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3	Cognitive-behavioral therapy for eating disorders in primary care settings:
4	Does it work, and does a greater dose make it more effective?
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1	Cognitive-behavioral therapy for eating disorders in primary care settings:
2	Does it work, and does a greater dose make it more effective?
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4	
5	Abstract
6	
7	Objective: This study aimed to determine whether cognitive behavioral therapy (CBT) for
8	eating disorders can be effective in a routine, primary care clinical setting, and to assess
9	dose response.
10	Methods: The participants were 47 patients who commenced treatment with a publicly-
11	funded primary care eating disorder service. They attended 7-33 sessions of individual CBT
12	(mean = 17), using an evidence-based approach. Routine measures were collected pre- and
13	post-therapy.
14	Results: Three-quarters of the patients completed treatment. Using intention to treat
15	analysis (multiple imputation), the patients showed substantial improvements in eating
16	attitudes, bulimic behaviours and depression. However, there was no association between
17	the level of improvement and the length of therapy past the 8^{th} to 12^{th} session
18	Discussion: The level of effectiveness shown here is comparable to that previously
19	demonstrated by more specialist services in secondary and tertiary care. The non-linear
20	association between number of sessions and recovery highlights the importance of early
21	change, across the eating disorders.
22	
23	
24	Key words:
25	Cognitive-behavioral therapy; community sample; treatment dose; eating disorders
26	

1

Cognitive-behavioral therapy for eating disorders in primary care settings:

2

Does it work, and does a greater dose make it more effective?

Eating disorder services are configured differently both within and between countries, 3 according to national and local patterns of provision. Many are specialist services at 4 5 secondary or tertiary levels of care, taking referrals from more generalist primary care level services. However, such specialist services are not always present, and they do not always 6 7 have the capacity to see the full range of patients with eating disorders (e.g., not accepting 8 referrals for individuals with binge-eating disorder; not treating non-underweight cases). 9 Where services have to select which patients they have the capacity to see, they are likely to 10 focus on anorexia nervosa cases, given their higher risk levels. Such services also tend to 11 see patients for extended periods of time. While existing evidence-based protocols 12 recommend relatively long periods of treatment for eating disorders compared to anxiety and 13 depressive disorders, it is clear that clinicians routinely extend therapy so that it is substantially longer than those recommendations (e.g., Cowdrey & Waller, 2015). 14 Consequently, many clinicians and services have a relatively slow turnover of cases, making 15 it even less likely that patients in the community will be able to access treatment. 16

17 As a result of this limited access to specialist services, some primary care eating disorders services have been established (Devlin, 2014) with the intention of providing 18 treatment for normal-weight patients within non-specialist services. They do not have the 19 range of professional backgrounds that are common in specialist eating disorders teams, but 20 usually have training in appropriate therapies. For adult patients, this therapy base is 21 commonly cognitive behavioral therapy (CBT), given its proven benefits in clinical trials 22 (Fairburn et al., 2009) and in routine practice in specialist eating disorder services (Byrne, 23 Fursland, Allen & Watson, 2011; Knott, Woodward, Hoefkens & Limbert, 2015; Turner et al., 24 2015). However, no studies to date have explored the effectiveness of CBT for eating 25 disorders when delivered in a primary care setting. This study addresses the effectiveness of 26 CBT in such settings, in order to determine whether such services are able to provide 27 outcomes that are comparable to those in secondary and tertiary care levels. 28

1 In addition to providing access to services, it is also important to consider the duration of therapy in such settings. If therapy can be delivered over a shorter time frame, 2 3 this would allow for more patients to be treated from within the same resources. While recommendations for length of treatment for CBT for eating disorders vary from 15-40 4 5 sessions (depending on the version of CBT and the patient's BMI - Fairburn, 2008), there is 6 provision within protocols for CBT to be extended if appropriate (Fairburn, 2008; Waller et 7 al., 2007). However, effectiveness studies have also suggested that the therapy might be 8 shortened in response to early changes, as well as allowing for extension (e.g., Turner et al., 9 2015). While it might be assumed that adding more sessions would have a stronger clinical 10 effect, there is some indication that therapy effects are not linear with time. There is usually a 11 dose-response effect at first, which tails off to show limited or no gains thereafter. For example, Delgadillo et al. (2014) have demonstrated that the optimal length of therapy for 12 13 mild to moderate anxiety and depression is approximately 4-6 sessions, and that additional sessions do not result in better outcomes. In the eating disorders, Bell et al. (2017) have 14 shown a similar pattern in a specialist service – within a group of patients receiving a mean 15 of 16.2 sessions of one of a range of therapies, there was no link between treatment 16 17 duration and outcomes, even among anorexia nervosa cases. Such a pattern stresses the importance of early gains, so that greater change levels are in place before the dose 18 response effect has faded. However, the possibility of such a pattern is yet to be established 19 in non-specialist eating disorders services of the type outlined above, to allow clinicians to 20 plan for the optimum number of sessions to be offered. 21

Given the limited evidence base regarding eating disorder services in primary care settings, this study has two aims. First, it will determine whether CBT for eating disorders can be effective in a routine, primary care setting. Second, it will assess dose response does the provision of more treatment sessions continue to facilitate further recovery gains?

Method

- 26
- 27 Ethics
- 28

The local National Health Service (NHS) Research and Development Office

approved collection of these outcome data as a service evaluation. Thus, NHS Research
 Ethics Committee approval was not required. Service users provided consent for their data
 to be used for this purpose.

4 **Participants**

5 The patients were aged 18 years or above at the point where they were referred to the service by their General Practitioner. All referred patients were triaged to ensure that 6 7 they met the criteria for the service (body mass index \geq 17; not requiring multiagency/ 8 multidisciplinary care to address additional psychiatric or social needs; no alcohol or 9 substance abuse; no psychotic diagnosis; medically stable and monitored by the responsible 10 family physician). Each had a DSM-5 (American Psychiatric Association, 2013) diagnosis of 11 anorexia nervosa, bulimia nervosa, atypical anorexia nervosa or atypical bulimia nervosa. 12 Other OSFED cases and binge-eating disorder cases were not eligible for the service, due to 13 local service commissioning arrangements. Unlike Knott et al. (2015), motivation to engage in therapy was not an eligibility criterion. 14

All patients who attended for assessment and met the criteria agreed to participate in 15 therapy (though some dropped out later – see below). At the time of data collation, the case 16 17 series consisted of 47 patients who started CBT for eating disorders with a UK primary care eating disorders service. Forty-four were female and three were male. Eleven had a 18 diagnosis of anorexia nervosa and six had a diagnosis of atypical anorexia nervosa (BMI 19 above 18 and below 20, with marked restriction of intake and current weight loss), while 29 20 had a diagnosis of bulimia nervosa and one had a diagnosis of atypical bulimia nervosa 21 (frequency of bulimic behaviour below the DSM-5 criteria). 22

23 Treatment

All patients were treated individually in primary care settings. They were seen by therapists who had been trained in the delivery of CBT via the UK Improving Access to Psychological Therapies (IAPT) programme, which is a scheme focusing on the delivery of evidence-based treatments (particularly CBT) for common psychological disorders (though not eating disorders). Each of the therapists was supervised weekly from within the team (i.e., by other eating disorder clinicians with the same training background) rather than by
 external specialists. The therapists included one counsellor, two occupational therapists, a
 trainee clinical psychologist and one nurse.

The CBT was based on individual case formulations, as described by Ghaderi 4 5 (2006). Treatment included: conceptualisation of beliefs about food, eating, body image and 6 emotion; sharing of information about regular eating, food and weight; in-session open weighing; support in identifying triggers to eating disorder behaviors through food records; 7 8 and exposure/behavioral experimentation to address barriers to regular balanced, flexible 9 eating. Where formulation identified maintenance caused by specific beliefs relating to the 10 meaning of body image, those beliefs were targeted. Where behaviors such as body checking or avoidance were identified as maintaining body image importance, then 11 12 behavioral experiments were planned as homework tasks. In-session mirror exposure was 13 not used.

Early sessions included completion of assessment and formulation, moving to the focus on behavioural change outlined above. When patients stated that they wanted to control their weight in a maladaptive way (e.g., restrict; remain underweight; avoid dietary normalisation), formulation and psychoeducation was used to Socratically explore the potential impact of making changes (e.g., reduced preoccupation, bingeing and purging; positive effect on relationships) in order to enhance motivation for change.

Those starting treatment with a BMI of 17-18 were offered up to 30 weekly sessions in order to allow sufficient time for weight restoration. Other patients were usually offered up to 20 weekly sessions. Sessions were booked in 4-6 week blocks. **6** If the patient failed to develop motivation towards constructive change (e.g., they maintained efforts towards weight loss), therapists were advised to discontinue CBT after eight sessions. If recovery goals were achieved early (i.e., before the 20-30 sessions were concluded), therapists were advised to aim to complete sessions sooner, following completion of maintenance planning.

27 Measures

28

As indices of the dose of CBT, the number of sessions completed and the number of

weeks in therapy were recorded. Height and weight were measured at the outset of
treatment, and weight was measured at each session thereafter. The duration of the eating
disorder was recorded from clinical assessment. Each patient completed the following two
well-validated measures at the beginning and end of therapy.

5 Eating Disorders Examination-Questionnaire (EDE-Q, version 6; Fairburn & 6 Beglin, 2008). The EDE-Q is a 33-item self-report questionnaire, which measures disordered 7 eating attitudes and behaviors over a 28-day period. The EDE-Q Global score is a summary 8 of the four attitudinal subscales (Eating Concern, Shape Concern, Weight Concern, and Restraint). The Global score was used in this case because it has better psychometric 9 10 properties than the subscales (Allen, Byrne, Lampard, Watson & Fursland, 2011). The EDE-Q was also used to provide frequencies of objective binge-eating, vomiting and laxative 11 abuse (over the previous 28 days). 12

Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer & Williams, 2001). The
 PHQ-9 is a nine-item self-report questionnaire, which measures symptoms of depression
 over a two-week period.

16 Data analysis

Ten patients did not complete therapy, and two negotiated leaving therapy early due to reluctance to engage in change (loss to therapy rate = 25.5%). A further three patients completed the treatment but did not provide final outcome data (loss to research rate = 32%). Prediction of attrition was tested using chi-squared and independent sample *t*-tests.

Intention to treat analyses were used to determine the outcome of treatment. Multiple imputation (SPSS v.24 – Fully Conditional Specification method, based on linear regression) was used to deal with missing data. Paired *t*-tests were used to determine changes in symptoms, and Cohen's *d* was used as the measure of effect size. Remission was defined by the patient meeting the following criteria at the end of therapy – BMI > 18.5, absence of any binge or purge behaviours over the previous month, and an EDE-Q Global score of < 2.77 (one SD above the mean for a UK non-clinical female population).

28 Partial correlations (controlling for initial EDE-Q score) were used to determine the

association of temporal factors (age, duration of disorder, number of sessions, duration of treatment in weeks), initial BMI and initial PHQ-9 scores with final EDE-Q and PHQ-9 scores. Finally, curve fit estimates were used to determine whether there was a relationship between therapy dose (number of sessions; number of weeks) and the level of change across therapy (completer sample only). Independent samples t-tests were used to determine whether those receiving more therapy sessions had different outcomes to those who received fewer, based on the cut-point suggested by those curve fit estimates.

8

Results

9 Sample characteristics

10 Initial EDE-Q and PHQ-9 scores were available for the 47 patients who started 11 treatment. Demographic details were available on all of these patients, apart from duration of treatment for three patients and weight for four patients. All four with missing weights had 12 13 diagnoses of bulimia nervosa and were at a normal weight (as confirmed at subsequent therapy sessions). At the beginning of treatment, the mean BMI of the sample was 22.5 (N =14 43; SD = 3.87; range = 17.04-32.94). Their mean age was 27.1 years (N = 47; SD = 6.64; 15 range = 18-42), and the mean duration of the eating disorder was 9.22 years (N = 44; SD =16 17 6.53; range = 1-23). Thirty-five of these patients completed treatment. End of therapy EDE-Q and PHQ-9 scores were available for 32 patients. 18

19 **Predictors of attrition**

Twelve patients did not complete therapy. This included both those who stopped 20 attending sessions without prior discussion, and those who negotiated early termination of 21 therapy sessions due to being unwilling or unable to work on recovery goals within the 22 service. Thus, there was an overall drop-out rate of 25.5%. There was no evidence that 23 completer status was associated with diagnosis (chi-squared = 2.73, df = 6, NS) or with any 24 temporal characteristic (age, duration of eating disorder, number of treatment sessions, 25 number of weeks in treatment – F < 2.4, P > .11 in all cases). Independent sample t-tests 26 were used to compare those who completed therapy and those who dropped out on BMI, 27 28 EDE-Q and PHQ-9 scores, but no comparison approached significance (t < 1.7, P > .12 in all

cases). Therefore, as with other such studies (e.g., Byrne et al., 2011; Waller et al., 2014),
 there was no evidence of pre-treatment characteristics that predicted attrition.

3 Outcome of treatment for eating disorders

The mean length of treatment for the patients who completed treatment was 17 attended sessions (SD = 5.84; range = 7-33), delivered over a mean of 25.2 weeks (SD =10.2; range = 10-51.7). It is noteworthy that there was no significant difference in either the length of treatment in weeks or in the number of sessions completed by anorexia nervosa or bulimia nervosa cases (t < 1.4 for each of these two treatment duration variables).

9 Table 1 shows the patients' BMIs, frequency of bulimic behaviours (objective binges, vomiting and laxative abuse), EDE-Q and PHQ-9 scores at the beginning and end of 10 11 treatment. Their pre- and post-therapy scores were compared using paired t-tests (multiple imputation used to correct for missing data). Effect sizes are shown using Cohen's d 12 13 (corrected for paired samples). BMI and frequency of laxative abuse were unchanged across treatment, but there were significant reductions in eating attitudes, depression and bulimic 14 behaviours. The effect sizes were small to medium for reduction in binge-eating, medium for 15 the reductions in eating attitudes and vomiting, and large for the reduction in depression 16 17 levels. Mean PHQ-9 and EDE-Q total scores both fell to below the clinical scores that have been identified as indicating a shift to more healthy ranges. 18

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Insert Table 1 about here

The pre-treatment EDE-Q Global score of this sample (mean = 3.89) was very similar to the comparable intention to treat figures for Byrne et al.'s (2011) and Turner et al.'s (2015) clinical samples (means = 3.96 and 4.17, respectively). The end of treatment score for this group (mean = 2.33) was slightly lower than those of Byrne's and Turner's samples (mean = 3.00 and 2.92, respectively), which might reflect the more limited inclusion criteria used in this clinical setting.

1 Remission rate

Eleven patients met the full remission criteria at the end of therapy. This represents 3 23.4% of the 47 patients who started therapy, and 34.4% of the 32 patients who completed 4 therapy and provided the necessary data. These results are similar to the remission rates 5 reported from specialist eating disorders services in effectiveness studies (Turner et al., 6 2015).

7 Association of patient characteristics with level of improvement

Table 2 shows the associations (partial correlations, controlling for initial EDE-Q scores) of pre-treatment characteristics (age, duration of eating disorder, BMI, PHQ-9) and therapy duration (weeks in treatment; number of sessions attended) with post-treatment EDE-Q Global and PHQ-9 scores. The analyses involving treatment duration were carried out for the treatment completers only. None of the associations with initial characteristics approached significance, indicating that treatment outcome was not moderated by initial severity.

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Insert Table 2 about here

18

19 Association of treatment duration with level of improvement

The duration of treatment (measured either in terms of number of sessions or 20 number of weeks) was also not associated with the final levels of eating attitudes or 21 depression (Table 2). Such a lack of associations might be explained by therapy effects 22 being non-linear. For example, effects of early treatment gains might result in a non-linear 23 24 pattern of association, where there was less change to be made later in therapy. Therefore, 25 curve fit estimates were calculated, to determine whether the best explanation of treatment outcomes (change in EDE-Q total; change in PHQ-9; change in BMI) was a linear, quadratic 26 or cubic association with each therapy duration variable (length in weeks; number of 27 sessions). The curve estimates showed that the length of treatment in weeks was not 28

1 associated with change in EDE-Q total score, regardless of whether one considered the linear, quadratic or cubic effects (F < 0.6 in all cases). Nor was there any effect of length of 2 treatment on change in PHQ-9 scores (F < 1.7 in all cases) or BMI (F < 0.45 in all cases). 3 Similarly, the number of sessions was not associated in any of these ways with change in 4 5 EDE-Q total scores (F < 0.5 in all cases), PHQ-9 scores (F < 1.5 in all cases), or BMI (F < 1.5) 6 1.0 in all cases). Examination of the curves demonstrated that the optimum length of therapy 7 was between eight and 12 sessions, with gains by that point but no pattern of further gains 8 thereafter.

9 To test this examination of the curves, the degree of change in clinical characteristics was compared between those patients who received up to 12 sessions (N = 14) and those 10 who received more (N = 23), using independent sample t-tests (multiple imputations used to 11 correct for missing data). The improvement in EDE-Q scores was slightly greater among 12 13 those patients who had fewer sessions (mean reduction = 1.89, SE = 0.38) than among those who had more sessions (mean reduction = 1.23, SE = 0.45). BMI change also differed 14 slightly between those who had fewer sessions (mean increase = 0.48, SE = 0.73) and those 15 who had more (mean reduction = 0.18, SE = 0.73). Finally, the reduction in PHQ-9 scores 16 17 was slightly lower among those patients who had fewer sessions (mean reduction = 5.29, SE = 1.50) than among those who had more sessions (mean reduction = 6.76, SE = 1.25). 18 However, in none of these cases did the difference approach significance (t < 1.0; NS in all 19 cases). These findings support the conclusion that additional sessions did not result in better 20 21 outcomes.

22

Discussion

This study aimed to establish whether CBT could be effective in the treatment of eating disorders when delivered within a primary care setting, and to determine whether there is a dose-response effect. The retention rate (c.75%) was strong relative to other effectiveness studies (e.g., Byrne et al., 2011; Turner et al., 2015). CBT was effective in this setting, reducing eating disorder symptoms and depression. The level of remission was similar to that shown in effectiveness studies conducted in specialist eating disorder services. There was no dose-response effect within this sample, despite the wide range of
 sessions (7-33) and despite the fact that clinicians were able to extend the therapy duration
 on a case-by-case basis, if they judged that the patient would benefit from more sessions.

4 These findings add to the evidence (e.g., Byrne et al., 2011; Fairburn et al., 2009; 5 Knott et al., 2015; Turner et al., 2015) that the effects of CBT for adults with eating disorders 6 are generalizable across settings and service configurations, although this conclusion would 7 be firmer if there had been a waiting list control group. It is possible that the impact would 8 have been even greater if mirror exposure work had been used for patients with body 9 avoidance issues. It is worthy of note that these benefits were achieved despite the mean 10 duration of the patients' eating disorders (9.22 years) being longer than is commonly used in 11 definitions of 'severe and enduring' eating disorders, adding to the evidence that the duration of eating disorders is not related to poor outcomes (e.g., Wildes et al., 2017). The lack of 12 13 reliable predictors of attrition is similar to findings in the wider literature (Byrne et al., 2011; Turner et al., 2015), though it is possible that studies with a larger number of participants will 14 find such predictors, possibly pointing to heuristics that might be used for treatment matching 15 purposes. 16

17 The findings also confirm the finding from the eating disorders and other disorders (e.g., Bell et al., 2017; Delgadillo et al., 2014) that adding sessions beyond a basic level 18 does not automatically enhance therapy outcomes. It is well-established that early change in 19 CBT for eating disorders is very important for longer-term outcomes (Raykos et al., 2013; 20 Turner et al. 2015; Waller et al., 2014). If treatment gains are limited after 8-12 sessions, 21 then the importance of making substantial early gains is even more vital than has been 22 suggested previously. However, such a conclusion will depend on these findings being 23 replicated with a wider range of outcome measures, and with a well-validated diagnostic 24 interview (which was not available for this clinical sample). Constructs that were not 25 specifically measured in this clinical study (e.g., quality of life; longer-term abstinence and 26 27 remission) might be influenced more by longer therapy, and therefore merit consideration in 28 future.

1 There are a number of ways in which this research needs to be extended. For example, studies of single diagnostic groups of patients would be helpful, as it is possible 2 3 that the findings will differ according to the ego syntonicity or dystonicity of the disorder (e.g., anorexia nervosa patients might need longer to engage with the treatment). It will also be 4 5 important to understand whether the pragmatic considerations that were implemented in this 6 real-life setting (e.g., shortening therapy when it was clear that the patient was not 7 demonstrating motivation to change or when the patient improved rapidly; lengthening 8 therapy when further work appeared likely to be useful) mean that the findings partially 9 reflect clinician decisions rather than patient change per se. Schibbye et al. (2015) suggest 10 that it is possible to develop algorithms for use in progress monitoring and supervision to 11 enhance such clinical decisions. It should also be noted that this study's generalisability was limited by the fact that the service was not commissioned to treat patients with binge-eating 12 13 disorder. Finally, it will also be important to consider how one could measure therapist competence and treatment fidelity in such real-life settings, as the lack of such 14 measurements is a weakness in this and most such studies. Measures of competence and 15 fidelity that can be applied readily using the resources available in everyday clinical settings 16 17 would be an asset for demonstrating the viability of rolling out evidence-based therapies to real-life clinical practice. 18

If these findings are replicated and extended, they support treatment of eating 19 disorders within primary care settings, delivered by individual practitioners working in clinical 20 teams consisting only of CBT therapists. However, they also raise the important 21 consideration of how long such therapies should be. If the maximum dose response can be 22 achieved in a much shorter number of sessions than recommended (e.g., Fairburn, 2008), 23 then the commonly perceived clinical drawback of shorter therapy (weaker outcomes) might 24 25 be invalid, while the potential economic and quality of life benefits of offering fewer sessions (less time per patient spent on treatment; greater access to treatment for more patients) 26 27 could be substantial. There is clearly a strong case for investigating the potential of briefer 28 versions of CBT and other therapies, given these findings and those of Bell et al. (2017).

1 Certainly, the case for longer therapies is weakened by such research, and any clinical case 2 for extension of treatment should be considered in supervision and monitored in practice 3 (e.g., Schibbye et al., 2015). Finally, clinicians should be encouraged to use frequent 4 measures of progress, focusing on weekly changes in behaviors and attitudes (e.g., Tatham, 5 Turner, Mountford, Tritt, Dyas & Waller, 2015). Detailed monitoring of this sort should be 6 used to identify and drive early change, to indicate when change is slowing, and to measure 7 whether any extension of therapy is justified.

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10 Authors' declaration of interest

11 The authors have no interests to declare.

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8 9	

1 <u>Table 1</u>

- 2 Outcome of treatment for eating disorders in terms of body mass index, eating pathology
- 3 (EDE-Q Global score), bulimic behaviours (per month) and depression (PHQ-9), using
- 4 multiple imputations to replace missing data (N = 47).

5

	Start of		End of		Paired t-test		
	treatment		treatment				
	Mean	(SD)	Mean	(SD)	t	Ρ	d
Body mass index	22.5	(3.98)	22.5	(3.70)	0.37	NS	-
EDE-Q total	3.89	(4.04)	2.33	(3.98)	5.88	.001	0.52
Objective binges (month)	8.55	(10.6)	4.31	(8.78)	2.21	.03	0.33
Vomiting (month)	6.47	(9.18)	2.55	(7.88)	3.48	.001	0.56
Laxatives (month)	0.41	(1.71)	0.47	(1.72)	0.21	NS	-
PHQ-9 depression	13.5	(5.48)	7.42	(6.38)	7.73	.001	1.22

6

7

1 Table 2

2 Partial correlations, testing the association between pre-treatment scores and end of

3 treatment scores on measures of eating pathology (EDE-Q Global), depression (PHQ-9) and

4 treatment duration, controlling for initial scores on the EDE-Q. Multiple imputation scores

5 were used for the correlations with initial scores (N = 47), while completer analysis was used

6 for associations with duration of treatment (N = 32). No associations were significant.

7

	End of treatment scores ⁸			
	EDE-Q Global	PHQ-9 ⁹		
Initial scores		10		
BMI	.172	.185 11		
Age	.156	220 ¹²		
Duration of eating disorder	.203	081		
PHQ-9	.323	-		
Duration of therapy				
Number of sessions	002	302		
Weeks in treatment	068	056		