Thesis Title

Online guided self-help to augment standard treatment for people with anorexia nervosa: feasibility, efficacy and process measures

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Abstract

Background: There is mounting evidence on the effectiveness of guided self-help (GSH) interventions to augment, shorten or replace standard care for eating disorders (EDs). However, only few studies have tested the use of GSH for people with anorexia nervosa (AN). Aims: 1) to conduct a systematic review and meta-analysis of GSH in AN, with a focus on clinical outcomes and feasibility; 2) to evaluate the feasibility, acceptability and efficacy of a novel digital GSH intervention for AN (*RecoveryMANTRA*) tested in addition to treatment as usual (TAU) in the outpatient setting, 3) to assess predictors of drop-out from the *RecoveryMANTRA* + TAU condition; 4) to establish the role of working alliance (WA) with mentors guiding the use of *RecoveryMANTRA* on patient's symptom change over time and 5) to measure how language style matching between mentors and patients predicts clinical outcomes in the *RecoveryMANTRA* + TAU condition.

Method: 187 patients accessing outpatient services for AN across different sites in England were randomized to receive TAU only (n= 88; control group) or TAU plus *RecoveryMANTRA* (n= 99; experimental group). The primary outcome included change in body mass index (BMI) at the end of six weeks of intervention and changes in eating disorder symptoms at 6 and 12 months follow-up. Process measures, such as motivation for treatment, confidence to change, and working alliance with the therapist at the outpatient service were longitudinally investigated. The GSH intervention was delivered by peer mentors (recovered individuals or carers, n=12) or mentors (psychology graduates, n=14) over six weekly synchronous chat-based sessions. The impact of type of mentorship and of linguistic style matching between patients and mentors on clinical outcomes and treatment adherence was measured.

Results: Findings showed that: 1) GSH in AN was associated with significantly lower drop-out rates from the end of treatment assessments compared to a control condition; 2) those in the *RecoveryMANTRA* + TAU condition reported a trend level reduction in anxiety, higher levels of confidence in own ability to change, and a better alliance with the therapist at the outpatient service; 3) patient's clinical outcomes were in part associated with the characteristics of the mentor delivering

guidance 4) peer mentors working alliance in the previous session was significantly associated with eating psychopathology ratings in the next session, and 5) greater linguistic style matching between patients and mentors was associated to patient's engagement with clinical treatment.

Conclusions:

Findings provided empirical support for the feasibility and effectiveness of online GSH for adults with AN. Strengths, weaknesses and clinical implications have been discussed.

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Common abbreviations used

ACMTQ	autonomous and controlled motivation for treatment questionnaire
AN	anorexia nervosa
ARFID	avoidant/restrictive food intake disorder
ASD	autism spectrum disorder
AVP	arginine vasopressine
BMI	body mass index
BED	binge eating disorder
BN	bulimia nervosa
CIF	comparative fit intex
CBT	cognitive behavioural therapy
CG	control group
CI	confidence interval
CMR	crude mortality rate
CRH	corticotrophin
d.	cohen's d. (effect size)
DASS-21	depression, anxiety, and stress scales (21-item version)
DSM	the diagnostic and statistical manual of mental disorders
EDs	eating disorders
EDE-Q	eating disorder examination questionnaire
EDE-QS	eating disorder examination questionnaire (short version)
EM	expectation-maximization
EOT	end of treatment

ES	effect size
FBT	family based therapy
GSH	guided self-help
HPA	hypothalamic pituitary adrenal
HR	hazard ratio
ICD	the international statistical classification of diseases and related health problems
LIWC	linguistic inquiry and word count
LSM	language style matching
M	mean
MANTRA	Maudsley model of AN treatment for adults
NHS	national health service
NIA	network intervention analysis
NICE	the national institute for health and care excellence
OCD	obsessive compulsive
OR	odd ratio
OSFED	other specified feeding and eating disorders
p.	critical value of statistical significance
PRISMA	preferred reporting items for systematic reviews and meta-analysis
PTSD	post-traumatic stress disorder
QoL	quality of life
RCS	randomized controlled trials
RevMAN	review manager
RI-CLPM	random intercept cross-lagged panel model

RMSEA	root mean square error of approximation
SD	standard deviation
SE-AN	severe and enduring AN
SEM	structural equation model
SH	self-help
SHARED	self-help and recovery guide for eating disorders
SSCM	specialist supportive clinical manegement
SMN	standardized mortality rate
SMR	standardized mean difference
SPSS	statistical package for the social sciences
TIDieR	template for intervention description and replication
TAU	treatment as usual
UK	united kingdom
USH	unguided self-help
VAS	visual analogues scale
WA	working alliance
WHO	world health organization
WLSMV	weighted mean and variance adjusted
WSAS	work and social adjustment scale

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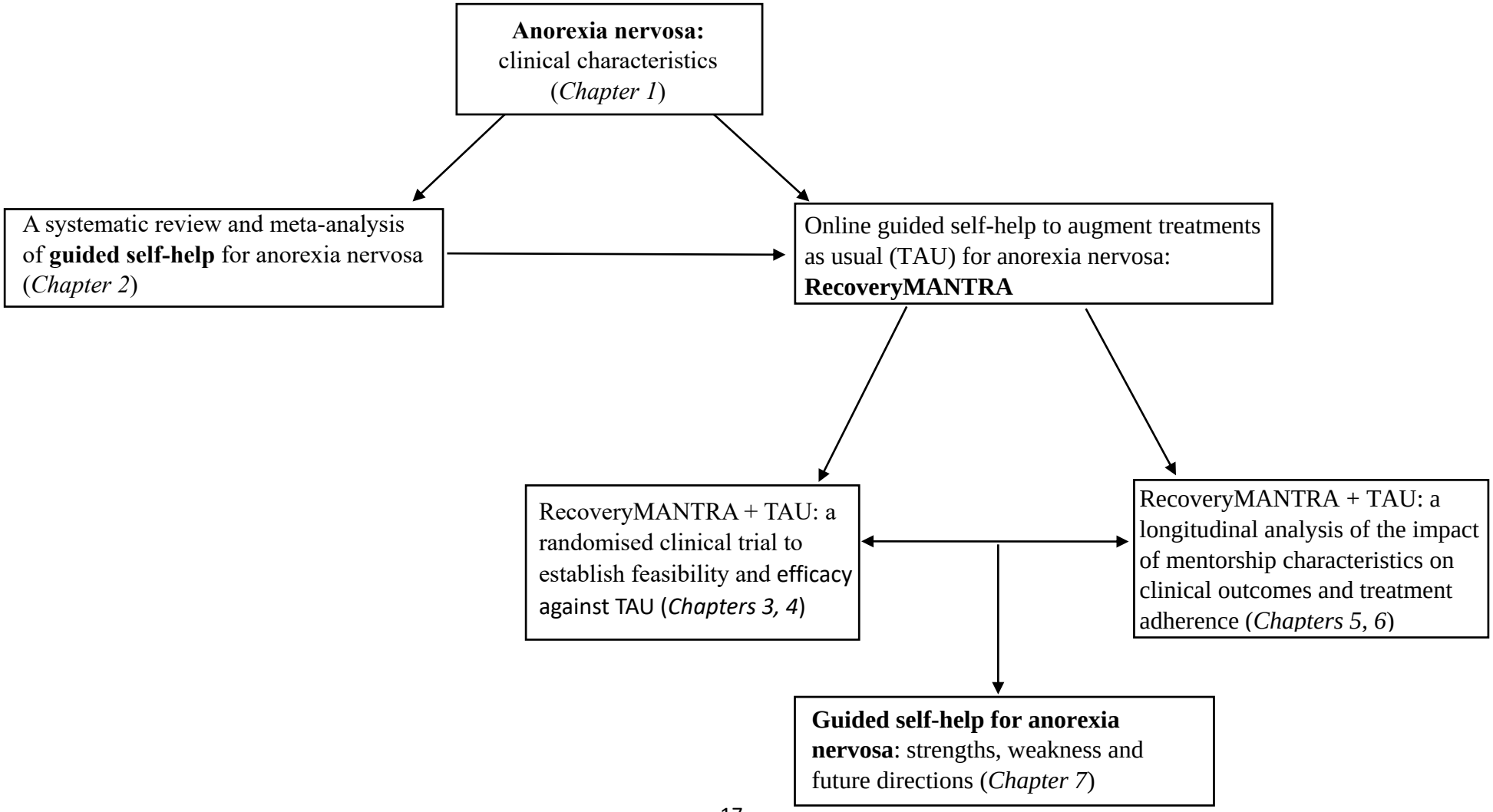
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Chapter 1. INTRODUCTION

1.1 Chapter aims

The aim of this chapter is to present the background for the research aims of the present thesis. There are three sections: the first section gives an overall introduction to eating disorders (EDs), mainly anorexia nervosa (AN) and even more specifically, it presents current evidence about the diagnostic criteria, incidence, prevalence, mortality rates and disorder trajectories of AN. The second part will discuss the secondary medical complications and common comorbidities of the illness. In this second section, AN risk factors and theoretical models of illness maintenance will be described too. The third section provides an overview of current treatment approaches and response to treatment in patients suffering from AN. Finally, aims and hypotheses of the studies conducted will be discussed.

1.2 Introduction to Eating Disorders diagnostic criteria

The Diagnostic and Statistical Manual of mental disorders, fifth edition (DSM-5, 2013) has defined feeding and Eating Disorders as psychiatric problems "characterized by a persistent and severe disturbance in eating behaviour that results in abnormal food intake, physical health and psychological functioning" (American Psychiatric Association, 2013, p. 329). The DSM-5 for feeding and eating disorders specifies diagnostic criteria for Anorexia Nervosa (AN), Bulimia Nervosa (BN), Binge Eating Disorder (BED), Other Specified Feeding and Eating Disorder (OSFED) and also Pica, Rumination Disorder and Avoidant/Restrictive Food Intake Disorder (ARFID). A diagnosis of OSFED is usually made to those who do not meet the diagnostic criteria for the other eating disorders listed above. Individuals with OSFED present extremely disturbed eating habits, a distorted body image, overvaluation of body shape and weight, and an intense fear of gaining weight. Atypical anorexia nervosa, bulimia nervosa (of low frequency and/or limited duration), binge-eating disorder (of low frequency and/or limited duration), purging disorder, and night eating

syndrome are a few of the clinical examples of how OSFED can be classified. In many cases, eating disorders occur together with other psychiatric disorders like anxiety, panic, obsessive compulsive disorder and alcohol and drug abuse problems.

1.3 Anorexia Nervosa

1.3.1 Diagnostic criteria of Anorexia Nervosa

The DSM-5 (American Psychiatric Association, 2013) specifies three criteria for a diagnosis of Anorexia Nervosa (AN): 1) The individuals must exhibit a severe restriction of energy assumption relative to parameters corresponding to a significant low Body Mass Index (BMI) in the context of age, sex, developmental trajectory, and physical health, 2) these individuals report an intense fear of gaining weight or becoming fat, even if they are significantly underweight. 3) Individuals with AN tend to experience a disturbance in body weight or shape perception which influences their own self-evaluation or denial of the current low body weight severity.

Regarding the criteria listed above, there are two AN subtypes:

- Restricting type: individuals not engaging in recurrent episodes of binge eating or purging behaviour (i.e., self-induced vomiting or laxatives/diuretics assumption) during the last three months. In this subtype weight loss is followed primarily by dieting, fasting, and/or excessive exercise.
- Binge-eating/purging type: individuals engaging in recurrent episodes of binge eating or purging behaviour (i.e., self-induced vomiting or laxatives/diuretics assumption) during the last three months, despite a low Body Mass Index (BMI< 18.5 kg/m^2).

The level of severity of AN can be established using the BMI criteria below:

Level of severity		
Mild:	BMI	> 17 kg/m2
Moderate:	BMI	16-16.99 kg/m2
Severe:	BMI	5-15.99 kg/m2
Extreme:	BMI	< 15 kg/m2

Table 1. Anorexia Nervosa level of severity based on Body Mass Index

Previously, in the DSM-IV-TR (American Psychiatric Association, 2000) individuals' weight had to be at, or under 85% (according to the BMI) of ideal body weight, thus excluding those who had not lost enough weight to be officially diagnosed. Also, women needed to report amenorrhea (three or more skipped menstrual cycles). Removing that criteria in the updated version of DSM-5 made it possible for males to meet the criteria for AN too and the small minority of females who continue menstruating despite extreme weight loss and malnutrition may be properly diagnosed.

Early reports of various forms of AN have been made cross-culturally and date back to the 1600s (Silverman, 1983). Since the original appearance of AN in the medical literature in the late 19th century (e.g. Gull, 1874; Lasegue, 1873; Pearce, 2004), the relevance of social and emotional difficulties has been discussed. For example, in 1873 Charles Lasegue noted that AN occured in a young woman who "suffers from some emotions, she avows or conceals" (cited in Vandereycken & van Deth, 1990). Additional insights into predisposing and precipitating socioemotional factors for EDs emerged a century later: Hilde Bruch, in her descriptions of AN in the mid-20th Century stated that women with AN "suffer from definite deficits in the way in which they interpret human relationships and think of their own role in life" (Bruch, 1977).

1.3.2 Anorexia Nervosa: Incidence, prevalence, and mortality rates

Epidemiology provides information of the occurrence of illnesses and trends in the frequency of disorders over time. There are some methodological issues

regarding epidemiological studies on eating disorders: 1) eating disorders are relatively rare among the general population; 2) patients tend to deny their illness avoiding professional help (Smink, Hoeken, & Hoek, 2012). Studies tend to use a narrow, broad or partial definition of AN, including the DSM-IV description of AN with or without amenorrhea, and the ICD-10 definition of atypical AN (Keski-rahkonen et al., 2007). In the next sections a brief overview of incidence, prevalence, mortality rates will be discussed, followed by a description of disorder trajectories. Firstly, a definition of the main epidemiology measures will be provided justified by specific data.

Incidence and prevalence rates in Anorexia Nervosa

The incidence rate is the number of new cases of a disorder in the population over a specified period. The incidence rate is commonly expressed in terms of per 100.000 persons per year (person-years). The study of new cases provides clues to aetiology (Smink et al. 2012) while the prevalence can be expressed as point prevalence, one-year prevalence rate and lifetime prevalence. The point prevalence is the prevalence at a specific point in time. The one-year prevalence rate is the point prevalence plus annual incidence rate (the number of new cases in the following year). The lifetime prevalence is the proportion of people that have had the disorder at any point in their life; it is the most useful measure for planning health care facilities, as it indicates the demand for care (Smink et al., 2012). From data reported in the literature, a large community study (Keski-Rahkonen et al., 2007.) found an AN incidence rate of 270 per 100.000 person per year in 15–19 year old female twins from Finland during 1990–1998. The incidence rate of broad AN was 490 per 100.000 person per year in the same sample (Keski-Rahkonen et al., 2007). In another Finnish study of 595 adolescent females (aged 15-18) for broad AN, a much higher incidence rate of 1204 per 100 000 person-years was found (95 % confidence interval (CI): 652-2181) (Isomaa, Isomaa, Marttunen, Kaltiala-Heino, & Bjorkqvist, 2009). Incidence rates from community studies are much higher than those reported in primary care and medical records (Van Son, Van Hoeken, Bartelds, Van Furth, & Hoek, 2006; Milos et al., 2004). Incidence rates reported in general practice represent eating disorders at the earliest stage of detection by the health care

system. Currin, Schmidt, Treasure, and Jick (2005) reported data from the General Practice Research Database in the UK related to new cases of AN between 1994 and 2000. Comparing these data with the findings of a similar study for 1988–1993 (Turnbull, Ward, Treasure, Jick, & Derby, 1996) it seems that the age and sex incidence rate of AN has remained stable over the two study periods; i.e. in 2000 it was 4.7 (95 % CI: 3.6-5.8) per 100 000 person-years, compared with 4.2 (95 % CI: 3.4-5.0) per 100 000 person-years in 1993. These results are also confirmed in a large representative sample of the Dutch population: in 1995–1999 where the incidence rate was 7.7 (95 % CI: 5.9-10.0) per 100 000 person-years, practically the same as the rate of 7.4 per 100 000 person-years in 1985–1989 (Van Son, Van Hoeken, Bartelds, Van Furth, & Hoek, 2006). The literature reports that incidence rates are highest for females aged 15–19 years. They constitute approximately 40% of all cases, resulting in an incidence rate of 109.2 per 100 000 15–19 year old girls per year in 1995–1999 (Van Son, et al., 2006). The incidence of AN among males is less than 1 per 100.000 person-years in general practices in the Netherlands and the UK (Son et al., 2006; Currin et al., 2005). AN can occur among children <13 years of age, but it is relatively rare in this age group (Van Son, et al., 2006; Currin et al.2005). In a large representative sample of US adolescents, the lifetime prevalence of AN was 0.3% in 13–18 year-old females as well as males (Swanson, Crow, Le Grange, Swendsen, & Merikangas, 2011). AN may be even more frequently under detected in males than in females (Keski-Rahkonen et al., 2007); however, a large study of Swedish twins born during the period 1935–1958 documented a higher prevalence of AN in both male and female participants born after 1945 than those born before 1945 (Bulik et al., 2006). In British pediatric and psychiatric care, an overall frequency of 1.1 per 100 000 person-years for AN was found among children <13 years of age (Nicholls, Lynn, & Viner, 2011). Among middle aged and elderly women, AN is relatively rare as well (Hoek, & Van Hoeken, 2003; Lapid et al., 2010; Mangweth-Matzek et al., 2006). In a Spanish population-based study using the Public Health Registry to identify eating disorder cases diagnosed by mental health professionals, new cases of AN were found among women over 45 years of age,

constituting 64% of all new eating disorder diagnoses in this age-group (Larranaga, Docet, & Garcia-Mayor,2012). It is unknown whether this reflects late detection or late age at onset. In a large Italian sample of 1,666 outpatients with AN, examining trends in illness onset in accordance to the year of birth of participants, was found that age at onset decreased to year of birth between 1985 and 2008 (Favaro, Caregaro, Tenconi, Bosello, & Santonastaso, 2009). Stice, Marti, Shaw, and Jaconis (2009), in a longitudinal sample of 496 adolescent girls recruited over an 8-year study, from early adolescence into young adulthood, found a lifetime prevalence of 20 years of 0.6% for AN and 2.0% for broad AN (Stice et al., 2009), and in a Portuguese study, the point prevalence of AN among adolescent girls was 0.39% and for broad AN 0.64% (Machado, Machado, Goncalves, & Hoek, 2007). Although EDs have previously been characterised as culture-bound syndromes, specific to Caucasian subjects in Western industrialised societies (Keel & Klump, 2003), recent studies have demonstrated the occurrence of EDs and abnormal eating behaviours in non-Western countries and among ethnic minorities as well (Eddy, Hennessey, & Thompson-Brenner, 2007; Lee, Ng, Kwok, & Fung, 2010; Marques et al., 2011).

Mortality rates in Anorexia Nervosa

Anorexia nervosa has been associated with the highest rate of mortality among all mental disorders (Harris& Barraclough, 1998). In a meta-analysis of 35 studies, the weighted crude mortality rate (i.e., the number of deaths within the study population over a specified period of time, CMR) for AN was 5.1 deaths (95% CI: 3.99-6.14) per 1000 person-years, translating into 5.1% per decade or 0.51% per year. One in five AN suffers committed suicide (Arcelus, Mitchell, Wales, & Nielsen, 2011). In a meta-analysis of standardised mortality ratios (SMRs) in 2001, the overall SMR in studies with 6–12 years of follow-up was 9.6 (95% CI: 7.8-11.5) and 3.7 (95% CI: 2.8-4.7) in studies with 20–40 years of follow-up (Nielsen). In a Swedish study (Lindblad, Lindberg, & Hjern, 2006), female patients hospitalized due to AN in 1977–1981 had a significantly higher mortality rates compared with those hospitalized in 1987–1991. Finally, in an audit study conducted in the UK, death certificates emerged as a flawed source of information with both over- and underreporting of AN as a cause of death, the

latter probably more common (Keski-Rahkonen et al., 2007; Muir & Palmer, 2004).

1.3.3 Anorexia Nervosa: Disorder Trajectories

The course and outcome of EDs like AN are highly variable with possible complications from malnutrition and compensatory behaviours including growth retardation, osteoporosis, infertility, changes in brain structure (Katzman, 2005) and cognitive impairment (Hatch et al., 2010; Lang et al., 2015). These complications are more evident during early adolescence due to disruption of critical periods of physical, psychological, and social development (Golden et al., 2003; Katzman, 2005). Evidence suggests that the onset of an ED during adolescence (i.e. typical onset) is associated with a better prognosis than onset during adulthood (Fisher, 2003). Outcomes for AN are poorer than other ED classifications. The ED course is often protracted (5 years on average) and the behavioural expressions of AN tend to change depending on the age of the patient and length of illness (Fairburn & Cooper, 2011), whereas younger individuals tend to improve over time (Halvorsen, Andersen, & Heyerdahl, 2004; Nicholls et al., 2011; Steinhausen, 2002). Although more promising outcomes are associated with longer follow-up periods in community samples, with recovery rates of 34% reported in short-term studies vs. 73% in longer-term studies (Steinhausen, 2002), a sizeable proportion suffer of a chronic course of illness. It has been estimated that between 10-20% (Keski-Rahkonen et al., 2007; Steinhausen, 2002, 2009; Zipfel, Löwe, Reas, Deter, & Herzog, 2000) to as high as 50% (Støving, Andries, Brixen, Bilenberg, & Hørder, 2011) of cases remain chronically ill. These cases have been defined with the term “severe and enduring AN” (SEED-AN; Robinson, 2014). The minimum criteria for this term is suggested to be three years and this usually applies to an illness lasting more than six years (Touyz et al., 2013). It has also been highlighted that even though the duration of illness does not necessarily predict a change in the quality of life in AN (Bamford & Sly, 2010), patients with severe and enduring AN do undergo repeated hospital admissions, which means a heavy burden on health and public sectors, and also a considerable strain on carers and families sectors (Arcelus et al.,2011; Steinhausen, 2002). Although according to Dawson, Rhodes, and

Touyz, (2014) there is a lack of consensus regarding what constitutes ED recovery; full remission is defined in the DSM-5 when an individual no longer meets AN diagnostic criteria for a defined period of time and when body weight has been restored. The lack of agreement in defining recovery between studies (Couturier & Lock, 2006) contributes to difficulties in determining useful measures for research and clinical practise. In exploring what constitutes recovery in adolescent AN, Couturier and Lock concluded that both weight and psychological symptoms appear to be important; although definitions of recovery may depend on the specifics goals of a particular study or treatment (Couturier & Lock, 2006). Broader assessment of psychological distress or psycho-social and interpersonal functioning also provide useful indicators for future ED symptom improvement and recovery.

1.3.4 Secondary medical complications of anorexia nervosa

AN is associated with a wide range of secondary medical complications, largely due to self-starvation, malnutrition and marked weight loss. All the organs can be compromised by AN. Most of the complications are fully reversible with effective nutritional rehabilitation and weight gain, whereas others are too compromised. Giovinazzo et al., (2019), in a systematic review described changes in the structure and function of heart, automatic parameters and cardiac repolarization in AN patients. Among the several diseases that occur in those who suffer from AN, it is possible to find:

- **Myocardial atrophy**, characterized by a reduction in the left ventricular mass index and a decrease in the left ventricular volume.
- **Mitral valve prolapse**, is very typical in AN and it is thought to be a consequence of myocardial atrophy. It is explained as a reduced left ventricular chamber size leading to relative valvular laxity even in the absence of myxomatous valve degeneration. The “valvular-ventricular disproportion theory” suggests that either excessive mitral valve tissue or inadequate left ventricular cavity size results in prolapse. Supporting this theory, the prolapse disappears in patients after weight restoration but recurs when patients lose weight again (Cheng TO, 1987;).

- **Sinus bradycardia**, profound reversible sinus node dysfunction, and orthostatic hypotension, are uniformly observed in patients with severe AN (Cotter et al., 2019). Electrocardiography may be appropriate depending on the patient's body mass index. It is unlikely to reveal much if the BMI is higher than 17 kg/m2, but on the other hand it is like to show significant bradycardia or other arrhythmia if less than 15. As BMI drops, bradycardia and hypotension become more pronounced.
- **Sudden cardiac death** is often the cause of premature death in patients with AN. Autonomic dysfunction, as measured by reduced heart rate variability, has been described in AN patients, although a consistent pattern has not emerged when evaluated systematically (Krantz et al., 2012; Frederiksen et al.,2018).

As a direct result of weight loss and malnutrition, gastrointestinal transit time slows presenting the following pathological scenarios:

- **Gastroparesis and constipation** are therefore common in patients with AN, especially as weight loss becomes more severe (Kamal et al.,1991).
- AN patients report the **Superior mesenteric artery syndrome**; People suffering with this syndrome complain of fullness, nausea, and epigastric pain which starts soon after eating and is relieved by vomiting. The diagnosis is made by abdominal computed tomography (Mascolo, Dee, Townsend, Brinton, & Mehler, 2015). A soft or liquid diet until sufficient weight gain occurs to reconstitute the fat pad is the treatment used for Superior mesenteric artery syndrome.
- Because of a small-bowel atrophy and a reduction in the absorptive area **diarrhea** often occurs initially in the refeeding process, this is supported by the low level of blood diamine oxidase etiology (Takimoto, Yoshiuchi, Shimodaira, & Akabayashi, 2014).

For many years, the lungs were thought to be immune to the ravages of AN. However recent studies have demonstrated that this is not always true (Jensen, Stoving, & Andersen, 2017). In fact, many endocrine abnormalities may occur in patients with AN:

- **Amenorrhea** is present in the majority of females with low estrogen levels due to a reversion to a prepubertal state in the hypothalamic-pituitary axis (Boyar et al., 1974), and most males have low testosterone. Menses generally resume when approximately 95% of ideal body weight is achieved (Kimmel, Ferguson, Zerwas, Bulik, & Meltzer-Brody,2016), although it can take 6 to 9 months for this to occur. Of note, pregnancy can occur even with amenorrhea and is dangerous both for the patient and the fetus.
- **Low leptin levels** normalize with weight restoration and nutritional rehabilitation (Mehler, Eckel, & Donahoo,1999). Leptin levels may correlate with onset of regular menses.
- **Growth hormone resistance** accompanies AN, as do **elevated serum cortisol levels**. Most patients have **euthyroid sick syndrome,** which is self-limited and reverses after nutritional rehabilitation.
- **Hypoglycemia** is most often detected in patients with more severe forms of the illness and BMIs of less than 15 kg/m^2. Hypoglycemia is a bad prognostic sign, as it leeds to (conduce) hepatic failure and an inability to actualize gluconeogenesis and glycogenolysis (Rich, Caine, Findling, & Shaker, 1990).

Sarcopenia and bone loss are also recurrent in AN:

- **Sarcopenia.** Even young AN patients can suffer from significant sarcopenia and loss of skeletal muscle mass. This in turn causes a dangerous state of weakness and increases the risk of falls in more severely ill patients. These complications are completely reversible with weight gain and physiotherapy.
- **Bone loss.** A serious and possibly irreversible complication of AN due to the presence of sarcopenia is the loss of bone mineral density and a proclivity toward early development of osteopenia and osteoporosis, even in adolescent patients. The etiology of this exuberant loss of bone mineral density is likely multifactorial and includes elevated cortisol levels, low leptin and sex hormone levels, low body weight, and growth hormone resistance (Drakin, Rothman, Wassenaar, Mascolo, & Mehler 2017). As a result, these patients are often left with a markedly increased risk of fragility fractures, even long after their AN has remitted (Misra, Golden, & Katzman, 2016).

Finally, AN is characterized by marked brain atrophy in brain imaging studies. Particular areas of the brain seem to be preferentially damaged, including both grey and white matter and areas of the insula and thalamus (Lazaro et al., 2013). With weight restoration, these brain-size abnormalities seem to reverse, but there may be ongoing cognitive deficits that persist as secondary medical complications of AN with permanent adverse sequelae. Brain atrophy may explain the abnormalities in taste, smell, thalamic function, and temperature regulation as well as the overall mental slowness seen in people with more severe forms of the illness.

Finally, patients with AN can develop a variety of skin conditions, including xerosis, which results in painful, dry, and fissured skin, acrocyanosis, and lanugo hair growth on the sides of the face and along the spine. The hair growth occurs as a result of the body attempting to conserve heat and is not a sign of masculinization (Strumia, 2013). Brittle hair and nails and unexplained hypercarotenemia, which gives the skin a yellowish appearance are also evident.

1.3.5 Common psychiatric comorbidities of anorexia nervosa

EDs are associated with high levels of psychiatric comorbidity (Jacobi, Hayward, De Zwaan, Kraemer, & Agras, 2004). The most common comorbidities are with anxiety disorders including obsessive-compulsive disorder (OCD), and major depressive disorder (Braun, Sunday, & Halmi, 1994; Hudson, Hiripi, Pope Jr, & Kessler, 2007; Milos, Spindler, Buddeberg, & Crameri, 2003; Steinhausen, 2002; Swanson et al., 2011; Swinbourne & Touyz, 2007; Von Lojewski, Boyd, Abraham, & Russell, 2012), and this is true for both adolescent and adult AN. Substance misuse disorders (Mann et al., 2014) and personality disorders (Godt, 2008) may also co-occur in less than 25% of individuals with AN. Furthermore, autism spectrum disorder (ASD) is over-represented in AN (Gillberg, 1992; Huke, Turk, Saeidi, Kent, & Morgan, 2013; McKnight & Boughton, 2009; Treasure, 2013; Zucker et al., 2007), with several studies reporting an approximate 20% lifetime prevalence of ASD in AN (Råstam et al., 2013; Wentz, Gillberg, Anckarsater, Gillberg, & Rastam, 2009). Given the similarities between the highly comorbid conditions AN, ASD, and

OCD (e.g. need for sameness/compulsivity, rigidity, obsessionality), the evaluation of the transdiagnostic traits and the study of endophenotypes has recently been the subject of much examination across the research fields (e.g. Baron-Cohen et al., 2013; Hambrook, Tchanturia, Schmidt, Russell, & Treasure, 2008; Koch et al., 2015; Mandy & Tchanturia, 2015; Oldershaw, Treasure, Hambrook, Tchanturia, & Schmidt, 2011; Renwick et al., 2015; Tchanturia et al., 2013; Zucker et al., 2007) because it is thought to provide clues to subserving neurocognitive processes.

In the study of Nicholls et al. (2011), the three main comorbidities were anxiety, depression and obsessional-compulsive disorders (possible in 41 %). Overall, in 427 patients with EDs, the vast majority females, the prevalence of OCD, panic disorder, social phobia, specific phobia, agoraphobia, and generalized anxiety disorder did not differ significantly across the three eating disorder subtypes. PTSD was significantly less common among individuals with anorexia nervosa than among those with bulimia nervosa and those with both anorexia and bulimia. In the cases of both anorexia and bulimia, obsessions may lead to levels of anxiety which can only be reduced with ritualistic compulsions. The compulsive behaviors of patients with anorexia nervosa can often be seen in their careful procedures of selecting, buying, preparing, cooking, ornamenting, and eventually consuming food. Just as with OCD, compulsions are commonly increased because of other personality traits, such as uncertainty, meticulousness rigidity, and perfectionism (Yaryura-Tobias, Pinto, & Neziroglu, 2001). People with AN often exhibit overvalued ideation, cognitive distortions, such as all-or-none thinking, and attempts to gain control of their environment too.

1.4. Risk factors for anorexia nervosa

The following section will provide a summary of psychological, environmental and genetic factors which seem to confer heightened risk of AN. Key development and maintenance models of AN which link these factors to the progression and perpetuation of AN will be further discussed. In the scientific literature the terms used to express the concept of risk vary considerably from vulnerability, to predisposing or preceding or causal factor (Jacobi, Hayward,

De Zwann, Kraemer, & Agras, 2004). Following the definition provided by Kraemer et al., (1997), a risk factor is a measurable characteristic of each subject in a specified population which precedes the outcome of interest and can be shown to divide the referred population into two groups: one high and other low risk group. In the next sections each risk factor category will be discussed separately; however, it should be noted that an integrative perspective (biopsychosocial model) will also be presented.

1.4.1 Psychological risk factors for anorexia nervosa

There are a number of personality traits and cognitive styles which have been found to confer a heightened risk for the onset of AN or a worsening of the symptoms. Personality traits may help to understand why only some people with weight concerns develop an eating disorder (Keel & Forney, 2013). Negative affect depends mostly on different personality traits which include several subdomains such as: 1) tendency to experience dysphoria, 2) negative self-evaluation, and 3) low self-esteem. Perfectionism, involves setting unrealistically high expectations for oneself and is, more in general, the "tendency to strive to achieve flawlessness" (Keel & Forney, 2013). Perfectionism has been theorized to be one of the main risk factors for an ED and more specifically for AN (Shafran, Cooper, & Fairburn, 2003). Fear of mistakes is correlated to social acceptance and the pressure to achieve unrealistic ideals conducts to inevitable failures; these aspects are associated with a negative self-evaluation connected to the larger construct of negative emotions (Stroeber, Otto, & Dalbert, 2009). In a four-year longitudinal study of adolescents, the findings reported that negative emotions, body dissatisfaction, ineffectiveness and poor interoceptive awareness are predictors of the onset of eating pathologies (Leon, Fulkerson, Perry, Keel, & Klump, 1999). A controlled retrospective study in line with the above findings reports that negative self-evaluation and perfectionism emerged as specific risk factors for the development of AN compared control groups (Fairburn, Cooper, Doll, & Welsh, 1999). According to Stice, perfectionism seems to represent a significant personality trait in eating pathology diagnoses (Stice, 2002). Finally, both negative emotionality and perfectionism demonstrate associations with weight

concerns therefore we should consider weight concern as a "common pathway through which perfectionism and negative affect become funnelled into distress of the inability in reaching an ideal weight (Keel & Forney, 2013)". Another personality trait relevant for the purposes of this thesis is the examination of exaggerated cognitive control and impaired cognitive-behavioural flexibility typical of those suffering from AN. As we have already discussed above AN patients are characterized by obsessive-compulsive temperament traits that manifest in a maladaptive preoccupation with food, weight, and body shape (Friederich & Herzog, 2010). Therefore, in accordance to these concerns, patients show rigid and stereotyped behaviors in controlling eating and weight. Cognitive flexibility is a fundamental component of cognitive ("executive") control together with inhibition, planning, attentional control, and a working memory. Cognitive flexibility allows us to adapt our behavior to ever-changing environmental demands. It is understood as the ability to override automatic or "prepotent" behaviors in favor of planned and intended behaviors (Miller & Cohen, 2001). Cognitive inflexibility instead is associated with perseverative errors, stereotyped reactions, and rigid behaviours. This pattern of deficits has been linked to abnormalities in parietal and prefrontal cortical circuits (Uher et al., 2002). Several studies demonstrated the neuropsychological profile of people affected by AN as characterized by low cognitive flexibility expressed in terms of poor set-shifting and a detail-focused (poor central coherence) thinking style (Roberts, Tchanturia, Stahl, Southgate, & Treasure, 2007). To corroborate this assumption many studies reported a moderate to large superiority in detail processing tasks (Lopez et al., 2008; Tenconi et al., 2010) and after recovery (Lopez et al., 2009; Tenconi et al., 2010; Harrison et al., 2011; Roberts et al., 2012) as well. Superior detail-focus was found in first-degree unaffected relatives (sisters) (Tenconi et al., 2010; Roberts et al., 2012; Kanakam et al., 2013). Therefore, global integration is poor in AN, and it may be a consequence of starvation (Harrison et al., 2011). In an adolescence sample week central coherence is present at the initial stage of the disorder (difficulty seeing the bigger picture) (Lang, Lopez, Stahl, Tchanturia, & Treasure, 2014).

1.4.2 Environmental and social risk factors for anorexia nervosa

Environmental triggers (e.g. perinatal events) have also been found to predispose an individual towards anxiety and shyness (Troop, Allan, Serpell, & Treasure, 2008; Troop, Allan, Treasure, & Katzman, 2003). For instance, people with AN are more likely to report social anxiety (Swinbourne et al., 2012) and an impoverished social network before the onset of the illness (Fairburn et al., 1999; Karwautz et al., 2001), fewer social activities (Krug et al., 2012), and less social support (Kim, Heo, Kang, Song, & Treasure, 2010). These are thought to relate to the temperamental characteristics such as shyness, inhibition, and internalising problems (Adambegan et al., 2012).

Adverse early interpersonal experiences, such as exposure to sudden death of a relative (Su et al., 2016), poor communication and care within the family (Haynos, Watts, Loth, Pearson, & Neumark-Stzainer, 2016; Munsch et al., 2017), and critical comments about the self particularly regarding weight, shape and eating (Menzel et al., 2010; Puhl et al., 2017; Fairweather-Schmidt & Wade, 2017), have been found to increase the risk for the development of eating disorder symptoms. Interpersonal difficulties seem to predispose individuals to the onset of several psychiatric disorders ["eco-phenotype" hypothesis (Teicher & Samson, 2016)]. However, specific aspects, such as perceived involuntary submissiveness, high social and self-standards, and fear of negative evaluation may be of particular relevance to the development and maintenance of AN (Bruch, 1982; Rieger et al., 2010; Treasure, Corfield, & Cardi, 2012; Gunnard et al., 2012). This is supported by patients' tendency to feel inferior to others (Cardi, Di Matteo, Gilbert, & Treasure, 2014; Connan, Troop, Landau, Campbell, & Treasure, 2007), lack of assertiveness (Arcelus, Haslam, Farrow, & Meyer, 2013) and sensitivity to rejection (Cardi, Di Matteo, Corfield, & Treasure, 2013), and abnormal cognitive processing of social stimuli (Via et al., 2015). Patients display attention biases toward threatening or rank-related stimuli, and negative interpretation biases of ambiguous scenarios depicting the risk of rejection (Cardi et al., 2014; Cardi et al., 2017; Ambwani et al., 2015). They report lacking social skills and believe that they are a burden to those close to them as well as the rest of the society. Recent studies have found that

perceived burdensomeness (PB) (i.e., lack of social competence) correlates with abnormal eating behaviors (Forrest et al., 2016) and also with suicidal ideation (Smith et al., 2016; Pisetsky, Crow, & Peterson, 2017). In the study conducted by Cardi et al., 2018, involuntary submissiveness and fear of negative evaluation predicted AN symptoms and these associations were partially mediated by a perceived lack of social competence. In the same study approximately two-thirds of participants with AN (N = 62/90) could recall early social difficulties before illness onset and an even greater proportion (81/90) recognised that the eating disorder had affected their social relationships in a negative way. Finally, social difficulties had played a role in the development of the illness for two-thirds of the sample (N = 63). As demonstrated by this study, social difficulties are important in maintaining this eating disorder (e.g.: Bruch, 1982; Rieger et al., 2010; Treasure et al., 2012; Arcelus et al., 2013; Peñas-Lledó et al., 2010), This is particularly relevant when we consider the paucity of studies investigating the chronology of the occurrence of social difficulties in AN (Carrot et al., 2017). This study provides the first evidence that submissiveness and fear of negative evaluation might also be causally involved in the development of the eating disorder psychopathology. Compared to the general population, people with a lifetime diagnosis of AN have recalled memories of submissiveness within the family to a greater extent than the general population (Gilbert, Cheung, Grandfield, Campey, & Irons, 2003; Castilho, Pinto-Gouveia, Amaral, & Duarte, 2014). This provides support for Hilde Bruch's (Bruch, 1982) early theorisations of the illness that people with AN struggle with asserting themselves within the family and tend to act in response to others' expectations instead (Treasure & Cardi, 2017). The finding that patients experience an intense fear of negative evaluations supports again Bruch's etiological hypothesis of AN (Rieger et al., 2010; Connan et al., 2007).

In a study where I gave my contribution (Cardi, Mallorqui-Bague, Albano, Monteleone, Fernandez-Aranda, & Treasure, 2018), I conducted qualitative analyses of participants' answers to three questions, in order to investigate the quality of interpersonal relationships before and after AN onset, and the role that social difficulties have played in the development of the illness. As shown in

Table 2, two-thirds of the participants reported early interpersonal difficulties before illness onset and realized that these have played an important role in the manifestation and evolution of the illness. A larger proportion of participants stated that the eating disorder have affected their social relationships in a negative way. Therefore, the patients' perspective on the predisposing and maintaining environmental and social risk factors helped to identify key psychological variables that could foster the AN treatment.

Question	Answer	Main themes	Examples
Please think back to the time when you were a child/adolescent, prior to the onset of your ED. How would you describe your relationships with others at the time Responders: N=90	Difficulties causing significant impairment of social functioning N=40	Fear of rejection	*"Felt pressure to fit in with peers and be in the 'popular' group. Worried about what others thought about me (including my looks) and wanted everyone to like me. Felt pressure to always try to 'impress' my dad for attention / him to notice me."*
		Feeling different from others	*"I generally found it difficult interacting with peers, feeling I had interests that others didn't generally share."*
		Lack of social skills	*"Found very challenging/unable to join or interject in a conversation. It was very tiring and stimulating to be around people so I struggled with wanting to be with others while needing alone time."*
		Low self-esteem	*"I struggled to interact as had no confidence within myself, always worries people seen me as fat."*
		Being victim of bullism	*"Bullying was an issue in school. Not only from peers but from teachers when I was in primary school then it continued in secondary school. So interaction was a big problem for me. I felt isolated and alone throughout growing up."*
		Problems within family	*"Having been abused as a child I did not make friends easily and mistrusted everyone."*
		Comorbid disorder	*"I have recently been diagnosed with Asperger which retrospectively had a big impact on my relationships growing up. I never really understood my peers and the things they were interested in and as such didn't have many close friends."*

	Some difficulties that did not cause impairment to social functioning N = 22	Difficulties to interact with strangers and within groups	*"I was always a little shy and socially awkward around people I don't know but very comfortable around people I know."*
		Difficulties interacting with peers	*"I have always been quite naturally shy but could generally interact with others quite well, usually more comfortable in the presence of adults than of peers my age."*
	No difficulties recalled N = 28	Easy to interact with others	*"Before my eating disorder I had good social relations, I found it easy to interact with others, of all ages and backgrounds. I felt comfortable around adults, and was able to adapt to different situations."*
	The eating disorder had a negative impact on	Lack of flexibility in social situations	*"I think without an eating disorder I would be able to do more social things and be confident to be in different situations without anything being so planned."*
		Intense experience of negative feelings	*"I would like to be able to be free and happy and be able to attend social events without fear, worry, guilt and shame."*
		Lack of social skills	*"I much prefer "doing things" with people - e.g. going for a walk, than just sitting down and talking as I get restless and don't know what to talk about. I feel uncomfortable if there are pauses and don't know what to say. I find it easier making small talk and talking to strangers than talking to people I know better."*

Please Think about your current situation. How do you experience the interaction with others now? How does your ED affect your relationships at the moment? Responders: N=89	interpersonal relationships N=81	Isolation due to fear of food or body image concerns	*"My relationships are very much affected by my eating disorder. It has isolated me from my family and friends and I don't spend much time with them at all. This is mainly due to the fear of having to eat while with them/them seeing me eat etc,."*
		Fear of being judged for having an eating disorder	*"I don't what people to find out and think I'm a freak and stop interacting with me."*
		Poor capacity to concentrate on conversations due to eating disorder thoughts	*"I do find it hard when such events are based around food, as I find it hard to focus on chatting to people when I am aware of the presence of food (particularly buffet-style) nearby - my main focus is on eating the food as I consider it to be "allowed" as "a treat".*
	The eating disorder did not have any impact on interpersonal relationships N=8	Social difficulties ascribed to comorbid mental disorders	*"If I didn't have eating disorder it would still be the same because I have a social phobia."*
Do you feel that the quality of your social relationships as child/adolescent	The eating disorder is a way to respond to a need	Need to fit in	*"Yes, definitely! I wanted to be a popular, attractive girl, have many friends and a boyfriend. Getting skinny was supposed to be a way to do that."*
		Need to feel control	*"When I lost control of other things in my life (family related and later, stress related), I started restricting to cope and feel better."*

might have played a role in the development of your eating disorder? If so, in what way(s)? Responders N=90	N=63	Need to hide due to inadequacy or way to self-punish	*"I always felt like a bit of a sub-par person in terms of how others regarded me which contributed to the feelings like I do not deserve things like normal people do. Like food."*
		Need to distract from loneliness and isolation	*"I would often eat for comfort as an adolescent, consoling my lack of human connection with large amounts of fatty/sugary foods. This resultantly contributed to a move in the opposite direction, a hyper-awareness of that tendency and a connection between restriction and social "success".*
		Restriction of energy intake as a mean of silencing negative thoughts and emotions	*"I believe I have always felt responsibility for other people's happiness, which makes it difficult for me to express negative emotions. I fear abandonment and rejection. For this reason I have tended to internalise negative thoughts and used food restriction as a means of managing them."*
	Not sure as to whether early social experiences have played a role in the eating disorder onset N=4		*"The development of my eating disorder was mainly due to low self-esteem, but I don't think that was a result of my social relationships. I grew up with a twin sister who helped me with social relationships."*
	Definitely no role played N=23		*"Not really as I was always sociable and got to spend loads of time with my friends and family."*

Table 2. Main themes emerging in response to three open questions to investigate the quality of social relationships before and after illness onset.

1.4.3 Biological and genetic risk factors of anorexia nervosa

The scientific literature of main biological risk factors in AN, reported in a national Danish study were the following: i) having a sibling with AN (Walters & Kendler, 1995; Lilenfeld et al.,1998; Strober, Freeman, Lampert, Diamond, & Kaye, 2000); ii) affective disorders in family members, and iii) comorbid affective, anxiety, obsessive-compulsive personality, or substance use disorders. Furthermore, female gender and year of birth were significantly associated to AN whilst urbanisation did not seem to be related to the number of of AN family cases (Steinhausen, Jakobsen, Helenius, Munk-Jorgensen, & Strober, 2015). In order to confirm these findings a large multigenerational Swedish study (n=286.232), found that eating disorders in either parent was independently associated with eating disorders which developed in their daughters (hazard ratio [HR] 1.97 (95% confidence interval [CI]: 1.17–3.33), p=0.01) and that an eating disorder in mothers was independently associated with an eating disorder in their daughters (HR 2.35 [95% CI: 1.39–3.97] p=0.001) (Bould et al.,2015).

Genetic factors are estimated to contribute 58–88% of the risk of developing AN (Bulik, Sullivan, Wade, & Kendler, 2000), although it is extremely unlikely that a single gene effect could account for this heritability. Multiple genes probably contribute to the genetic liability via a range of phenotypic features, including components of nutritional homeostasis (Hebebrand & Remschmidt, 1995), and temperamental traits (Lilenfeld et al.,1998). Prior to the birth of a child who goes on to develop AN, 25% of parents may have experienced severe obstetric difficulty and loss compared with only 7.5% of matched comparison parents (Shoebridge& Gowers, 2000). In addition, the incidence of prematurity and birth trauma is elevated by two-to threefold in the birth histories of those with AN (Cnattingius, Hultman, Dahl, & 1999). It is perhaps understandable in this context that mothers report heightened anxiety during pregnancy and the perinatal period, and therefore possibly become over controlling and overprotective throughout the child's development (Shoebridge & Gowers, 2000). Biological risk factors for AN have been examined in both human and

animal research, and these identify a number of environmental triggers (e.g. perinatal events; Favaro et al., 2006) which induce alterations across the hypothalamic–pituitary–adrenal (HPA) ('stress system') and the appetite regulation system, as well as alterations in the intestinal microbiota (Kleiman, Carroll, Tarantino, & Bulik, 2015). Other biological risk factors relate to alterations in the dopaminergic response system, that may predispose an individual to a higher reward from starvation, exercising, and alterations in oxytocin (Kim, Kim, Kim, & Treasure, 2014), although the extent to which these alterations are activated by starvation is still unclear. It has been suggested that a unique biological make-up could contribute to the adaptive functions associated with self-starvation in AN (e.g. a 'soothing' effect, reduction of social threat), which may help to explain the valued nature of starvation in the disorder and subsequent low motivation towards change (Vitousek, Watson, & Wilson, 1998). This is in line with Paul Gilbert's evolutionary approach to psychopathology, suggesting that psychiatric symptoms are 'often related to the activation of defence mechanisms which have evolved in response to social threats to key biosocial goals and evolutionary relevance (Gilbert, 1997, 1998a, 1998b, 2001a, 2001b). Therefore, as highlighted by Schmidt and Treasure (2006) self-starvation in AN may be understood as a manoeuvre with complex defensive functioning which results in reducing harm and social threats.

1.5 Theoretical models of maintenance in anorexia nervosa

A maintaining illness factor is defined as 'a factor that predicts symptom persistence over time versus remission among initially symptomatic individuals […]. If an experimental increase or decrease in a factor among initially symptomatic individuals results in symptom expression or suppression, respectively, it may be referred to as a causal maintenance factor' (Stice, 2002, p. 826). A number of models with different degrees of specificity for AN and empirical support have been developed. The first model (see Figure 1) is a multi-factorial neurodevelopmental theoretical model of EDs developed by Connan and colleagues (2003) which integrates genetics, early attachment style and perinatal factors, the stress response system, personality traits, and socioemotional processes in the aetiology of AN (Connan, Campbell, Katzman,

Lightman, & Treasure, 2003). In this model, it is theorized firstly that the genetic risk, previously described (i.e. perinatal stressors (Favaro et al., 2006; Favaro, Tenconi, & Santonastaso, 2008) and attachment experience (Ward et al., 2001) contribute to a biological susceptibility to chronic stress and hypothalamic-pituitary-adrenal (HPA) axis dysregulation. This model highlights that social-communicative and emotional processing difficulties, coupled together with perfectionist tendencies and the rigid coping styles (Anderluh, Tchanturia, Rabe-Hesketh, & Treasure, 2003) which are characteristic of AN, facilitate chronic stress thereby predisposing an individual to the development of AN (Connan et al., 2003). An overactive serotonergic system and HPA axis are biological mechanisms that contribute to a hyper-sensitive stress response and hormonal changes around the time of puberty which may trigger a set of responses and precipitate the onset of AN. A failure to up-regulate activity of the adrenocorticotrophic hormone secretagogue, arginine vasopressine (AVP) and persistent over activity of the corticotrophin releasing hormone (CRH) modulates an over-sensitive stress response and may have subsequent effects on appetite and weight loss. Both psychological (e.g. feelings of safety and pseudo-control) and biological (e.g. starvation) factors may serve to maintain symptoms. Therefore, this model states that stress response and socio-emotional processes are central to the aetiology and maintenance of AN.

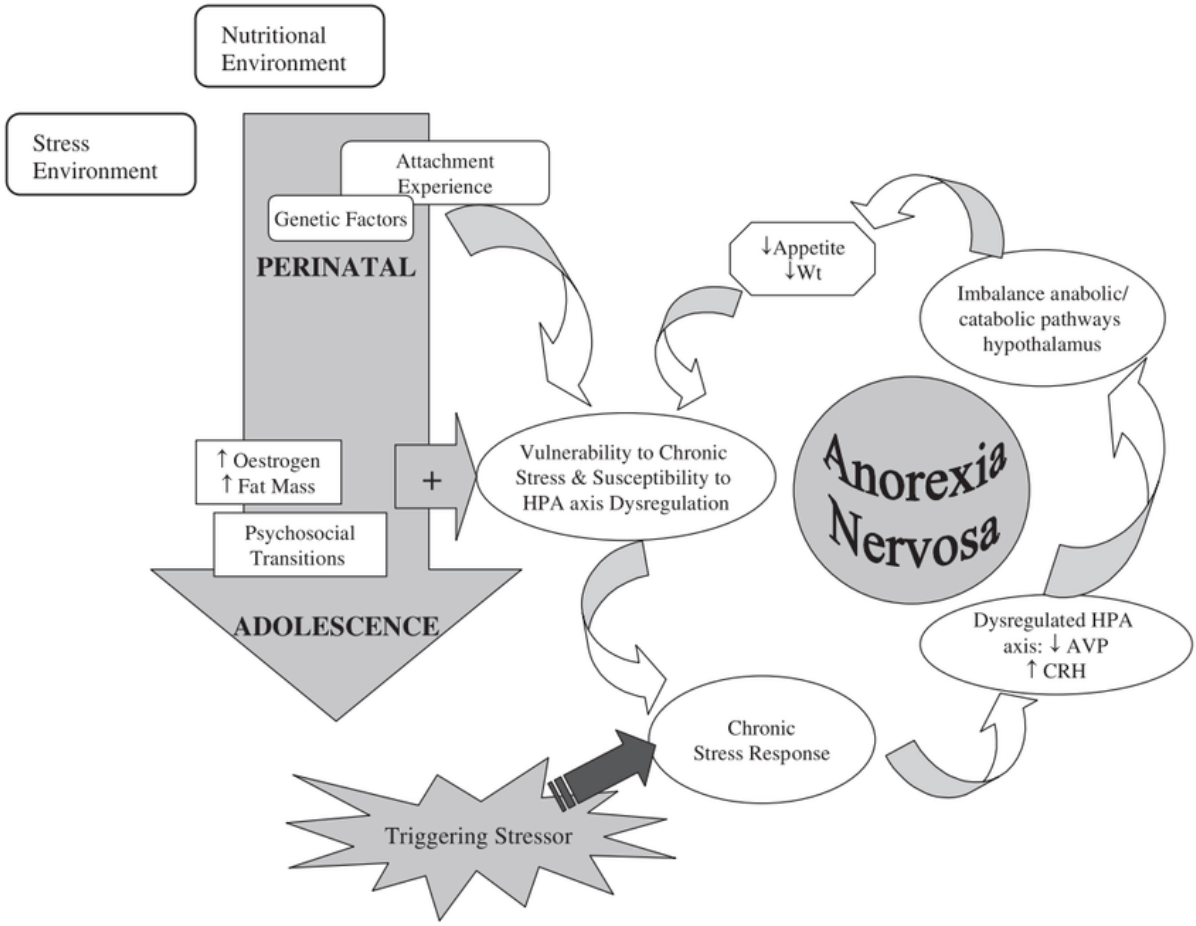


Figure 1: A neurodevelopmental model of AN (from Connan et al., 2003)

A three phase model of social emotional functioning in EDs (Treasure, Corfield, & Cardi, 2012) has since been proposed (see Figure 2), building on the before mentioned neurodevelopmental model and integrating both intra- and inter-personal factors. Phase 1 of this model suggests that environmental triggers (e.g. perinatal events), as already described ('risk factors'), predispose an individual to certain negative feelings (e.g. shyness, shame proneness, social comparison; Troop et al., 2008; Troop et al., 2003) and attachment styles (eg. insecure; Ward et al., 2001) which affects socio-emotional development and functioning (e.g. harm avoidance, childhood anxiety; Favaro et al., 2008). Phase 2 highlights the effects of the illness on social attention, emotion recognition, and regulation (Cardi, Matteo, Corfield, & Treasure, 2013; Oldershaw et al., 2011). These socio-emotional difficulties may be caused or exacerbated by the state of illness. The third phase focuses on the role of interpersonal relationships

in the upkeeping of illness. The reciprocal interaction between parent and proband, which is likely to be influenced by multiple genetic, trait and state effects, can exacerbate illness symptoms (Goddard et al., 2011; Treasure et al., 2008).

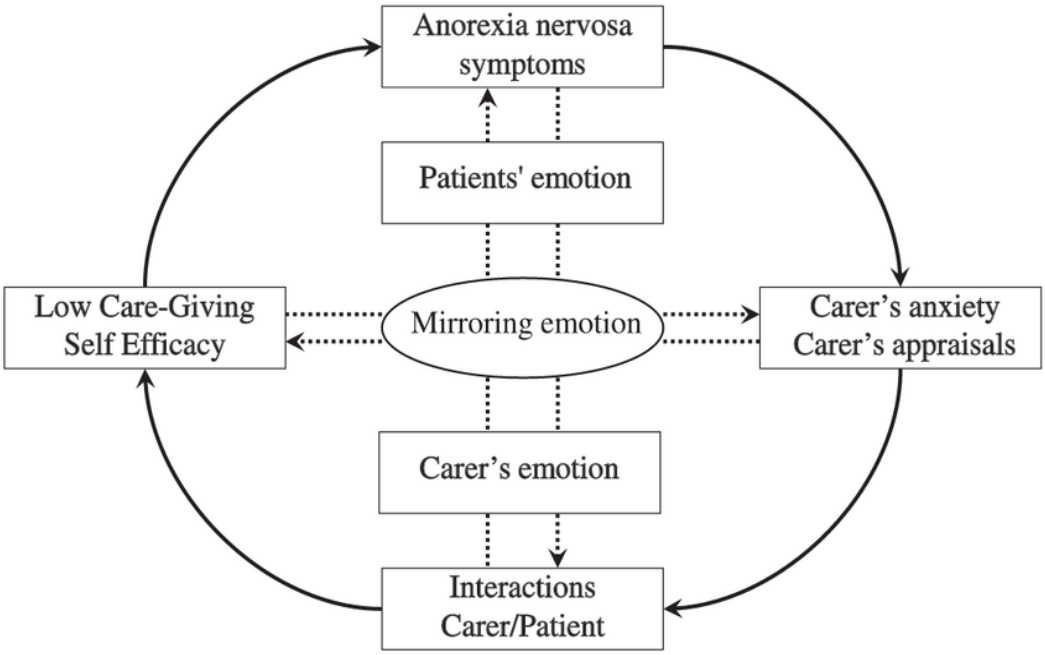


Figure 2. Three-phase model of interpersonal maintenance in AN (from Treasure et al., 2012)

The cognitive-interpersonal maintenance model of EDs (see Figure 3) provides another conceptualisation of risk and maintenance in EDs that integrates intra- and interpersonal factors and emphasises the role of socio-emotional functioning and specific behaviours in loves one which contribute to the vicious cycle of AN (Schmidt & Treasure, 2006; Treasure & Schmidt, 2013). In this model, four key components are theorized as the maintaining factors (illustrated in Figure 1): (i) the 'thinking style' component includes perfectionistic traits, OCD, and a neuropsychological profile characterised by poor set shifting and weak central coherence that manifests as rigid thinking and detail focusing; (ii) the 'emotional and relational style' component describes an anxious and avoidant temperament style in AN that manifests as shyness, aloofness and difficulties with peers; (iii) the 'pro anorexia' component

describes valued aspects of the illness that have been previously highlighted in detail in the literature (e.g. Vitousek et al., 1998), acknowledging the possible adaptive functionality of starvation in moderating the negative affect in the individual, for example through activation of the 'drive' system and/or defence mechanisms to reduce social threat, as already described (Gilbert, 1997, 1998a, 1998b, 2001a, 2001b); and (iv) the 'response of loved ones' component proposes that maladaptive patterns of interaction with others that develop in response to the manifestation of AN play a major role in illness maintenance. The two primary interpersonal behaviours which here are described are expressed emotion and the accommodating and/or enabling behaviours.

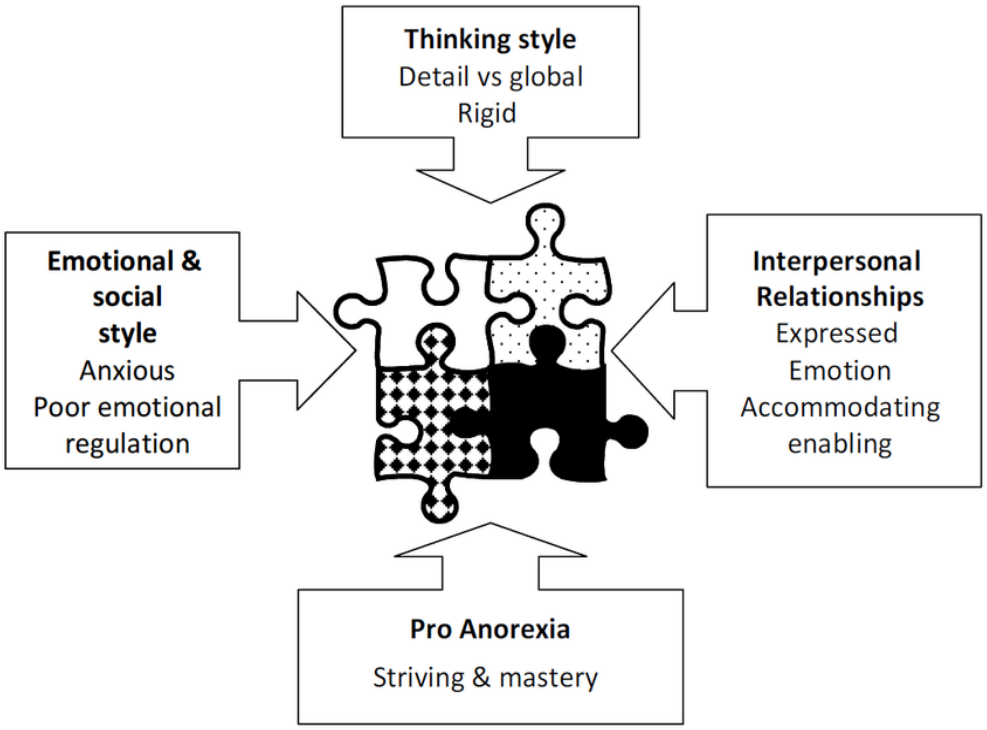


Figure 3. The cognitive-interpersonal maintenance model of EDs (Treasure & Schmidt, 2013).

1.6 Treatment of anorexia nervosa

The treatment of AN has focused on remediating the eating and weight symptoms through inpatient care. Although weight and medical stabilisation remains a key treatment goal, current treatment guidelines in the UK (NICE, 2004) and internationally (e.g. Hay et al., 2014) now endorse, as general

principles, a less restrictive (i.e. outpatient treatment in the first instance), multidisciplinary (encompassing medical, dietetic, and psychological interventions), approach to treatment that is person-centred, recovery-oriented care, and involves the family (and significant others). Most notably, the case for early intervention and phase-specific treatment in AN is of utmost importance. Furthermore, because people with AN are often ambivalent about treatment, leading them to commonly deny that there is a problem and subsequently resist, refuse or feign compliance (Nesbitt & Uprichard, 2009), motivational enhancement approaches should be endorsed (NICE, 2004). Although the increased availability of empirically investigated treatments and systematic reviews has facilitated more specific guidelines, particularly for adolescent AN, the evidence base is still relatively limited. As a result, a 'best available practice' (i.e. evidence-led and practise-based, rather than evidence based) approach is taken, and treatments tend to vary considerably across services, which may be challenging when integrating and interpreting results from studies across services (i.e. heterogeneity in what 'treatment as usual' constitutes) and the use of 'treatment as usual' as a control condition in pragmatic randomised controlled trials.

1.6.1 Treatment of adult and severe/enduring anorexia nervosa

There is insufficient evidence to facilitate high-grade evidence-based recommendations for specific treatment of adult AN. However, 'best available' treatments include cognitive behavioural therapy (CBT), specialist supportive clinical management (SSCM), the Maudsley model of AN treatment for adults (MANTRA) (Schmidt et al., 2015), motivational-based therapies, and family therapies (e.g. Fisher, 2003; Hay et al., 2014; NICE, 2004). However, treatment response for this group is generally poor, and a substantial number develop a chronic course of illness (Keski-Rahkonen et al., 2007; Steinhausen, 2002, 2009; Støving et al., 2011; Zipfel et al., 2000) associated with repeated hospital admissions (Hjern, Lindberg, & Lindblad, 2006), which, according to the results of an economic study in the UK, lead to a two-year average cost of £34,500 per AN individual (Byford et al., 2007). In response to poor treatment, novel approaches have been developed targeting the cognitive, social, and emotional

factors (see Figure 4) (Treasure, Cardi, Leppanen, & Turton, 2015) which are thought to maintain the illness (Treasure & Schmidt, 2013). Cognitive Remediation Therapy targets these neuropsychological inefficiencies and aims to ameliorate the one aspect which may maintain symptoms (Tchanturia, Lounes, & Holttum, 2014). These approaches offer potential for this otherwise 'treatment resistant' group. Furthermore, although these difficulties are associated with secondary effects of illness over time, as previously mentioned, aspects of this more severe profile (e.g. ASD traits) may be present early on in the illness and relate to risk factors for illness chronicity.

1.6.2 Treatment of adolescent anorexia nervosa

Family therapy is the most highly studied treatment for adolescents with AN (e.g. randomised controlled trials: Ball & Mitchell, 2004; Crisp et al., 1991; Eisler et al., 2000; Godart et al., 2012; Gowers et al., 2007; Le Grange, Eisler, Dare, & Russell, 1992; Lock, Agras, Bryson, & Kraemer, 2005; Lock et al., 2010; Rhodes, Baillee, Brown, & Madden, 2008; Robin, Siegel, & Moye, 1995; Robin et al., 1999; Russell, Szmukler, Dare, & Eisler, 1987) and is the only specific treatment for AN partially endorsed by NICE (a grade B recommendation). A 2010 Cochrane review concluded that family therapy is the most effective form of intervention in the early phase of illness (Fisher, Hetrick, & Rushford, 2010), albeit with the caveat that many studies in AN have methodological limitations, especially problems of power due to small sample sizes. Furthermore, the dose or nature of family inclusion in treatment is not specified as the evidence relating to this is still relatively inconclusive (e.g. Eisler et al., 2000; Le Grange et al., 1992; Lock et al., 2005; Rhodes et al., 2008). One treatment approach for adolescents is Family Based Treatment (FBT), devised by Gerald Russell and colleagues at the Maudsley Hospital in the 1970s. FBT is based on the principle that parents have within themselves the skills to facilitate their child's recovery. In this approach, anxiety is increased as a technique to mobilise parents who are then empowered with full responsibility in restoring their child's eating behaviour (Lock & Le Grange, 2013). Although this approach can be effective if delivered in the early (less than 3 years; Russell et al., 1987) phase of AN (Fisher et al., 2010; Lock et al., 2010; Stiles-Shields,

Hoste, Doyle, & Le Grange, 2012) the response diminishes over time, and a sizeable proportion of patients show a poor treatment outcome (Asen, 2002). Furthermore, this approach is not acceptable to all families, some of whom request information and help with their role, most notably practical and emotional help in managing the ED symptoms (Haigh & Treasure, 2003). In particular, research suggests that high levels of OCD, OCPD or autism traits are associated with poor treatment response and outcome (Crane, Roberts, & Treasure, 2007). Furthermore, most research using FBT have only measured patient outcome and the impact on carers is still unknown, also the mechanisms underlying change are not fully understood. Other types of interventions involving the family have also been developed and have demonstrated efficacy. For example, 'separated family therapy', in which the patient is seen individually and the parents are seen in parallel (Le Grange et al., 1992), is particularly helpful for families with high levels of expressed emotion (Eisler et al., 2000). A further adaptation is multifamily therapy (Asen, 2002), in which several families are seen as a group, and has also produced similar outcomes to FBT (Eisler, 2005). However, this format can be demanding on family time and because of the group format, can be somewhat inflexible.

Access to treatment is one of the key barriers to early detection and intervention in AN. A recent report by BEAT, the leading charity for EDs in the UK, found that respondents on average experience a 15-month wait between recognising ED symptoms and starting treatment (BEAT, 2015). The benefit of programme-lead approaches, such as self-help and guided self-help in terms of accessibility has recently been highlighted by Fairburn and Patel and supported by evidence. The results of several systematic reviews and meta-analyses have found comparable effects of self-help vs traditional face-to-face treatments for depression and anxiety (e.g. Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Cuijpers, Donker, Van Straten, Li, & Andersson, 2010; Haug, Nordgreen, Öst, & Havik, 2012), and have highlighted advantages in terms of acceptability and a practical alternative for those who otherwise may not receive care in a timely manner. Furthermore, the addition of guidance to self-help programmes (e.g. by a telephone or 'etherapist') has proven advantageous in minimising

potential problems with treatment adherence in self-help programmes (e.g. Newman, Szkodny, Llera, & Przeworski, 2011). A recent meta-analyses (Albano, Hodsoll, Kan, Lo Coco, & Cardi, 2019) of randomised controlled studies on guided self-help or self-help in AN (targeting either the individual affected by AN or their carers) related to the evaluation of the following outcomes: (1) drop-out from end-of-treatment assessment, (2) body mass index (BMI), (3) anxiety, (4) depression and (5) quality of life, demonstrated that guided self-help was associated with significantly lower drop-out rates from the completion of end-of-treatment assessments compared to control conditions and reported an improvement in carers' wellbeing from skill-sharing interventions. Therefore, guided self-help may facilitate patients' treatment engagement and also improve carers' wellbeing. In light of these findings seems that guided self-help/self-help can foster a timely access to treatment (reducing the time spent in waiting list and avoiding risk of chronicity), and might keep people suffering from AN engaged and in contact with medical care. On the other hand, skill-sharing interventions to carers is particularly helpful in view of strengthening patients' positive bonds with others (this study will be further discussed in chapter 2).

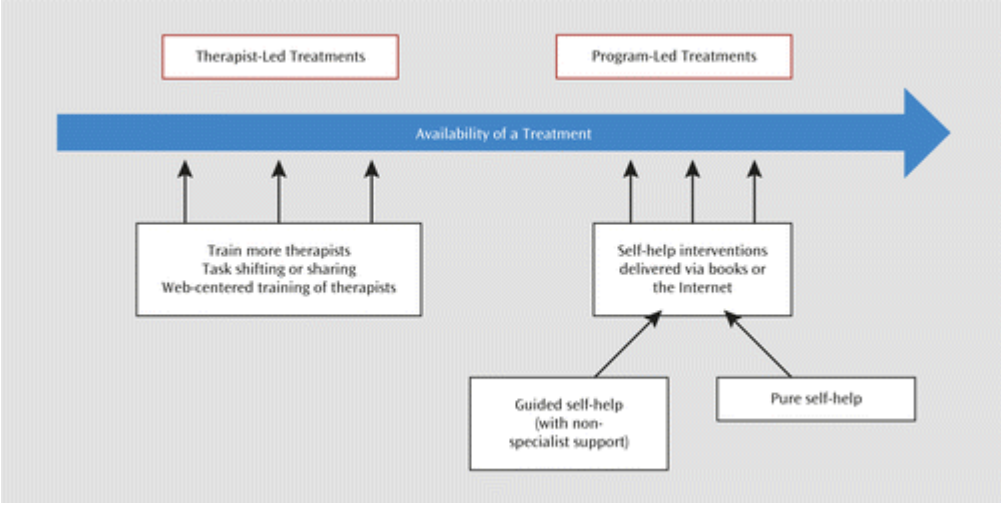


Figure 4. Forms of Treatment Delivery and Their Influence on the Availability of a Psychological Treatment (from Fairburn & Patel, 2014).

1.6.3 Self-help interventions

A recent evidence map for research in eating disorders identified a clear need for empirical examinations of interventions for anorexia nervosa. There has also been a recent call to make psychological treatments more widely available by using strategies to make them more affordable and scalable. One of the strategies for meeting these needs involves the sharing of information and behaviour change skills through guided self-management interventions. This approach has previously been demonstrated beneficial for people with bulimia nervosa and binge-eating disorder in terms of symptom change and motivation to change. However, there is much variability in terms of effect sizes and the acceptability of these interventions. Although self-management strategies have been less studied for anorexia nervosa, two studies in which they were used as additional steps, either before inpatient admission or after hospital treatment, reported improvements in symptom change and service use. (Fichter, Cebulla, Quadflieg, & Naab, 2008; Fichter, Quadflieg, & Lindner, 2013), showing a reduction of inpatient treatment duration (by 5.2 days) among those receiving guided self-help and general ED psychopathology (body image, slimness ideal, bulimic symptoms) improvement during the treatment. The next step, main focus of this thesis, was to extend these findings, examining if guided self-help strategies can enhance outpatient care in anorexia nervosa us well.

1.7 Aims and Hypotheses of the thesis

The main aim of this thesis is to evaluate the efficacy, acceptability, and feasibility of a digital, six weeks, guided self-help for patients suffering from AN. The main outcomes measured (eating disorders symptoms, symptoms of stress, depression, anxiety) and moderators and mediators of clinical change (such as motivation, importance to change, working alliance) are relevant in extending the evidence for novel interventions in the ED field. More specifically this thesis aimed to contribute to the EDs literature through a 1) A systematic review and meta-analysis on guided self-help in anorexia nervosa; with a focus on primary and secondary outcomes, predictors of change and degree of

acceptability; 2) the evaluation of the feasibility, acceptability and efficacy of a novel digital guided self-help intervention for anorexia nervosa (*RecoveryMANTRA*) tested in addition to treatment as usual (TAU) in the outpatient setting, 3) a quantitative analysis of predictors of drop-out from the *RecoveryMANTRA* + TAU; 4) an examination of the role of WA with mentors delivering the guidance and 5) an evaluation of the role of language style matching as predictor of WA in RecoveryMANTRA + TAU. The thesis is structured as a series of research studies with separate but related aims and hypotheses. Aims and hypotheses of each study are presented in Table 3.

Title of the study (Chapter)	Aim	Hypothesis
Chapter 2: *Task-sharing interventions for patients with anorexia nervosa or their carers: a systematic evaluation of the literature and meta-analysis of outcomes.*	To examine the efficacy of Task-sharing interventions for patients with AN or their carers in terms of clinical outcomes.	(i)To describe the content, context, and form of task-sharing interventions. (ii) To undertake meta-analyses of main end-of-treatment outcomes (i.e. drop-out from end-of-treatment assessments, body mass index, anxiety, depression, and quality-of-life) from randomized-controlled trials (RCTs) that compared task-sharing interventions with a control condition.
Chapter 3: *A randomised clinical trial to evaluate the acceptability and efficacy of an early phase, online, guided augmentation of*	To examine the acceptability and efficacy of an online, GSH(*RecoveryMANTRA*) for AN outpatients, through an investigation of clinical outcomes.	(i) It was hypothesised that *RecoveryMANTRA*, used to augment TAU, would increase BMI and reduce eating disorder symptoms, psychological distress and work and social impairment over time.

outpatient care for adults with anorexia nervosa.		(ii) It was also hypothesised that RecoveryMANTRA would increase scores on process measures such as cognitive and behavioural flexibility, motivation to change and therapeutic alliance. (iii) Frequencies of service use were compared between groups over time.
Chapter 4: *The Feasibility of Using Guided Self-Help in Anorexia Nervosa: An Analysis of Drop-Out From the Study Protocol and Intervention Adherence.*	To examine drop-out rates (i.e., non-completion at EOT of assessment measures) and intervention adherence rates (attendance of a minimum of four of six sessions) to establish the acceptability of delivering*RecoveryMANTRA* to AN patients.	(i)It was hypothesized that could be some differences between "Completers" and "Dropped-out" groups in terms of perceived quality of the relationship with their mentors. (ii) It was expected that "Completers" reported greater satisfaction with their mentors and (iii) autonomous motivation, importance and ability to change would be associated with lower rates of drop-out.
Chapter 5: *The relationship between working alliance with peer mentors and eating psychopathology in a digital six-week guided self-help intervention for anorexia nervosa*	To examine the role of WA with peer mentors (people with lived experience of illness) and student mentors (psychology students) in a 6-week, digital, GSH intervention for AN.	(i) It was hypothesized that higher alliance with the mentor/peer mentor in a session would predict lower eating psychopathology in the following session, and (ii) the causal association between WA and eating psychopathology would be stronger for patients assigned to a peer mentor

		compared to those assigned to a postgraduate student mentor.
Chapter 6: *Patients and mentor Language Style Matching as a predictor of alliance and engagement with clinic treatment over the course of an online guided self-help intervention for anorexia nervosa.*	To investigate patient/mentor language style matching (LSM) over the course of an online, 6-weeks, guided self-help intervention for AN patients.	(i)It was hypothesized that patient/peer mentor LSM scores would be greater than patient/student mentor LSM scores. (ii) LSM scores would remain stable over the six weeks of treatment. (iii) Controlling for ED symptoms and levels of depression and anxiety at baseline, lower levels of patient/mentor or patient/peer mentor LSM at any time point would predict lower TAU alliance and lower motivation for TAU treatment at the EOT, especially for patient/peer mentor dyads.

Table 3 Aims, hypotheses, and related study/chapter

Chapter 2.

Study 1: Task-sharing interventions for patients with anorexia nervosa or their carers: a systematic evaluation of the literature and meta-analysis of outcomes.

Publication:

Albano, G., Hodsoll, J., Kan, C., Lo Coco, G., & Cardi, V. (2019). Task-sharing interventions for patients with anorexia nervosa or their carers: A systematic evaluation of the literature and meta-analysis of outcomes. International Review of Psychiatry, 31(4), 367-381.

2.1 Abstract

The scientific community justifies the use of a shared approach to the healthcare actively involved in patients and carers. A systematic review of the literature on guided self-help or self-help in anorexia nervosa (directed to individual affected by anorexia nervosa or their carers) and meta-analyses of randomised controlled trials have been carried out to evaluate the following outcomes of guided self-help or self-help compared to a control condition: (1) drop-out from end-of-treatment assessment, (2) body mass index (BMI), (3) anxiety, (4) depression and (5) quality of life. Guided self-help has been directed to patients in 15 studies and to carers in seven studies. The guided self-help interventions used different formats, were based on various theoretical models and involved individuals with a diverse range of experiences and expertise to provide guidance (e.g. individuals recovered from the illness, graduate students, or clinical professionals). Guided self-help was associated with a significant lower drop-out from the completion of end-of-treatment assessments compared to a control condition and an improvement in carers' wellbeing.

2.2 Introduction

Scientific literature has demonstrated the efficacy and effectiveness in the use of self-help materials (e.g. manual, app mobile, and online platforms) when treating Bulimia Nervosa and Binge Eating Disorder to augment, shorten, or replace standard care (Beintner, Jacobi, & Schmidt, 2014; Perkins, Murphy, Schmidt, & Williams, 2006; Traviss-Turner, West, & Hill, 2017). In line with these findings, the National Institute for Health and Care Excellence (NICE) guidelines have recommend guided self-help as first-line intervention for these pathologies (National Institute for Health and Care Excellence, 2017). To date, little is known about guided self-help for people suffering from anorexia nervosa (AN). Some experts in the field have indicated that this approach is not suitable for patients with AN because of combination of high medical risk and patient’s ambivalence about treatment (Wilson & Zandberg, 2012). Recovery from AN in adults is a real challenge and individual psychotherapy is lengthy (e.g. 40 or more sessions for Enhanced-Cognitive Behavioural Therapy) (Fairburn, 2008).

The NICE guidelines (National Institute for Health and Care Excellence, 2017) recommend that treatments for anorexia nervosa should involve a form of 'task-sharing' and include loved ones in the recovery journey (Langley, Treasure, & Todd, 2018). One intervention which demonstrated some level of evidence and includes the involvement of close others in managing meals is family therapy. Family therapy for children/adolescents with anorexia nervosa is usually delivered over 20 sessions, although shorter forms have been found effective for those who report a short duration of illness (i.e. 10 sessions) (Lock, Agras, Bryson, & Kraemer, 2005). Some versions of this approach provide access to online resources and guidance (Lock, Darcy, Fitzpatrick, Vierhile, & Sadeh-Sharvit, 2017), such as multi-family therapy sessions (Eisler et al.,2016), or parent-to-parent consultations in the early phase of treatment (Ganci, Pradel, & Hughes, 2018). These evidence shows that task-sharing interventions (guided self-help and self-help), could have the potential to supplement standard treatment also in adult patients with anorexia nervosa. Several approaches of psychological therapy for anorexia nervosa involve materials for patients to use on their own. For example, educational handouts are provided in the context of Specialist Supportive Clinical Management (McIntosh et al., 2006) and homework assignments are given in Cognitive Behavioural Therapy (e.g. Fairburn, 2008). A patient workbook is used in the Maudsley Model of Anorexia Nervosa Treatment for Adults (Schmidt, Startup, & Treasure, 2018), and shorter versions of this workbook have been used in supporting the transition from hospitalization (Cardi et al., 2017) and as a means of helping involvement in the initial phase of outpatient treatment (Cardi et al., 2015). Guided self-help can be delivered in different formats (i.e. written as well as audio/video materials) and modalities (face-to-face, online through websites or through mobile applications) and is usually facilitated by individuals who have already recovered and non-clinically trained individuals (students).

The first aim of this work was to conduct a systematic review of guided self-help/self-help interventions for anorexia nervosa and describe the content, context, and form of task-sharing interventions (i.e. guided self-help and self-help) for patients and/or their carers using the Template for Intervention

Description and Replication (TIDieR) framework (Hoffmann et al., 2014). The second aim was to undertake meta-analyses of main end-of-treatment outcomes (i.e. drop-out from end-of-treatment assessments, body mass index, anxiety, depression, and quality-of-life) from randomized-controlled trials (RCTs) which compared self-help or guided self-help interventions with a control condition.

2.3 Methods

Information sources and searches

A systematic search was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines (Moher, Liberati, Tetzlaff, & Altman, 2009), using the following electronic databases: PubMed, Web of Knowledge and AGRIS (1991), Embase (1974–present), Medline (1946–present), PsychINFO (1806–present), and PsycARTICLES through Ovid. In paeallel two searches have been conducted: the first to identify task-sharing interventions directed to patients, and the second to identify task-sharing interventions directed to carers. For the first search, the following key words have been used: 'Self-Help', 'Self-improvement', 'Self-guided', 'Self-management' AND 'Anorexia Nervosa'. In the second one, the following key words have been used used: 'Education', 'Training', 'Skills', 'Self-Help', 'SelfImprovement', 'Self-guided', 'Self-management' AND 'Family', 'Carers', 'Parents', 'Social support', 'Partner support', 'Caregivers', and 'Anorexia Nervosa'. For both searches there were these limitations: studies conducted with human subjects and published in English between 1980 and June 2018.

Eligibility criteria

The inclusion criteria were: 1) a diagnosis of AN according to the Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM 5) (American Psychiatric Association, 2013) or the International Classification of Diseases 10th edition (ICD-10) (World Health Organization, 1992) and 2) if the intervention proposed met at least two in four of the following criteria: (1) a description of the theoretical background of the task-sharing intervention (guided self-help or self-help), (2) the use of self-directed educational and

practise materials (workbook, manuals/books, video-clips), (3) guidance facilitated by ex-service users or non-clinically trained individuals (e.g. postgraduate students, clinical psychologist trainees), and (4) over 20 or fewer sessions delivered as guided self-help/self-help treatments.

Studies were included in the meta-analyses if the following additional criteria were met: (1) the study was a RCT comparing guided self-help/self-help versus a control group (i.e. waiting list or standard treatment) and (2) quantitative data related to patients' outcomes (i.e. drop-out from the assessment at end-of-treatment (EOT), body mass index (BMI), anxiety, depression, quality-of-life) had been provided in the published manuscript or through personal correspondence with the corresponding author.

Study selection

From the first literature search (patient) we identified 592 papers. Three studies were added using reference lists from other studies. Eight–eight duplicates were removed and 461 papers were excluded because they did not meet inclusion criteria following screening of titles and abstracts. Twenty-eight papers were excluded after reading the full-texts. The final eligible papers were 15 (Aardoom et al., 2016; Brewin et al., 2016; Byrne et al., 2017; Cardi, Clarke, & Treasure, 2013; Deeble, Crisp, Lacey, & Bhat, 1990; Enrique et al., 2018; Fichter, Cebulla, Quadflieg, & Naab, 2008; Fichter et al., 2012; Franko, 1987; Goldstein, Peters, Thornton, & Touyz, 2014; Leung, Ma, & Russell, 2012; 2013; Schmidt et al., 2012; 2015; Sternheim, Startup, McClelland, Bonin, Beecham, & Schmidt, 2017), five of which were included in the meta-analyses (Byrne et al., 2017; Fichter et al., 2012; Schmidt et al., 2012; 2015; Sternheim et al., 2017). A flow-chart of the studies included in the systematic review and meta-analyses is presented in Figure 1. Screening was performed by three members of the research team (GA, VC, GL).

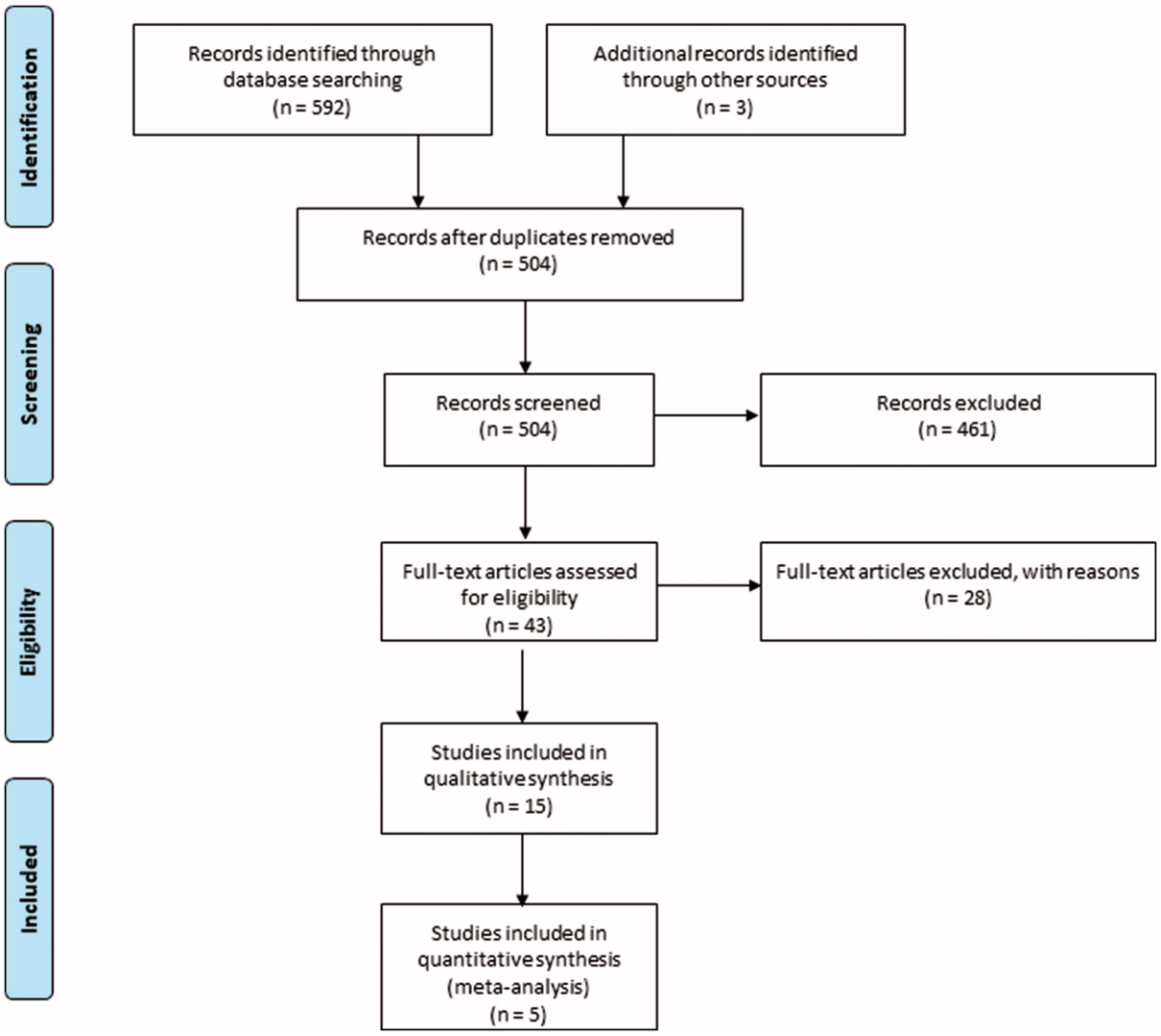


Figure 1: Flow-chart of studies investigating (guided) self-help in patients with anorexia nervosa included in systematic review and meta-analyses.

From the second literature search (carer) we identified 1538 papers. Four hundred and eighty-two duplicates were removed and 1033 papers were excluded because they did not meet inclusion criteria after the screening of titles and abstracts. Sixteen papers were excluded after reading the full-texts. The final eligible papers were seven (Gısladottir & Svavarsdottir, 2011; Hibbs et al., 2015; Hodsoll et al., 2017; Jones, Volker, Lock, Taylor, & Jacobi, 2012; Lock et al., 2017; Rhodes, Baillee, Brown, & Madden, 2008; Zucker, Marcus, & Bulik, 2006), two of which have been included in the meta-analysis (Hibbs et al., 2015; Hodsoll et al., 2017). A flow-chart of the studies included in the systematic

review and meta-analyses is presented in Figure 2. Screening was performed by three members of the research team (GA, VC, GL).

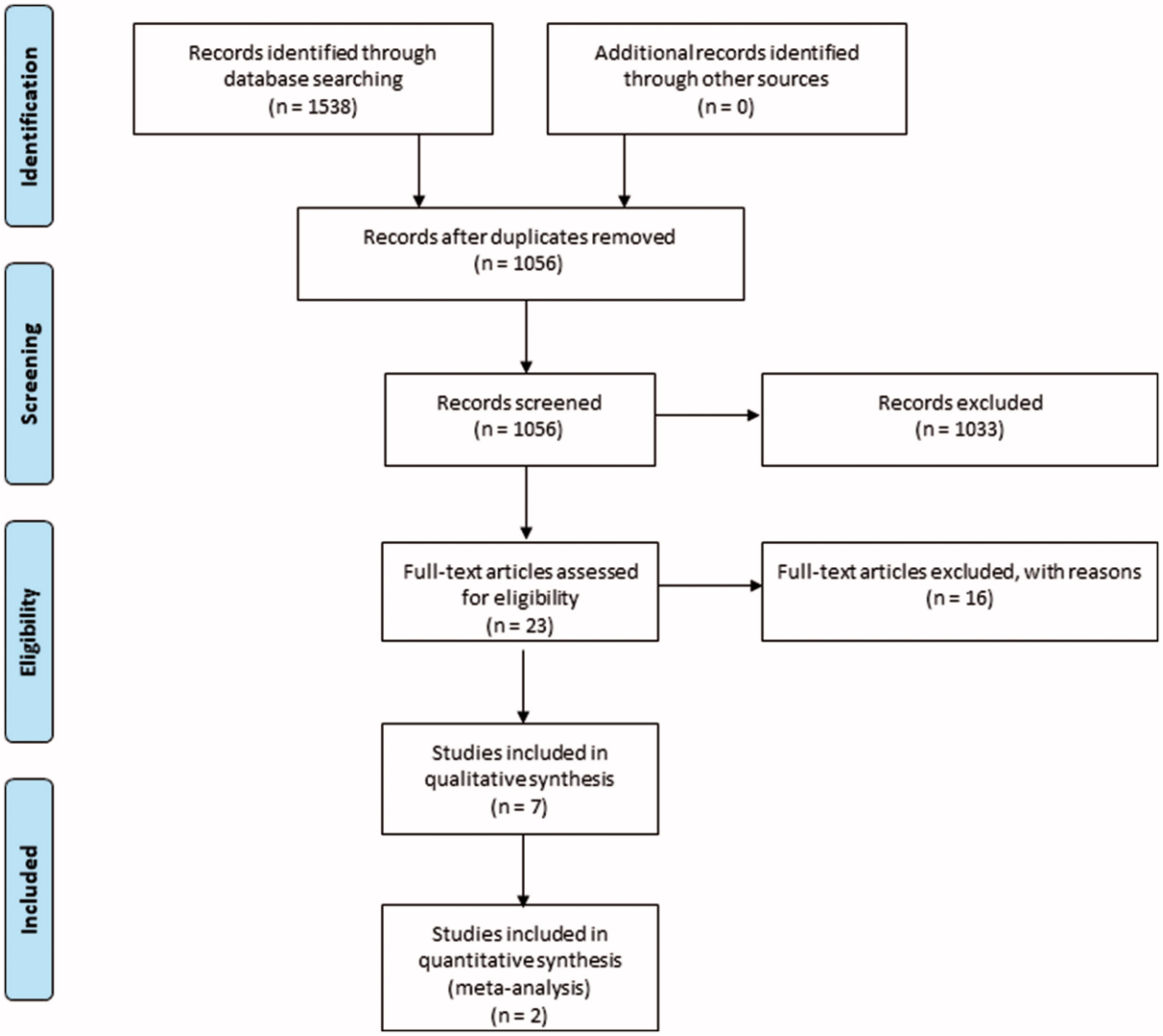


Figure 2: Flow-chart of studies investigating (guided) self-help in carers of patients with anorexia nervosa included in the systematic review and meta-analyses.

Quality assessment

The quality of the studies was assessed using the TIDieR template (Hoffmann et al., 2014); a 12-item checklist developed to support authors in describing their interventions to allow replication. The checklist includes items such as definition of intervention setting, content, duration, and description of control condition (Tables 1 and 2).

Author, year	Use of self-directed educational and practice materials	Intervention delivered by low-level trained individuals or recovered individuals	Intervention including 20 or fewer sessions	Description of theoretical background	Online
(G)SH directed to patients					
Aardoom et al 2016	✓	✓	✓	Psychoeducation	Yes
Brewin et al 2016	✓	×	✓	Motivational enhancement	No
Byrne et al 2017	✓	×	✓*	Cognitive-Interpersonal model	No
Cardi et al 2013	✓	×	✓	Cognitive-Behavioural Therapy	No
Deeble et al 1990	×	✓	✓	Peer support	No
Enrique et al 2018	✓	✓	✓	Positive psychology	Yes
Fichter et al 2008	✓	×	✓	Cognitive-Behavioural Therapy	No
Fichter et al 2012	✓	✓	✓	Cognitive-Behavioural Therapy	Yes
Franko et al 1987	×	×	×	Peer support	No
Goldstein et al 2014	✓	×	✓	Cognitive-Behavioural Therapy	No
Leung et al 2012	✓	×	✓	Motivational enhancement	Yes
Leung et al 2013	✓	×	✓	Motivational enhancement	Yes
Schmidt et al 2012	✓	×	✓*	Cognitive-interpersonal model	No

Schmidt et al 2015	✓	×	✓*	Cognitive-interpersonal model	No
Sternheim et al 2017	✓	×	✓*	Cognitive-interpersonal model	Yes
Author, year	**Use of self-directed educational and practice materials**	**Intervention delivered by low-level trained individuals or recovered individuals**	**Intervention including 20 or fewer sessions**	**Description of theoretical background**	**Online**
(G)SH directed to carers					
Gisladottir et al 2011	✓	✓	✓	The Calgary Family Intervention Model (CFIM)	No
Hibbs et al 2015	✓	✓	✓	Cognitive-interpersonal model	No
Hodsoll et al 2017	✓	✓	✓	Cognitive-interpersonal model	No
Jones et al 2012	✓	✓	✓	Family-Based Therapy	Yes
Lock et al 2017	✓	×	✓	Family-Based Therapy	Yes
Rhodes et al 2008	✓	×	✓*	Family-Based therapy	No
Zucker et al 2006	✓	×	✓	Dialectical-Behavior Therapy	No

Table 1. Definitional characteristics of (guided) self-help met by each of the studies reviewed.

Author, year	N	Diagnosis	Age group	Setting	Intervention	Intervention content	Control group	Duration of Intervention (weeks)	Drop-out definition
Patient (G)SH									
Aardoom et al., 2016	354	Eating Disorders (Anorexia Nervosa= 103)	Adults	Not specified	Featback Featback + Featback ++	Featback: automated monitoring and feedback. Featback +: weekly 20 minutes contact (chat,emails, skype). Featback ++: support 3 times a week (chat/emails)	Waiting List	8 weeks	Drop-out from assessment and treatment
Brewin et al., 2016	79	Eating Disorders, (Anorexia Nervosa = 28)	Adults	Waiting list	Motivation and psychoeducation	Workbook and guidance	n/a	3 weeks	Drop-out from assessment and treatment
Byrne et al., 2017	120	Anorexia Nervosa	Adults	Outpatient	Maudsley Model of Anorexia Nervosa Treatment for Adults	Face-to-face sessions and patient workbook	Specialist Supportive Clinical management	40 weeks	Drop-out from treatment
Cardi et al., 2013	31	Eating Disorders (Anorexia Nervosa= 18)	Adults	n/a	Psychoeducation, motivational interviewing and goal setting	Workbook, face-to-face sessions, video-clips	n/a	3 weeks	Drop-out from assessment and treatment
Deeble et al., 1990	30	Eating Disorders (Anorexia Nervosa= 16)	Adults	n/a	Anorexic Aid mutual support group	Guidance from recovered patients and/or careers	Hospital sample	36 weeks	Drop-out from assessment
Enrique et al 2018	54	Eating Disorders (Anorexia Nervosa= 9)	Adults	Outpatient	Positive Psychology	Workbook, multimedia content (audio, images and video)	Daily activity diary	4 weeks	Drop-out from assessment
Fichter et al, 2008	129	Anorexia Nervosa	Adults	Before inpatient treatment	CBT	Self-help manual and telephone sessions with clinician	Waiting List	6 weeks	Drop-out from assessment
Fichter et al., 2012	258	Anorexia Nervosa	Adults	Discharge from inpatient	CBT-based relapse prevention	Self-help manual, peer support, therapist guidance	Outpatient treatment	36 weeks	Drop-out from treatment
Franko et al., 1987	25	Eating Disorders (Anorexia Nervosa=7)	Adults	n/a	Peer support	Group sessions facilitated by therapist	n/a	24 weeks	Drop-out from assessment

Goldstein et al, 2014	61	Anorexia Nervosa = 23	Adults	Day care	Treatment as usual + CBT for perfectionism	Self-help book, group sessions facilitated by therapist	Day care	3.5 weeks	n/a
Leung et al, 2012	12	Eating disorders (Anorexia Nervosa = 4)	Adults	Outpatient	Smart eating self-help program (psychoeducation + motivation)	Worksheets, feedback emails	n/a	4 weeks	n/a
Leung et al, 2013	185	Eating Disorders	Adults	Outpatient	Smart eating self-help program (psychoeducation + motivation)	Worksheets, feedback emails	n/a	4 weeks	Drop-out from assessment and treatment
Schmidt et al, 2012	71	Anorexia Nervosa	Adults	Community	Maudsley Model of Anorexia Nervosa Treatment for Adults	Workbook and face-to-face therapist sessions	Specialist Supportive Clinical management	24 weeks	Drop-out from assessment
Schmidt et al, 2015	142	Anorexia Nervosa	Adults	Outpatient	Maudsley Model of Anorexia Nervosa Treatment for Adults	Workbook and face-to-face therapist sessions	Specialist Supportive Clinical management	24 weeks	Drop-out from assessment
Sternheim et al, 2017	41	Anorexia Nervosa	Adults	inpatients	Maudsley Model of Anorexia Nervosa Treatment for Adults + treatment as usual	Workbook and email sessions with a therapist	Inpatients treatment	48 weeks	Drop-out from assessment
					Carer (G)SH				
Gisladottir et al 2011	14 patients 21 carers	Eating disorders (Anorexia Nervosa = 3)	Adults	Outpatients	Calgary Family Intervention Model	Psychoeducation, group sessions, homework	n/a	3 weeks	Drop-out from treatment
Hibbs et al, 2015	178 patients 268 carers	Anorexia Nervosa	Adults	Inpatient	Experienced Caregivers Helping Others + treatment as usual	Workbook, DVDs, coaching sessions	Inpatients treatment	24 weeks	Drop-out from assessment

Hodsoll et al, 2017	149 patients 149 carers	Anorexia Nervosa	Adolescents	Outpatients	Experienced Caregivers Helping Others + treatment as usual	Workbook, DVDs, coaching sessions	Outpatients treatment	24 weeks	Drop-out from assessment
Jones et al, 2012	46 patients 46 carers	Anorexia Nervosa	Adolescents	n/a	Family-based internet facilitated intervention	Facilitated online discussion groups, phone calls, written materials and videos	n/a	6 weeks	Drop-out from assessment
Lock et al, 2017	19 patients 19 carers	Anorexia Nervosa	Adolescents	None	Guided self-help version of family-based treatment	Lecture materials (videos), homework, discussion forum and expert guidance sessions	n/a	24 weeks	Drop-out from assessment and treatment
Rhodes et al, 2008	20 patients 20 carers	Anorexia Nervosa	Adolescents	One-week post-discharge	Parent-to-parent consultations + Maudsley Model of family-based treatment	Peer support (parent to parent)	Maudsley Model of family-based treatment	24 weeks	Drop-out from assessment and treatment
Zucker et al, 2006	Npt:16 AN= 9 Ncarers: 16	Eating disorders, AN= 9	16.0 (2.8)	Outpatients	Skill-based group parent training Program	Psychoeducation, homework and group sessions	n/a	16 weeks	n/a

Table 2: Studies' characteristics table, including detailed description of intervention' content and duration and control group.

2.4 Statistical analyses for the meta-analyses

Odds ratios (OR) were calculated for drop-out at EOT for the randomized controlled studies included in the meta-analyses. Peto's OR was used considering the potential small number of drop-outs, with OR >1 indicating a lower drop-out rate in the guided self-help/self-help group and OR < 1, indicating a greater drop-out rate in this group. Mean differences between baseline and EOT scores were calculated ('change scores') and the standard deviations of the change scores were used as measures of variance according to the Cochrane guidelines (Higgins & Green, 2011) for the BMI, depression and anxiety levels and quality of life. Correlations between baseline scores and EOT scores were provided through personal communication by Hodsoll et al. (2017) and assumed to be representative for all studies. Standardized mean differences (SMD) of the change scores between treatment groups were used to synthesize the findings. Hedges' g values were calculated as a summary measure of SMD because Cohen's d is biased upwards for small samples. Effect sizes (ESs) were interpreted as small ($\geq$ 0.20), medium ($\geq$ 0.50), and large ($\geq$ 0.80). The statistical significance was set at $p < 0.05$. All meta-analyses were conducted with a random effects model. A fixed-effects model was deemed inappropriate because studies included random samples of potential study populations and different methods and interventions. Between-studies heterogeneity was estimated with I^2 statistics. The potential presence of publication bias was investigated through funnel plots. However, funnel plot asymmetry may be a result of the small number of studies in the present meta-analyses. All statistical analyses were conducted with Review Manager (RevMan) 5.3 (Review Manager, 2014).

Quality assessment of studies included in the meta-analyses

The quality of the included studies in the meta-analyses was examined using an a-priori defined set of criteria listed in the Cochrane Risk of Bias Tool (Higgins & Green, 2011) (e.g. randomized allocation of participants to study conditions and blinding of participants and personnel). In addition, criteria

reported by Svaldi et al. (2018) were used. All the studies met at least nine of the 14 criteria considered for the qualitative assessment.

2.5 Results

The characteristics of the 22 studies included in the systematic review and meta-analyses are reported in Tables 1 and 2. Most studies involved the use of self-help materials for patients or carers (self-help manual, workbook, video-clips, DVDs, homework, facilitated forum, feedback). Two studies (Deeble et al., 1990; Franko, 1987) did not use self-help materials but included groups for mutual support. Guided self-help/self-help were based on the principles of psychoeducation (n = 1), positive psychology (n = 1), dialectical behaviour therapy (n = 1), the Calgary family intervention model (n = 1), family-based therapy (n = 2), peer support (n = 2), motivational enhancement (n = 3), cognitive-behavioural therapy (n = 4), or cognitive interpersonal maintenance model of anorexia nervosa (n = 7). Twenty or fewer sessions were offered in 21 studies and, amongst those, five studies included the option of having additional sessions based on patient's severity of illness. Guidance in guided self-help interventions was delivered by low-trained individuals in eight studies and by trained clinicians in 14 studies and was given face-to-face in 14 studies and online in eight studies. Support from individuals with lived experience of the illness was reported in four studies (Deeble et al., 1990; Franko, 1987; Hodsoll et al., 2017; Lock et al., 2017; Rhodes et al., 2008). A comparison group was included in 13 studies (n =1 psychiatric population, n = 1 daily activity exercise, n = 1 Maudsley model of family based treatment for anorexia nervosa, n = 1 day-care, n = 2 waiting list, n = 2 inpatient treatment, n = 2 outpatient treatment, n = 3 specialist supportive clinical management).

Meta-analyses

Drop-out rates from the assessment at EOT

Seven studies had available drop-out data to be included in the meta-analysis; five studies from the patients' literature search (Byrne et al., 2017; Fichter et al., 2012; Schmidt et al., 2012; 2015; Sternheim et al., 2017) and two from the

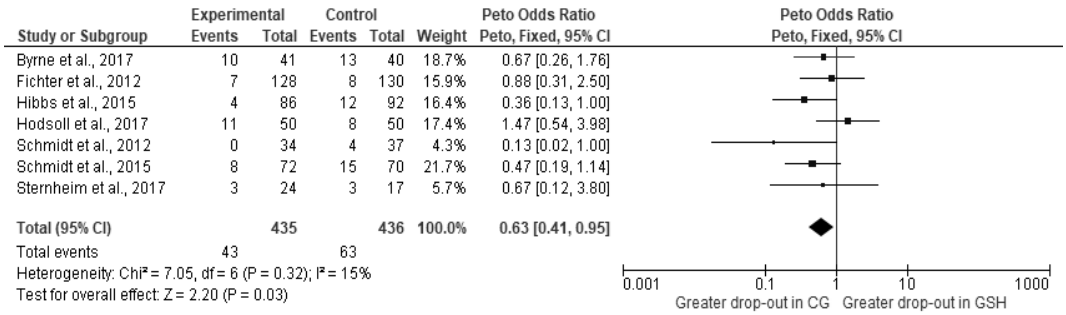
carers' literature search (Hibbs et al., 2015; Hodsoll et al., 2017). A random-effects meta-analysis of unadjusted data demonstrated a moderate difference in the drop-out rates between groups (Peto OR [95% CI] = 0.63 [0.41–0.95], Z = 2.20, p = 0.03, Figure 3(a)), with reduced drop-out rates for guided self-help/self-help rather than the treatment in comparison (SSCM, TAU). Visual inspection of the funnel plot suggested no potential publication bias (Supplementary Figure S1(a) in appendix).

Body mass index

Seven studies had available BMI data to be included in the meta-analysis; five studies from the patients' literature search (Byrne et al., 2017; Fichter et al., 2012; Schmidt et al., 2012; 2015; Sternheim et al., 2017) and two from the carers' literature search (Hibbs et al., 2015; Hodsoll et al., 2017). A random-effects meta-analysis of unadjusted data showed only negligible differences in BMI changes between groups (ES [95% CI] = 0.08 [-0.10–0.27], Z = 0.87, p = 0.39, Figure 3(b)), indicating little impact of guided self-help/self-help relative to the comparison treatment. Visual inspection of the funnel plot suggested potential publication bias (Supplementary Figure S1(b) in appendix).

Figure 3 a-b

(a)



(b)

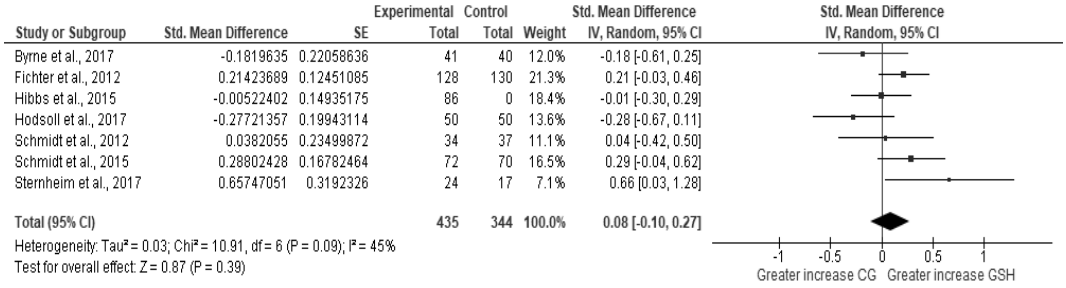


Figure 3. Forest plots comparing guided self-help (GSH) with a control group (CG) in relation to (a) drop-out from completion of end-of-treatment measures, and (b) baseline to end-of-treatment changes in body mass index (BMI)

Anxiety

Six studies had available data to be included in the meta-analysis, four studies from the patients' literature search (Fichter et al., 2012; Schmidt et al., 2012; 2015; Sternheim et al., 2017) and two from the carers' literature search (Hibbs et al., 2015; Hodsoll et al., 2017). A random-effects meta-analysis of unadjusted data demonstrated negligible differences in anxiety changes between groups (ES [95% CI] = -0.03 [-0.17–0.11], Z = 0.42, p = 0.67, Figure 4(a)), indicating little impact of guided self-help/self-help on anxiety at EOT relative to the comparison treatment. Visual inspection of the funnel plot suggested potential publication bias (Supplementary Figure S1(c) in appendix). The asymmetry was mainly due to the relatively large ES of one study (Sternheim et al., 2017).

Depression

Six studies had available data to be included in the meta-analysis, four studies from the patients' literature search (Fichter et al., 2012; Schmidt et al., 2012; 2015; Sternheim et al., 2017) and two from the carers' literature search (Hibbs et al., 2015; Hodsoll et al., 2017). A random-effects meta-analysis of unadjusted data demonstrated negligible differences in depression changes between groups (ES [95% CI] = -0.07 [-0.21–0.07], Z = 0.99, p = 0.32, Figure 4(b)), indicating little impact of guided self-help/self-help on depression at EOT relative to the comparison treatment. Visual inspection of the funnel plot suggested potential

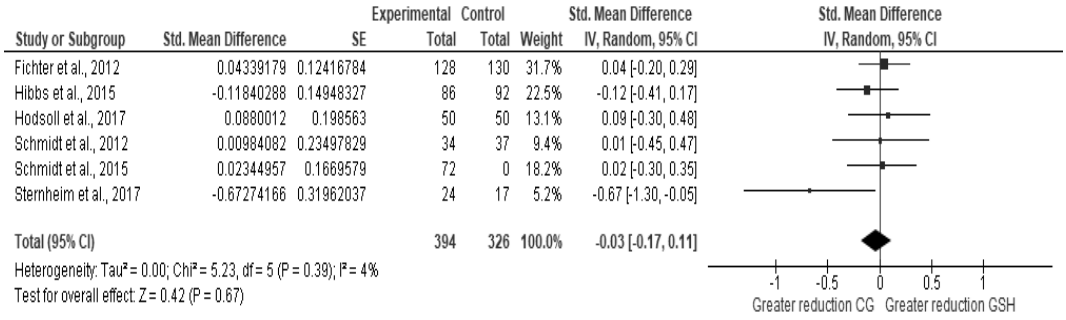
publication bias (Supplementary Figure S1(d) in appendix), mostly due to the large ES of one study (Sternheim et al., 2017).

Quality-of-life

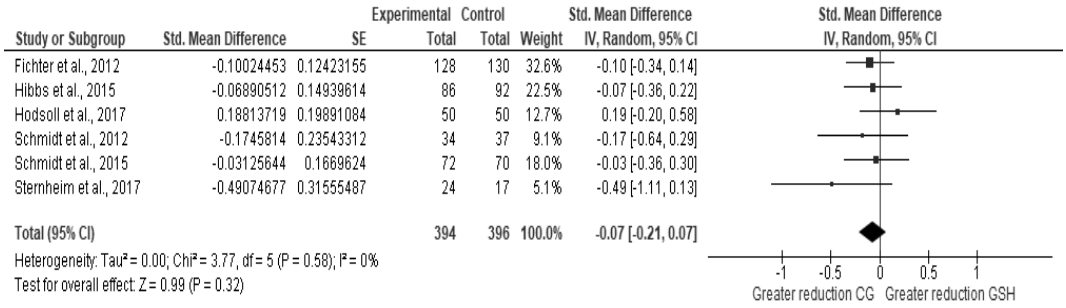
Three studies had available quality of life data to be included in the meta-analysis, two studies from the patients' literature search (Schmidt et al., 2012; 2015) and one from the carers' literature search (Hibbs et al., 2015). A random-effects meta-analysis of unadjusted data demonstrated small differences in quality-of-life changes between groups (ES [95% CI]= -0.04 [-0.24–0.16]; Figure 4(c)), indicating little impact of guided self-help/self-help on quality-of-life at EOT relative to the comparison treatment.

Figure 4 a-b-c

(a)



(b)



(c)

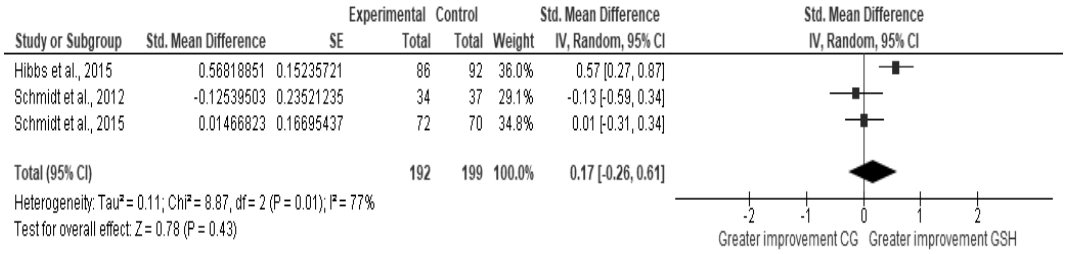


Figure 4. Forest plots comparing guided self-help (GSH) with a control group (CG) in relation to (a) baseline to-end-of-treatment changes in anxiety, (b) baseline to end-of-treatment changes in depression, and (c) baseline to end-of-treatment changes in quality-of-life (QoL)

Outcomes of studies not eligible for the meta-analyses

Patients' drop-out rates

Seven studies reported data on patients' drop-out rates from EOT assessment for guided self-help/self-help interventions (Aardoom et al., 2016; Brewin et al., 2016; Cardi et al., 2013; Deeble et al., 1990; Fichter et al., 2008; Franko, 1987; Leung et al., 2013). One study reported lower drop-out rates in the comparison group (Fichter et al., 2008). In two studies, the rates of drop-out in both groups were similar (Aardoom et al., 2016; Deeble et al., 1990). Four studies did not include a comparison group and reported drop-out rates ranging from 0–25% following task sharing interventions (Brewin et al., 2016; Cardi et al., 2013; Franko, 1987; Leung et al., 2013).

Patients' body mass index

Six studies reported data on patient's BMI at EOT (Aardoom et al., 2016; Cardi et al., 2013; Deeble et al., 1990; Fichter et al., 2008; Goldstein et al., 2014; Leung et al., 2013). All found a significant, moderate-to-very large sized increase in BMI following the use of guided self-help/self-help interventions (Aardoom et al., 2016; Cardi et al., 2013; Deeble et al., 1990; Fichter et al., 2008; Goldstein et al., 2014; Leung et al., 2013). Four of these studies included a comparison group (Aardoom et al., 2016; Deeble et al.,1990; Fichter et al., 2008;

Goldstein et al., 2014). Three papers reported data on patients' BMI following carers' guided self-help/self-help (Gısladottir & Svavarsdottir 2011; Lock et al., 2017; Rhodes et al., 2008) and found a moderate, not significant increase in patient BMI at EOT. Only one study included a comparison group (Rhodes et al., 2008).

Patients' anxiety and depression

Three papers reported data on patients' levels of depression and anxiety following guided self-help/self-help interventions (Aardoom et al., 2016; Cardi et al., 2013; Fichter et al., 2008). A significant decrease in depression and anxiety following these interventions was found in two studies (Aardoom et al., 2016; Cardi et al., 2013), one of which included a comparison group (Aardoom et al., 2016). A slight, not significant reduction in anxiety and depression in the guided self-help/self-help intervention group compared to the control group was found in one study (Fichter et al., 2008).

Patients' quality-of-life

Data on quality-of-life were reported in one study, reporting a significant improvement in the guided self-help/self-help group over the comparison group (Aardoom et al., 2016).

Carers' outcomes

The use of skill-sharing interventions for carers was associated with reduced burden, reduced expressed emotion and less time spent caregiving for adults with anorexia nervosa admitted for inpatient care (Hibbs et al., 2015). The use of skill-sharing interventions was also associated with a reduction of unhelpful behaviours (i.e. accommodating and enabling behaviours) in carers of adolescent outpatients with anorexia nervosa (Hodsoll et al., 2017) at six months, compared to treatment as usual. Online parental guided self-help (Lock et al., 2017) and group parent training (Zucker et al., 2006) were associated with an increased sense of self-efficacy in challenging the illness up to three months following training (Lock et al., 2017) and with improved parenting skills (including self-care; Zucker et al., 2006) in carers of adolescents with anorexia nervosa.

Furthermore, skill-sharing interventions for carers were associated to reductions in early symptoms and risk factors (Jones et al., 2012) and with increased rate of weight restoration (Rhodes et al., 2008) in adolescent patients. Skill-sharing interventions for carers were also associated to lower levels of weight and food concerns in patients, based on carers' perception (Gısladottir & Svavarsdottir 2011).

2.6 Conclusion

The findings of these systematic review and meta-analyses demonstrated that task-sharing interventions have the potential to increase patients' treatment adherence and carers' skills. There are still questions remaining as to who might benefit the most from these approaches, at what stage of treatment they are indicated, which could be the best combination of resources provided, and how task-sharing interventions can be most efficiently delivered. RCTs involving the collaboration with a wide network of eating disorder services are suited to provide answers to these questions. Based on these premises, the authors of this manuscript are currently conducting two large RCTs aimed at testing guided self-help for patients with anorexia nervosa (Cardi et al., 2015; 2017).

Chapter 3.

Study 2: A randomised clinical trial to evaluate the acceptability and efficacy of an early phase, online guided augmentation of outpatient care for adults with anorexia nervosa

Publication:

Cardi, V., Albano, G., Ambwani, S., Cao, L., Crosby, R. D., Macdonald, P., ... & Treasure, J. (2020). A randomised clinical trial to evaluate the acceptability and efficacy of an early phase, online, guided augmentation of outpatient care for adults with anorexia nervosa. Psychological medicine, 50(15), 2610-2621.

3.1 Abstract

Background. Outpatient interventions for adults suffering from anorexia nervosa can be associated with high drop-out rates and small clinical changes. This study explored whether adding a six-week, digital, guided self-help intervention (*RecoveryMANTRA*) to treatment as usual (TAU) in the outpatient setting would augment clinical outcomes in adult patients with anorexia nervosa.

Methods. Patients with anorexia nervosa (n = 187) were recruited from 22 eating disorders outpatient services across the UK. Ninety-nine participants were randomised to receive *RecoveryMANTRA* plus TAU and 88 received TAU alone (control group). The assessments were collected at end-of intervention (six weeks), six and 12 months.

Results. Adherence rates to *RecoveryMANTRA* were 83% for the online guidance sessions and 77% for the use of self-help materials (workbook and/or short video clips). No significant differences in body mass index (primary outcome) were found at six weeks. There were not significant between-group differences in eating disorder symptoms, psychological wellbeing and work and social adjustment (at 6 weeks and at follow-up). However, a trend-level greater reduction in anxiety at six weeks was found in the intervention arm, compared to the control group ($p = 0.06$). Those allocated to *RecoveryMANTRA* + TAU also reported significantly higher levels of confidence in own ability to change ($p = 0.02$) and greater alliance with the therapist at the outpatient service ($p = 0.005$) at end of treatment.

Conclusions. Boosting outpatient treatment for anorexia nervosa with a digital guided self-help intervention focused on recovery and motivation was associated with short-term reductions in anxiety and increased confidence to change and therapeutic alliance.

3.2 Introduction

Anorexia Nervosa (AN) is one of the most difficult illnesses to treat because starvation impairs several areas of functioning, including physical health and psychological wellbeing. Some results from naturalistic, long-term follow-up studies report that only 40–62% patients recover over a period of 20 years (Zipfel et al., 2000; Eddy et al., 2017; Fichter et al., 2017). One way of optimising treatment efficacy is to augment current interventions in the early phases of treatment. Evidence demonstrated that a rapid change in symptoms in the first weeks of treatment is associated with positive clinical outcomes at the end of treatment and/or follow-up for both adolescents and adult individuals (Linardon et al., 2016; Wales et al., 2016; Nazar et al., 2017). To date, there are no published data on the efficacy of different treatment augmentation strategies in the initial phase of treatment for adults with AN. We have developed a digital, six-week guided self-help treatment, *RecoveryMANTRA*, to augment treatment as usual (TAU) for adult outpatients with anorexia nervosa by targeting motivation to change (Cardi et al., 2015). The intervention is based on the cognitive interpersonal model and Maudsley Model of Anorexia Nervosa Treatment for Adults (MANTRA; Schmidt and Treasure, 2006; Treasure and Schmidt, 2013) and developed within a recovery framework. These frameworks emphasise the centrality of peer support, positive thoughts about the future, confidence in own ability to change, development of identity and meaning, empowerment (Leamy et al., 2011), social support and skills-sharing as main aspects of recovery (Smith-Merry et al., 2011). The focus of *RecoveryMANTRA* on motivation and confidence to change is also based on the evidence that patient's motivation to change predicts better clinical outcomes and treatment adherence (Clausen et al., 2013; Vall and Wade, 2015; Thaler et al., 2016; Denison-Day et al., 2018).

The aim of the current study is to examine the acceptability and efficacy of *RecoveryMANTRA*. It was hypothesised that *RecoveryMANTRA* plus TAU, would increase body mass index (BMI) at six weeks (primary outcome) and would reduce eating disorder symptoms, psychological distress (depression, anxiety, stress) and work and social impairment over time (end of treatment and

six- and 12-month follow-up). It was also hypothesised that the intervention would increase cognitive and behavioural flexibility, motivation to change and therapeutic alliance. Frequency of service use (including outpatient treatment, intensive treatment, appointments with general practitioners, family therapy and group therapy) was compared between intervention and control groups at six and 12 months.

3.3 Method

The protocol of this study (Cardi et al.,2015) has been described in Chapter 1. Participants were recruited from 22 adult eating disorder outpatient services throughout the UK, between April 2015 and December 2016. Informed written consent was requested from participants after description of the study. The study received ethical approval from a National Research Ethics Service Committee (London Brent, approval number 14/LO/1347) and from the local research and development offices at the participating centres.

Participants

Patients referred at one of the participating centres could be recruited if (1) they were aged 16 or over, (2) had a diagnosis of anorexia nervosa based on the criteria of the Diagnostic and Statistical manual of Mental Disorders, 5th Edition (DSM-5; American Psychiatric Association, 2013) or atypical anorexia nervosa, (3) had a BMI of 18.5 kg/m2 or below and (4) had access to the Internet.

Participants were ineligible if they had (1) insufficient knowledge of English and/or (2) severe mental or physical illness (i.e. psychosis or diabetes mellitus). Participant eligibility was assessed by the clinicians recruiting at the centres and clinical diagnoses were confirmed by the clinicians at the participating sites. The consort diagram in Fig. 1 reports the number of participants assessed and the number of those who had completed the assessment measures at baseline, six weeks, six and 12 months. Two-hundred and two people were assessed for study eligibility, of these 187 participants were found to be eligible and were consequently randomised to the *RecoveryMANTRA* + TAU group (n = 99) or to the TAU only group (n = 88). 79.8% participants in the intervention group and

80.68% participants in the control condition completed the six-week questionnaires. The six-month questionnaires were completed by 78.79% and 71.59% participants in the experimental and control groups, respectively. The 12-month BMI data were obtained from 70.05% of the entire sample (see Fig. 1).

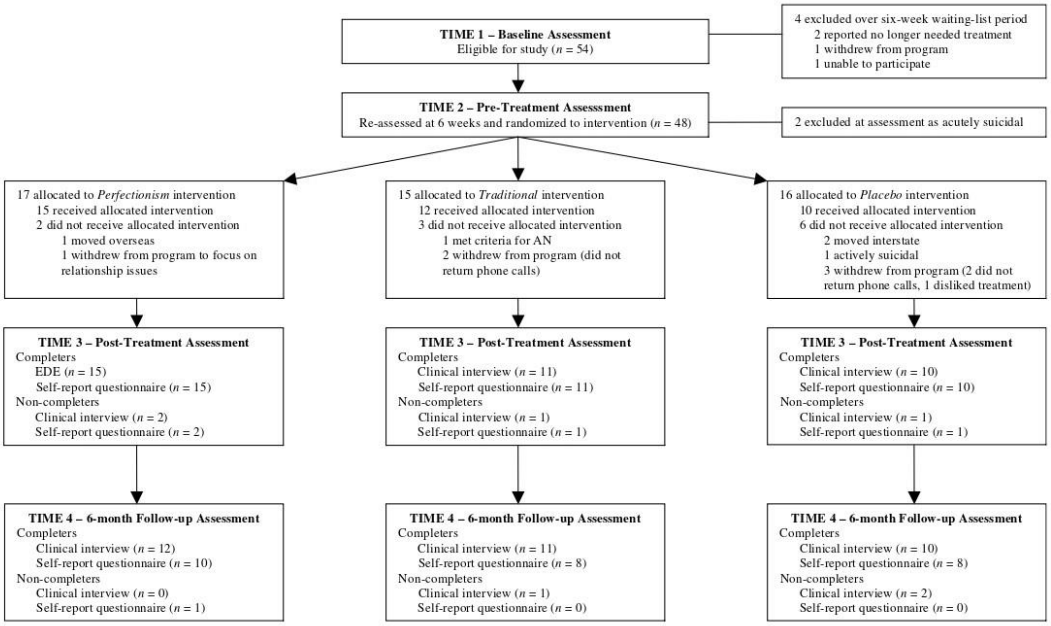


Figure 1. CONSORT diagram showing the flow of participants through each stage of the study

Randomisation

Eligible participants were randomly allocated to: (1) *RecoveryMANTRA* plus TAU or (2) TAU only. The TAU treatment at the participating centres included elements such as psychoeducation, symptom monitoring, and psychotherapy based on the recommendations of the National Institute for Health and Care Excellence (NICE, 2017).

Intervention

Participants allocated to *RecoveryMANTRA* in addition to TAU had the opportunity to receive self-help materials: 1) a workbook, a 2) library of short video clips (‘vodcasts’) and six, one-hour, chat sessions with a mentor (postgraduate student in psychology, or a carer, or an individual recovered from

an eating disorder for at least one year). The intervention materials were developed in collaboration with recovered individuals with lived experience. Principles and techniques of motivational interviewing were adopted by the mentors to facilitate the use of the self-help materials. After six months, patients in the control group (i.e. TAU only) had the opportunity to access the intervention materials. Recovery mentors (n = 24) completed 2-3-day trainings in motivational interviewing and principal contents of *RecoveryMANTRA*. Mentors received weekly email supervision from expert clinical supervisors with experience in the assessment and treatment of eating disorders.

Assessment

Participants accessed the online questionnaires and *RecoveryMANTRA* materials through the IESO Digital Health platform (http://www.iesohealth.com). Participants completed online self-report questionnaires at four time points: baseline, six weeks, six- and 12-month follow-up. Following baseline assessment, participants were randomised to one of the two study conditions. Clinicians at the participating centres were blind to participants' allocation.

Self-reported clinical measures

Eating disorder symptoms were assessed using the Eating Disorder Examination Questionnaire (EDE-Q; Fairburn and Beglin, 1994); mood was measured using the Depression, Anxiety and Stress Scales (DASS-21; Lovibond & Lovibond, 1995) and quality of life was assessed through the Work and Social Adjustment Scale (WSAS; Mundt et al., 2002) at baseline, six weeks, 6 and 12 months.

Self-reported process measures

Motivation for treatment was assessed at baseline and six weeks with The Autonomous and Controlled Motivations for Treatment Questionnaire (Zuroff et al., 2007; adapted from Williams et al., 1998). This questionnaire includes two subscales: one assesses people's intrinsic motivation to change (i.e. autonomous motivation), and the other assesses motivation to change due to external

pressures (i.e. controlled motivation). Motivation to change was assessed at baseline, six weeks, 6 and 12 months, through two visual analogue scales (scales ranging from 0 to 10) which measured confidence in one's own ability to change and importance to change. Alliance with the therapist at the outpatient service was measured at baseline and six weeks, using five, visual analogue scales (0 to 7) developed by the study team. Cognitive and behavioural flexibility was measured at baseline and six weeks, using two, seven-point visual analogue scales developed by the study team (small details vs bigger picture thinking style).

Participants service use

Participant service use was assessed asking participants to report their usage of clinical services (including outpatient treatment, inpatient or day-care services, group therapy, family therapy and appointments with the general practitioner) over the previous six and 12 months.

3.4 Statistical analyses

All analyses were performed using SPSS version 24.0 (SPSS, Inc, USA, IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp.). Univariate analyses were used to compare the intervention and control groups on sociodemographic and clinical variables at six weeks, 6 and 12 months. Logistic regression was used for dichotomous measures. All analyses were based on an intention-to-treat (ITT) approach, except for use of clinical services. Missing data for outcomes at six weeks, 6 and 12 months were imputed using multiple imputation based upon the Markov chain Monte Carlo method (Schafer, 1997) and maximum likelihood imputation based upon the Expectation-Maximization (EM) algorithm. Results were compared across the two methods. Effect sizes for the outcomes were established using Cohen's d and interpreted as small (0.2), medium (0.5) and large (0.8) (Cohen, 1988).

3.5 Results

Participants' characteristics

187 participants (181 females) completed the baseline assessment (see Table 1 for demographic and descriptive information). No significant differences in demographic or clinical variables between the control and intervention groups were found at baseline, except for a trend-level difference in BMI ($p = 0.06$; higher BMI in the TAU alone group). As reported in Table 1, assessment of clinical functioning indicated clinically significant elevations on eating disorder symptoms (EDE-Q) and moderate to severe levels of depression, anxiety and stress (DASS-21). Mean scores on the WSAS indicated significant functional i mpairments.

Variable	All			*recovery*MANTRA + TAU			TAU group			Test and p values for comparison between groups
	N	Mean or frequency	SD	N	Mean or frequency	SD	N	Mean	SD	
Gender	187	Females = 181 (96.8%) Males = 6 (3.2%)	--	99	Females: N=96 (97%)	--	88	Females: N=85 (74.8%)	--	$X^2(1)= .022$ $p= .883$
Ethnicity	160	White= 156 (97.5%). Mixed white/black= 2 (1.3%) Asian = 2 (1.3%)	--	85	White = 83 (97.6%) Mixed white/black=1 (1.2%) Asian = 1 (1.2%)	--	75	White = 73 (97.3%) Mixed White/Black =1 (1.3%) Asian = 1 (1.3%)	--	$X^2(4)= .119$ $p= .998$
Age	177	27.813	9.304	93	26.602	8.468	84	29.154	10.030	$t(175)= 1.835$ $p=.068$
Education	163	15.478	3.153	86	15.593	2.838	77	15.350	3.485	$t(161)= -.489$ $p= .626$
Employment	150	Part Time= 30 (20.0%) Full Time= 53 (35.3%)	--	80	Part Time=18 (22.5%) Full Time=30 (37.5%)	--	70	Part Time=12 (17.1%)	--	$X^2(10)= 9.291$ $p= .505$

		Housewife= 4 (2.7%) Sick Leave = 13 (8.7%) Student = 40 (26.7%) Retired = 2 (1.3%) Other = 8 (5.3%)			Housewife=3 (3.8%) Sick Leave =8 (10%) Student=19 (23.8%) Retired=1 (1.3%) Other =1 (1.3%)			Full Time=23 (32.8%) Housewife=1 (1.4%) Sick Leave = 5 (7.1%) Student = 21 (30%) Retired = 1 (1.4%) Other = 7 (10%)		
Social status	163	Single= 98 (60.1%) Relationship= 56 (34.34%) Separated= 9 (5.53%)	--	86	Single= 50 (58.1%) Relationship= 35 (39.5%) Separated=1 (1.2%)	--	77	Single= 48 (62.3%) Relationship=21 (27.3%) Separated= 8 (10.4%)	--	$X^2(5)= 8.289$ $p= .141$

Duration of illness (years)	166	7.767	8.915	89	7.242	8.818	77	8.373	9.046	*t*(164)= .814 *p*= .417
Age at illness onset	125	19.508	8.325	72	19.187	7.629	53	19.943	9.245	*t*(122)= .611 *p*= .542
Age when first diagnosed	125	23.612	9.691	72	22.743	9.388	53	24.792	10.058	*t*(122)= 1.006 *p*= .316
Age when first treated	116	24.310	10.002	68	23.970	10.031	48	24.791	10.048	*t*(114)= .434 *p*=.665
Lowest lifetime body mass index	159	14.876	1.558	86	14.813	1.405	73	14.951	1.727	*t*(157)= .018 *p*= .986
Highest lifetime body mass index	132	21.241	2.915	70	21.315	3.071	62	21.157	2.752	*t*(130)= -.309 *p*= .758
Previous hospital admissions (yes/no)	158	Yes = 42 (26.6%) No = 116 (73.4%)	--	85	Yes=22 (25.9%)	--	73	Yes=20 (27.4%)	--	$X^2(1)$= .046 *p*= .830

Psychiatric medication (yes/no)	158	Yes = 70 (44.3%) No = 88 (55.7%)	--	87	Yes = 41 (47.1%)	--	71	Yes = 29 (40.8%)	--	$X^2(1)= .625$ $p=.429$
Diagnosis of psychiatric comorbid disorder (yes/no)	153	Yes= 40 (26.1%) No = 113 (73.9%)	--	82	Yes= 21 (25.6%)	--	71	Yes=19 (26.8%)	--	$X^2(1)= .026$ $p=.872$
Outpatient treatment started when completing baseline	175	Yes= 123 (70.3%) Waiting List= 52 (29.7%)	--	90	Yes= 67 (74.4%)	--	85	Yes= 56 (65.9%)	--	$X^2(1)= 1.534$ $p= 0.215$
Body Mass Index (self-reported)	162	16.293	1.586	84	16.211	1.841	78	16.380	1.263	$t(160)= .254$ $p= 0.800$
Body Mass Index (clinician-reported)	187	16.245	1.364	99	16.069	1.446	88	16.443	1.245	$t(185)= 1.883$ $p= 0.061$
Purging (yes/no)	186	Yes= 71 (38.2%)	n/a	99	Yes: 40 (40.4%)	NA	87	Yes=31 (35.6%)	NA	$X^2(1)= .504$ $p= .303$
Eating Disorder	187	4.113	1.127	99	4.028	1.113	88	4.209	1.142	$t(185)= 1.098$

Examination Questionnaire – Total score										*p*= .273
Depression Anxiety Stress Scales - Depression subscale	186	21.784	10.950	99	21.858	10.962	87	21.701	10.999	*t*(184)= -.098 *p*= .922
Depression Anxiety Stress Scales - Anxiety subscale	186	14.215	9.220	99	13.757	8.472	87	14.735	10.028	*t*(184)= .721 *p*= .472
Depression Anxiety Stress Scales - Stress subscale	186	25.053	8.788	99	24.747	8.439	87	25.402	9.206	*t*(184)= .506 *p*= .613
Work and Social Adjustment	187	19.887	7.897	99	19.798	7.911	88	19.988	7.925	*t*(185)= .164 *p*= .870
Cognitive and	187	3.361	1.052	99	3.479	1.020	88	3.227	1.077	*t*(185)= -1.646

behavioural flexibility										*p*= .102
Autonomous motivation to change	187	4.858	.950	99	4.782	0.952	88	4.943	0.947	*t*(185)= 1.152 *p*= 0.251
Controlled motivation to change	187	4.562	.939	99	4.597	0.948	88	4.522	0.932	*t*(185)= -.543 *p*= 0.588
Confidence in own ability to change	187	5.187	2.360	99	5.232	2.284	88	5.136	2.455	*t*(185)= -.409 *p*= .683
Importance to change	187	7.967	2.247	99	7.777	2.197	88	8.181	2.297	*t*(185)= 1.229 *p*= 0.221
Alliance with therapist delivering outpatient therapy	179	4.897	1.351	96	4.854	1.332	83	4.947	1.378	*t*(177)= .457 *p*= .648

Table 1. Baseline demographic and clinical data for the entire sample, RecoveryMANTRA + treatment as usual (TAU) group and TAU-only group.

Completion of guidance sessions and the use of self-help materials

Eighty-two participants completed four or more of the six guidance sessions (82.83%; Fig. 1). The self-help materials were used by 76/99 participants (76.77%). Frequency of usage of the self-help materials was variable, and ranged between one (n = 6), six and 10 times (n = 21) and up to 21–26 times (n =9) over the course of the six-week program.

Primary and secondary outcomes

Differences between groups are described in Table 2. No significant differences in BMI were found between groups at six weeks (primary outcome). No significant group differences were found on BMI at six and 12 months and no significant differences were found in eating disorder symptoms, depression, stress and work and social adjustment at assessment point. We found a trend-level difference in anxiety scores between groups at end of treatment ($p = 0.06$), with a reduction in anxiety in the intervention group and an increase in the control group. The same pattern of findings was found using the maximum likelihood imputation based upon the EM algorithm for repeated analyses.

Variable	Time point	All			RecoveryMANTRA + TAU			TAU			Test values (Wald Chi Square or t-test) and p values for between-group comparisons	Effect size for comparison between groups	95% CI of effect size of group comparison [lower, upper]
		N of actual completers	Mean	SD	N of actual completers	Mean	SD	N of actual completers	Mean	SD			
CLINICAL OUTCOMES													
Body Mass Index	Baseline	187	16.24	1.36	99	16.06	1.44	88	16.44	1.24	*t*(185)= 1.88 *p*= 0.06	0.20	[0.12, 0.28]
	6 weeks	126	16.61	1.66	67	16.43	1.58	59	16.82	1.72	*t*(184)= .28 *p*= .77	0.03	[-0.05, 0.12]
	6 months	131	17.40	2.45	71	17.16	2.61	60	17.67	2.21	Wald Chi-Square= 0.57 *p*= .48	0.07	[-0.01, 0.16]
	12 months	131	17.15	1.83	72	17.01	1.83	59	17.31	1.82	Wald Chi-Square= 0.43 *p*= .73	0.12	[0.02, 0.22]
Eating Disorder Examination	Baseline	187	4.11	1.12	99	4.02	1.11	88	4.20	1.14	*t*(185)= 1.09 *p*= .27	0.12	[0.03, 0.20]
	6 weeks	148	3.63	1.21	77	3.47	1.19	71	3.80	1.22	*t*(184)=1.24 *p*= .21	0.14	[0.05, 0.22]

Questionnaire – Total score	6 months	140	3.08	1.44	78	3.00	1.40	62	3.17	1.49	Wald Chi-Square= 0.38 *p*=.88	0.02	[-0.07, 0.10]
	12 months	117	3.50	1.36	63	3.39	1.32	54	3.63	1.40	Wald Chi-Square= 0.06 *p*= .91	0.12	[0.02, 0.23]
Depression Anxiety Stress Scales – Depression subscale	Baseline	186	21.78	10.95	99	21.85	10.96	87	21.70	10.99	*t*(184)= -.09 *p*= .92	0.01	[-0.09, 0.07]
	6 weeks	146	20.65	9.53	75	20.80	9.41	71	20.49	9.68	*t*(184)= -.19 *p*= .84	0.02	[-0.10, 0.06]
	6 months	139	17.96	11.08	77	17.75	10.87	62	18.21	11.33	Wald Chi-Square= 0.18 *p*=.70	0.04	[-0.05, 0.12]
	12 months	115	17.81	10.69	63	17.86	10.53	52	17.74	10.89	Wald Chi-Square= 0.14 *p*=.98	0.01	[-0.12, 0.10]
Depression Anxiety Stress Scales - Anxiety subscale	Baseline	186	14.21	9.22	99	13.75	8.47	87	14.73	10.02	*t*(184)= .72 *p*= .47	0.08	[-0.01, 0.16]
	6 weeks	146	14.73	8.42	75	13.52	7.22	71	16.08	9.42	*t*(184)= 1.90; *p*= .06	0.20	[0.12, 0.28]
	6 months	139	12.37	8.23	77	11.82	8.12	62	12.99	8.32	Wald Chi-Square= 0.04 *p*= .86	0.02	[-0.07, 0.10]

	12 months	115	12.58	8.63	63	12.34	8.38	52	12.86	8.90	Wald Chi-Square= 0.33 *p*=.61	0.04	[-0.06, 0.15]
Depression Anxiety Stress Scales - Stress subscale	Baseline	186	25.05	8.78	99	24.74	8.43	87	25.40	9.20	*t*(184)= .50 *p*= .61	0.05	[-0.03, 0.14]
	6 weeks	146	24.31	7.85	75	23.80	7.58	71	24.88	8.11	*t*(184)= .75 *p*= .44	0.08	[0.00, 0.16]
	6 months	139	19.96	8.74	77	20.08	8.68	62	19.82	8.81	Wald Chi-Square= 0.20 *p*= .66	0.04	[-0.13, 0.04]
	12 months	115	20.43	9.54	63	20.36	9.53	52	20.51	9.57	Wald Chi-Square= 0.16 *p*=.80	0.01	[-0.10, 0.12]
Work and Social Adjustment	Baseline	187	19.88	7.89	99	19.79	7.911	88	19.98	7.92	*t*(185)= .16 *p*= .87	0.02	[-0.07, 0.10]
	6 weeks	145	18.97	7.69	74	19.50	7.55	71	18.38	7.80	*t*(184)= 1.04 *p*= .30	0.12	[-0.20, -0.03]
	6 months	118	16.52	10.23	63	16.32	9.89	55	16.74	10.60	Wald Chi-Square= 0.30 *p*= .81	0.02	[-0.06, 0.11]
	12 months	115	17.79	7.63	64	17.74	7.50	51	17.86	7.79	Wald Chi-Square= 1.47 *p*= .30	0.01	[-0.10, 0.12]
PROCESS MEASURES													

Cognitive and behavioural flexibility	Baseline	187	3.36	1.05	99	3.47	1.02	88	3.22	1.07	*t*(185)= -1.64 *p*= .10	0.17	[-0.26, -0.09]
	6 weeks	145	3.42	1.08	74	3.39	1.08	71	3.46	1.08	*t*(184)= 1.01 *p*= .31	0.11	[0.02, 0.19]
Autonomous motivation to change	Baseline	187	4.85	.95	99	4.78	0.95	88	4.94	0.94	*t*(185)= 1.15 *p*= 0.25	0.12	[0.04, 0.21]
	6 weeks	145	4.77	1.09	74	4.82	1.10	71	4.72	1.08	Wald Chi-Square= 2.15 *p*= .17	0.14	[-0.23, -0.06]
Controlled motivation to change	Baseline	187	4.56	.93	99	4.59	0.94	88	4.52	0.93	*t*(185)= -.54 *p*= 0.6	0.06	[-0.14, 0.03]
	6 weeks	145	4.55	1.05	74	4.57	1.08	71	4.53	1.00	Wald Chi-Square= 0.16 *p*= .98	0.01	[-0.09, 0.08]
Confidence in own ability to change	Baseline	187	5.18	2.36	99	5.23	2.28	88	5.13	2.45	*t*(185)= -.40 *p*= .68	0.03	[-0.11, 0.05]
	6 weeks	147	5.28	2.53	76	5.74	2.55	71	4.77	2.42	*t*(184)= -2.41 *p*= .02	0.27	[-0.35, -0.18]
	6 months	140	5.488	2.525	77	5.670	2.455	63	5.282	2.589	Wald Chi-Square= 1.06 *p*= .34	0.10	[-0.18, -0.01]

	12 months	110	5.3347	2.309	61	5.5085	2.258	49	5.1312	2.352	Wald Chi-Square= 1.48 *p*= .31	0.12	[-0.23, -0.01]
Importance to change	Baseline	187	7.967	2.247	99	7.777	2.197	88	8.181	2.297	*t*(185)= 1.22 *p*= 0.22	0.13	[0.05, 0.21]
	6 weeks	147	7.864	2.506	76	8.019	2.477	71	7.693	2.529	Wald Chi-Square= 1.92 *p*= .20	0.13	[-0.22, -0.05]
	6 months	140	7.654	2.683	77	7.641	2.763	63	7.670	2.593	Wald Chi-Square= 0.34 *p*= .69	0.04	[-0.13, 0.04]
	12 months	110	7.8168	2.265	61	7.7413	2.333	49	7.9059	2.183	Wald Chi-Square= 1.40 *p*= .58	0.05	[-0.06, 0.16]
Alliance with therapist delivering outpatient therapy	Baseline	179	4.897	1.351	96	4.854	1.332	83	4.947	1.378	*t*(177)= .45 *p*= .64	0.05	[-0.03, 0.13]
	6 weeks	142	4.956	1.730	74	5.288	1.579	68	4.585	1.816	Wald Chi-Square= 9.40 *p*= .005	0.30	[-0.38, -0.21]

Table 2. Baseline, 6-week, 6- and 12-month clinical outcome data and process measures for the trial's participants

Table 2 describes baseline, six-week and six- and 12-month clinical data. Significant differences between groups were found on confidence in own ability to change and alliance with therapist at end of treatment ($p = 0.02$ and $p = 0.005$, respectively), both of which were higher in the intervention group. Group differences in confidence in own ability to change reduced over time and were no longer significant at six or 12 months. Group differences in the other variables were not statistically significant. The type of mentor allocated to participants did not affect findings. Similar findings were reported when data were imputed using maximum likelihood imputation based upon the EM algorithm, except for the variable importance to change, which increased significantly more in the intervention group compared TAU, at six weeks ($p = 0.03$).

Service use

At six months, a greater proportion of individuals in the intervention arm (88.31%) than the control group (71.42%) were still attending outpatient treatment, $\chi2(1) = 6.34$; $p = 0.01$. This difference was not significant at 12 months, $\chi2\ (1) = 0.85$; $p = 0.35$. There were no other significant differences between groups in terms of frequency of service use over the previous six or 12 months.

3.6 Conclusions

RecoveryMANTRA increased confidence in own's ability to change and therapeutic alliance with TAU clinicians in the short-term. The treatment was also associated with slight improvements in anxiety levels compared to TAU alone. Longer periods of guidance and/or a greater focus on interpersonal elements could improve clinical outcomes over time. Strategies such as involving loved ones to provide guidance and encourage the use of self-help materials (Hibbs et al., 2015; Cardi et al., 2017), and greater use of peer support to boost the recovery identity (Leamy et al., 2011) might better augment outpatient interventions for anorexia nervosa.

Chapter 4.

Study 3: The Feasibility of Using Guided Self-Help in Anorexia Nervosa: An Analysis of Drop-Out from the Study Protocol and Intervention Adherence

Publication:

Cardi, V., Albano, G., Salerno, L., Lo Coco, G., Ambwani, S., Schmidt, U., ... & Treasure, J. (2020). The feasibility of using guided self-help in anorexia nervosa: An analysis of drop-out from the study protocol and intervention adherence. Frontiers in psychology, 11, 707.

4.1 Abstract

The promotion of wellbeing through the implementation of online technology is increasingly becoming a worldwide priority. This secondary analysis study examined drop-out rates and predictors of drop-out following the use of digital guided self-help for anorexia nervosa. Rates of drop-out from the end of treatment assessment (i.e., six-week assessment) were examined, as well as intervention adherence (minimum of four of six online guidance sessions) and differences between completers and participants who dropped-out. Motivation to change and associated individuals' variables were used as predictors of drop-out in a structural equation model. Ninety-nine patients were randomly allocated to the intervention group of the trial. Data from 82 patients were available, 67 of whom completed the six-weeks assessment and attended a minimum of four online sessions. No significant differences were found between completers and non-completers, at baseline. At the end of the first week of the intervention, participants who did not complete the six-week assessment reported less satisfaction with their mentor delivering online guidance. Greater confidence in their own ability to change and higher controlled motivation (external motivation due to pressure from others) predicted lower drop-out rates from the end of the six-week assessment. Stronger alliance with the therapist at the outpatient centre and lower psychological distress were associated with greater autonomous motivation (internal motivation) and importance and ability to change. These findings show that a digital guided self-help intervention for those suffering from anorexia nervosa is feasible. Early satisfaction with the treatment and external pressure to change have a protective role against drop-out.

4.2 Introduction

Following the indications of the World Health Organization (WHO), the use of digital technologies to favour mental wellbeing has become a priority (World Health Organization, 2016), due to advantages, such as large reach and high scalability. Technological aids have been developed and tested to promote the prevention and treatment of mental health issues (Zhang & Ho, 2015) and are potentially helpful to engage and treat individuals who experience high levels of shame and stigmatisation in relation to mental health issues. However, there are some concerns regarding the high drop-out rates from digital interventions (on average 31%) among those suffering from psychological disorders (Melville et al., 2010) and recent studies have underlined the need for more research on individual factors associated with drop-out (Fernández-Álvarez et al., 2017). The purpose of this paper is to explore dropout from a digital guided self-help intervention for adults with anorexia nervosa.

In recent years, there has been a large increase in the use of computerized interventions for patients with eating disorders, especially for those suffering from loss of control over-eating and purging (Aardoom et al., 2013; Schlegl et al., 2015). Most of these interventions involve self-help materials and different kinds of guidance delivered by health professionals or lay people and are mainly associated with a reduction in eating disorder symptoms (medium effect size) and binge abstinence (small effect size) (Traviss-Turner et al., 2017). However, drop-out rates from manualized self-help interventions for eating disorders vary greatly across studies (ranging between 1 and 88%; Beintner et al., 2014), and intervention- and person-related variables associated with early drop-out from study protocols and interventions are largely unknown (e.g., Barakat et al., 2019). Furthermore, evidence on the efficacy and acceptability of online treatment for anorexia nervosa is still limited. This is justified by concerns related to the use of non-traditional forms of therapy (e.g., regular and intensive face-to-face contact with a mental health professional) with individuals at risk of medical complications (Wilson and Zandberg, 2012).

We have developed a six-week digital guided self-help intervention for patients with anorexia nervosa, *RecoveryMANTRA*, and recently compared *RecoveryMANTRA* + TAU to TAU alone in a randomized two armed controlled trial (i.e., SHARED) of patients with anorexia nervosa assessed for outpatient treatment (Cardi et al., 2015). Patients receiving *RecoveryMANTRA* plus TAU showed higher confidence in their own ability to change ($p = 0.02$, small effect size), greater alliance with the therapist at the outpatient service ($p = 0.005$, small to medium effect size) and trend-level greater reductions in anxiety ($p = 0.06$, small effect size) at end of treatment, compared to a TAU alone (Cardi et al., 2019). The greatest emphasis of *RecoveryMANTRA* is on empowering individuals by maximizing their motivation and confidence to change (Cardi et al., 2015). This is in line with the assumptions of self-determination theory and with the evidence that a patient's motivation to change predicts drop-out in eating disorders (Vall and Wade, 2015; Thaler et al., 2016). Autonomous motivation to change before treatment (intrinsic motivation) seems related to lower levels of eating disorder symptoms at the end of treatment (Mansour et al., 2012; Thaler et al., 2016) or to faster improvement in symptoms (Carter and Kelly, 2015). On the other hand, there is no evidence of controlled motivation (external motivation) predicting treatment outcomes (Mansour et al., 2012; Carter and Kelly, 2015; Thaler et al., 2016).

In this secondary analysis study from the SHARED trial (as published in Cardi et al., 2015, 2019), we explored drop-out (i.e., non-completion of end-of-six weeks intervention assessment) and intervention adherence rates (adherence defined as attendance of a minimum of four of six online guidance sessions) in the intervention arm of the trial. We also assessed differences in demographic and clinical parameters between drop-out and completers and explored differences between these two groups over the first week of participation in the intervention. Finally, we assessed the role of autonomous and controlled motivation in predicting drop-out from completing the end-of-intervention assessment. Therefore, it was hypothesized that there would be differences between groups in terms of perceived quality of the relationship with the mentor within the first week of *RecoveryMANTRA* intervention. In particular, it was

expected for the completers group to report a greater satisfaction with their mentors. It was also predicted that higher levels of autonomous motivation to change and higher levels of importance and confidence in one's own ability to change would be associated with lower rates of drop-out from the end-of-intervention assessment and from *RecoveryMANTRA* program.

4.3 Methods and materials

Participants

This study is part of a multi-center, randomised clinical trial comparing the effects of treatment as usual (TAU) plus guided self-help (*RecoveryMANTRA*) versus TAU alone, on clinical outcomes of patients suffering from anorexia nervosa, assessed for outpatient treatment (Cardi et al., 2015, 2019). The sample included 99 individuals, aged 16 or over, with a diagnosis of anorexia nervosa or atypical/partial anorexia nervosa according to the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (American Psychiatric Association, 2013). Participants were recruited from 22 eating disorder outpatient services across the United Kingdom. The study procedure was carried out in accordance to the latest version of the Declaration of Helsinki and the study design was reviewed by ethical committee (Research Ethics Committee of London-Brent, project reference number: 14-LO-1347). Informed consent of the participants was required after the nature of the program had been fully explained. Due to missing data on key baseline variables, 17 subjects were excluded from the analyses. The final sample included 82 participants. Clinical and sociodemographic characteristics of the sample are described in Table 1.

		Drop-out from the assessment				Drop-out from the intervention			
	Total Group (n= 82)	***Completers (n=67)***	***Drop-outs (n=15)***	***Test and p-values***	***Cohen's d ES***	***Completers (n=70)***	***Drop-outs (n=12)***	***Test and p-values***	***Cohen's d ES***
	Mean (SD)	*Mean (SD)*	*Mean (SD)*	*Completer vs. Drop-out groups*		*Mean (SD)*	*Mean (SD)*	*Completer vs. Drop-out groups*	
				Baseline variables					
Age	26.57 (8.29)	27.03 (8.86)	24.53 (4.67)	t(80) = 1.05, *p* = .294	.35	26.81 (8.73)	25.17 (4.99)	t(80) = .63, *p* = .528	.23
Years of education	15.78 (2.59)	15.87 (2.54)	15.33 (2.87)	t(72) = .66 *p* = .514	.20	15.85 (2.50)	15.33 (3.28)	t(72) = .55 *p* = .581	.18

Body Mass Index	16.09 (1.41)	16.06 (1.41)	16.24 (1.43)	t(80) = -.45 *p* = .652	.13	16.06 (1.42)	16.24 (1.39)	t(80) = -.40 *p* = .690	.13
Duration of illness	6.75 (7.80)	7.22 (8.33)	4.67 (4.35)	t(80) = 1.15 *p* = .255	.38	7.04 (8.20)	5.08 (4.75)	t(80) = .80 *p* = .426	.29
Eating Disorder Examination Questionnaire	4.01 (1.14)	3.91 (1.13)	4.43 (1.13)	t(80) = -1.61 *p* = .112	.46	3.92 (1.10)	4.53 (1.26)	t(80) = -1.75 *p* = .084	.52
Depression Anxiety and Stress Scales	59.71 (23.49)	58.15 (21.99)	66.67 (29.13)	t(80) = -1.27 *p* = .206	.33	57.89 (21.78)	70.33 (30.75)	t(80) = -1.72 *p* = .090	.47
Work and Social Adjustment Scale	19.91 (7.86)	19.85 (7.60)	20.20 (9.21)	t(80) = -.15 *p* = .877	.04	19.90 (7.58)	20.00 (9.70)	t(80) = -.04 *p* = .968	.01
Importance to change	7.85 (2.19)	7.76 (2.22)	8.27 (2.09)	t(80) = -.81 *p* = .422	.24	7.81 (2.20)	8.08 (2.19)	t(80) = -.39 *p* = .697	.12

Confidence in own ability to change	5.19 (2.34)	5.32 (2.31)	4.60 (2.47)	t(80) = 1.09 *p* = .279	.30	5.34 (2.29)	4.33 (2.57)	t(80) = 1.39 *p* = .169	.41
Autonomous Motivation	4.84 (.98)	4.83 (1.02)	4.86 (.81)	t(80) = -.08 *p* = .937	.03	4.86 (1.01)	4.72 (.82)	t(80) = .44 *p* = .662	.15
Controlled Motivation	4.63 (.91)	4.69 (.93)	4.36 (.78)	t(80) = 1.29 *p* = .202	.38	4.63 (0.96)	4.60 (.61)	t(80) = .13 *p* = .900	.04
Alliance with therapist	4.84 (1.30)	4.92 (1.26)	4.49 (1.46)	t(80) = 1.14 p = .256	.31	4.95 (1.24)	4.17 (1.45)	t(80) = 1.98 *p* = .051	.58
Cognitive and behavioral flexibility	3.51 (1.06)	3.50 (.97)	3.53 (1.43)	t(80) = -.11 *p* = .913	.02	3.53 (1.00)	3.37 (1.38)	t(80) = .46 *p* = .645	.13
Variables at week 1									
Confidence in own ability to change week 1	2.53 (1.02)	2.62 (1.01)	2.00 (.89)	t(76) = 1.88 p = .064	.65	2.59 (1.01)	2.00 (.93)	t(76) = 1.56 p = .123	.61
Hope week 1	2.53 (1.03)	2.60 (1.00)	2.00 (1.09)	t(76) = 1.81	.57	2.57 (1.00)	2.00 (1.19)	t(76) = 1.50	.52

				p = .074				p = .138	
Restriction week 1	.75 (1.05)	.72 (1.01)	.92 (1.26)	t(78) = -.65 p = .519	.17	.71 (1.01)	1.00 (1.33)	t(78) = -.65 p = .529	.25
Purging week 1	.30 (.75)	.19 (.63)	.85 (1.07)	t(78) = -2.13 p = .052	.61	.21 (.66)	.90 (1.10)	t(78) = -1.92 p = .084	.76
Use of self-help materials week 1	1.68 (.47)	1.65 (.48)	1.80 (.42)	t(60) = -.98 p = .344	.33	1.67 (.47)	1.71 (.49)	t(60) = -.22 p = .828	.08
Comfortable working with mentor week 1	5.04 (1.68)	5.19 (1.61)	4.00 (1.87)	t(70) = 2.03 p = .046	.68	5.17 (1.62)	3.67 (1.86)	t(70) = 2.14 p = .036	.86
Agreed goals with mentor week 1	4.82 (1.74)	5.06 (1.60)	3.30 (1.89)	t(71) = 3.15 p = .002	1.00	4.94 (1.69)	3.71 (1.98)	t(71) = 1.80 p = .077	.67

Table 1. Participants' demographics and clinical variables.

Measures

Baseline assessments included the following self-reported measures:

Demographic and clinical survey (i.e.: age, gender, ethnicity, years of education, employment and social status, duration of illness, time of illness onset, diagnosis and first treatment received, previous hospital admissions, psychiatric comorbidity and medication and self-reported body mass index).

Autonomous and Controlled Motivations for Treatment Questionnaire (ACMTQ; Zuroff et al., 2007): a 12-item questionnaire which consists of two six-item subscales assessing autonomous motivation and controlled motivation for treatment. Participants are asked to rate the extent to which they agree with each statement using a seven-point rating scale. The ACMTQ showed good/acceptable internal consistency in this study (Cronbach's α values: 0.89 and 0.71 for autonomous and controlled motivation subscales, respectively).

Importance and confidence in own ability to change were assessed using two items ranging from 1 ("not important at all"/not confident at all") to 10 ("extremely important"/"extremely confident in my ability to change") and it was developed by study authors.

Eating Disorder Examination Questionnaire (EDE-Q; Fairburn and Beglin, 1994), a 36-item self-report measure of eating disorder symptoms. The EDE-Q has been validated for both clinical and non-clinical groups (Mond et al., 2004) and shows good reliability and validity. Items are rated on a six-point Likert scale, where higher scores indicate a greater level of eating pathology. It includes four subscales, but only the total score has been considered in this study (Cronbach's α:0.92).

Depression, Anxiety and Stress Scales (DASS-21; Lovibond and Lovibond, 1995) a 21-item self-report measure of patients' psychological distress over the past 7 days. Items are scored on a four-point Likert scale. It includes three subscales (i.e., anxiety, depression, and stress), but only the total score was considered in this study (Cronbach's α:0.91).

Work and Social Adjustment Scale (WSAS; Mundt et al., 2002), a five-item self-report scale aimed to evaluate patients' perceptions of impairment in everyday functioning which derived from a given problem. The scale investigates the following domains: work, home management, social and private leisure activities, and close relationships. Scores for each item range from 0 to 8 and higher scores reflect more severe functional impairment (Cronbach's α:0.73).

Alliance with therapist at the outpatient treatment centre was evaluated using five self-developed visual analogue scales [ranging from 0 (never) to 7 (always)] assessing patients' feelings that the therapist understood them, could be trusted, and that they worked towards mutually agreed and relevant goals. A mean score of the five scales was calculated to reflect overall alliance and used in this study (Cronbach's α: 0.92).

Cognitive and behavioural flexibility was assessed using four visual analogue scales (ranging from 0 – never, to 7 – always) measuring patient's attention to details and use of rigid behaviours.

All these measures, apart from the demographic and clinical survey, were repeated at six weeks. Patients also completed daily assessments of importance and confidence in their ability to change, hope of change (all measured using visual analogue scales ranging from 1 "not at all" to 5 "extremely") and weekly measures of frequency of eating disorder behaviours (restriction, purging, over-exercising, on a Likert scale ranging from 0: "0 days," to 3: "6–7 days"), use of self-help materials (workbook and video-clips, on a Likert scale ranging from 1 "0 days" to 5 "6–7 days") and alliance with their mentor delivering the online sessions (i.e., easiness of working with the mentor and degree to which they both agreed on reaching the goals for the sessions, measured on a Likert scale ranging from 1 "never" to 7 "always").

RecoveryMANTRA plus Treatment As Usual (TAU)

Participants in the RecoveryMANTRA + TAU condition had access to online self-help materials (workbook and video-clips) and weekly one-hour, chat sessions with a peer mentor or mentor. Peer mentors were individuals with past

experience of eating disorders, whereas mentors were postgraduate psychology students. Peer mentors and mentors they were trained in the use of motivational interviewing strategies. TAU varied among the recruitment centers, but mainly consisted in psychoeducation, individual or group psychotherapy, nutritional support, and medical monitoring.

4.4 Statistical analyses

Means and standard deviations or percentages were used to describe demographic and clinical variables. Independent t-tests were used to explore differences between groups at baseline and week 1. Bivariate (Pearson) correlations coefficients between variables were computed. A structural equation model (SEM) was tested to explore the relationships between baseline patient variables, motivation to change and drop-out from end of six-week assessment or the intervention. Model testing was performed using Mplus 6.0 (Muthén & Muthén, 1998–2012). A theoretical representation of the tested model is shown in Figure 1. Skewness and kurtosis were assessed and the Weighted Least Squares Mean and Variance adjusted (WLSMV) estimator was used as the method of parameter estimation. The following indices were considered to evaluate the overall model goodness fit: χ2-test statistics (χ2/df ratios < 3 indicate models with reasonable fit, Schermelleh-Engel et al., 2003), the comparative fit index (CFI, with values between 0.80 and 0.89 indicating adequate but marginal fit and values of ≥0.95 indicating better fit, Hu and Bentler, 1999) and the root-mean-square error of approximation (RMSEA, with values of ≤0.05 indicating close fit, and < 0.08 indicating reasonable fit) (Hoyle and Panther, 1995; MacCallum et al., 1996).

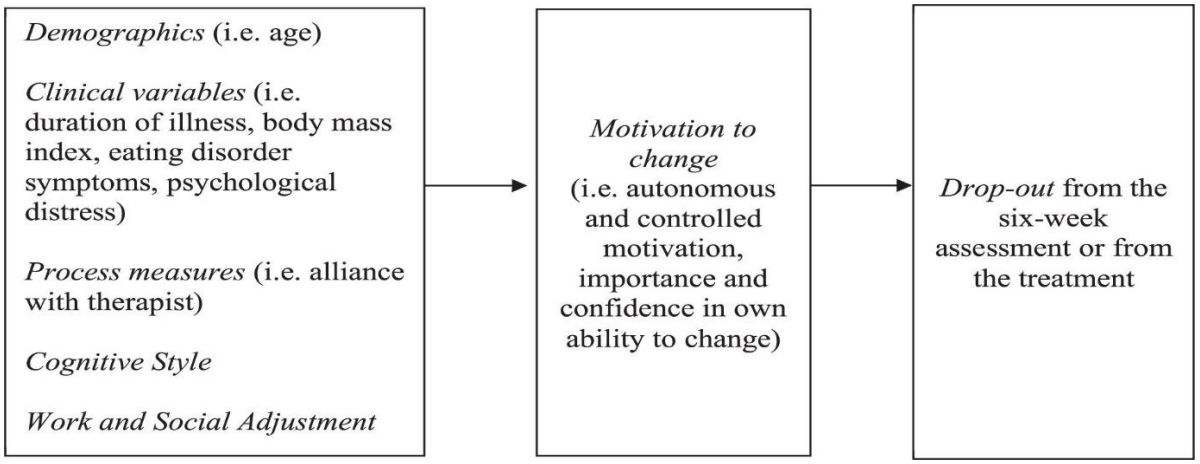


Figure 1. Theoretical model related to hypothesized relationships between the variables investigated.

4.5 Results

Demographic characteristics

The majority of participants were female (80/82) with a mean age of 26.57 years (SD = 8.29). Almost half of the sample (41/82) was employed (part-time or full-time) and were single (43/82). The mean body mass index (BMI) was 16.09 kg/m2 (SD = 1.41) and on average, patients had already been ill for seven years (SD = 7.80). Just a small subgroup reported psychiatric comorbidity (n = 19), previous hospital admission (n = 20) and psychiatric medication assumption (n = 34). Twenty-three participants (28%) reported purging symptoms. In Table 1 the demographic and clinical variables are reported.

Pearson correlations coefficients reported at baseline, a greater alliance with the therapist at the outpatient centres and a lower psychological distress were related to higher autonomous motivation ($p < 0.01$) and importance and confidence in own ability to change ($p < 0.01$). Patients with lower BMI reported higher importance to change ($p < 0.05$). However, this finding needs to be interpreted cautiously because the BMI was self-reported.

Completion rates of assessment and treatment

Completion rates of the online assessments and attendance of the six guided sessions are shown in Figure 2. Sixty-seven participants completed the six-weeks assessment and attended at least four guided sessions (n = 2 patients

attended four sessions; *n* = 6 attended five sessions; *n* = 59 attended six sessions). Fifteen participants did not complete the six-week questionnaires. Among those, 12 completed less than four sessions (*n* = 3 patients attended no sessions, *n* = 1 completed one session, *n* = 6 completed two sessions, *n* = 2 completed three sessions, *n* = 1 completed four sessions, *n* = 1 completed five sessions, *n* = 1 completed six sessions). Forty-nine participants (59.8%) received online support from graduate psychology students and 33 participants (40.2%) received online support from people with past experience of eating disorders (recovered individuals or carers of people with lifetime eating disorders). The type of mentor did not impact on drop-out levels.

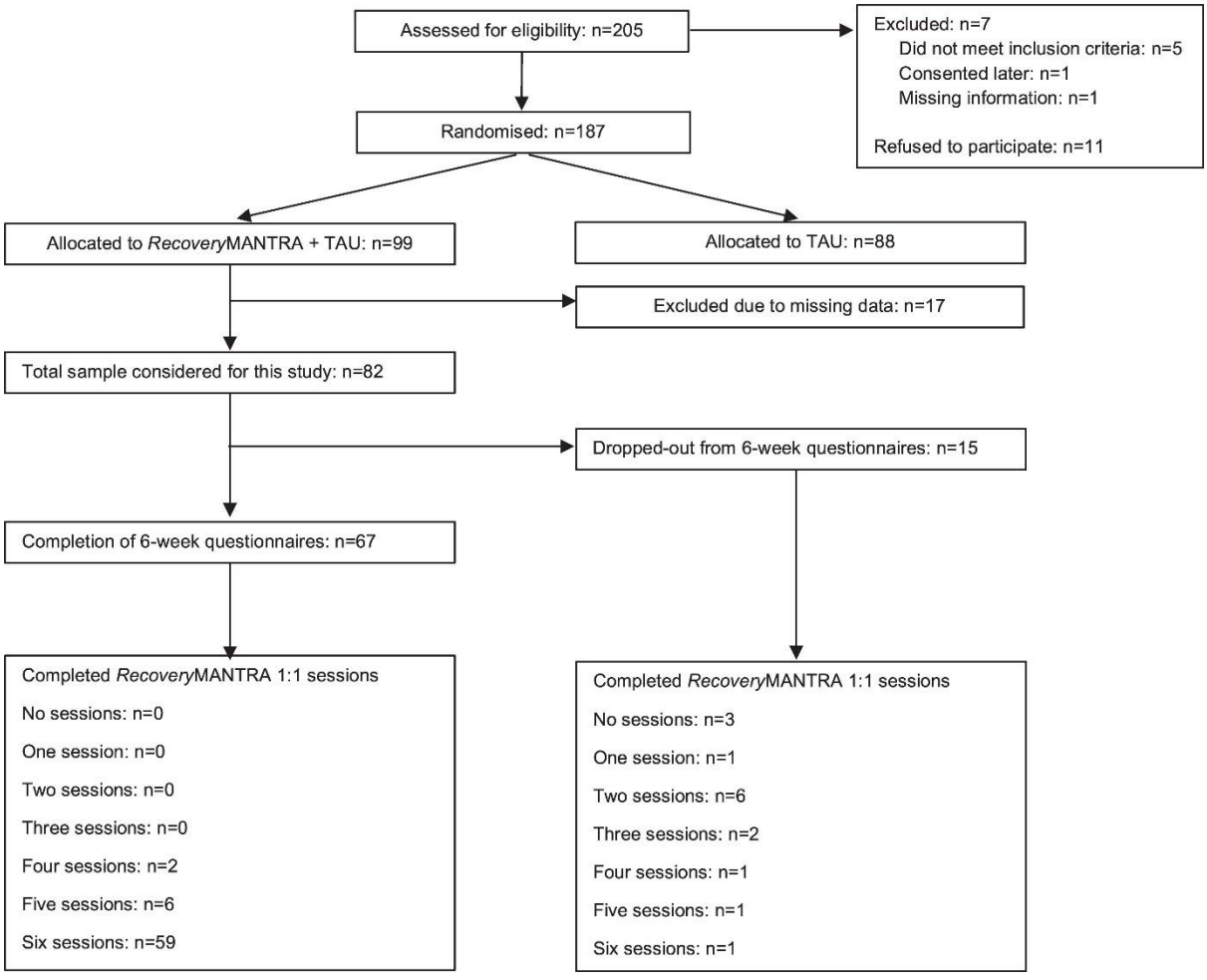


Figure 2. Study flow-chart of process of assessing and randomizing participants, including number of participants who completed the 6 weeks assessments and the RecoveryMANTRA intervention sessions

Baseline differences between completers and drop-outs

No significant differences at baseline were found between completers of the assessment or the intervention and drop-outs (Table 1). There was just a trend ($p = 0.05$, medium effect size) for those who did not complete the intervention to report lower alliance with the therapist delivering TAU (Table 1).

Differences between groups at the end of the first week of RecoveryMANTRA program

Patients who dropped-out from the end-of-intervention assessment reported feeling less at ease with their mentors ($p < 0.05$, medium effect size) and lower levels of agreement with them on the goals for the sessions ($p < 0.01$, large effect size) at the end of their first week of participation. There were also trends relating to increased episodes of purging ($p = 0.05$, medium effect size) and lower confidence in their ability to change ($p = 0.06$, medium effect size).

Participants who completed less than four online sessions felt less comfortable working with their mentor at the end of the first week of their participation in the RecoveryMANTRA program ($p < 0.05$, large effect size).

Structural Equation Modeling

In Figure 3 the model of the relationships among age, clinical impairment (eating disorder symptoms, body mass index, duration of illness, psychological distress), cognitive style, alliance with the therapist at the outpatient center, social and work adjustment, autonomous and controlled motivation for treatment, importance and confidence in own ability to change at baseline and drop-out from the assessment and from the intervention are reported. The model presented a good fit to the data considering the following parameters: $\chi 2 = 15.573$, $df = 18$, $\chi 2/df = 0.86$, CFI = 1.000, RMSEA = 0.000, RMSEA 90% CI = 0.000–0.084. The parameter estimates in Table 3 showed that the alliance with the therapist delivering TAU at baseline was associated with patient motivation to change (i.e., autonomous motivation, ability and importance to change and a trend toward significance for controlled motivation, $p = 0.06$). Patients reporting more psychological distress presented lower importance ($p < 0.01$) and confidence in their ability to change ($p < 0.001$) and lower autonomous

motivation (p <. 05), whilst those with lower body mass index reported greater importance to change (p < 0.05). A trend toward significance indicated that greater work and social adjustment was associated with higher importance to change (p = 0.06). Higher controlled motivation and greater confidence in one's own ability to change predicted lower drop-out from the six-week assessment (p < 0.05). Finally, a trend toward significance (p = 0.06) was found for greater confidence in one's own ability to change to predict lower drop-out from the treatment.

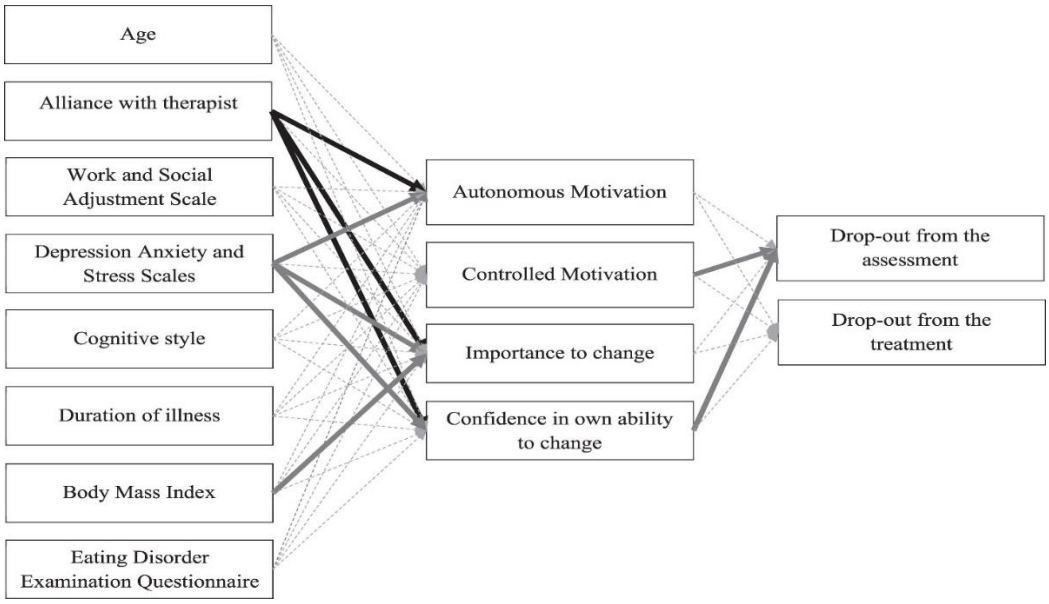


Figure 3. Structural equation model. This model describes the relationships between patient demographic and clinical variables, self-reported motivation and drop-out from the 6-weeks assessments and *RecoveryMANTRA* intervention. Errors are omitted from the diagram. Significant positive parameters are represented by black solid lines. Significant negative parameters are represented by gray solid lines. Non-significant parameters are represented by gray dashed lines. For clarity, correlations between variables are omitted from the diagram: autonomus motivation is not significantly correlated to controlled motivation ($p < 0.001$), importance to change ($p < 0.01$) and confidence in ability to change ($p < 0.01$); moreover, importance to change is correlated to confidence in ability to change ($p < 0.01$) and drop-out from the assessment is correlated to drop-out from the treatment ($p < 0.001$).

	Autonomous motivation		Controll d motivation		Importance to Change		Confidence in own ability to change		Drop-out from the assessment		Drop-out from the treatment	
	b	R^2	b	R^2	B	R^2	b	R^2	b	R^2	B	R^2
		.293		.148		.281		.448		.273		.199
Age	-.15 (ns)		-.01 (ns)		-.17 (ns)		-.08 (ns)		-		-	
Alliance with the therapist	.39***		.27 (p=.055)		.28**		.40***		-		-	
Work and Social Adjustment Scales	.22 (ns)		.24 (ns)		.28 (p=.062)		.08 (ns)		-		-	
Depression Anxiety and Stress Scales	-.47*		-.08 (ns)		-.51**		-.56***		-		-	

Cognitive style	.04 (ns)	-.07 (ns)	.05 (ns)	.08 (ns)	-	-
Duration of illness	-.18 (ns)	-.08 (ns)	-.01 (ns)	-.16 (ns)	-	-
Body Mass Index	-.09 (ns)	-.18 (ns)	-.25*	-.03 (ns)	-	-

Eating Disorder Examination Questionnaire	.21 (ns)	-.03 (ns)	.20 (ns)	.11 (ns)	-	-
Autonomous motivation	-	-	-	-	.34 (ns)	.19 (ns)
Controlled motivation	-	-	-	-	-.34*	-.07 (ns)
Importance to change	-	-	-	-	.32 (ns)	.36 (ns)
Confidence in own ability to change	-	-	-	-	-.46*	-.46 (p=.056)

*Note: * p < .05; ** p < .01; *** p < .001* - **Table 2. Standardized coefficients of the structural equation model.**

4.6 Conclusion

The findings of this study demonstrated that an online guided self-help for patients with anorexia nervosa is acceptable and feasible. To a certain degree, a patient's tendency to adhere to treatment because of external pressure or expectations from others seems to play a protective role in completing the online treatment. Further studies are needed on monitoring patients 'clinical symptoms, expectations and satisfaction with digital guided self-help during the earlier phases of participation to reduce the risk of drop-out.

Chapter 5.

Study 4: The relationship between working alliance with mentors and eating disorder psychopathology over the course of a digital six-week guided self-help intervention for anorexia nervosa

Albano, G., Cardi, V., Kivlighan Jr., D.M., Ambwani, S., Treasure, J., Lo Coco, G. The relationship between working alliance with peer mentors and eating psychopathology in a digital six-week guided self-help intervention for anorexia nervosa (under review).

5.1 Abstract

Objective: Quality of Working Alliance (WA) is associated with treatment outcomes across several types of psychiatric disorders and psychological interventions. This study examined the role of WA with peer mentors (people with lived experience of illness) and student mentors (graduated psychology students) over the course of a six-week, digital, guided Self-Help intervention for Anorexia Nervosa (AN).

Methods: Ninety-nine patients rated weekly, for six weeks: 1) eating disorder psychopathology using the short version of the Eating Disorder Examination Questionnaire (EDE-QS) and 2) WA with a student mentor (n=14) or a peer mentor (n=10). WA was assessed asking patients the extent to which they felt comfortable working with their mentor and the extent to which they agreed with them on the goals for support. WA with mentors and the association with eating psychopathology change were measured on a session-by-session basis. The analysis involved a random intercepts cross-lagged panel model.

Results: WA with peer mentors was slightly higher (ES = 0.3) than WA with student mentors. Peer mentors WA in the previous session was significantly associated with eating disorder psychopathology in the next session. No significant relationship was found between previous session's EDE-QS scores and peer mentor alliance in the following session. In the student mentor group, there were no session-by-session associations between WA and eating psychopathology. However, greater WA with the student mentor across sessions was associated with lower eating psychopathology.

Discussion: These findings suggest that clinical outcomes are in part associated with the characteristics of the mentors delivering guidance in an online guided self-help for eating disorders.

5. 2 Introduction

Digital therapies have been largely tested in the field of eating disorders for the treatment of bulimia nervosa and binge eating disorders (Beintner, Jacobi, & Schmidt, 2014; Schlegl, Bürger, Schmidt, Herbst, & Voderholzer, 2015). Guided self-help (GSH) is recommended for these conditions by the National Institute for Health and Care Excellence (NICE) (National Institute for Health and Care Excellence, 2017). However, GSH and digital interventions have been less studied in anorexia nervosa, with experts in the field expressing concerns for patients' safety (Wilson & Zandberg, 2012). Interestingly, recent meta-analytic results demonstrate that the use of GSH in anorexia nervosa is associated with reduced drop-out rates compared to Specialist Supportive Clinical Management (SSCM) or Treatment as usual (TAU) (OR [95% CI] = 0.63[0.41–0.95], although there were only small effects for changes in body mass index (BMI), depression and anxiety, (ES of 0.08, -0,07 and -0,03; Albano, Hodsoll, Kan, Lo Coco, & Cardi, 2019). In this project, we used data from the Self-Help and Recovery guide for Eating Disorders (SHARED) trial, (which was one of the studies included in Albano et al., 2019). The SHARED trial tested the use of a six-week digital GSH intervention to augment treatment as usual for anorexia nervosa (i.e. RecoveryMANTRA), (Cardi et al., 2015). Patients receiving GSH in addition to treatment as usual (TAU) reported a greater reduction in anxiety (small effect size) at the end of the intervention (six weeks), but not at follow-up (six months), compared to TAU only (Cardi et al., 2019). Furthermore, patients receiving GSH in addition to TAU reported greater confidence in their own ability to change (small effect size) and greater alliance with their mentor at the outpatient clinic (small-to-medium effect size) at six weeks, compared to the TAU only group (Cardi et al., 2019). Patients who dropped-out early from the intervention were less satisfied with the online guidance received from the mentor delivering guidance at the end of the first week (Cardi et al., 2020). These results indicate that further research is needed to establish how effective mentoring strategies can be implemented in digital GSH for anorexia nervosa. In the current study, we examined how working alliance with the mentors

delivering online guidance in the SHARED trial impacted on eating disorder psychopathology.

The concept of working alliance (WA) includes the quality of the emotional bond established in the therapeutic dyad and also patient-therapist agreement about the goals of therapy (Zilcha-Mano & Errázuriz, 2017). The relation between quality of WA and treatment outcomes has been consistently documented across different psychotherapy treatments, and a meta-analysis of 18 studies supported a predictive relation between alliance and outcomes (d= .57) in e-mental health, with therapy delivered via Internet, e-mail or videoconferencing (Fluckiger, Del Re, Wampold, & Horvath, 2018). In the eating disorder field, a recent meta-analysis of 20 studies suggested that there is a bi-directional relationship between symptom reduction and alliance in the early phase of treatment, especially for younger patients with anorexia nervosa (Graves et al., 2017). All the studies included in the meta-analysis considered WA with a professional delivering therapy. The impact of WA with less specialized individuals, including peer mentors, on clinical outcomes from guided self-help is less clear. Recently, there has been growing interest in understanding how recovered individuals, also defined as peer mentors, can contribute to clinical change. There is some indication that peer mentorship can help patients feeling understood and improve clinical outcomes and treatment attendance (Beveridge et al., 2019; Perez, Van Diest, & Cutts, 2014; Ramjan, Fogarty, Nicholls, & Hay, 2018). A recent pilot randomized controlled trial (RCT) examining the feasibility and efficacy of peer mentorship for individuals with an eating disorder found a preference for, and higher engagement with peer mentors, compared to general social support mentorship (Ranzenhofer, Wilhelmy, Hochschild, Sanzone, Walsh, & Attia, 2020). The current study is the first to examine the role of WA with both peer mentors and psychology student mentors over the course of digital GSH for anorexia nervosa. We conducted a process analysis of data from the SHARED trial, with the overall goal of examining the association between WA with a student mentor or peer mentor and eating disorder outcomes, on a session-by-session basis. It is worth noting that the evidence on the association between WA and outcome in the treatment

of eating disorders is still inconsistent across diagnoses, treatments and time of assessment (Brauhardt et al., 2014; Graves et al., 2017), and there is a lack of research examining the role of WA in patient improvement across sessions. This is one of the first papers to explore day-by-day associations between WA and clinical outcomes in anorexia nervosa.

Zilcha-Mano (2020) distinguished between trait-like and state-like measures of the WA. Trait-like WA is the between-patient aspect of the alliance; it involves averaging WA across multiple occasions, and captures patients' ability to form an alliance with the therapist or mentor. State-like WA is the within-patient aspect of the alliance because it changes across time and has direct and specific associations to outcomes. Both trait- and state-like WA can contribute to clinical change and this study will explore their different contributions to patients' outcomes.

In this study, patients in the intervention arm (RecoveryMANTRA + TAU) had access to self-help materials (workbook and short video-clips) and received weekly online chat-based guidance from a student mentor (i.e. a trained postgraduate student of psychology) or from a peer mentor (i.e. a recovered patient who suffered from an eating disorder). Based on the literature on WA, we examined whether (1) higher alliance with the mentor/peer mentor in a session would predict lower eating psychopathology in the following session, and 2) whether the causal association between WA and eating psychopathology would be stronger for patients assigned to a peer mentor compared to those assigned to a postgraduate student mentor.

5.3 Methods

This is a process data analysis from a multi-centre randomized clinical trial for outpatients with a diagnosis of anorexia nervosa. The trial tested the efficacy of a digital, six-week guided self-help intervention (*RecoveryMANTRA*) facilitated by student mentors or peer mentors, in addition to TAU *versus* TAU alone. Participants who were randomly allocated to the RecoveryMANTRA + TAU, received self-help materials and weekly guidance from mentors to supplement their TAU. The self-help materials included a collection of short

video clips and a self-care workbook. The intervention materials were developed with the goal to increase confidence to change, internal motivation, connectedness to others and hope. In addition, the participants were supported one hour per week via online text chat (using a secure platform) through peer mentors or student mentors over the six-weeks intervention. In the treatment arm, patients were allocated to mentors on the basis of mentorship availability. Patients were blinded to the type of mentoring assigned and for the peer mentors was mandatory not to reveal any details about their illness or recovery. Participants allocated to the control group received the TAU provided by their participating centers (e.g., group psychoeducation, individual psychotherapy, nutritional support, medical monitoring). Full details of the study protocol are reported in Cardi et al. (2015) and the main outcome findings are reported in Cardi et al. (2019).

Participants

Participants were involved in the trial if they met the following inclusion criteria: 1) they were aged 16 or over, 2) had a diagnosis of anorexia nervosa, atypical or subclinical anorexia nervosa, based on the criteria of the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition ((American Psychiatric Association, 2013); and a body mass index (BMI) of 18.5 kg/m^2 or below and 3) had been referred, at the time of the recruitment, to one of the 22 UK outpatient eating disorder centers that participated in the trial.

Participants were considered ineligible if they had a 1) insufficient knowledge of English, 2) severe mental or physical illness needing treatment (i.e. psychosis or diabetes mellitus) and/or 3) did not have access to the Internet. For the purposes of the present study, only patients in the treatment arm (*RecoveryMANTRA* + TAU) were included into the analysis. These were 99 participants (97% were female), with a mean age of 26.60 (8.46) and 15.59 (2.83) years of education. At baseline assessment, 67/99 (74.4%) of patients had started outpatient treatment, their average BMI was 16.06 (1.44) and mean illness duration was 7.24 (8.81) years. Forty-one participants (47.1%) were using psychiatric medications and 22 (25.9%) had had previous hospital admissions for their eating disorder.

Mentors/Peer mentors

Twenty-four mentors were recruited; ten were individuals recovered from an eating disorder and 14 (2 males) were postgraduate psychology students who provided weekly online guidance through 1:1 synchronous chat sessions for six weeks. All were aged above 19. All mentors attended training in motivational interviewing and received 1:1 weekly supervision by clinical psychologists and highly qualified professionals for the whole duration of their involvement in the project. Online guidance was delivered once/week, for six weeks, through 1:1 written chats on the IESO Digital Health online platform (http://www.iesohealth.com). The goal of the online sessions was to guide participants through the use of the *RecoveryMANTRA* self-help materials (workbook and short video-clips). These materials were based on the cognitive interpersonal model of AN (Schmidt & Treasure, 2006; Treasure & Schmidt, 2013) and were aimed at providing psychoeducation and support with goal setting in four areas: emotion regulation, social connection, cognitive flexibility and healthy eating. In the treatment arm, patients were allocated to mentors on the basis of mentorship availability; i.e. the maximum case load was three participants/mentor, from April 2015 to December 2016 (recruitment time).

Measures

Patients rated their eating psychopathology on a weekly-basis, for six weeks, using the short version of the Eating Disorder Examination Questionnaire (EDE-QS; Gideon, Hawkes, Mond, Saunders, Tchanturia, & Serpell, 2016). The original version of the EDE-QS showed good internal consistency (Cronbach's alpha= .91) and temporal stability (ICC=.93; p= <.001), and was highly correlated with the original EDE-Q (Fairburn & Beglin, 1994; Gideon et al., 2016). In the current study, the Cronbach's alpha for the EDE-QS total score was .81. Patients rated the perceived alliance with the mentor/peer mentor on a weekly basis, for six weeks, using a two-item ultra-brief visual analogue scale (VAS) ranging from 1 (never) to 7 (always). The items were "How often do you feel comfortable working with your mentor?" and "How often do you and your mentor agree on what needs to be done to improve your situation"? These items

were adapted from the session rating scale used by Duncan et al. (2003) to measure bond and agreement on task. The two items were averaged to create a composite alliance score, and Cronbach's alpha values for the six time points ranged between 0.89 and 0.93.

5.4 Data analyses

We used the random intercepts cross-lagged panel model (RI-CLPM: Hamaker, Kuiper, & Grasman, 2015), implemented in Mplus. RI-CLPM models between-patient effects by including a random intercept for each of the variables (mentor/peer mentor alliance and EDEQS) (i.e., a factor with the six time loadings constrained to 1). This analysis is important with nested datasets with three levels (i.e., time [Level 1], patients [Level 2], and mentors/peer mentors [Level 3]). The random intercept in the CLPM removes between-person variance (i.e., Level 2) such that the lagged relationships in the RI-CLPM characterize within-person change over time (i.e., Level 1; see Hamaker et al., 2015). To address the nesting of patients within mentors/peer mentors, we followed the suggestion of McNeish, Stapleton, and Silverman (2017) and estimated cluster robust-standard errors for Level 3 (mentor level). We used the grouping command in MPLUS to estimate separate RI-CLPM models for the student mentor and peer mentor groups.

Three fit indices were used to evaluate the fit of the model: the comparative fit index (CFI), root mean square error of approximation (RMSEA), and standardized root mean square residual (SRMR). According to the recommendations from Hu and Bentler (1999), criteria for acceptable fit have ranged from CFI $\geq$ .90 and SRMR and RMSEA $\leq$ .10, to more conservative criteria of CFI $\geq$ .95, SRMR $\leq$ .08, and RMSEA $\leq$ .06.

We estimated two models, one with the auto-correlation and the cross-lagged paths freely estimated and a second model with the auto-correlation (e.g., Alliance1 $\rightarrow$ Alliance2 = Alliance2 $\rightarrow$ Alliance3 = Alliance3 $\rightarrow$ Alliance4…) and the cross-lagged paths constrained to be equal across time periods (e.g., Alliance1 $\rightarrow$ EDEQS2 = Alliance2 $\rightarrow$ EDEQS3 = Alliance3 $\rightarrow$ EDEQS4…). The Santorra-Bentler scaled χ^2 different test (Muthén & Muthén, 2017)

examined the difference between these nested models. Based on the parsimony principle, a non-significant χ^2 different test indicates that the constrained model (i.e., the auto correlation and cross-lagged paths were set to be equal) is the preferred model.

The χ^2 different tests indicated the unconstrained model was not a significantly better fit to the data than the constrained model (p = .612). This constrained RI-CLPM model had an adequate fit ($\chi2$ = 165.462, df = 118, p = .003, CFI = .961, RMSEA [90% CI] = 0.091 [0.055, 0.122], SRMR = .109.

5. 5 Results

Twenty-four mentors were recruited in the trial and each one supported a range of 1 to 13 (mean= 11.12; SD= 6.94) participants. Specifically, peer mentors (i.e. people with lived experience of the illness, n=10) assisted 40 patients, whilst student mentors (n=14) assisted 59 patients. The average rating of WA for peer mentors was slightly higher (d=0.34) (Mean= 5.56, SD = 1.12;) than the average rating of WA for student mentors (Mean= 5.13; SD = 1.32). The mean eating psychopathology scores (EDE-Q) and BMI at baseline for participants assigned to peer mentors were 3.90 (SD=1.22) and 16.14 (SD= 1.46), respectively; whilst they were 4.12 (SD= 1.04) and 16.02 (SD= 1.45) for patients assigned to student mentors. There was a small difference between groups for EDE-Q ratings at baseline (d= - 0.19), but not for the BMI (d=0.08).

Cross-lagged panel model for student mentors

For the student mentor group, the mentor WA across all six sessions loaded significantly on the mentor WA random intercept (loadings ranged from 0.521 – 0.662, ps < .001). EDE-QS ratings across the six sessions loaded significantly on the EDE-QS random intercept (loadings ranged from 0.667 – 0.744, ps < .001). Between-patient student mentor WA correlated significantly and negatively with between-patient EDE-QS, (-.33, t = -2.26, p = .024). Therefore, when the trait-like (i.e. across the six sessions) WA with the student mentor was stronger, patients reported less eating psychopathology.

Figure 1 displays the significant standardized auto correlations, cross-lagged paths and within-time period correlations. As seen in Figure 1, there was significant stability (auto-correlations for WA with students, for all measurement

occasions (e.g., between Times 1 and 2 (.31, t = 5.82, p < .001). For student mentors, the cross-lagged paths between early mentor alliance and later EDE-QS ratings were all small and not significant (ps > .49). In addition, the cross-lagged paths between early EDE-QS and later mentor alliance were all small and not significant (ps > .50). Therefore, earlier mentor WA was not related to later eating psychopathology and earlier eating disorder psychopathology was not related to later mentor WA at any point in time. With student mentors, state-like changes in WA were not related to less eating disorder psychopathology. There were two contemporaneous relationships between within-mentor WA and eating psychopathology; at session 1 (-.43, t = -3.50., p < .001) and session 3 (-.34, t = -2.01, p = .044), WA was negatively and significantly correlated with EDE-QS. Stronger alliance during these sessions was associated with less eating psychopathology at these sessions.

Cross-lagged panel model for peer mentors

For the peer mentor group, peer mentor WA across all six sessions loaded significantly on the mentor WA random intercept (loadings ranged from 0.589 – 0.717, ps < .001). EDE-QS ratings across the six sessions loaded significantly on the EDE-QS random intercept (loadings ranged from 0.451 – 0.603, ps < .001). Between-patient mentor WA correlated positively but not significantly with between-patient EDE-QS (.35, t = 1.84, p = .067). Therefore, there was no relationship between trait-like, peer mentor WA and eating psychopathology.

Figure 1 displays the significant standardized auto correlations, cross-lagged paths and within-time period correlations. As seen in Figure 1, there was significant stability Auto-correlations) for peer mentor WA across all measurements, (e.g., between Times 1 and 2 (.27, t = 5.77, p < .001)).

For peer mentors, the cross-lagged paths between early mentor WA and later EDE-QS ratings were all significant (e.g., between Times 1 and 2 (-.20, t = -3.98, p < .001)). However, the cross-lagged paths between early EDE-QS and later peer mentor WA were all small and not significant (ps > .280). Therefore, if state-like, peer mentor WA in a session was higher than usual, the eating disorder psychopathology the following session was lower than usual for the patient. However, earlier eating disorder psychopathology was not related to

later WA with the peer mentor. For contemporaneous relationships, at session 1 (-.43, t = -3.05., p = .002), working alliance with the peer mentor was negatively and significantly correlated with EDE-QS. Stronger alliance at session 1 was associated with less eating disorder psychopathology in that session.

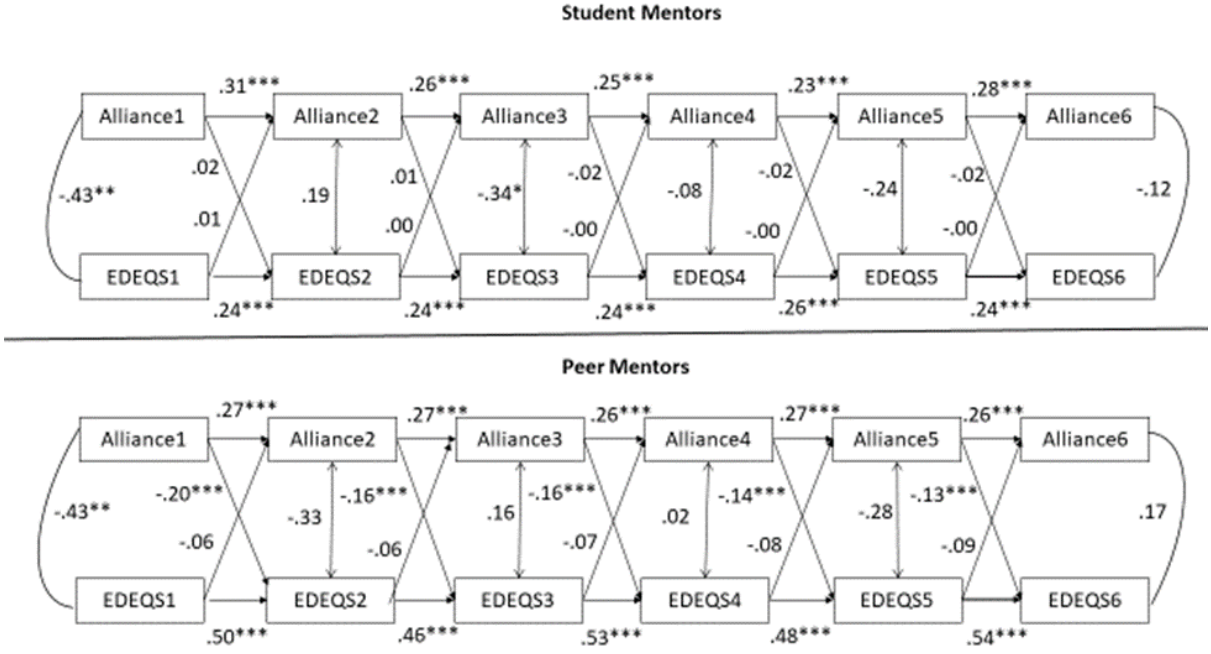


Figure 1: Random intercept cross-lagged panel model with mentor alliance and eating psychopathology (EDE-QS) at sessions 1 – 6.

Only the within-person relationships are depicted in the figure. Estimates are standardized regression coefficients and covariances. Auto-regressive and cross-lagged paths were constrained to be time-invariant. The cross-lag relationships (lines between two points in time for different variables) depict the temporal ordering of variables. For example, if a patient's alliance increases between week 2 and week 3, compared to their own average WA change, do they decrease more in eating disorder symptoms from week 3 and 4 than other weeks. The contemporaneous relationships (lines between two different variables at the same point in time) depict cross-sectional relationships. For example, if a patient's alliance increases between week 2 and week 3, compared to their own average WA change, do they also decrease more in eating disorder symptoms from weeks 2 and 3 than other weeks.

* p < .05, ** p < .01, *** p < .001.

5.6 Conclusions

This study corroborates the importance of working alliance in GSH for anorexia nervosa. These finding suggest that WA with peer mentors is slightly higher that WA with student mentors. Most importantly, this study indicates that working alliance is associated with clinical change when established with peer mentors. Higher WA with peer mentors in a session predicted lower than usual eating psychopathology in the following session, over six weeks. Given the limitations of this study, further research is warranted to examine the specific peer mentor characteristics which can help patients in the process of therapeutic change.

Chapter 6.

Study 5: Patients and mentor Language Style Matching as a predictor of alliance and engagement with clinic treatment over the course of an online guided self-help intervention for anorexia nervosa

Albano, G. Salerno L., Cardi, V., Ambwani, S., Brockmeyer, T., Treasure, J. and Lo Coco, G. Patients and mentor Language Style Matching as a predictor of alliance and engagement with clinical treatment over the course of an online guided self-help intervention for anorexia nervosa (paper under review).

6.1 Abstract

Objective: To investigate patient/mentor language style matching (LSM) over the course of an online, six-week, augmentative intervention (RecoveryMANTRA) for patients with anorexia nervosa (AN). The *RecoveryMANTRA* intervention, was delivered by peer mentors (recovered individuals or carers) or mentors (psychology graduates) over six weekly synchronous chat-based sessions. It was hypothesized that patient-peer mentor LSM scores would be greater than patient-mentor LSM scores. It was also hypothesised that LSM scores would predict patients' engagement with clinic treatment (working alliance with the therapist, and higher motivation to treatment), and their adherence to the augmentative intervention (defined as completion of four or more guidance sessions). Method: Eighty-seven adults with AN receiving the RecoveryMANTRA were included in the study. The LSM algorithm was used for calculating verbal attunement between patients and mentors/peer mentors during the online sessions. Participants were assessed at baseline for eating disorder symptoms and levels of depression and anxiety, and at the end of the augmentative intervention (six weeks) with regards to working alliance with the therapist delivering clinic treatment, and motivation for the outpatient treatment. Results: No significant changes were found in LSM over time. It was found that patient/peer mentor dyads reported greater late attunement (6th session) than patient/mentor dyads. Early and late LSM predicted higher working alliance, whereas late LSM predicted autonomous motivation for clinic treatment. LSM did not predict drop-out from RecoveryMANTRA. Conclusions: This study provides preliminary evidence that verbal attunement in an online augmentative intervention for AN is greater between patients/peer mentors, and that this variable is associated with patient engagement with clinic treatment, in terms of alliance and motivation for treatment.

6. 2 Introduction

Anorexia Nervosa (AN) is a dangerous eating disorder characterized by food-restriction and dramatic weight loss (American Psychiatric Association, 2013). Its complex aetiology and prognosis lead to high mortality rates, risk of chronicity and relapse (Arcelus et al., 2011). There is evidence that a failure to respond to outpatient treatment for AN in the early phase is associated with persistent symptoms (Nazar et al., 2017). Augmentative intervention in the early stage of therapy, for outpatients with AN, can help to enhance patient's engagement to treatment (Wade et al., 2021). Most of these interventions include self-help materials and different forms of guidance (guided self-help; GSH) delivered by professionals (defined as "mentors" from now on) or peer mentors, those with lived experience of the illness (defined as "peer mentors" from now on). A recent meta-analysis of guided self-help for patients with AN (Albano et al., 2019) showed a reduction in drop-out rates but a minimal difference in changes in psychopathology or wellbeing compared to the control condition. In this study we examine the process of an early online augmentation through a brief GSH (RecoveryMANTRA) delivered by mentors and peer mentors for outpatient with AN.

One area which requires further investigation in this context, is the examination of mechanisms of change that contribute to the efficacy (or lack thereof) of augmentative GSH, especially when delivered in an online format. This is particularly important considering the dramatic changes to health care delivery associated with the COVID-19 pandemic and potential future pandemics (Clark Bryan et al., 2020; Fernandez-Aranda et al., 2020). Moreover, there is a dearth of research examining how peer mentors who have a lived experience of the illness can help patients feeling more engaged with treatment (Perez et al., 2014). A recent trial examining the feasibility of peer mentorship for individuals with an eating disorder reported higher engagement with peer mentors compared to general social support mentorship (Ranzenhofer et al., 2020). However, there is a dearth of research examining the process of change in AN patient/mentor dyads that contribute to a stronger engagement for clinic treatment.

Language style matching (LSM) reflects a largely unconscious process of verbal attunement (Gonzalez et al., 2010; Niederhoffer & Pennebaker, 2002) and indicates how patient and mentor spontaneously synchronise their word use. Ireland and Pennebaker (2010) used nine word categories to establish a language style matching (LSM) index (Lord et al., 2015). This index reflects the degree of similarity in the use of so-called function words (e.g. prepositions, conjunctions, articles, and other relatively content-free parts of speech) in dyadic interactions and indicates the extent to which there is verbal synchrony, or attunement between two or more people talking with each other (Pennebaker et al., 2001). There is some evidence that LSM is a predictor of relationship stability (Ireland et al., 2011) and social dynamics (Gonzales et al., 2010; Bayram & Ta, 2019). In the clinical setting, LSM has been found to reflect the degree to which conversational partners coordinate language styles to achieve a common goal in therapy (Aafjes-van Doorn et al., 2020; Borelli et al., 2019), and empathy between patients and therapists (Lord et al., 2015).

The current study investigated whether LSM between patients and mentors/peer mentors over the course of an online, six-session augmentative intervention (RecoveryMANTRA) for patients with AN would predict greater motivation for treatment and greater engagement to therapist delivering clinic treatment at the referred outpatients centres. We performed a process analysis of clinical data from the SHARED trial (Cardi et al., 2015) using the LSM procedure. Patients in the treatment arm of the trial received six –week online guided augmentative intervention (RecoveryMANTRA) in addition to clinic treatment (i.e. psychoeducation, symptom monitoring, individual or group psychotherapy) provided by twenty-two outpatient services across UK. The aim of RecoveryMANTRA was to enhance clinical outcomes of standard outpatient treatment through the use of self-help materials (workbook and short video-clips) and weekly online chat-based guidance from a mentor (i.e. a trained student in psychology) or from a peer mentor (i.e. carers or recovered patient who suffered from an ED). The role of the mentors/peer mentors was to guide patients through the use of self-help materials, and the identification of targets and strategies for behaviour change (Cardi et al., 2015). The trial's findings

indicated that patients in the RecoveryMANTRA arm reported significantly higher levels of alliance with the therapist at the outpatient service than patients in the control arm, at end of the intervention (i.e. six weeks, Cardi et al., 2019) as well as their overall treatment engagement. Two more studies examined the efficacy of short treatment modules to improve patient engagement with standard treatment, and both reported that brief interventions focused on psychoeducation and motivational enhancement increased the probability of treatment engagement with eating disorders services compared to a control condition (Brewin et al., 2016; Denison-Day et al., 2019).

The aim of the present study was to examine changes in patient-mentors/peer mentors LSM at the early (1^{stc}session), mid (3rd session) and late (6th session) stages of the augmentative intervention and find differences between patient-mentors and patient-peer mentors LSM at each stage. It was also investigated whether patient-mentors/peer mentors LSM would predict clinical outcomes of the ongoing standard clinical treatment (i.e. patient's working alliance with the therapist delivering clinical treatment and motivation for clinical treatment). Finally, we explored whether greater LSM between patient and mentor was associated with adherence to RecoveryMANTRA (i.e., completion of four or more weekly sessions). We expect that patients-peer mentors LSM scores would be greater than patient- mentors LSM scores, given previous evidence supporting higher engagement with peer mentors compared to general support mentorship (Ranzenhofer et al., 2020). Moreover, controlling for eating disorder symptoms and levels of depression and anxiety at baseline, we expect that greater levels of patient-mentor or patient-peer mentor LSM at any time point would predict greater alliance with the therapist and greater motivation for the ongoing clinical treatment (i.e. both autonomous and controlled motivation).

6.3 Method

Participants

This is a process analysis of data from the SHARED trial, a randomized clinical trial testing a six-week RecoveryMANTRA augmentative intervention for patients with anorexia nervosa. Inclusion criteria were: 1) age ≥ 16 years, 2) to be referred to one of the 22 participating specialist outpatient eating disorder

services across UK, 3) to report a diagnosis of anorexia nervosa according to the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5; American Psychiatric Association, 2013) or atypical anorexia nervosa, 4) a body mass index (BMI) ≤ 18.5 kg/m2 and 5) having access to the Internet. The main purpose of the trial was to test the acceptability, feasibility and impact on clinical symptoms, of an online, six-week guided self-help intervention (RecoveryMANTRA) combined with clinic treatment (outpatient treatment), compared to clinic treatment alone. Clinic treatment in the participating centres consisted of outpatient treatment (including psychoeducation, symptom monitoring, psychotherapy) as recommended by the NICE guidelines (National Institute for Health and Care Excellence, 2017). Clinic treatment varied between centres (for example group psychoeducation versus individual psychotherapy or versus nutritional support and medical monitoring).

More information about this study is reported in the protocol and main outcome papers (Cardi et al., 2015, 2019, respectively). Following eligibility check and provision of informed consent to participate, patients were randomly allocated to RecoveryMANTRA + Clinic treatment (treatment arm) or only Clinic treatment (control arm). Before randomisation, participants completed a baseline assessment consisting of self-report questionnaires through the IESO Digital Health platform.

RecoveryMANTRA + Clinic treatment group (treatment arm)

Out of the 99 participants who were originally included in the RecoveryMANTRA + Clinic treatment group (Cardi et al., 2019), transcripts of RecoveryMANTRA sessions were available for 95 participants. Eight participants were identified as outliers and subsequently excluded in order to improve the normality of data (see the Plan of Data Analysis section). The final sample comprised 87 participants (see Figure 1 for the participant's flow diagram). Table 1 reports sociodemographic and clinical characteristics of the sample. The main goal of the online sessions was to facilitate the use of the workbook and make behavioural plans to overcome some of the dysfunctional behavioural patterns which maintain the eating disorder symptomatology (for

more information about the intervention framework, goals and materials, see Cardi et al., 2015).

Twenty-six individuals were involved in the RecoveryMANTRA intervention as peer mentors/mentors, of these 12 were peer mentors (i.e. ten people with past experience of an eating disorder and two carers of people suffering from an eating disorder) and 14 were mentors (postgraduate psychology students). In the treatment arm, patients were allocated to peer mentors/mentors on the basis of mentors' availability; the maximum case load was three participants per peer mentor/mentor, from April 2015 to December 2016 (recruitment time). Mentors provided guidance to a range of 1 to 13 participants/each (mean = 11.12; SD = 6.94). Specifically, peer mentors assisted 40 patients and mentors assisted 59 patients.

Both mentors and peer mentors received three days of training in the use of motivational interviewing and goal planning, and weekly supervision from professionals with experience in the assessment and treatment of eating disorders. Copies of the text-chat messages between mentors and participants were used for supervision and to assess treatment quality and fidelity.

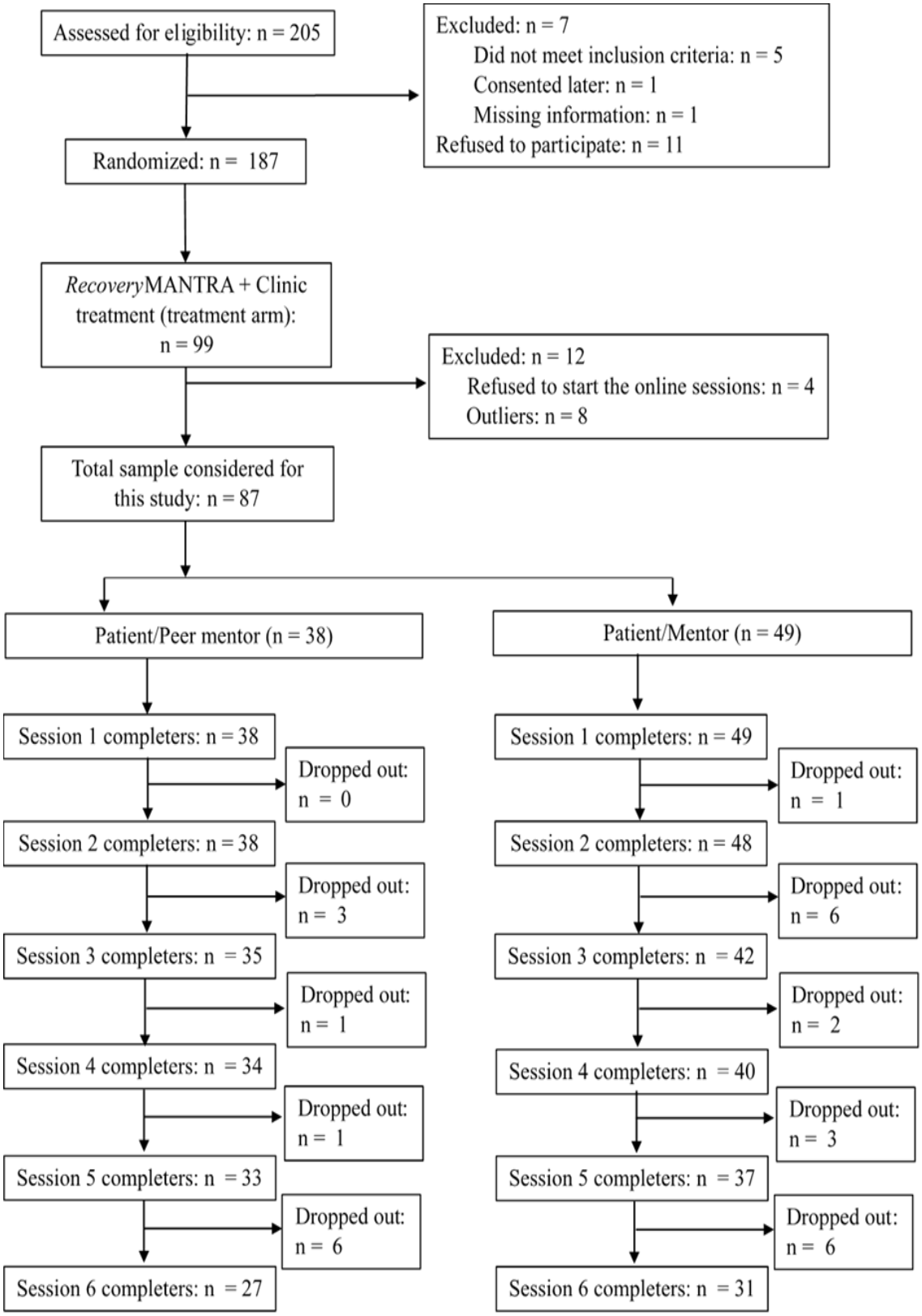


Figure 1. Participants Flow Diagram

	Total group (n = 87) §	*Patient/peer mentor (n = 38)*	*Patient/mentor (n = 49)*
Age – Mean (SD)	26.39 (8.28)	26.36 (8.16)	26.41 (8.47)
Gender (females) – F (%)	84 (96.6)	38 (100.0)	46 (93.9)
Years of education – Mean (SD)	15.43 (2.80)	15.15 (2.92)	15.65 (2.71)
Marital Status – F (%)			
In a relationship/married/living together	29 (33.3)	15 (39.4)	14 (28.6)
Single/separated	46 (52.9)	18 (47.4)	28 (57.1)
Missing	12 (13.8)	5 (13.2)	7 (14.3)
Duration of illness (years) – Mean (SD)	7.27 (8.63)	7.62 (7.91)	7.00 (9.23)
Employment Status – F (%)			
Part Time	17 (19.5)	7 (18.4)	10 (20.5)
Full Time	24 (27.6)	11 (28.9)	13 (26.5)
Housewife/sick leave/maternity leave/students/retired	29 (33.4)	16 (42.1)	13 (26.5)
Missing	17 (19.5)	4 (10.6)	13 (26.5)
Psychiatric medication (yes) – F (%)	33 (37.9)	16 (42.1)	17 (34.7)
Previous hospital admission (yes) – F (%)	19 (21.8)	8 (21.1)	11 (22.4)
Psychiatric comorbidity (yes) – F (%)	18 (20.7)	6 (15.8)	12 (24.5)

Table 1. Participants' sociodemographic and clinical characteristics for the RecoveryMANTRA + Clinic treatment group

Measures

At baseline, patients completed the 36-item Eating Disorder Examination Questionnaire (EDE-Q, Fairburn & Beglin, 1994), a well-established self-report instrument that measures eating disorder psychopathology over the previous 28 days. Items are rated on a six-point Likert scale, where higher scores indicate a greater level of eating pathology. The EDE-Q includes four subscales (i.e., Restraint, Eating Concern, Shape Concern, and Weight Concern), but for the purpose on the present study only the total score was used. The EDE-Q showed excellent internal reliability in previous studies (Luce & Crowther, 1999) and also in this study (Cronbach's alpha values: .917, .912 and .914 for patient/peer mentor, patient/mentor dyads and the whole group, respectively). Moreover, at baseline, patients completed the 21-item Depression, Anxiety and Stress Scale (DASS-21, Lovibond & Lovibond, 1995) to assess symptoms of depression, anxiety and stress. Items are scored on a four-point Likert scale, where higher scores indicate greater severity of symptoms. The DASS-21 includes three subscales (i.e., anxiety, depression, and stress), but only the total score was considered in this study. The DASS-21 showed excellent internal reliability in this study (Cronbach's alpha values: .901, .920 and .914 for patient/peer mentor, patient/mentor dyads and the whole group, respectively). At baseline, the Body Mass index (BMI) was reported by clinicians from the outpatient centres.

Working alliance with the therapist at the outpatient service (Clinic treatment) was assessed at the end of six weeks. The assessment consisted of five single items adapted from the session rating scale used by Duncan et al. (2003) to measure bond and agreement on task. Items were scored on a 7-point Likert scale. The items were: 1) How often do you feel like your therapist understands you? 2) How often do you feel confident that your therapist is pointing you in the right direction? 3) How often do you feel that you and your therapist are working toward mutually agreed upon goals? 4) How often do you trust your therapist? 5) How often do you feel that your therapist is offering you new ways of looking at your problem? (Cardi et al., 2020). A total score was computed as mean of the item scores (Cronbach's alpha values: .948, .935 and .943 for patient/peer mentor, patient/mentor dyads and the whole group, respectively).

Motivation for treatment was assessed at six weeks, using the 12-item self-report Autonomous and Controlled Motivation for Treatment Questionnaire (ACMTQ; Zuroff et al., 2007). This questionnaire includes two subscales: Autonomous Motivation (i.e. it refers to motivations with are driven by personal interest and internal incentives; e.g. “I feel personally satisfied when I follow my eating disorder treatment”) and Controlled Motivation (it refers to external motivating factors for rewards and punishment, such as praise from others or avoidance of punishment; e.g. “I would be ashamed of myself if I didn't”). Items were rated on a seven-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). The two subscales showed largely varying internal reliability from poor to good (Cronbach’s alpha values for Autonomous Motivation: .833, .762 and .795 for patient/peer mentor, patient/mentor dyads and the whole group, respectively; Cronbach’s alpha values for Controlled Motivation: .562, .769 and .725 for patient/peer mentor, patient/mentor dyads and the whole group, respectively; mean inter-item correlation for ACMTQ-CM for patient/peer mentor dyads: .187). Attendance of online chat-based sessions was also recorded.

Finally, LSM scores were calculated using the Linguistic Inquiry and Word Count software (LIWC; Pennebaker et al., 2007). The LIWC is an automated text analytic technique to examine linguistic features in clinical (e.g. therapy dialogues or patient narratives; Frattaroli, 2006; Lepore & Smith, 2002) and non-clinical settings (Ireland & Pennebaker, 2010; Ireland et al, 2011; Niederhoffer & Pennebaker, 2002). LIWC generates percentages of total words in the text for nine function word categories. The basic-level categories are: auxiliary verbs, articles, common adverbs, personal pronouns, indefinite pronouns, prepositions and relative pronouns, negations, conjunctions, and quantifiers (Gonzales et al., 2010). Separate LSM scores were calculated for each category of words using the formula (the numbers 1 and 2 refer to patient and therapist speech, respectively): $LSMpreps = 1 - (\left| preps1 - preps2 \right| / (preps1 + preps2))$.

6.4 Plan of Data Analyses

Transcripts of patient and mentor/peer mentor sessions were downloaded from the online platform (http://www.iesohealth.com) and were segmented by writers, producing two aggregate text files for each session (one for the patient and one for mentor/peer mentor, respectively). The individual LSM scores for all nine function word categories were aggregated to calculate average LSM scores for each patient-mentor dyad. These scores could range from 0 to 1, with scores of .60 indicating relatively low and scores of .85 or larger indicating relatively high verbal synchrony (Cannava & Bodie, 2017).

Four hundred and sixty transcripts were analysed in total and for the purpose of this study early, mid and late sessions LSM scores (1st, 3rd and 6th sessions, respectively) were calculated.

Preliminary analyses revealed a positive skewed distribution for mid LSM, autonomous motivation and controlled motivation. Eight participants (one dropout and seven completers) were identified as outliers and were removed in order to improve the normality of these variables. Transcripts from 87 participants were available for the first online session (early LSM); of these, transcripts for the third session were available for 77 participants (88.5%; mid LSM) and transcripts for the sixth session were available for 58 participants (66.7%; late LSM). Cases with complete data on all time points totalled 58 (66.7%). Missing data on LSM scores (due to missed GSH sessions) likely occurred completely at random (Little's (1988) Missing Completely At Random (MCAR) test was not significant: $\chi^2 2(3) = 5.368$, $p = .147$) and were dealt with by using the Expectation Maximization (Schafer, 1997) algorithm. Cronbach's α was computed for all scales to assess internal consistency and the mean inter-item correlation was examined for the ACMTQ-CM for patient/peer mentor dyads. Mean inter-item correlations between .15 and .50 indicate adequate internal consistency (Clark & Watson, 1995). Independent samples t-tests were calculated to examine differences in LSM scores between patient/peer mentor and patient/mentor dyads as well as to examine differences in early LSM between patients who did and those who did not drop out from GSH. Repeated measures analyses of variance (ANOVA) were computed to assess change

between early, mid and late LSM, with time of measurement as within-subject factor and type of mentoring (mentor vs. peer mentor) as between-subjects factor. As the preconditions of sphericity and normal distribution of residuals were met, the repeated-measures ANOVA was computed without corrections. Correlations were computed separately for patient/mentor and patient/peer mentor dyads. Hierarchical regressions were computed to assess the relationship between LSM and patient's engagement to treatment (i.e. alliance and motivation to TAU treatment) and to establish whether this relationship was moderated by type of mentoring. In the first step of the hierarchical regression analysis, control variables (i.e. baseline EDE-Q, DASS-21 and BMI) were entered in the model. LSM (after it was centered) and type of mentoring were tested in the second step. The interaction term (e.g., centered LSMxType of mentoring) was entered in the third step. Finally, hierarchical binary logistic regression was computed to assess the relationship between early LSM (first session) and treatment adherence (by controlling for eating disorder symptoms (i.e. EDE-Q and BMI) and depression and anxiety (i.e. DASS-21) at baseline. Analyses were conducted using the Statistical Package for the Social Sciences software (SPSS, version 22.0).

6.5 Results

Changes in LSM over the course of treatment (RecoveryMANTRA) and type of mentoring influence

The total sample show relatively high verbal attunement at each time point (early LSM: M = .852, SD = .050; mid LSM: M = .851, SD = .036; late LSM: M = .851, SD = .037). Moreover, LSM scores remain stable over the course of the RecoveryMANTRA (Wilks' Lambda = .999, F (2, 170) = .042, p = .959, $\eta 2p$ = .000). Figure 2 shows the overall level of attunement during the first (early LSM), third (mid LSM) and sixth (late LSM) session for patient/mentor and patient/peer mentor dyads, separately. No significant differences were found regarding early (patient-peer mentor: M = .860, SD = .035; patient-mentor: M =.846, SD = .058; t (85) = 1.479, p = .143, Cohen's d ES = .309) and mid (patient-peer mentor: M = .858, SD = .032; patient-mentor: M =.846 , SD = .038; t (85) = 1.575, p = .119, Cohen's d ES = .342) LSM scores. However, patient/peer

mentor dyads showed higher late LSM than patient/mentor dyads (patient-peer mentor: M = .861, SD = .035; patient-mentor: M =.843, SD = .036; t (85) = 2.328, p = .022, Cohen's d ES = .503). Also, the effect for the interaction between Time and Type of Mentoring (Wilks' Lambda = .995, F (2, 170) = .155, p = .857, η2p = .002) was not significant. However, the main effect of type of mentoring on the average LSM score was statistically significant (F(1, 85) = 5.774, p = .018, η2p = .064). Thus, higher average attunement was found for patient/peer mentors dyads than patient/student mentors.

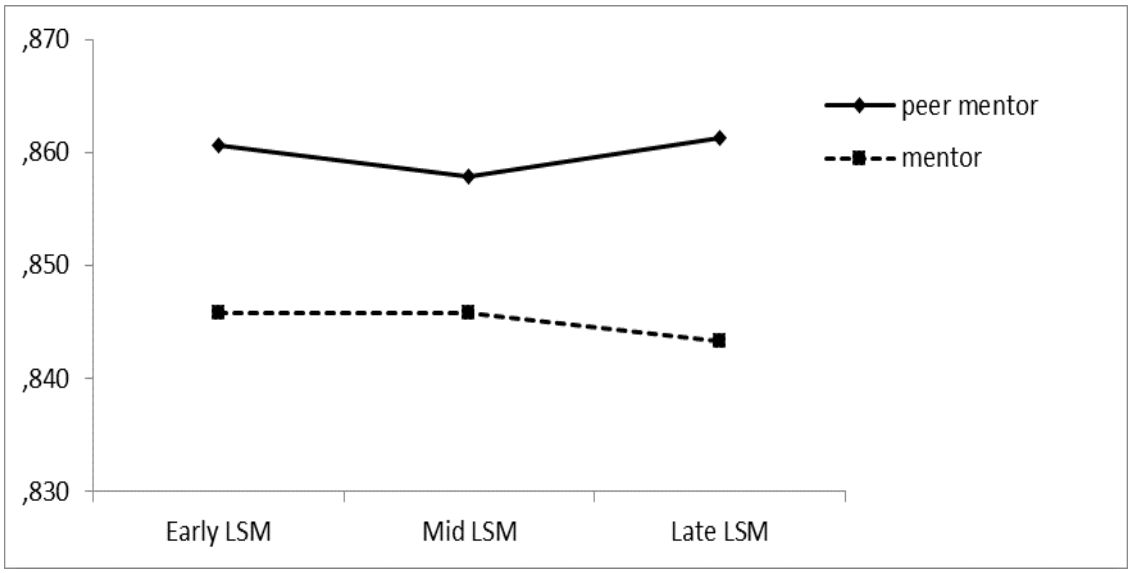


Figure 2. Overall level of attunement (LSM) in patient/therapist dyads at first (early LSM), third (mid LSM) and sixth (late LSM) sessions for mentor and peer mentor separately.

Relationships between LSM scores and working alliance and motivation for treatment

Descriptive analyses and correlations among variables reported only for patient/peer mentor dyads, higher 1st session LSM (early LSM) scores and higher 6th session LSM (late LSM) scores associated with higher working alliance with the therapist at the treatment center, at the end of GSH. Hierarchical regression analyses (Table 2) indicated that, controlling for baseline EDE-Q, DASS-21 and BMI, higher early and late LSM were associated with greater working alliance with the therapist at the treatment center at the end of GSH,

regardless of type of mentorship. Both for patient/mentor and patient/peer mentor dyads, no significant relationships were found between mid LSM and TAU alliance and type of mentoring was not a significant moderator of this association. Also, hierarchical regression analyses indicated that, controlling for baseline EDE-Q, DASS-21 and BMI, higher late LSM was related to higher autonomous motivation for treatment (Table 3). No significant relationships were found between LSM and controlled motivation for treatment.

	Adj R^2	ΔR^2	F	ΔF	B
DV: Clinic Treatment Alliance					
Step 1	.041	.085	1.924	1.924	
EDE-Q					.165
BMI					.136
DASS-21					-.336*
Step 2	.110	.094	2.611*	3.416*	
EDE-Q					.128
BMI					.122
DASS-21					-.269
Early LSM (1st session)					.266*
Type mentoring					-.122
Step 3	.130	.032	2.617*	2.353	
EDE-Q					.085
BMI					.137
DASS-21					-.261
Early LSM (1st session)					.568*
Type mentoring					-.086
Early LSM x Type mentoring					-.350
Step 1	.041	.085	1.924	1.924	
EDE-Q					.165
BMI					.136
DASS-21					-.336*
Step 2	.105	.088	2.520*	3.209*	
EDE-Q					.137
BMI					.125
DASS-21					-.315*
Late LSM (6th session)					.263*
Type mentoring					-.079
Step 3	.137	.043	2.718*	3.238	
EDE-Q					.066
BMI					.127
DASS-21					-.318*
Late LSM (6th session)					.519**
Type mentoring					-.063
Late LSM x Type mentoring					-.331

Table 2. Hierarchical regression analyses with Clinic treatment alliance at the end of RecoveryMANTRA intervention (GSH) as dependent variable.

	Adj R^2	ΔR^2	F	ΔF	β
	DV: ACMTQ-AM				
Step 1	.094	.135	3.235*	3.235*	
EDE-Q					-.100
BMI					-.163
DASS-21					-.246
Step 2	.128	.058	2.901*	2.211	
EDE-Q					-.121
BMI					-.171
DASS-21					-.227
Late LSM (6th session)					.170
Type mentoring					-.129
Step 3	.161	.045	3.082*	3.404	
EDE-Q					-.193
BMI					-.169
DASS-21					-.230
Late LSM (6th session)					.428*
Type mentoring					-.113
Late LSM x Type mentoring					-.334

Table 3. Hierarchical regression analyses with autonomous motivation at the end of RecoveryMANTRA treatment intervention as dependent variable and baseline EDE-Q, BMI, DASS-21 as well as late LSM and type mentoring as independent variables.

Note: LSM = Language Style Matching; EDE-Q = Eating Disorder Examination Questionnaire at baseline; BMI = Body Mass Index at baseline; DASS-21 = Depression, Anxiety and Stress Scale at baseline. * $p < .05$.

Relationships between early LSM score and drop out from the GSH intervention

Of the 87 participants who completed baseline data, 11 (12.6%) did not complete the GSH (3 from the patient/peer mentor group and 8 from the patient/mentor group but without significant differences in the proportion of dropout between the two groups: $\chi 2 = 1.378$, $p = .241$). No differences were found in early LSM (1st session) between patients who did and those who did not drop out from GSH, in the entire group ($t (85) = 1.743$, $p = .085$, Cohen's d ES = .452), as well as in the group receiving guidance from a peer mentor ($t (36) = .587$, $p = .561$, Cohen's d ES = .260) or a mentor ($t (47) = 1.370$, $p = .177$, Cohen's d ES = .447) . Hierarchical binary logistic regression was conducted to examine predictors of adherence to a minimum of four sessions of GSH (0 = completers, 1 = drop-out). The first block of explanatory variables included baseline EDE-Q, DASS-21 and BMI; the second block included early LSM (1st

session). The full model does not offer significant improvements over the null model ($\chi 2 = 3.934$, df = 4, p = .415) and therefore the variables were not assumed to be significant predictors in the equation.

6.6 Conclusions

Linguistic style matching can be a marker of the early therapeutic process of an online augmentative intervention for AN. LSM between patients and peer mentors/mentors was associated with indices of treatment adherence, such as working alliance with the therapist at the treatment centre and autonomous motivation for treatment. Therefore, there is promising evidence that LSM between AN and mentors/peer mentors can represent a predictor of early response in relation to standard care engagement provided by clinical treatment.

Chapter 7.

DISCUSSION

7.1 Overview of research aims and findings

The current thesis explored the efficacy, acceptability and feasibility of a novel, online Self-Help and Recovery guide for Eating Disorders (SHARED); a randomized clinical trial investigating whether a digital guided self-care intervention (RecoveryMANTRA) would be a useful addition to Treatment as Usual (TAU) for those suffering from Anorexia Nervosa in the outpatient setting. Throughout this thesis several evidences have been provided on how to extend novel intervention in the ED field, in relation to the following aims: 1) to conduct a systematic review and meta-analysis on GSH in AN; with a focus on primary and secondary outcomes, and degree of acceptability; 2) the evaluation of the feasibility, acceptability and efficacy of a novel digital GSH intervention for AN (*RecoveryMANTRA*) tested in addition to treatment as usual (TAU) in the outpatient setting, 3) a quantitative analysis of predictors of drop-out from the *RecoveryMANTRA* + TAU; 4) an examination of the role of working alliance (WA) with mentors delivering the guidance and 5) an evaluation of the role of language style matching as predictor of WA in *RecoveryMANTRA*.

In the second chapter, the findings of a systematic review and meta-analysis on the task-sharing approaches for patients with AN and their carers reported data from 22 studies: 15 discussed the use of guided self-help/self-help for patients and 7 discussed the use of guided self-help/self-help for carers. All task-sharing interventions involved psychoeducation based on several theoretical models of the illness; some interventions also implemented the use of motivational enhancement or behaviour change techniques. Most of interventions were delivered face-to-face (14/22), by clinically trained individuals (14/22) in fewer than 20 sessions (21/22). The guided self-help/self-help interventions were assessed at different stages of patient journey (e.g. before or after hospital admission, during outpatient treatment) and were compared to a control condition (13/22). Seven studies used a RCT design and for this reason were included in the meta-analyses. The meta-analyses results indicated a reduction of drop-out rate at EOT in the GSH/SH; this suggests that task-sharing interventions can encourage a more collaborative approach to clinical treatment. GSH/SH also produced clinical improvements in BMI, anxiety, depression, and

quality-of-life which were comparable to other treatments. There are at least three main reasons which might support efforts to implement guided self-help in AN: 1) GSH might be key to improve early detection of symptoms and timely access to treatment, both of which are key in the management of AN (Eddy et al., 2017); 2) GSH might facilitate the use of a collaborative approach to eating disorder treatment by overcoming geographical distance; and 3) GSH based on a recovery approach might provide a useful strategy to improve social connection (Linville et al., 2012). Finally, the access to evidence-based self-help resources can counteract the harmful effects of pro-anorexia nervosa groups.

The third chapter, aimed to evaluate the acceptability and efficacy of RecoveryMANTRA + TAU for anorexia nervosa. The high level of adherence (83% completed four or more sessions) to the online guidance is in line with the findings of the systematic review and meta-analysis reported in the previous chapter. Over three-quarters of participants accessed the self-help resources (workbook, video-clips) during the six-week digital intervention. Although no between-group differences in BMI were found, a trend-level reduction in anxiety symptoms in the intervention arm was recorded in comparison to an increased level of anxiety in the control condition. It is possible that the psychological processes targeted in the intervention and changes in BMI might need more sustained efforts (i.e. longer duration and more guidance) when using GSH strategies.

The fourth chapter, investigated the feasibility of *RecoveryMANTRA* by examining drop-out rates from the treatment and from the end-of-treatment assessment. Baseline differences in demographic and clinical variables between completers and non-completers and between-group differences at the end of first week of participation in the intervention were measured. Finally, the relationship between motivation and drop-out was examined. In line with the first hypothesis, no baseline differences were found between completers and non-completers. This is in line with what found in previous studies examining drop-out from online interventions in people with eating disorders (Schlegl et al., 2015). We also found that those who dropped out (from the end-of-intervention assessment or the intervention) reported less satisfaction with their mentors/peer mentors

and more frequent purging behaviours. These findings demonstrate the importance to monitor patient variables in the early phase of digital interventions (kelders et al., 2012). This is also in line with studies indicating that poor early alliance with the therapist is associated with premature termination of treatment (Jordan et al., 2017). Finally, patients who reported a greater confidence in their own ability to change were less likely to drop-out from the assessment or the intervention. Also, greater controlled motivation was associated with lower drop-out. Controlled motivation indicates an individual's proneness to change due to expectations or pressure from others. Patients' tendency to align to others expectations at the beginning of treatment could have a protective role against non-adherence to treatment.

The last two chapters of this thesis examined the association between working alliance with mentors delivering online guidance and eating disorder psychopathology, with the goal of analysing differences between mentors (i.e. postgraduate students) and peer mentors (people with lived experience of the illness). The cross-lagged findings described in Chapter 5 indicated that higher WA with a peer mentor in a session predicted lower than usual eating disorder symptoms in the following session. Regardless the mentor group, higher average patient's WA was associated with reduced eating disorder symptoms across all sessions. However, early WA did not predict reduced eating symptoms at the following session and early eating disorders symptoms were not related to later WA at any points in time. Overall, these results highlight the importance of establishing a positive WA with peer mentors or mentors to improve eating disorder outcomes over the course of digital GSH for AN. In particular, WA between patients and peer mentors with past experience of the illness was associated with lower eating disorder psychopathology on a session-by-session basis. This aligns with evidence indicating that peer mentorship can help patients to feel understood, providing hope and fostering positive affect (Ranzenhofer et al., 2020). Our results have demonstrated that peer mentors help patients get better by enhancing WA at each session. These findings seem to support the importance of distinguishing between trait-like and state-like components of WA that characterize the individual patient (Zilcha-Mano, 2017). The trait-like

component of alliance refers to a patient's ability to form satisfactory relationships with others, and it is seen as a mean alliance level which the patient is able to form with the therapist. In this regard, our findings indicate that this interpersonal ability is especially important when patients work with student mentors. The state-like component of the alliance on the other hand refers to changes in WA during treatment which can predict changes in clinical outcomes. Our findings suggest that changes in the state-like component of WA result from in-session work with the peer mentor, which in turn contributes to better outcome. The distinction between WA with peer mentors or student mentors can pave the road to optimizing treatment efficacy and personalizing treatment (Zilcha-Mano, 2020), by offering peer mentorship especially to patients who need a collaborative way of working in self-help interventions. Previous research in psychotherapy demonstrated that early working alliance between patient and therapist is associated with symptom change in young patients with anorexia nervosa (Graves et al., 2017). Our findings add to this literature demonstrating that this effect extends also to adult patients, regardless of how psychological support is delivered (online, or face-to-face) (Berger, 2017; Sucala, Schnur, Constantino, Miller, Brackman, & Montgomery, 2012). Moreover, our findings showed an association between higher WA and lower eating symptoms at session 1 both for the peer mentor and student mentor groups. This result indicates the relevance of early alliance in GSH for anorexia nervosa, and the importance of considering the extent to which patients feel comfortable and in agreement with their mentors/peer mentors at the beginning of treatment. It is worth noting that when the WA with the student mentor was higher, across all six sessions, patients reported an increased improvement in eating disorder symptoms. Therefore, patients with stronger ability to build a positive WA with the student mentor are more likely to get better in GSH. This finding is in line with the characteristics of GSH, where patients are required to take an active role in driving the process of change (Falbe-Hansen, Le Huray, Phull, Shakespeare, & Wheatley, 2009) and using their abilities and skills.

In the sixth chapter, changes in Language Style Matching (LSM) between patient and mentors or peer mentors over time, as well as the association between LSM

and patient's alliance, motivation to treatment and drop-out in a six-week GSH intervention for patients with AN have been examined. The results of this study have shown that LSM scores remained stable through the six sessions. The level of late attunement (at 6th session) was higher for patient/peer mentors dyads than patient/mentors dyads whereas no differences were found in the early and mid-points. Regarding the hypothesis that greater levels of patient-mentor or patient-peer mentor LSM at any time point would predict greater alliance with the therapist and greater motivation for the ongoing clinical treatment, both greater early and late LSM was related to higher working alliance with the therapist delivering guidance at the treatment center, and late LSM was related to higher autonomous motivation for treatment. No significant relationships were found between LSM and patient's controlled motivation to treatment. The finding related to the association between LSM scores and working alliance provides support to previous evidence that an early augmentative intervention for AN enhances working alliance with the therapist at the outpatient service (Cardi et al., 2015). This finding is also in line with studies indicating that the use of a self-help motivational approach can improve subsequent engagement in therapy (Brewin et al., 2016) and strengthens the importance of using a motivational enhancement approach to maximise adherence to treatment. Contrary to our expectations, early LSM scores in RecoveryMANTRA did not predict treatment adherence, after adjusting for baseline clinical variables. However, the rate of drop-out from RecoveryMANTRA was low in this study (12.6%) and further research is needed to replicate this finding. Overall, our findings provide preliminary evidence regarding the importance of LSM when delivering online augmentative interventions (Kelders et al., 2012).

7.2 Studies strengths and weaknesses

In the following section strengths and weaknesses for each of the studies conducted will be described accordingly to the chapters' order used above.

Study 1.

Conducting a systematic evaluation of the literature on GSH in AN it was difficult to define a standardized 'treatment as usual', rendering direct

comparisons between studies difficult (Zeeck et al., 2018); most studies do not use a waiting list comparison condition due to the high medical risk for this patient group, and non-treatment conditions are often not considered ethical. A further limitation was the selection of a clinically meaningful outcome measure. A major strength of this study lies in its comprehensive review of clinical outcomes in relation to the use of task-sharing interventions. However, this approach is different to the principle underlying RCT designs, in which a primary outcome is selected and used for the estimation of power and reporting (Murray, Quintana, Loeb, Griffiths, & Le Grange, 2018). An additional point for reflection when assessing the effectiveness of clinical interventions is the definition of drop-out (Gregertsen, Mandy, Kanakam, Armstrong, & Serpell, 2018). Drop-out can occur for a variety of reasons and could include, for example, patient preference to discontinue treatment or participation in the assessment protocol. In the meta-analyses reported in this study, data on drop-out from the completion of the EOT measures were used as a proxy measure of participants' disengagement from treatment.

Study 2.

A possible weakness of this study is related to the participants' access to the Internet. It was not assessed continuously throughout the project. Difficulties with connection can explain the reduced use of the SH materials. A further limitation is that patients' BMI was not measured by the study team because participants were recruited from the centres across UK and face-to-face research assessments were not feasible. However, the current study has several strengths: 1) a published protocol paper (Cardi et al., 2015) with a full description of rationale, methods and plans for analyses, ensuring that no changes to the original plan were made based on the trial findings. 2) Missing data were addressed using two different ways of imputing missing data; 3) randomisation biases were minimised using block randomisation and adjustment for baseline variables in the analyses and 4) external validity of the study was ensured involving several services across the UK (thereby reflecting real-life clinical practice with no control over TAU). 5) A range of heterogeneous outcomes were used to capture changes in transdiagnostic psychological variables. 6) The

sample size was above minimal requirements for capturing clinically significant treatment effects (n = 50; Kraemer and Thienemann, 1987) and attrition rates were within the lower end of those typically observed in the field (20–40%; DeJong et al., 2012).

Study 3.

The rates of completion of this study compare very favourably with the findings of a systematic review of 26 technology-based studies in eating disorders that reported mean compliance to treatment (defined as attendance to all treatment sessions) at 57.6% (ranging from 18.4 to 95.5%; Schlegl et al., 2015). These rates also compare favourably to the finding that 20–40% for patients with AN do not complete standard, psychotherapy-based interventions (DeJong et al., 2012). Based on this evidence, it seems plausible to state that online guided self-help for anorexia nervosa is acceptable and is not associated with lower adherence than standard treatment. However, these findings cannot generalize to the use of standalone online interventions to replace standard treatment or as only form of support after care in anorexia nervosa. The finding that non-completers report lower satisfaction with their online mentor after the first week of participation in the program highlights the importance of attending early to the quality of the WA and the need to ensure that the work of the mentors is supervised, especially when guidance is delivered by mentors.

Study 4.

This is the first study to analyse patient and mentor/peer mentor contributions to working alliance in predicting clinical change in anorexia nervosa, and investigating the process of change over time, for six weeks. As limitations it was used only self-reported eating psychopathology to measure clinical change. Further research is needed to test whether WA is associated with different eating disorder outcome measures, such as body mass index, depression and anxiety (Albano et al., 2019). In the current study, BMI was not included in the analyses because this information was not ascertained on a weekly basis. However, measures of global eating disorder psychopathology remain the most widely used to evaluate the efficacy of GSH in eating disorders (Traviss-Turner et al.,

2017). Second, non-standardized visual analogue scales were used to assess WA. Although brief assessments have many practical benefits for repeated measurements compared to longer questionnaires, and the VAS demonstrated excellent internal consistency across the time points, a more comprehensive assessment of working alliance might better represent the breadth of the construct. Finally, further research with the aim of testing the differences in alliance between peer mentors and student mentors should adopt random assignment of patients to these conditions.

Study 5.

To our knowledge, this is the first study to analyse patient and mentor LSM in relation to treatment engagement in an online GSH for AN. However, some limitations must be considered. First, we analysed LSM in the early, mid and late sessions of an online brief GSH intervention. Therefore, larger-scale research is needed to examine the development and fluctuations of LSM in patient/mentor dyads. Another limitation is that we used a non-standardized scale to assess working alliance. A more comprehensive assessment of working alliance might better represent the breadth of the construct, although brief assessments have many practical benefits for repeated measurements compared to longer questionnaires, and our measure demonstrated excellent internal consistency in the current study.

7.3 Declaration of candidate's role

Chapter 1: Introduction

All work is candidate's own. The candidate independently conducted a literature search for relevant theoretical ideas and previous empirical findings. The candidate wrote the introduction independently, before subsequently receiving comments and recommendations for improvement from Professor Gianluca Lo Coco, Dr Valentina Cardi and Professor Janet Treasure.

Chapter 2:

The candidate independently proposed the research question examined in the systematic review and meta-analysis. The candidate subsequently developed the

systematic search strategy and conducted the systematic search. Abstract and full-text screening was subsequently repeated by the candidate and she also attended the consultation sessions with Dr John Hodsoll for statistical advice. The candidate subsequently conducted the meta-analyses and conducted a qualitative synthesis of the results independently. The candidate wrote most of the paper and holds first authorship.

Study 1: Task-sharing interventions for patients with anorexia nervosa or their carers: a systematic evaluation of the literature and meta-analysis of outcomes.				
CONCEIVED AND DESIGNED THE ANALYSIS	COLLECTED THE DATA	CONTRIUTED DATA OR ANALYSIS TOOLS	PERFORMED THE ANALYSIS	WROTE THE WHOLE PAPER
X	X	X	X	X

Chapter 3:

The candidate recruited all participants and conducted all data collection for the study. The author refined the study's hypotheses, conducted all statistical analyses, and contributed to the methods section. For the analyses contained within the paper Dr Cao Li (statistician) provided statistical advice and consultation. The candidate subsequently received comments and recommendations for improvement from the paper's co-authors.

Study 2: A randomised clinical trial to evaluate the acceptability and efficacy of an early phase, online, guided augmentation of outpatient care for adults with anorexia nervosa.				
CONCEIVED AND DESIGNED THE ANALYSIS	COLLECTED THE DATA	CONTRIUTED DATA OR ANALYSIS TOOLS	PERFORMED THE ANALYSIS	WROTE THE WHOLE PAPER
	X	X	X	

Chapter 4:

The candidate recruited all participants and conducted all data collection for the study. The candidate in collaboration with Dr Valentina Cardi proposed the research question for this secondary analysis study and consulted the referred literature. The candidate in collaboration with Dr. Salerno Laura performed the analysis and wrote the methods and analysis sections. The candidate subsequently received comments and recommendations for improvement from the paper's co-authors.

Study 3: The Feasibility of Using Guided Self-Help in Anorexia Nervosa: An Analysis of Drop-Out from the Study Protocol and Intervention Adherence.				
CONCEIVED AND DESIGNED THE ANALYSIS	COLLECTED THE DATA	CONTRIUTED DATA OR ANALYSIS TOOLS	PERFORMED THE ANALYSIS	WROTE THE WHOLE PAPER
X	X	X	X	

Chapter 5:

The candidate was the main contributor to this paper in collaboration with Professor Gianluca Lo Coco. The candidate recruited all participants and conducted all data collection for the study. The candidate consulted the referred literature and in collaboration with Professor Dennis M. Kivlighan performed all the analysis. The candidate wrote most of the paper and holds first authorship.

Study 4: The relationship between working alliance with the mentor and eating disorder symptoms over time in a digital six-week guided self-help intervention for anorexia nervosa				
CONCEIVED AND DESIGNED THE ANALYSIS	COLLECTED THE DATA	CONTRIUTED DATA OR ANALYSIS TOOLS	PERFORMED THE ANALYSIS	WROTE THE WHOLE PAPER

X	X	X	X	X

Chapter 6:

The candidate was the main contributor to this paper in collaboration with Professor Gianluca Lo Coco and Dr. Valentina Cardi. The candidate recruited all participants and conducted all data collection for the study. The candidate consulted the referred literature and in collaboration with Dr. Laura Salerno performed all the analysis. The candidate wrote most of the paper and holds first authorship.

Study 5: Patients and mentor Language Style Matching as a measure of alliance in the context of an online guided self-help intervention for anorexia nervosa				
CONCEIVED AND DESIGNED THE ANALYSIS	COLLECTED THE DATA	CONTRIUTED DATA OR ANALYSIS TOOLS	PERFORMED THE ANALYSIS	WROTE THE WHOLE PAPER
X	X	X	X	X

Chapter 7: Discussion

All work is candidate's own.

7. 4 List of other publications associated with thesis

Three more studies have been undertaken during the time of the PhD and in the context of the SHARED trial. The three studies investigated: 1) the utility of "staging" anorexia nervosa based on duration of illness and psychological wellbeing to predict 12-month symptom trajectories and service usage; 2) the trajectory of clinical change and treatment effects based on a network intervention analysis; 3) the investigation of patients with anorexia nervosa who do not show an early response to a six-week digital intervention and reported poorer outcome. In the next section the abstract of the studies will be presented.

Study 1: A multicenter audit of outpatient care for adult anorexia nervosa: Symptom trajectory, service use, and evidence in support of "early stage" versus "severe and enduring" classification

Abstract:

Background: The utility of "staging" anorexia nervosa by duration of illness and psychological wellbeing is explored in this study. 12-month symptom trajectories and service usage in a large sample of outpatients with AN were also examined.

Method: Secondary analyses from a multicentric clinical trial of adults with AN (n = 187) recruited from 22 eating disorder (ED) services into an online treatment augmentation study was conducted. Clinical variables and service use were measured at end of treatment (six weeks), 6- and 12-months follow-up. Patients were grouped into two categories: "early stage" (illness duration <3 years; n = 60) and "severe and enduring" stage (SE-AN; n = 41) indicated by distress (Depression Anxiety and Stress Scales, DASS ≥60) and illness duration (≥7 years).

Results: At 12 months, patients reported large improvements in body mass index, small to moderate improvements in eating disorder symptoms, mood, and work and social adjustment. 23.6% of patients met criteria for recovery. Those classified as SE-AN reported higher rates of accessing intensive services, higher eating disorder symptomatology, and poorer work and social adjustment at baseline, and lower rates of improvement in work and social adjustment at 12 months compared to "early stage" respondents.

Discussion: These findings suggest overall symptomatic improvements over the course of outpatient treatment in patients with AN. Exploratory results highlight significant differences in service use between AN patient at different stages of illness. Further research is needed to differentiate between clinical subtypes of AN and to guide the use of more personalized approaches to better fit patient necessities.

Publication: Ambwani, S., Cardi, V., Albano, G., Cao, L., Crosby, R. D., Macdonald, P., Schmidt, U., & Treasure, J. (2020). A multicenter audit of outpatient care for adult anorexia nervosa: Symptom trajectory, service use, and evidence in support of "early stage" versus "severe and enduring" classification. *The International journal of eating disorders, 53*(8), 1337–1348. https://doi.org/10.1002/eat.23246

Study 2: Network intervention analysis to assess the trajectory of change and treatment effects associated with the use of online guided self-help for anorexia nervosa

Abstract:

Aim: The aim of this study was to adopt the innovative technique of Network Intervention Analysis (NIA) to explore the trajectory of change in symptoms associated with the use of an online guided self-help intervention (RecoveryMANTRA) to augment treatment as usual in adults with anorexia nervosa.

Methods: Self-reported eating disorder symptoms and mood (stress, anxiety and depression), work and social adjustment, motivation and treatment (Treatment as usual + RecoveryMANTRA or Treatment as usual alone) were considered as nodes in the network and were examined using NIA. Networks were computed at baseline (n = 88, 99), end of treatment (six weeks, n = 71, 75) and at 6- (n = 58, 63) and 12-month (n = 52, 63) follow-up.

Results: RecoveryMANTRA was associated with a direct effect on anxiety, shape concern and restraint at the end of the intervention. This effect was not maintained at follow-up. There were no direct effects of RecoveryMANTRA on motivation, stress and depression.

Conclusions: These findings indicate that RecoveryMANTRA exerts a direct effect on anxiety and eating disorder symptoms. NIA is a promising method to evaluate trajectories of clinical change and direct and indirect effects of a therapeutic intervention compared to a control condition.

Publication: Monteleone, A. M., Cardi, V., Ambwani, S., Cascino, G., Albano, G., Pellegrino, F., & Treasure, J. (2020). Network intervention analysis to assess the trajectory of change and treatment effects associated with the use of online guided self-help for anorexia nervosa. Early intervention in psychiatry, 10.1111/eip.13064.Advanceonlinepublication.https://doi.org/10.1111/eip.13064.

Study 3: Outcomes for adults with anorexia nervosa who do not respond early to outpatient treatment

Abstract:

Objective: The aim of this study was to understand patients with anorexia nervosa who are not early responders (those reported poorer outcomes) in a six-week digital intervention.

Method: 187 patients with anorexia nervosa recruited across 22 eating disorder outpatient services across the United Kingdom were involved in a secondary analyses study. Of 187 patients, 65 participants were included in the current analyses because they had started treatment and had at least one body mass index (BMI) observation in the first six weeks of treatment. We identified a group of patients with no changes in BMI (N=56) over this period and examined remission at 12-month follow-up in the 40 participants who reported these data. Predictors included global EDE-Q, negative affect and functional impairment.

Results: Twenty-three percent achieved remission at 12-month follow-up. Good outcome was predicted by less functional impairment at baseline.

Discussion: Adjunct treatment possibilities focused on improving quality of life t can be introduced early in treatment to facilitate anorexia nervosa recovery. To identify sub-groups of patients with anorexia nervosa who do not achieve good outcome can be useful in targeting engagement approaches.

Publication: Wade, T., Ambwani, S., Cardi, V., Albano, G., & Treasure, J. (2021). Outcomes for adults with anorexia nervosa who do not respond early to outpatient treatment. *The International journal of eating disorders*, 10.1002/eat.23508. Advance online publication. https://doi.org/10.1002

7.5 List of Presentations associated with thesis

Albano G, Cardi V, Dennis K, Ambwani S, Treasure J, Lo Coco G. PATIENT'S AND MENTOR/PEER MENTOR'S CONTRIBUTIONS TO THE RELATIONSHIP BETWEEN WORKING ALLIANCE AND EATING DISORDER SYMPTOMS IN A DIGITAL GUIDED SELF-HELP INTERVENTION FOR ANOREXIA NERVOSA. EU-SPR poster session for young researchers (online poster presentation). 27 November 2020.

Albano G, Bonfanti RC, Gullo S, Salerno L, Lo Coco G. THE PSYCHOLOGICAL IMPACT OF LOCKDOWN FOR PEOPLE BELONGING TO AN EATING DISORDERS COMMUNITY: A LINGUISTIC ANALYSIS. Giornate di Studio della Sezione di Psicologia Clinica e Dinamica (online poster presentation). 18-19 September 2020.

Cardi V, Albano G, Ambwani S, Treasure J. THE SHARED TRIAL: A NOVEL SIX WEEKS, ONLINE, GUIDED SELF-HELP INTERVENTION (RecoveryMANTRA) FOR PATIENTS WITH ANOREXIA NERVOSA. XXI Congresso Nazionale Associazione Italiana di Psicologia (AIP). Sezione di Psicologia Clinica e Dinamica, Milan, Italy. (Simposio). 27 – 29 September 2019.

Albano G, Hodsoll J., Kan C., Lo Coco G., Cardi V. Task sharing interventions for patients with anorexia nervosa and their carers: a systematic evaluation of the literature and meta-analysis of outcomes. 5th Joint European & UK SPR Chapters Conference, Krakow, Poland. (poster presentation)". 19 -21 September 2019

Albano G. "SHARED Trial, descrizione del metodo e dei materiali utilizzati, testimonianze. Evidence based on the use of online guided self-help treatment". ASL Turin, Italy, (workshop). 24 May 2019.

Albano G., Hodsoll J., Kan C., Lo Coco G., Cardi V. Task sharing interventions for patients with anorexia nervosa and their carers: a systematic evaluation of the literature and meta-analysis of outcomes. "Royal College of Psychiatrics

Conference-Faculty of Eating Disorders Psychiatrics Conference, London (poster presentation)". 1 November 2018.

Cardi V., Albano G., Cao L., Ambwani S., Macdonald P., Todd G., Schmidt U., Crosby R. & Treasure J. What is the impact of adding online guided self-help to outpatient treatment for anorexia nervosa? The Self-Help and Recovery guide for Eating Disorders (SHARED) trial. "Royal College of Psychiatrics Conference-Faculty of Eating Disorders Psychiatrics Conference, London, UK (poster presentation)". 1 November 2018.

Albano G., Cardi V., Hodsoll J., Kan C., Lo Coco G., Treasure J. Self-help and guided self-help for patients with anorexia nervosa or their carers: a systematic evaluation of the literature and metaanalysis of outcomes. SPR - Italy Area Group Sezione italiana della SOCIETY FOR PSYCHOTHERAPY RESEARCH XII Congresso Nazionale: OLTRE LE TECNICHE, Palermo, Italy (2 Oral Presentations). 4-6 October 2018.

Cardi V., Albano G., Ambwani S., Crosby R., Lo Coco G., Macdonald P., et al. The SHARED trial: an investigation of a novel online guided self-help intervention for patients with anorexia nervosa assessed for outpatient treatment. SPR - Italy Area Group Sezione italiana della SOCIETY FOR PSYCHOTHERAPY RESEARCH XII Congresso Nazionale: OLTRE LE TECNICHE, Palermo, Italy (1 Oral Pesentations). 4-6 October 2018.

Cardi V., Albano G., Ambwani S., Crosby R., Lo Coco G., Macdonald P., et al. The SHARED trial: an investigation of a novel online guided self-help intervention for patients with anorexia nervosa assessed for outpatient treatment. XX Convegno Nazionale AIP Sezione Psicologia Clinica e Dinamica Urbino, Italy. 7-9 September 2018.

Cardi V., Albano G., Ambwani S., Crosby R., Lo Coco G., Macdonald P., et al. The SHARED trial: an investigation of a novel online guided self-help intervention for patients with anorexia nervosa assessed for outpatient treatment. 49th Annual International meeting of SPR in Amsterdam - Society for

Psychotherapy Research (oral communication). Amsterdam, Netherlands. 29 June 2018.

Cardi V., Albano G., Ambwani S., Crosby R., Macdonald P., et al. I trattamenti psicologici dei disturbi dell'alimentazione (presentazione orale). Interventi di auto-aiuto guidato in Anorexia Nervosa: the SHARED trial. SPR - Italy Area Group Sezione italiana della SOCIETY FOR PSYCHOTHERAPY RESEARCH, Milan, Italy. 18 May 2018.

Cardi V., Albano G., Ambwani S., Crosby R., Lo Coco G., Macdonald P., et al. SHARED trial: indagine di un nuovo intervento online di guided self-help per pazienti con anoressia nervosa in regime ambulatoriale. Societa' Italiana di Psicopatologia (SOPSI), XXII congresso nazionale, Rome, Italy (poster presentation). 21-24 February 2018.

Cardi V., Albano G., Treasure J. Interventi di auto-aiuto guidato in Anorexia Nervosa: the SHARED and TRIANGLE trials. Master in Riabilitazione psiconutrizionale progressiva dei DCA, Udine (Italy) (oral presentation). 17 December 2017.

Cardi V., Albano G., Ambwani S., Crosby R., Macdonald P., Todd G., Schmidt U. & Treasure J. The SHARED trial: an investigation of a novel online guided self-help intervention for patients with anorexia nervosa assessed for outpatients treatment. "Royal College of Psychiatrics Conference-Faculty of Eating Disorders Psychiatrics Conference, London, UK (poster presentation)". 3 November 2017.

International Meeting on Eating Disorder" – King's College London, UK. 1 August 2017.

7.6 List of publications not associated with thesis

Research field: COVID-19 impact on mental health and general population
Study 1: The psychological impact of lockdown for people belonging to an eating disorders community: a linguistic analysis
Aims: 1) To analyse the trend of the LIWC categories in all the Facebook posts and comments in an ED online forum group during the 56 days of COVID-19 Italian lockdown. 2) To explore which differences were found between Facebook posts dealing with Covid-19 concerns and contents dealing only with EDs concerns. 3) To explore the links between Covid-19 and eating behaviours issues through a qualitative analysis of the shared contents in the Facebook forum.
Hypothesis: i)We expected an increasing trend over time in the use of linguistic categories related to negative emotions: Anxiety, Negemo, Anger, Ed Concerns; and a decreasing trend of words related to positive emotions and social connection: Discrepancy, Peer Support and Posemo. Similar patterns of change were expected for the comments to the examined posts. ii) Specifically, we wanted to investigate differences in linguistic categories related to affectivity and perception of social connection.

Research field: COVID-19 impact on mental health and general population
Study 2: The impact of emotion regulation and mental health difficulties on health-related behaviors during the COVID-19 outbreak
Aims: 1) To establish the role that emotion regulation and individual factors play in shaping health-related behaviours at the time of COVID-19. We explored emotion regulation, mood and health-related behaviours surveying a sample of adults during the first-wave lockdown in Italy (April-May 2020).

Hypothesis: i) It was expected that baseline factors, such as younger age, female gender, unemployment, pre-existing medical or psychiatric conditions and the prominent use of suppression to regulate emotions would be associated with (1) higher negative mood (i.e. sadness, anxiety, anger), (2) more frequent use of risky health behaviours (i.e. overating, drinking alcohol, sleep disturbances) and (3) lower resilience (i.e. feelings of hope and resourcefulness and access to social support and enjoyable activities). We also anticipated that participants would report a worsening of physical and/or psychiatric symptoms and greater use of risky health behaviours (smoking, alcohol use and overeating) following the outbreak of the pandemic, compared to before.

Research field: An unguided self-help examination for patients suffering of Binge Eating Disorders in a stepped-care approach
Study 1: Predictors of drop-out in an unguided self-help for Binge Eating Disorder
Aims: 1) To investigate the predictors of drop-out in an unguided self-help for BED
Hypothesis: i)Self-reported levels of Depression and Eating Concerns will predict non-completion of USH for BED? ii)Attachment avoidance levels will predict non-completion over and above levels of depression and eating concerns?

7.7 Future directions

The expected future directions from the SHARED trial development and implementation are mainly two. The first is to explore the findings of another clinical trial that has taken in consideration the procedure and background of the *RecoveryMANTRA* intervention for further investigations in relation to a different population target and self-help resources. TRIANGLE is a multicentre

trial investigating whether the addition of a new intervention for patients and carers (ECHOMANTRA) to treatment as usual (TAU) improves outcomes for patients with AN. ECHOMANTRA is based on the cognitive interpersonal model of AN and includes assessments, workbooks, videos, online groups and joint skype sessions for patients and carers. The target population includes people receiving intensive hospital treatment and the goal of the intervention is to favour the transition from hospital to home. Compared to the SHARED trial, the TRIANGLE project includes carers and examines the joint effects of offering skill-based trainings to them as well as patients.

The second direction is to extend the online guided self-help procedure and design (following the SHARED example) to patients with a binge eating with a focus on the social support component. This suggestion is based on findings from a systematic-review and meta-analyses which explored interpersonal difficulties in people with overweight or obesity (Albano, Rowlands, Baciadonna, Lo Coco, & Cardi, 2019). Results from this study indicated that overweight/obese individuals reported more frequent experiences of teasing/bullying, greater interpersonal stress, and poorer quality of social life than healthy weight individuals. The hope is to expand this evidence base and develop psychological interventions targeting social difficulties in people with loss of control over eating. The Maudsley Model of Anorexia Nervosa Treatment for Adults MANTRA (Schmidt et al., 2014) and the New Maudsley Approach (Treasure et al., 2015) could be of some benefit for people with obesity also. This is particularly true when considering that perception of interpersonal stress and quality of social life are psychological processes that are amenable to change. Psychological interventions to remediate social difficulties in the context of abnormal eating are mostly focused on psychoeducation around the reciprocal impact of interpersonal relationships on abnormal eating behaviours and negative emotions, goal planning for positive behaviour change and the involvement of close others to break unhelpful habits. These elements, in combination with trainings to strengthen individuals' resilience to positive social feedback might contribute to reduce individuals' perception of interpersonal stress and improve their quality of social life. Positive changes in the

interpersonal domain might in turn determine positive changes in eating behaviours.

7.8 Conclusions

Overall, this thesis provides evidence that the implementation of an online guided self-help intervention for adults suffering from AN is feasible and effective, when delivered in addition of Treatment as Usual. From the literature on the field it was assessed that guided self-help use is associated with significantly lower drop-out rates from the completion of EOT assessments. Therefore, guided self-help may facilitate patients' treatment engagement and also improve carers' wellbeing. From the evidences of a digital guided self-help (SHARED trial) for patients with AN we found anxiety reduction at EOT, and improved confidence to change and working alliance with the therapist at the outpatient service. 3) Early satisfaction with the RecoveryMANTRA program and external pressure to change have a protective role against drop-out rates. Finally, we demonstrated as 4) clinical outcomes are in part associated with the characteristics of mentor delivering guidance in an online guided self-help for eating disorders and as 5) verbal attunement is greater between patients/peer mentors in a late phase of GSH. In light of these latest results we found that the support offered through the guidance seem to contribute to the patient's treatment engagement, in terms of therapeutic alliance and motivation for treatment.

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