



## Predictors and moderators of outcome for severe and enduring anorexia nervosa



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### ABSTRACT

Few of the limited randomized controlled trials (RCTs) for adults with anorexia nervosa (AN) have explored predictors and moderators of outcome. This study aimed to identify predictors and moderators of outcome at end of treatment (EOT) and 6- and 12-month follow-up for adults with AN ( $N = 63$ ). All participants met criteria for severe and enduring AN (duration of illness  $\geq 7$  years) and participated in an RCT of cognitive-behavioral therapy (CBT-AN) and specialist supportive clinical management (SSCM). General linear models were utilized and included all available outcome data at all time points. Outcome was assessed across three domains: eating disorder quality of life (EDQOL), mental health (MCS), and depressive symptoms (BDI). Predictors of better outcome included: lower age, shorter duration of illness, having AN-R, being employed, not taking psychotropic medication, and better social adjustment. Four moderators of treatment outcome emerged: eating disorder psychopathology (EDE Global), depression (BDI), age, and AN subtype. Participants with higher baseline scores on these measures, older age, or binge eating/purging subtype benefited more from CBT-AN than SSCM. Older patients with more severe eating-related psychopathology and depression have better outcomes in a behaviorally targeted treatment such as CBT-AN rather than a supportive treatment such as SSCM.

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### Introduction

Few randomized controlled trials (RCTs) examining different psychosocial treatments for adults with anorexia nervosa (AN) have been conducted (e.g., Dare, Eisler, Russell, Treasure, & Dodge, 2001; Lock, Agras, Fitzpatrick, et al., 2013; McIntosh et al., 2005; Pike, Walsh, Vitousek, Wilson, & Bauer, 2003; Russell, Szmukler, Dare, & Eisler, 1987). Most of these studies are compromised through lack of statistical power, and findings are generally inconclusive. The most recent published RCT for this patient population compared the relative efficacy of cognitive-behavioral therapy (CBT-AN) to specialist supportive clinical management (SSCM) in 63 women with severe and enduring anorexia nervosa (SE-AN).

While this study was also compromised due to a modest sample size, satisfactory retention in treatment and follow-up was achieved (85% of patients remained in treatment and follow-up). This study demonstrated that patients with SE-AN could make significant and meaningful improvements with both therapies. Both CBT-AN and SSCM contributed to improvements over time in several outcome domains: health-related quality of life, body weight, depression, and motivation to change (Touyz et al., 2013).

Kraemer, Wilson, Fairburn, and Agras (2002) remind us that while the evaluation of the relative efficacy of two or more treatments in an RCT is helpful, our understanding for whom a specific treatment may be best suited for (moderators of outcome), or the mechanisms through which a treatment might achieve its aims (mediators on outcome), has significant clinical relevance. Few, if any, of the published RCTs for adults with AN have examined moderators and mediators on outcome. Some of the RCTs for adults with AN have examined predictors of treatment outcome. In a study of 33 females with AN treated with CBT or nutritional counseling, Pike et al. (2003) found no significant effect of

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medication status on outcome for those treated with nutritional counseling. They did find a medication effect for CBT in that seven out of eight patients who met criteria for a good outcome were receiving medication compared to four of ten who did not meet criteria for good outcome. McIntosh et al. (2005) randomized 56 females with AN to CBT, SSCM or interpersonal therapy (IPT). These authors found that differences in outcome among the treatment groups were not explained by any difference among treatment groups at baseline. Outside of RCTs, moderators on treatment outcome have also received some attention. Lockwood, Serpell, and Waller (2012) examined moderators of weight gain in the early stages of treatment for 40 females with AN receiving CBT. They found that neither age nor body mass index (BMI) at the start of therapy predicted degree of weight change during the first 10 sessions of CBT. However, participants with elevated anxiety or phobic anxiety were slower to gain weight in the first 10 sessions (or even lost weight), and more severe levels of dietary restraint and shape concern were associated with lower levels of weight change from sessions 6–10. In a study of 218 adults with either BN or BED receiving CBT, Castellini et al. (2011), showed that eating psychopathology, psychiatric comorbidity, impulsivity and emotional eating differ in their association with both objective and subjective binge eating across BN and BED patients. Most recently, Lock, Agras, Le Grange, et al. (2013) demonstrated that for adults with AN, the most efficient predictor of weight recovery at follow-up (BMI > 19 kg/m<sup>2</sup>) was weight gain to greater than 85.8% of expected body weight at the end of treatment. In addition, the most efficient predictor of psychological recovery was achievement of a low score on the Eating Disorder Examination (EDE) Weight Concern subscale (<1.8).

Exploring mediators and moderators of outcome for adolescents with AN has been equally limited (Eisler et al., 2000; Le Grange, Eisler, Dare, & Hodes, 1992; Lock, Agras, Bryson, & Kraemer, 2005; Lock, Couturier, Bryson, & Agras, 2006). In the largest such study to date, Le Grange et al. (2012), were able to identify at least two moderators at end-of-treatment: eating-related obsessionality (Yale–Brown–Cornell Eating Disorder Total Scale) and eating disorder specific psychopathology (EDE Global). In an RCT of family-based treatment (FBT) and adolescent focused therapy (AFT), participants with higher baseline scores on these measures benefited more from FBT than AFT. No mediators of treatment outcome were identified. Taken together, it is clear that the treatment of AN is not only hampered by a limited number of RCTs, but also by the lack of studies exploring for *whom* treatments work best, or *how* one treatment versus another brings about therapeutic change.

In the present study we examine predictors and moderators of outcome (i.e., eating disorder-related quality of life, mental health, depressive symptoms) for participants in the RCT of CBT-AN and SSCM briefly described above. Given the scarcity of prior work in this domain, we did not advance any specific hypotheses. Rather, we chose to investigate several variables as possible predictors and moderators, and our procedure was therefore an exploratory analysis. Findings should thus be regarded as hypothesis generating as opposed to hypothesis testing.

## Method

### Design

This RCT occurred at two intervention sites (University of Sydney and St. George's, University of London). The main outcome report, which has been published elsewhere (Touyz et al., 2013), compared CBT-AN (Pike et al., 2003) to SSCM (McIntosh et al., 2006; McIntosh, Jordan, & Bulik, 2010) among females with SE-AN. Participants ( $N = 63$ ) were randomly assigned to either CBT-AN

( $n = 30$ ) or SSCM ( $n = 33$ ). This study was reviewed and approved by the Institutional Review Boards at each site.

Recruitment for this RCT occurred from 2007 to 2010. After telephone screening ( $n = 159$ ) to determine eligibility, 73 (46%) individuals were invited for an in-person assessment. Participants were eligible if they were female (males were excluded as we estimated that the number of such cases would be negligible), aged  $\geq 18$  years, met DSM-IV criteria for AN excluding the amenorrhea criterion, and had an illness duration of at least seven years. Participants were also included if they met the criteria above, and were at a BMI of 18.5 or lower. Participants were excluded from the study if they presented with a current manic episode or psychosis, current alcohol or substance abuse or dependence, significant current medical or neurological illness (including seizure disorder) with the exception of nutrition-related alterations that impact on weight, were currently engaged in psychotherapy and not willing to suspend treatment for the duration of their participation in the study, had plans to move beyond commuting distance from the study site in the following 12 months, or did not live within commuting distance to the study site. Eighty-six percent ( $N = 63$ ) of eligible screened participants agreed to randomization. The majority of those ineligible did not meet the DSM-IV weight criterion or the illness duration criterion.

### Treatments

Treatment was provided on an outpatient basis and involved 30 individual treatment sessions provided over the course of eight months. Sessions were conducted weekly and were 50 min in length. Participants were told that the focus of treatment was on improving quality of life rather than weight gain per se and that specific treatment goals would be decided upon collaboratively at the beginning of therapy. This does not imply that weight gain and other eating disorder symptoms were not a priority, rather, that these were somewhat deemphasized relative to quality of life improvements.

The two manualized treatments and their implementation are described in detail elsewhere (McIntosh et al., 2006, 2010; Pike et al., 2003). Briefly, CBT-AN (Pike et al., 2003) focuses on the cognitive and behavioral factors that play a role in the core features of AN and on more global issues associated with AN (e.g., motivation, schema-based work). It is comprised of four phases. In Phase I, treatment is initiated, patients are oriented to CBT-AN, and motivation is addressed. In Phase II, weight gain and cognitive distortions and behavioral disturbances associated with eating and weight are addressed. In Phase III, the focus of treatment is expanded to schema-based work that addresses relevant issues that extend beyond the specific domain of eating and weight. In Phase IV, the course of treatment is reviewed, gains are consolidated and continuing the work of CBT-AN independently after therapy ends is discussed. Although the four phases are described sequentially, CBT-AN is flexible in terms of applying modules of the protocol as needed throughout the course of treatment. For the current study, weight gain and recovery from core eating disorder pathology were not assumed to be treatment priorities. Rather, treatment goals were decided upon collaboratively at the outset of treatment. Weight gain was encouraged but not identified as the primary goal or focus of therapy (although medical stability was monitored and required in order to remain in the study). In general, CBT-AN was implemented flexibly in this study. For example, the motivational enhancement section of the manual was allowed to continue as long as needed.

SSCM (McIntosh et al., 2006, 2010) combines features of clinical management and supportive psychotherapy. More specifically, clinical management includes education, care, and

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