The Effectiveness of 6 versus 12 Months of Dialectical Behavior Therapy for Borderline Personality Disorder: A Noninferiority Randomized Clinical Trial

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Abstract
Introduction: Evidence-based psychotherapies for borderline personality disorder (BPD) are lengthy, posing a barrier to their access. Brief psychotherapy may achieve comparable outcomes to long-term psychotherapy for BPD. Evidence is needed regarding the comparative effectiveness of short-versus long-term psychotherapy for BPD. Objective: The aim was to determine if 6 months of Dialectical Behavior Therapy (DBT) is noninferior to 12 months of DBT in terms of clinical effectiveness. Methods: This two-arm, single-blinded, randomized controlled noninferiority trial with suicidal or self-harming patients with BPD was conducted at two sites in Canada. Participants (N = 240, M (SD) age = 28.27 (8.62), 79% females) were randomized to receive either 6 (DBT-6) or 12 months (DBT-12) of comprehensive DBT. Masked assessors obtained measures of clinical effectiveness at baseline and every 3 months, ending at month 24. DBT-6 and DBT-12 were outpatient treatments consisting of weekly individual therapy sessions, weekly DBT skills training group sessions, telephone consultation as needed, and weekly therapist consultation team meetings. Results: The noninferiority hypothesis was supported for the primary outcome, total self-harm (6 months: margin = −1.94, Mdiff [95% CI] = 0.16 [−0.14, 0.46]; 12 months: margin = −1.47, Mdiff [95% CI] = 0.04 [−0.17, 0.23]; 24 months: margin = −1.25, Mdiff [95% CI] = 0.12 [−0.02, 0.36]). Results also supported noninferiority of DBT-6 for general psychopathology and coping skills at 24 months. Furthermore, DBT-6 participants showed more rapid reductions in BPD symptoms and general psychopathology. There were no between-group differences in dropout rates. Conclusions: The noninferiority of a briefer yet comprehensive treatment for BPD has potential to reduce barriers to treatment access.
Introduction

Borderline personality disorder (BPD) is a serious and prevalent disorder [1–3] associated with high mortality [4, 5] and healthcare utilization [6, 7]. Practice guidelines recommend psychotherapy as the first-line treatment for BPD [8–10], but treatment access is often limited. Increasingly, due to concerns about treatment length and cost, shorter therapies (6 months or less) are being utilized in clinical settings in many countries. A sufficient duration of therapy for BPD, however, remains unknown.

Dialectical behavior therapy (DBT) [11] is a comprehensive program for BPD with efficacy (relative to treatment as usual) established by several randomized controlled trials [12–14]. Three studies have examined brief, 6 months of comprehensive, standard DBT for adult patients diagnosed with BPD. Findings generally supported the effectiveness or efficacy of 6 months of DBT compared with various control conditions [15–17]. In studies evaluating the effectiveness of 6 months of DBT for BPD, sample sizes ranged from 20 to 73, and only one study required recurrent self-harm or suicidality as an inclusion criterion [15]. No studies have compared 12 months of DBT to briefer DBT. A briefer, yet demonstrably noninferior form of DBT, would be less costly, easier to implement, and more accessible to patients requiring treatment. The FASTER study (The Feasibility of a Shorter Treatment and Evaluating Responses) compared the clinical and cost-effectiveness of 6 (DBT-6) versus 12 months (DBT-12) of DBT for chronically suicidal or self-harming individuals with BPD.

The FASTER study had several aims. The primary aims of the study were to examine the clinical- and cost-effectiveness of DBT-6 versus DBT-12. An additional aim was to identify patient characteristics that moderate response to DBT-6 versus DBT-12. This paper presents the results related to the clinical effectiveness of DBT-6 to DBT-12. Cost-effectiveness, health care utilization (e.g., changes in emergency room visits), and findings from moderator analyses will be presented elsewhere.

Materials and Methods

The detailed study trial protocol describing the methodologic details of the FASTER trial is published elsewhere [18].

Trial Oversight

The study protocol was approved by ethics review boards at each site. Participants provided written informed consent after receiving a complete description of the study prior to randomization. An independent data safety monitoring board, whose members were masked to treatment assignment, regularly reviewed the study data for participant safety, study conduct, and adverse events (AEs).

Trial Design

This was a 2-arm, randomized, single-blind noninferiority clinical trial conducted at the Center for Addiction and Mental Health (CAMH) in Toronto, ON, Canada and Simon Fraser University (SFU) in Burnaby, BC, Canada.

Participants

Inclusion criteria were as follows: a Diagnostic and Statistical Manual Version IV (DSM-IV) diagnosis of BPD [19]; age 18–60 years; at least two episodes of suicide attempts or non-suicidal self-injury (NSSI) in the past 5 years, including one or more within the past 2 months; proficiency in English; and valid provincial health insurance in Ontario or British Columbia during the past year. Exclusion criteria included a DSM-IV diagnosis of bipolar I disorder, dementia, and/or a psychotic disorder; a serious physical health issue with anticipated hospitalization in the next year; IQ of 70 or less; at least 8 weeks of DBT in the last year; and plans to move out of the province during the trial.

All participants self-referred to the trial and received study details from treatment waitlists at each site, advertisements, and/or clinicians. Study enrollment occurred between February 2015 and June 2017. The last follow-up visit took place in July 2019.

Randomization and Masking

A detailed description of the randomization procedure is provided in the study protocol [18]. Patients at each site were randomly allocated in a 1:1 ratio to either DBT-6 or DBT-12. Treatment allocation was known to patients and therapists but masked to study assessors, except for assessors administering the Treatment History Interview-2 [20].

Interventions

DBT is a comprehensive outpatient treatment that integrates acceptance-based strategies with cognitive-behavioral interventions. Consistent with Linehan’s [11] standard DBT, treatment involved weekly individual therapy sessions, weekly 2-hour group sessions for skills training, 24/7 access to telephone coaching, and weekly consultation meetings for therapists. DBT-6 and DBT-12 differed only in length. Treatment was delivered at no financial cost to patients.

Therapist Training and Supervision

Treatment was administered by 64 therapists trained in DBT (PhD psychologists, 50%; MDs, 20%; MSWs, 16%; and Master’s-level registered psychotherapists/RNs, 14%). Most therapists were assigned to work with patients in both conditions. With the exception of professional designation and highest degree, for which there was a broader spectrum at CAMH, therapist characteristics were comparable across sites. Treatment adherence was assessed by 12 independent trained raters using the University of Washington DBT Adherence Scale [21].

Diagnostic Procedures

BPD diagnosis was established using the International Personality Disorder Examination (IPDE) [22]. Additional diagnoses
were assessed using the Structured Clinical Interview for DSM-IV Axis I Disorders [23] and the Structured Clinical Interview for DSM-IV Axis II Personality Disorders [24], respectively. Inter-rater reliability for the diagnosis of BPD based on the IPDE was excellent (intraclass correlation [ICC] = 0.99).

Outcome Measures
Outcomes were assessed at baseline and every 3 months up to 24 months. The predefined primary outcome was the total frequency of self-harm episodes, including suicide and NSSI episodes, during the previous 3 months, based on the Suicide Attempt Self-Injury Interview (SASII) [25]. Following Linehan et al. [25], we classified self-harm episodes as suicide attempts if they were scored with a 7 or above on the SASII Item 25.

Given the structure of the SASII, we evaluated reliability of the lifetime SASII at baseline, which was excellent (ICCs: 0.77–1). Secondary outcomes were changes in the following: BPD symptoms (Borderline Symptom List-23) [26], general psychopathology (Symptom Checklist-90-Revised – Global Severity Index) [27], anger expression (State-Trait Anger Expression Inventory-2 – Anger Expression-Out Subscale) [28], depression (Beck Depression Inventory-II) [29], interpersonal functioning (Inventory of Interpersonal Problems-64) [30], and skills uptake (DBT Ways of Coping Checklist, Skills Use Subscale) [31]. The number of non-study psychosocial treatments and psychotropic medications was measured using the Treatment History Interview-2 [20].

Statistical Analysis
Piecewise, 3-leg models were used to model change in all outcomes, thereby allowing rates of change to vary from baseline to 6 months, 6–12 months, and 12–24 months. Generalized linear mixed models (GLMMs), using the log-link function and assuming a negative binomial distribution, were used to model the piecewise change in the non-normally-distributed primary outcomes and NSSI. Linear mixed models (LMMs) were used to model the piecewise change in normally distributed outcomes (e.g., BPD symptoms). Standard maximum likelihood estimation was used to estimate all multi-level models.

The random-effects structure for all models was determined based on likelihood-ratio tests, comparing a full model (i.e., intercepts and slopes random and fully correlated) to models that progressively removed each random effect and its correlation. Based on these results, intercepts and slopes for each of the three segments of the piecewise GLMMs were specified as random but uncorrelated. Random effects for all LMMs were fully unstructured. Change in the probability of suicide attempts was modeled using piecewise models and implemented using generalized estimating equations (GEEs) with the logit-link and an exchangeable correlation matrix.

Noninferiority tests were based on planned between-group contrasts of estimated marginal means for the per-protocol sample and confirmed with the intent to treat (ITT) sample. Contrasts for non-normally distributed outcomes represented the difference in estimated absolute mean rates or probability of occurrence at 6, 12, and 24 months. For the per-protocol analyses, these differences were adjusted to offset differences at baseline. Two-tailed 95% bias-corrected bootstrapped confidence intervals (1,000 samples) were constructed around these differences. Bootstrap samples were constructed by resampling at the individual level and then including all outcome data for the participant in the bootstrapped samples. Contrasts for normally distributed outcomes represented between-condition differences in change, baseline to 6, 12, and 24 months. Two-tailed 95% confidence intervals around these differences were constructed using standard methods. DBT-6 was considered noninferior to DBT-12 if the lower limit of the confidence interval was greater than the predetermined noninferiority margin. Superiority was established by examining the confidence intervals around the planned contrasts for the ITT sample after first establishing an outcome’s noninferiority in this sample [32].

The noninferiority margin for the primary outcome of 1.53 (SD = 4) was established a priori to test for between-condition differences in absolute means of total self-harm at the end of 12 months. This margin represents a statistically based maximally acceptable treatment difference and was obtained via simulation using data from a previous study [33]. Using this margin and assuming a 30% dropout rate, a sample of 240 was found to yield adequate power (1 − β = 0.80) to verify whether DBT-6 was noninferior to DBT-12.

Experts recommend defining noninferiority margins based on clinical judgment in addition to statistical considerations [34]. Therefore, in addition to testing for noninferiority based on the per-protocol margin, additional tests for noninferiority of the primary outcome at 12 months were also conducted based on clinician-defined margins. These margins were obtained after data collection, but prior to starting data analysis.

Independent expert clinicians (n = 5) defined the clinically acceptable difference for the primary outcome. To improve accuracy, the clinical experts recommended the use of different noninferiority margins at 6 months, 12 months, and 24 months. Clinical experts also defined noninferiority margins for secondary outcomes.

Noninferiority margins for all primary and secondary outcomes were determined by taking the average of margins (with ranges shown in online suppl. material; for all online suppl. material, see www.karger.com/doi/10.1159/000525102) provided by experts in the treatment of BPD (2–7 experts dependent on outcome, see www.karger.com/doi/10.1159/000525102) provided by experts in the treatment of BPD (2–7 experts dependent on outcome measures). Investigators, co-investigators, and anyone with access to study data were excluded from the expert pool. All were masked to the results for the DBT-6 condition. See online supplementary material for further details.

Margins for non-normally distributed outcomes represented the maximum allowable absolute difference in rates or probability between conditions at months 6, 12, and 24. Margins for normally distributed outcomes represented the maximum allowable difference in improvement on outcomes between conditions from baseline to all time points. Margins are shown in Tables 1 and 2 under the column “Margin.”

Random effects repeated-measures 2-Factor ANOVAs (implemented as GLMMs using the log-link and assuming a Poisson distribution) were used to test for significant changes in both the number of psychotropic medications and non-study psychosocial treatments, baseline to month 24. Missing data for each outcome increased as time progressed (see online suppl. material). LMMs and GLMMs, however, produce unbiased parameter estimates when outcome data are missing at random (MAR). As GEEs assume data are missing completely at random, multiple imputation was used to obtain estimates, making it possible to satisfy the less restrictive MAR assumption. MAR was confirmed by testing for significant differences in each outcome at baseline between those with and without missing data first at 6, then at 12 and 24 months. Visual inspection of baseline distributions for between-group dif-
Table 1. Results for non-normally distributed outcomes

| Outcome                      | Estimated marginal means (DBT-12 minus DBT-6) | Differences (DBT-12 minus DBT-6) | Estimated mean change in outcome (Baseline to end of period) |
|------------------------------|-----------------------------------------------|----------------------------------|-------------------------------------------------------------|
|                              | DBT-12 M [95% CI]                              | DBT-6 M [95% CI]                 | DBT-12 M [95% CI]d                                          | DBT-6 M [95% CI]d                                          |
| **Noninferiority analysis based on per-protocol sample** |                                               |                                  |                                                             |                                                             |
| **Total self-harm**          |                                               |                                  |                                                             |                                                             |
| Baseline                     | 7.39 [6.24, 8.76]                              | 7.39 [6.24, 8.76]                | –                                                           | –                                                           |
| Month 6<sup>a</sup>          | 0.57 [0.38, 0.82]                              | 0.41 [0.24, 0.67]                | **0.16 [−0.14, 0.46]**                                      | −1.94                                                      |
| Month 12<sup>a</sup>         | 0.30 [0.17, 0.47]                              | 0.26 [0.15, 0.44]                | **0.04 [−0.17, 0.23]**                                      | −1.53                                                      |
| Protocol margin              | 0.04 [−0.17, 0.23]                             |                                  |                                                             |                                                             |
| Clinician margin             | 0.04 [−0.17, 0.23]                             |                                  |                                                             |                                                             |
| Month 24                     | 0.22 [0.09, 0.46]                              | 0.10 [0.04, 0.21]                | **0.12 [−0.02, 0.36]**                                      | −1.25                                                      |
| **NSSI**                     |                                               |                                  |                                                             |                                                             |
| Baseline                     | 6.48 [5.36, 7.83]                              | 6.48 [5.36, 7.83]                | –                                                           | –                                                           |
| Month 6<sup>a</sup>          | 0.47 [0.33, 0.71]                              | 0.38 [0.22, 0.60]                | **0.10 [−0.17, 0.36]**                                      | −2.12                                                      |
| Month 12<sup>b</sup>         | 0.25 [0.16, 0.42]                              | 0.23 [0.13, 0.37]                | **0.02 [−0.15, 0.19]**                                      | −1.18                                                      |
| Month 24                     | 0.17 [0.07, 0.36]                              | 0.08 [0.03, 0.17]                | **0.09 [−0.02, 0.30]**                                      | −1.17                                                      |
| **Suicide<sup>b</sup>**      |                                               |                                  |                                                             |                                                             |
| Baseline                     | 0.15 [0.13, 0.18]                              | 0.15 [0.13, 0.18]                | –                                                           | –                                                           |
| Month 6<sup>a</sup>          | 0.03 [0.01, 0.08]                              | 0.01 [0.00, 0.03]                | **0.02 [0.00, 0.07]**                                      | −0.03                                                      |
| Month 12<sup>b</sup>         | 0.02 [0.01, 0.06]                              | 0.01 [0.00, 0.03]                | **0.01 [−0.01, 0.05]**                                      | −0.02                                                      |
| Month 24                     | 0.01 [0.00, 0.04]                              | 0.03 [0.01, 0.07]                | −0.01 [−0.06, 0.02]                                         | −0.02                                                      |
| **Superiority analysis based on intent to treat sample** |                                               |                                  |                                                             |                                                             |
| **Total self-harm**          |                                               |                                  |                                                             |                                                             |
| Baseline                     | 6.61 [5.32, 8.50]                              | 8.28 [6.45, 10.39]               | −1.67 [−4.12, 1.05]                                         | −1.94                                                      |
| Month 6<sup>a</sup>          | 0.41 [0.26, 0.59]                              | 0.49 [0.31, 0.75]                | **0.08 [−0.36, 0.16]**                                      | −1.94                                                      |
| Month 12<sup>b</sup>         | 0.19 [0.11, 0.30]                              | 0.27 [0.16, 0.46]                | **−0.08 [−0.28, 0.07]**                                     | −1.53                                                      |
| Protocol margin              | 0.19 [0.11, 0.30]                              | 0.27 [0.16, 0.46]                | **−0.08 [−0.28, 0.07]**                                     | −1.53                                                      |
| Clinician margin             | 0.19 [0.11, 0.30]                              | 0.27 [0.16, 0.46]                | **−0.08 [−0.28, 0.07]**                                     | −1.47                                                      |
| Month 24                     | 0.14 [0.06, 0.27]                              | 0.10 [0.05, 0.19]                | **0.03 [−0.07, 0.18]**                                      | −1.25                                                      |
| **NSSI**                     |                                               |                                  |                                                             |                                                             |
| Baseline                     | 5.77 [4.45, 7.37]                              | 7.29 [5.48, 9.48]                | −1.52 [−4.19, 0.87]                                         | −1.79                                                      |
| Month 6<sup>a</sup>          | 0.33 [0.21, 0.48]                              | 0.44 [0.28, 0.69]                | **−0.11 [−0.37, 0.10]**                                     | −2.12                                                      |
| Month 12<sup>b</sup>         | 0.16 [0.10, 0.26]                              | 0.24 [0.14, 0.40]                | **−0.08 [−0.24, 0.05]**                                     | −1.18                                                      |
| Month 24                     | 0.11 [0.05, 0.22]                              | 0.08 [0.04, 0.16]                | **0.03 [−0.06, 0.15]**                                      | −1.17                                                      |
| **Suicide<sup>b</sup>**      |                                               |                                  |                                                             |                                                             |
| Baseline                     | 0.15 [0.09, 0.21]                              | 0.16 [0.10, 0.23]                | −0.01 [−0.10, 0.09]                                         | −0.17                                                      |
| Month 6<sup>a</sup>          | 0.03 [0.02, 0.05]                              | 0.01 [0.00, 0.03]                | **0.02 [0.00, 0.03]**                                       | −0.03                                                      |
| Month 12<sup>b</sup>         | 0.02 [0.01, 0.03]                              | 0.01 [0.00, 0.03]                | **0.01 [−0.01, 0.02]**                                      | −0.02                                                      |
| Month 24                     | 0.02 [0.00, 0.04]                              | 0.03 [0.01, 0.06]                | −0.01 [−0.04, 0.01]                                         | −0.02                                                      |

Ninety-five percent confidence intervals (95% CI) are bias-corrected bootstrapped, based on 1,000 bootstrap samples. Per-protocol analysis: differences (DBT-12 minus DBT-6) highlighted in bold indicate DBT-6 noninferior to DBT-12. For analyses based on the per-protocol sample, differences for non-normally distributed outcomes were adjusted to offset differences at baseline. Intent to treat analysis: differences (DBT-12 minus DBT-6) highlighted in bold indicate DBT-6 superior to DBT-12. DBT-6, dialectical behavior therapy (6 months duration); DBT-12, dialectical behavior therapy (12 months duration – standard); Margin, margin used to determine noninferiority of DBT-6 based on between-condition mean difference in measure.<sup>a</sup> As rates of self-harm, NSSI, and suicide were measured over the 3 months previous to assessment, rates for months 6 and 12 are those assessed at the 9- and 15-month assessments and represent the rates over the 3 months immediately following end of 6 months and 12 months of treatment, respectively. <sup>b</sup> Results for suicide represent the probability of a reported suicide attempt. <sup>c</sup> Positive between-condition differences indicate rate for DBT-6 better than that for DBT-12 by amount indicated. Negative between-condition differences indicate rate for DBT-6 worse than that for DBT-12 by amount indicated. <sup>d</sup> Changes baseline to end of period all significant based on 95% and 99% confidence intervals.
Table 2. Results for normally distributed outcomes

| Outcome                                      | Estimated marginal means | Estimated mean change in outcome (baseline to end of period) |
|----------------------------------------------|--------------------------|-------------------------------------------------------------|
|                                              | DBT-12 [M [95% CI]]      | DBT-6 [M [95% CI]]a                                       |
|                                              |                          | DBT-12 minus DBT-6 [M [95% CI]]b                          |
| Noninferiority analysis based on per-protocol sample |                          |                                                             |
| General psychopathology (SCL-90R)            |                          |                                                             |
| Baseline                                     | 1.80 [1.67, 1.93]        | 1.73 [1.60, 1.85]                                         |
| Month 6                                      | 1.66 [1.49, 1.83]        | 1.30 [1.14, 1.46]                                         |
| Month 12                                     | 1.36 [1.19, 1.54]        | 1.40 [1.23, 1.57]                                         |
| Month 24                                     | 1.37 [1.18, 1.57]        | 1.48 [1.29, 1.67]                                         |
| Depression (BDI-II)                          |                          |                                                             |
| Baseline                                     | 35.90 [33.62, 38.19]     | 34.61 [32.48, 36.74]                                       |
| Month 6                                      | 28.65 [25.29, 32.00]     | 24.41 [21.24, 27.59]                                       |
| Month 12                                     | 25.15 [21.88, 28.41]     | 26.40 [23.26, 29.54]                                       |
| Month 24                                     | 24.01 [20.55, 27.47]     | 26.55 [23.09, 30.00]                                       |
| BPD symptoms (BSL-23)                        |                          |                                                             |
| Baseline                                     | 2.34 [2.17, 2.50]        | 2.22 [2.07, 2.37]                                         |
| Month 6                                      | 1.96 [1.76, 2.16]        | 1.51 [1.32, 1.69]                                         |
| Month 12                                     | 1.60 [1.39, 1.81]        | 1.68 [1.48, 1.88]                                         |
| Month 24                                     | 1.55 [1.32, 1.78]        | 1.67 [1.44, 1.89]                                         |
| Interpersonal functioning (IIP-64)            |                          |                                                             |
| Baseline                                     | 126.26 [119.61, 132.90]  | 117.66 [114.47, 123.85]                                    |
| Month 6                                      | 111.59 [103.41, 119.76]  | 96.36 [88.63, 104.09]                                      |
| Month 12                                     | 100.10 [91.30, 108.90]   | 101.12 [92.71, 109.52]                                    |
| Month 24                                     | 97.34 [87.75, 106.93]    | 102.17 [92.81, 111.53]                                    |
| Anger expression (STAXI-2 [AXOJ])            |                          |                                                             |
| Baseline                                     | 20.85 [19.65, 22.04]     | 19.06 [17.95, 20.17]                                       |
| Month 6                                      | 18.36 [17.24, 19.49]     | 16.95 [15.89, 18.01]                                       |
| Month 12                                     | 17.20 [16.13, 18.27]     | 17.10 [16.08, 18.11]                                       |
| Month 24                                     | 17.10 [16.00, 18.20]     | 17.28 [16.20, 18.36]                                       |
| Superiority analysis based on intent to treat sample |                          |                                                             |
| General psychopathology (SCL-90R)            |                          |                                                             |
| Baseline                                     | 1.77 [1.67, 1.88]        | 1.75 [1.65, 1.86]                                         |
| Month 6                                      | 1.67 [1.52, 1.81]        | 1.36 [1.22, 1.51]                                         |
| Month 12                                     | 1.40 [1.25, 1.55]        | 1.44 [1.29, 1.60]                                         |
| Month 24                                     | 1.35 [1.18, 1.52]        | 1.52 [1.34, 1.69]                                         |
| Depression (BDI-II)                          |                          |                                                             |
| Baseline                                     | 35.39 [33.42, 37.35]     | 35.06 [33.10, 37.03]                                       |
| Month 6                                      | 29.03 [26.16, 31.89]     | 25.16 [22.30, 28.03]                                       |
| Month 12                                     | 25.67 [22.82, 28.51]     | 26.81 [23.97, 29.65]                                       |
| Month 24                                     | 24.06 [20.97, 27.16]     | 26.90 [23.71, 30.10]                                       |
| BPD symptoms (BSL-23)                        |                          |                                                             |
| Baseline                                     | 2.28 [2.15, 2.42]        | 2.23 [2.10, 2.37]                                         |
| Month 6                                      | 1.93 [1.77, 2.10]        | 1.55 [1.38, 1.72]                                         |
| Month 12                                     | 1.62 [1.44, 1.80]        | 1.73 [1.55, 1.91]                                         |
| Month 24                                     | 1.53 [1.33, 1.73]        | 1.70 [1.50, 1.91]                                         |

Skills uptake (DBT-WCCL) [skills use]
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Participant Flow

A total of 1,181 individuals underwent initial screening, of whom 398 were assessed for eligibility. The 240 eligible participants were randomized to DBT-6 (n = 120) or DBT-12 (n = 120) (Fig. 1).

Consistent with other DBT RCTs [11, 12, 40–42], participants who missed 4 consecutive individual or group sessions were considered treatment dropouts. The dropout rate was 30% (n = 72), with no significant between-group differences: 30 (25.0%) DBT-6 versus 42 (35.0%) DBT-12 [χ²(1) = 2.00, p = 0.100]. In addition, there were no significant between-group differences in the dropout rates at 6 months [χ²(1) = 0.21, p = 0.647]. There were no significant differences in dropout rates between sites or conditions at each site. Treatment completers (N = 168; DBT-6 = 90; DBT-12 = 78) were included in the per-protocol sample. All 240 were included in the ITT sample. Dropout rates were consistent with those reported in previous RCTs [11, 12, 40–42].

Table 2

| Outcome                        | Estimated marginal means         | Estimated mean change in outcome (baseline to end of period) |
|--------------------------------|----------------------------------|---------------------------------------------------------------|
|                                | DBT-12 M [95% CI]                | DBT-6 M [95% CI]                                              | DBT-12 minus DBT-6 Margin M [95% CI] |
| Baseline                       | 1.43 [1.35, 1.51]                | 1.44 [1.37, 1.52]                                            | – | –0.05 |
| Month 6                        | 1.74 [1.65, 1.84]                | 1.78 [1.69, 1.88]                                            | 0.31 [0.22, 0.40] | 0.34 [0.25, 0.43] | 0.03 [-0.10, 0.16] |
| Month 12                       | 1.83 [1.73, 1.93]                | 1.70 [1.60, 1.80]                                            | 0.40 [0.31, 0.50] | 0.25 [0.16, 0.35] | -0.15 [-0.28, -0.01] |
| Month 24                       | 1.85 [1.74, 1.97]                | 1.70 [1.58, 1.82]                                            | 0.42 [0.31, 0.53] | 0.26 [0.15, 0.37] | -0.16 [-0.32, -0.01] |

Interpersonal functioning (IP-64)

| Baseline                       | 121.67 [115.95, 127.38]         | – | –10 |
| Month 6                        | 109.53 [102.54, 116.51]         | – | –10 |
| Month 12                       | 99.60 [92.11, 107.09]           | – | –10 |
| Month 24                       | 96.11 [87.53, 104.69]           | – | –10 |

Anger expression (STAXI-2 (AXO))

| Baseline                       | 20.77 [19.83, 21.71]            | 19.65 [18.71, 20.59]                                         | – | –2.67 |
| Month 6                        | 18.56 [17.62, 19.50]            | 17.28 [16.34, 18.21]                                         | –2.21 [-3.09, -1.32] | -2.37 [-3.26, -1.49] | 0.17 [-1.08, 1.42] |
| Month 12                       | 17.42 [16.48, 18.36]            | 17.62 [16.68, 18.55]                                         | -3.34 [-4.17, -2.52] | -2.03 [-2.85, -1.21] | -1.31 [-2.48, -0.15] |
| Month 24                       | 17.26 [16.26, 18.25]            | 17.80 [16.79, 18.82]                                         | -3.51 [-4.54, -2.47] | -1.85 [-2.90, -0.79] | -1.66 [-3.14, -0.19] |

R codes provided further confirmation. Analyses were performed using the following R [35] packages: lme4 [36] to estimate LLMs, geepack [37] and nlme [38] to estimate GEES and GLMMs, respectively, and emmeans [39] to estimate marginal means and the associated confidence intervals for normally distributed outcomes.

Results

Patient Characteristics

Baseline characteristics were comparable between treatment groups and sites for both the per-protocol sample (Table 3) and the ITT sample (see online suppl. material). The few significant between-group or -site differences in baseline characteristics are noted in the applicable table.

The maximum number of weekly individual sessions was 26 for DBT-6 and 52 for DBT-12. In the DBT-6 group, average attendance was 21.4 sessions (SD = 3.31; 82.3%) for the per-protocol sample and 18.1 sessions (SD = 6.86; 69.7%) for the ITT sample in the DBT-12 group.
Fig. 1. CONSORT diagram. Phone screens ($n = 1,211$) and in-person assessments ($n = 398$) were used to determine participant eligibility. Participants were randomized to either 6 months ($n = 120$) or 12 months ($n = 120$) of DBT and represented the intent to treat sample. Participants who completed 6 months ($n = 90$) or 12 months ($n = 78$) of DBT represented the per-protocol sample.
Table 3. Demographic and clinical characteristics of participants (per-protocol sample)

| Characteristic                          | Site      | Length of treatment | Overall (N = 168) |
|----------------------------------------|-----------|---------------------|-------------------|
|                                        | CAMH (n = 115) | SFU (n = 63) | 12 months (n = 78) | 6 months (n = 90) |           |
| Mean (SD) age                          | 28.13 [7.96] | 28.58 [9.99] | 27.65 [8.38] | 28.81 [8.84] | 28.27 [8.62] |
| Female                                 | 91 [79] | 41 [77] | 60 [77] | 72 [80] | 132 [79] |
| Marital status                         |           |                     |                   |                   |           |
| Married                                | 16 [14] | 10 [19] | 16 [21] | 10 [11] | 26 [15] |
| Separated, divorced, widowed           | 9 [8] | 5 [9] | 4 [5] | 10 [11] | 14 [8] |
| Never married                          | 90 [78] | 38 [72] | 58 [74] | 70 [78] | 128 [76] |
| Education                              |           |                     |                   |                   |           |
| High school or less                    | 25 [22] | 12 [23] | 17 [22] | 20 [22] | 37 [22] |
| Some post-secondary                    | 38 [33] | 13 [25] | 24 [31] | 27 [30] | 51 [30] |
| Post-secondary                         | 52 [45] | 28 [33] | 37 [47] | 43 [48] | 80 [48] |
| Employed                               | 42 [37] | 24 [45] | 24 [31] | 42 [47] | 66 [39] |
| Incomea                                |           |                     |                   |                   |           |
| <15,000 USD                            | 66 [57] | 25 [47] | 46 [59] | 45 [50] | 91 [54] |
| Between 15,000 USD and 29,000 USD      | 30 [26] | 25 [47] | 23 [29] | 32 [36] | 55 [33] |
| Between 30,000 USD and 49,000 USD      | 14 [12] | 2 [4] | 5 [6] | 11 [12] | 16 [10] |
| Mdn (IQR) lifetime suicide attempts    | 1 [5] | 2 [5] | 1 [4] | 2 [6] | 1 [5] |
| Mean (SD) GAF                          | 49.28 [6.79] | 51.49 [8.61] | 49.56 [7.75] | 50.33 [7.22] | 49.98 [7.46] |
| Lifetime comorbid axis I disorders     |           |                     |                   |                   |           |
| Major depressive disorder              | 95 [83] | 41 [77] | 62 [79] | 74 [82] | 136 [81] |
| Panic disorder                         | 35 [30] | 18 [34] | 25 [32] | 28 [31] | 53 [32] |
| Post-traumatic stress disorder         | 57 [50] | 29 [55] | 41 [53] | 45 [50] | 86 [51] |
| Any anxiety disorder                   | 96 [83] | 47 [89] | 64 [82] | 79 [88] | 143 [85] |
| Any substance use disorder             | 93 [81] | 39 [74] | 65 [83] | 67 [74] | 132 [79] |
| Any eating disorderb                   | 61 [53] | 19 [36] | 38 [49] | 42 [47] | 80 [48] |
| Current comorbid axis I disorders      |           |                     |                   |                   |           |
| Major depressive disorder              | 44 [38] | 22 [42] | 29 [37] | 37 [41] | 66 [39] |
| Panic disorder                         | 27 [23] | 16 [30] | 20 [26] | 23 [26] | 43 [26] |
| Post-traumatic stress disorder         | 34 [30] | 24 [45] | 25 [32] | 33 [37] | 58 [35] |
| Any anxiety disorder                   | 90 [78] | 65 [85] | 61 [78] | 74 [82] | 135 [80] |
| Any substance use disorderc            | 52 [45] | 11 [21] | 31 [40] | 32 [36] | 63 [38] |
| Any eating disorder                    | 26 [23] | 9 [17] | 11 [14] | 24 [27] | 35 [21] |
| Axis II cluster A diagnosisd           | 1 [1] | 12 [23] | 6 [8] | 7 [8] | 13 [8] |
| Axis II cluster B diagnosis (excl. BPD)d | 3 [3] | 8 [15] | 3 [4] | 8 [9] | 11 [7] |
| Axis II cluster C diagnosisd           | 27 [23] | 22 [42] | 16 [21] | 33 [37] | 49 [29] |
| Mean (SD) axis I current disorders     | 2.75 [1.50] | 3.02 [1.92] | 2.82 [1.64] | 2.84 [1.65] | 2.83 [1.64] |
| Mean (SD) axis I lifetime disorders    | 4.88 [2.22] | 5.12 [2.60] | 5.28 [2.33] | 4.67 [2.32] | 4.95 [2.34] |
| Mean (SD) axis II disorders (excl. BPD)f | 0.28 [0.47] | 1.00 [1.21] | 0.38 [0.74] | 0.61 [0.92] | 0.51 [0.85] |

Data reported are based on per protocol sample (N = 168). Values reported are n (%) unless otherwise noted. χ² and Fisher exact tests (and T tests for variables reporting a mean) revealed no significant differences between sites or conditions, except as noted. BPD, borderline personality disorder; CAMH, Center for Addiction and Mental Health, Toronto, ON, Canada; GAF, Global Assessment of Function; SFU, Simon Fraser University, Burnaby, BC, Canada. a The proportion of participants with income of 15–29K was significantly higher at SFU (p = 0.043). There were no significant differences between conditions. b The proportion of participants with any lifetime eating disorder was significantly higher at CAMH (p = 0.045). There were no significant differences between conditions. c The proportion of participants currently diagnosed with any substance use disorder was significantly higher at CAMH (p = 0.005). There were no significant differences between conditions. d The proportion of participants diagnosed with a comorbid cluster A, B, or C axis II disorder was significantly higher at SFU (p < 0.001, p = 0.005, p = 0.027, respectively). There were no significant between-condition differences for both comorbid cluster A and cluster B axis II disorders. e The proportion of participants with any cluster C axis II disorder was significantly higher in the 6-month treatment condition. f Participants at SFU were diagnosed with significantly more comorbid axis II disorders (p < 0.001). Participants assigned to the 6-month treatment were also diagnosed with significantly more comorbid axis II disorders (p = 0.034).
it was 39.9 (SD = 6.85; 76.7%) and 30.5 (SD = 15.5; 58.7%) sessions, respectively.

The mean number of psychotropic medications and the mean number of non-study psychosocial treatments decreased significantly from baseline to month 24 in both groups (for both ITT and per-protocol samples; see online suppl. material). There were no significant between-group differences in the rate of change for either outcome.

**Fig. 2.** Ninety-five percent confidence intervals for between-condition differences in primary outcome relative to noninferiority margins for the per-protocol sample at months 6, 12, and 24. Black dashed lines indicate location of noninferiority margins for difference in absolute rates of total self-harm at 12 months assuming per-protocol margin (−1.53), at 12 months assuming clinician-defined margin (−1.47), at 6 months assuming clinician-defined margin (−1.94), and at 24 months assuming clinician-defined margin (−1.25).
Treatment Adherence

Coders rated a random selection of 336 individual sessions and 62 group sessions. Computed Global Scores ≥4 were considered adherent. All coders were trained to acceptable reliability with the gold standard, defined as ratings within a 0.3 deviation with the gold standard’s computed global rating on the Adherence Coding Scale [21]. Inter-rater reliability with the gold standard was good, 0.80 (ICCs: 0.48–0.92).

Overall adherence to the DBT protocol was good for both individual therapy (M [SD] DBT-12 = 4.15 [0.21]; M [SD] DBT-6 = 4.14 [0.20]) and group therapy (M [SD] group = 4.13 [0.17]), with no significant difference between the conditions (Mdif = 0.004, 95% CI = [−0.04, 0.05], t(332.78) = 0.16, p = 0.872).

Outcomes

Estimated marginal means, tests of noninferiority and superiority, and tests for significant improvements in outcomes from baseline within each condition are shown in Table 1 (non-normally distributed outcomes) and Table 2 (normally distributed outcomes). Noninferiority tests for the per-protocol sample were confirmed in the ITT sample, except where noted, as were tests for significant within condition improvements in each outcome. Following Rehal et al. [43], when results from the per-
protocol and ITT analyses differ, conclusions regarding noninferiority are based on the per-protocol analysis. Plots of noninferiority tests and changes in estimated marginal means (based on both per-protocol and ITT samples) for each outcome can be found in the online supplementary material. There were no clinically relevant site differences for any primary or secondary outcomes.

**Primary Outcome: Self-Harm**

Participants in both conditions showed significant reductions from baseline in total self-harm, as well as for suicide attempts and NSSI separately, based on 95% (Table 1) and 99% confidence intervals. As shown in both Figure 2 and Table 1, noninferiority of DBT-6 based on total self-harm at 12 months was established based on both the noninferiority margin defined in the protocol and that based on clinical judgment. Additionally, noninferiority criteria (based on clinical judgment) were also met at 6 and 24 months.

For NSSI (see Table 1), the noninferiority criteria were also met at each time, post-baseline. For suicide attempts (see Table 1), however, noninferiority criteria were met at months 6 and 12, but not month 24.

**Secondary Outcomes**

Noninferiority criteria for reductions in general psychopathology as well as increases in coping skills (Table 2) were met at all time points. The noninferiority criteria for BPD symptoms were met at months 6 and 12; and at month 6 for improvements in depression, interpersonal functioning, and anger expression.

Significant improvements in all secondary outcomes from baseline to all time points were evident in both conditions (based on both 95%, per Table 2, and 99%...
confidence intervals) with the exception of improvements in general psychopathology for DBT-12 at month 6. Table 4 shows effect sizes for these improvements for normally distributed outcomes. Effect sizes were based on estimated marginal means for each outcome and time point and obtained following methods outlined in Feingold [44].

The within-group effect size estimate for improvements in general psychopathology for DBT-12 at month 6 was small ($d = 0.17$); however, at months 12 and 24, these estimates were moderate-large ($d = 0.59$ and 0.66, respectively). Participants in the DBT-6 condition showed superior improvements compared to DBT-12 in both general psychopathology (within-group effect size $d = 0.67$) and BPD symptoms (within-group effect size $d = 0.94$) at month 6. The effect size estimates in both treatment conditions for reduction in BPD symptoms were associated with large effect sizes.

Tests for the superiority of improvements in both anger expression and skills uptake by end of follow-up (month 24) were inconclusive. Improvements in skills uptake were significantly greater for DBT-12, with a large ($d = 0.94$) within-group effect size change at 24 months, and a medium effect size ($d = 0.58$) for DBT-6. Improvements in skills uptake for DBT-6, however, were noninferior to improvements in DBT-12 in both the per-protocol and ITT samples, suggesting statistically but not clinically significant differences between the two conditions. While improvements in anger expression were significantly higher for DBT-12, noninferiority for this outcome could not be established in the ITT sample.

**Diagnostic Remission and Recovery from Self-Harm**

We examined BPD diagnostic remission and recovery from self-harm in treatment completers with self-harm data at respective ends of treatment (6 [DBT-6] and 12 [DBT-12] months) and, separately, self-harm and BPD diagnostic data at 24 months (see Table 5).

Diagnostic remission was defined as no longer meeting five DSM-IV criteria for BPD at 24 months assessed using the IPDE. Based on this definition, the diagnostic remission rate was 56% in both conditions with no between-condition differences (tested via $\chi^2 (1) = 0.0, p = 1$). For recovery from self-harm, participants were classified as fully recovered, partially recovered, unchanged, or deteriorated based on changes in the presence and severity of self-harm at 12 and 24 months using the procedure described in online supplementary material [45]. The rate of full or partial recovery from self-harm was 75% for both conditions and no more than 5% deteriorated by end of treatment. Similar findings regarding recovery from self-harm were evident at 24 months.

**Adverse Events**

AEs were identified by contacting participants and contacts, hospital records, and coroner reports. No nonserious or serious AEs were attributable to study treatment. Two deaths occurred during the follow-up phase and it is not known whether these deaths were linked to the treatment. A DBT-6 treatment dropout died of a fentanyl overdose between months 15–18, and a DBT-12 treatment completor died of unknown causes between months 21–24. The status of 10 participants lost to follow-up could not be confirmed by study end.

**Discussion**

This is the first randomized trial to our knowledge to compare 6 to 12 months of comprehensive, standard DBT for recurrently self-harming or suicidal patients with BPD. The findings demonstrate that 6 months of DBT is noninferior to 12 months on several outcomes. Both the DBT-6 and DBT-12 groups showed significant improvement from baseline to month 24 on all primary and secondary outcome measures. Notably, our noninferiority hypothesis was established on the primary outcome, total self-harm, general psychopathology, and coping skills at all time points over the 2-year study. DBT-6 was associated with a more rapid reduction of BPD symptoms and general psychopathology. The findings demonstrate that DBT-6 was safe, associated with comparable retention, and associated with durable and comparable effects to DBT-12 on our primary outcome, total self-harm, as well as several other mental health outcomes.

These findings are important because they indicate that there was no additional benefit of long-term over short-term DBT for the treatment of a severe, polysymptomatic clinical sample with BPD pathology. Research on how much therapy is required to produce an optimal treatment effect for severe clinical populations is meager and the study findings add to this literature. Several studies to date have investigated questions about the dose-response effect in psychotherapy and have produced mixed results [46–50]. Our findings are consistent with those of a recent systematic review that found no evidence to support psychotherapies lasting beyond 30 sessions [46]; however, they contrast with those of Nordmo et al.
which found the effects of open-ended psychotherapy to be linearly related to treatment length, with the median time to clinically significant change being 57 sessions. Importantly, there are some differences between the samples and methodologies that may account for the conflicting results. In contrast to our study, Nordmo et al. [49] investigated an open-ended psychotherapy, the primary outcomes were interpersonal functioning and general symptoms, and the sample was less severe (only 54% with personality pathology). BPD is a highly heterogeneous disorder with patients responding differently to the same dose of psychotherapy at an individual level however focusing on group level effects, our findings indicate that shorter-term psychotherapy is “good enough.” Further research is needed to identify whether different subgroups will differentially respond to short- versus long-term psychotherapy and to determine how the optimal dose may vary according to different outcomes (e.g., functioning).

Given the high health burden of BPD and substantial barriers to accessing specialized psychotherapies, our study has important implications for the treatment of this disorder. The finding that DBT-6 was noninferior to DBT-12 at 24 months on our primary outcome, frequency of total self-harm, and general psychopathology and coping skills, adds to mounting evidence that shorter-term psychotherapy yields beneficial outcomes for individuals with BPD. Our study challenges the prevailing opinion that people with complex personality disorders require lengthy treatment and supports the use of briefer therapies for BPD and, by extension, the investment in brief treatment as a component of a broader treatment continuum for BPD. An abbreviated duration of DBT may help to stabilize patients and allow subsequent treatment (DBT or otherwise) to address quality-of-life and general functioning. Furthermore, given that access to BPD specialist therapies is a problem for many patients due to scarce resources and expense, shortening the overall length of therapy may be a suitable approach to staging specialist therapy. Lengthier therapy could be reserved for the most severe and complex patients [51]. Future research remains to be done to identify patient characteristics that will inform acceptable staging criteria.

Additionally, for acute symptoms, at least in terms of the reduction of BPD and general psychopathology symptoms, short-term DBT produced more rapid benefits. This finding is consistent with other research showing that short-term psychotherapy may be faster-acting than longer-term psychotherapy [52]. Knowing that time is limited, patients and therapists in the short-term treatment might be more motivated to engage in more productive work and address separation issues and termination from the outset. It is also possible that other nonspecific factors differed between conditions; for instance, briefer treatments may enhance patients’ expectancies regarding the timeline needed for therapeutic gains.

In terms of the effects of DBT in the present study, our findings are consistent with previous studies. Borderline and psychopathology outcomes are comparable to the effect sizes reported in meta-analytic studies evaluating the effectiveness of specialist psychotherapies for BPD [53, 54]. Moreover, although improvements in anger expression were significantly higher for DBT-12, the within-group effect size was only moderate, which is consistent with previous studies by McMain et al. [40] and Washburn et al. [55]. Collectively, our findings indicate that, while DBT is associated with statistically significant change in general psychopathology and other secondary clinical outcomes (e.g., skills uptake, anger expression), these changes are mostly moderate in size; thus, it is important that DBT, similar to other BPD-related treatments, continue to innovate ways to exert greater impact on these outcomes.

The current study did not establish the noninferiority of DBT-6 on all secondary outcomes at the end of 24 months (i.e., borderline symptoms, depression, interpersonal problems, anger, and suicide attempts). However, at the same time, there was no compelling evidence supporting the superiority of DBT-12 to DBT-6 on these outcomes. The failure to detect noninferiority for some secondary outcomes may be due to the study not being powered to test for noninferiority of the secondary outcomes. Future research with appropriate power is needed to establish noninferiority for these other outcomes.

This study has several limitations. First, the primary outcome was based on self-reports of self-harm in response to the SASII, a structured interview, and may have been subject to bias. Second, the protocolled plans were to use a noninferiority margin that was statistically derived for the primary outcome. Margins were later updated prior to data analyses to take into account clinical judgement, and this deviation may be subject to bias. Third, one challenge inherent in noninferiority trials is that noninferiority margins could always be too wide, resulting in an erroneous conclusion that the differences between conditions are not clinically significant. Margins could also be too narrow, resulting in increased probability of finding inferiority. Fourth, dose-response relationships in psychotherapy may take on distinct trajectories...
A Noninferiority Trial of Dialectical Behavior Therapy

Conflict of Interest Statement

Dr. McMain received personal fees from reimbursement for giving seminars and workshops on dialectical behavior therapy (DBT) and is co-owner of a practice offering DBT. Dr. Chapman received payment for providing seminars and workshops on DBT and royalties for books on DBT and is co-owner of a practice offering DBT. Dr. Kuo received payment from Behavioral Tech, LLC, for providing training and consultation in DBT and offering seminars and workshops on DBT and is co-owner of practices offering DBT. Dr. Dixon-Gordon received payment from Behavioral Tech, LLC, for providing training in DBT, royalties for a book on DBT, and a grant from the US government to study DBT. Dr. Guimond, Dr. Isaranuwatchai, Ms. Labrish, and Dr. Streiner have no conflicts of interest to report. The study authors declare that they have no financial or competing interests with this study. There was no involvement of the intervention developer or other stakeholders in the design, conduct, analysis, and/or reporting of the trial.

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Author Contributions

Drs. McMain, Chapman, and Kuo contributed equally to the study, had full access to all the data in the study, and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors contributed to the acquisition, analysis, or interpretation of data and reviewed the manuscript for important intellectual content, providing critical revision as necessary. The study was conceptualized and designed by McMain, Chapman, Kuo, Streiner, Guimond, and Dixon-Gordon who also secured funding. McMain, Chapman, Kuo, and Dixon-Gordon supervised the study. McMain and Labrish drafted the manuscript. Statistical analysis was performed by Labrish and Guimond. McMain, Chapman, Kuo, Dixon-Gordon, Guimond, and Labrish also provided administrative, technical, or material support.

Data Availability Statement

Access to data from this study may be obtained by contacting the corresponding author. All requests for data access must be approved by the IRBs of CAMH and SFU. Data access will be governed by a data sharing agreement executed between CAMH and the institution with whom the primary investigator is affiliated.

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Statement of Ethics

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Institutional Research Boards (IRBs) of both the Center for Addiction and Mental Health (CAMH; approval number 026-2014) and Simon Fraser University (SFU; approval number 15-5477), and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. All participants provided written informed consent. The original full trial protocol is available from the first author on request. The study was registered with clinicaltrials.gov (NCT02387736).

across subgroups [46]. Whereas some models propose that it is more important to determine how much therapy is “good enough,” a dose-response association implies that greater symptom improvement is better, which is a reasonable assumption when self-harm is the outcome. Fifth, inherent in RCTs of BPD, ancillary treatments such as pharmacotherapy were not rigidly controlled to maintain generalizability, and this may have influenced the results. Finally, in the absence of a control, we cannot disentangle the possible influence of nonspecific effects on outcomes, such as patients’ perceptions and expectations of the therapy.

In light of scarce treatment resources for BPD, briefer therapy (6 months instead of 12 months) should be considered a desirable option for people with BPD. Half the dose of the standard DBT yielded noninferior improvements across time points for the primary outcome, total self-harm frequency, as well as several clinical outcomes. Findings of noninferiority were not uniformly evident across every time point for all secondary outcomes, highlighting important avenues for future research. Clinicians and healthcare administrators should consider the benefits of briefer, comprehensive psychotherapy for complex, severe personality disorders such as BPD.

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