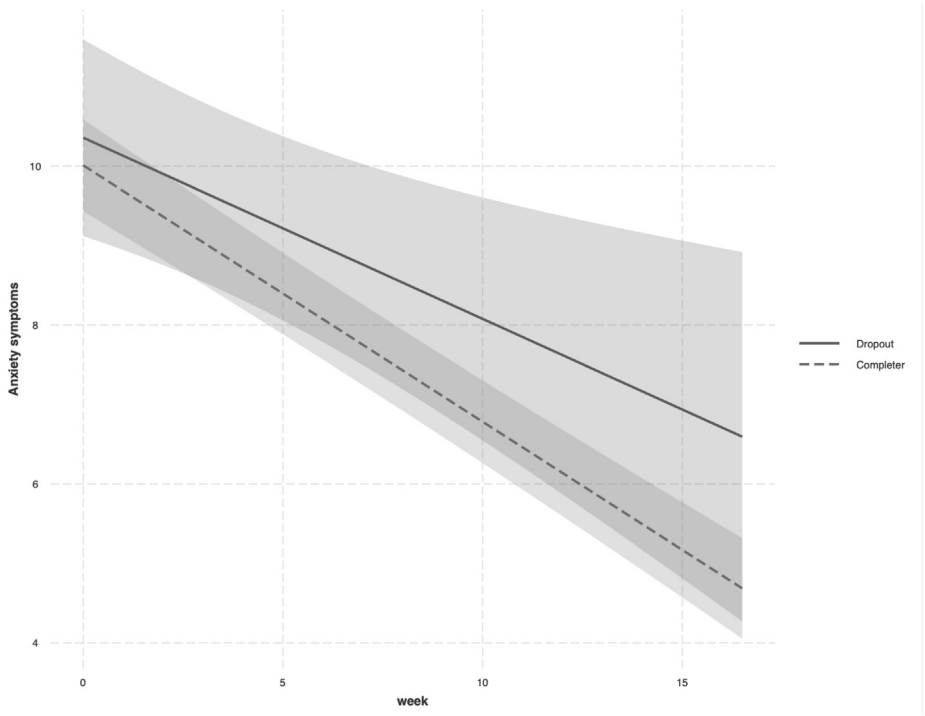

FIGURE 2 Estimated Anxiety Symptoms (OASIS Scores) and 95% Confidence Bands by Dropout Status from Multilevel Model.

Conflict of Interest Statement

Dr. Farchione receives royalties from Oxford University Press for one of the treatment manuals included in this study. Grant monies for various projects come from the National Institute of Alcohol and Alcohol Abuse and the John Templeton Foundation. Dr. Barlow receives royalties from Oxford University Press (which includes royalties for all five treatment manuals included in this study), Guilford Publications Inc., Cengage Learning, and Pearson Publishing. Grant monies for various projects including this one come from the National Institute of Mental Health, the National Institute of Alcohol and Alcohol Abuse, the Templeton Foundation, and Colciencias (Government of Columbia Initiative for Science, Technology, and Health Innovation). Consulting and honoraria during the past several years have come from the Agency for Healthcare Research and Quality, the Foundation for Informed Medical Decision Making, the Department of Defense, the Renfrew Center, the Chinese University of Hong Kong, Universidad Católica de Santa Maria (Arequipa, Peru), New Zealand Psychological Association, Hebrew University of Jerusalem, Mayo Clinic, and various American Universities and Institutes.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.beth.2021.03.007.

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