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**EFFECTIVENESS OF GENERAL PRACTITIONER
SUPPORTED SELF-HELP FOR BULIMIA NERVOSA**

Mary Alison Aine Durand BA (Hons) MA

Thesis submitted for the Degree of Doctor of Philosophy

University College London

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ABSTRACT

While bulimia nervosa may affect up to five percent of women attending general practice, little attention has been paid to the possibility of treating patients in primary care. Improvements have been reported in patients using cognitive behaviour, self-help manuals. General practitioners may be well placed to support such patients.

The study was designed to compare in a pragmatic, randomised controlled trial, the effectiveness of a general practice based self-help approach to the treatment of bulimia nervosa (a self-help manual with general practitioner support) with that of specialist out-patient treatment; ascertain, through two postal questionnaires, general practitioners' views about the experience of supporting patients in primary care; and explore, using qualitative and quantitative methods, patients' views of the treatment interventions. It was hypothesised that there would be no serious disadvantage in outcome for patients randomised to receive the self-help intervention in general practice compared to those receiving specialist care. Patients recruited from general practitioner referrals to specialist clinics were randomised to receive the general practice based self-help intervention (n=34) or specialist clinic treatment (n=34). The main outcome measure was the Bulimic Investigatory Test Edinburgh score assessed at baseline and at six and nine months. Secondary measures included eating pathology, depression, social adjustment and self-esteem. Seventy-four percent and 80% of patients were followed up at six and nine months respectively. An intention-to-treat analysis revealed that while bulimic symptoms declined in both groups over time, there was no significant difference in outcome between the two groups.

The general practitioner surveys and patients' subjective views highlighted advantages and drawbacks to the self-help approach, but suggested that in general neither patients nor general practitioners were averse to using a general practice based intervention.

The study findings suggest that general practitioners should consider offering self-help interventions to patients who present with bulimia nervosa.

CONJOINT STATEMENT

The former North Thames Regional Health Authority funded the study described in this thesis. My supervisor, Professor Michael King, developed the original idea for the study, wrote the funding bid, and obtained initial ethical approval for the study.

I devised the detail of the protocol, methods, and procedures, as well as originating and designing the general practitioner (GP) survey and patient qualitative components of the study. I also designed some of the questionnaires and measures used (e.g., patient demography and history, and problems questionnaires; questionnaires measuring expectations about treatment, perceptions of severity of illness and satisfaction with treatment; economic questionnaires; GP survey instruments etc). In addition, I finalised the choice of some of the standardised measures and the self-help manual used in the study. I conducted all of the literature searches and reviews.

I obtained ethical approval for the study from two further Local Research Ethics Committees. I recruited three eating disorders clinics to the study, visiting and preparing both clinical and administrative staff for participation, as well as recruiting all of the participating GPs and patients. I conducted all of the patient assessments. I entered and managed the data, and conducted the analysis (Mr. Bob Blizzard provided advice concerning the data analysis strategy.). I wrote up the findings for publication. The thesis is entirely my own work.

Mary Alison Durand

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INTRODUCTION

Descriptions of what we nowadays term eating disorders have been recorded for centuries. While anorexia nervosa has been the subject of clinical attention since early in the twentieth century, it was not until the 1970s that clinicians and researchers began to focus their attention on binge eating disorders. Interest arose when clinicians such as Bruch (1973) and Beumont *et al* (1976) began reporting that some of their anorectic patients displayed symptoms of what appeared to be a binge-eating syndrome (Vandereycken, 1994). Reports of normal and overweight people engaging in episodes of binge-eating followed by self-induced vomiting were also becoming more common at the time, leading to speculation that this might be a new form of eating problem (Vandereycken, 1994).

Professor Gerald Russell, working at the Royal Free Hospital, delineated the features of this binge-eating syndrome in a paper published in 1979 in which he described the disorder in 30 patients. He termed the new disorder ‘bulimia nervosa’ (the word ‘bulimia’ literally means ‘ox hunger’) and described it as having three key components: “1. patients suffer from powerful and intractable urges to overeat; 2. they seek to avoid the ‘fattening’ effects of food by inducing vomiting, abusing purgatives or both; and 3. they have a morbid fear of becoming fat (p. 445).” In 1980 the disorder ‘bulimia’ was distinguished from, and classified separately to, anorexia nervosa in the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders (DSM-III). Since then the criteria have undergone modification and refinement, resulting in the current DSM-IV criteria for ‘Bulimia Nervosa’ published in 1994. It is now recognised that both purging and non-purging forms of the disorder exist. While bulimia nervosa is differentiated clearly from anorexia nervosa, the boundaries between the former and ‘Binge Eating Disorder’, as yet only described in research criteria terms, remain somewhat blurred.

Since it was first described over twenty years ago bulimia nervosa has been the focus of much clinical and research attention. By 1990 some 50 epidemiological studies had been published (Fairburn and Beglin, 1990) and it is now established that approximately 1-3% of women in industrialised Western countries suffer from bulimia nervosa while the prevalence in men is one-tenth to one-twentieth of that in women (American Psychiatric Association, 1994). The clinical features of the disorder have been well described, as have the types and levels of co-morbid psychiatric problems seen in patients suffering from bulimia nervosa. However, factors involved in the aetiology of the disorder have not as yet been clearly distinguished (Hsu, 1997).

Much effort has been concentrated on establishing effective treatments for bulimia nervosa. Therapist-led, manual based, cognitive behaviour therapy has been found to be more effective than other psychotherapies, at least in the short-term, or antidepressant medication (e.g., Fairburn *et al*, 1991; Agras *et al*, 1992; Walsh *et al*, 1997; Agras *et al*, 2000 a). However, full cognitive behaviour therapy is relatively expensive (Agras, 2001) and not widely available (e.g., Cooper *et al*, 1996). Clinicians may also be sceptical about the applicability to routine clinical practice of the findings of large therapy trials conducted under optimum conditions and involving specially trained therapists and highly selected patients (e.g., Wilson, 1998, 1999). The imperative has therefore been to establish less expensive and less intensive forms of treatment that are more widely disseminable among clinicians and more accessible to individuals suffering from bulimia nervosa.

Cognitive behaviour therapy has the potential of being standardised for application by non-specialists and, because of its incremental nature, lends itself to a self-help format (e.g., Cooper *et al*, 1996). In recent years the use of cognitive behaviour orientated, self-help manuals has been the focus of a growing body of research, not only in the eating disorders field, but in psychiatry in general (Lewis *et al*, 2003). Findings have indicated that the less intensive self-help approach may be appropriate for at least some patients with bulimia nervosa and that non-specialists can provide support to patients using manuals (e.g., Schmidt *et al*, 1993; Treasure *et al*, 1994; Cooper *et al*, 1996; Thiels *et al*, 1998). While studies have been undertaken exclusively in specialist treatment settings, it has been suggested that the

self-help manual approach is potentially applicable to non-specialist settings (e.g., Schmidt *et al*, 1993) and should be studied in general practice (e.g., Cooper *et al*, 1996; Palmer *et al*, 2002).

With the exception of studies examining the epidemiology of bulimia nervosa in general practice (e.g., King, 1989; Whitehouse *et al*, 1992) and an open pilot study of an abbreviated form of full cognitive behaviour therapy (Waller *et al*, 1996), little attention has been paid to the possibility of treating patients suffering from bulimia nervosa in general practice. Treatment is usually provided in specialist eating disorder clinics where waiting lists are often several months long and treatment is expensive in terms of specialist input. However, the Royal College of Psychiatrists (2000) has suggested that general practice should play a role in the detection and management of eating disorders. General practitioners (GPs) may be ideally placed to support patients undertaking self-help treatments for a number of reasons. Patients with eating disorders have been found to consult their GPs more than matched controls (Ogg *et al*, 1997), and the majority of referrals to specialist services come from GPs. In addition, the past two decades have seen a move towards the treatment of the majority of mental health problems in the primary care or community setting. It is estimated that one-quarter of general practice attenders are suffering from mental health problems (Goldberg and Lecrubier, 1995), but that only nine out of every hundred people who consult their GPs about mental health problems are referred to specialist settings (Department of Health, 1999). Furthermore, studies involving GPs and general practice staff in the prevention and management of a range of mental health, psychological, and addiction-related problems have yielded encouraging results (e.g., Drummond *et al*, 1990; Kupshik and Fletcher, 1999).

The prevalence of bulimia nervosa in its full and sub-clinical forms, the evidence for the efficacy of less intensive forms of treatment, and GPs' increasing role in managing mental health problems generally, all suggest that an empirical investigation of a general practice based intervention for bulimia nervosa is warranted. The aim of the current study is to make just such an investigation.

The objectives of the study are threefold:

1. To compare, in a pragmatic randomised controlled trial, the effectiveness of a general practice based self-help approach to the treatment of bulimia nervosa (a self-help manual with GP support) with that of specialist out-patient clinic treatment. The study seeks to establish that patients randomised to receive treatment in the general practice setting will not be seriously disadvantaged compared to those receiving specialist care. Eating pathology, depression, social functioning and self-esteem will be assessed at baseline and at two follow-up points, and data will be analysed on an intention-to-treat basis. Not only will the study's main findings provide information concerning the effectiveness of managing this disorder in general practice but additional analyses will also be undertaken to explore possible predictors of outcome for patients treated in either the primary care or clinic setting. In addition, some of the economic implications of undertaking a self-help intervention in general practice will be explored.

2. To ascertain, by means of two postal surveys, the views of GPs providing support to self-help patients about the experience of managing patients suffering from bulimia nervosa in general practice. The results of the surveys will highlight the benefits and drawbacks of the approach as seen by GPs, along with other issues such as support requirements and willingness to use the self-help approach in the future.

3. To explore, using both quantitative and qualitative methods, patients' views and experiences of the treatment interventions received, in order to help contextualise study outcomes, ascertain the acceptability of the self-help approach to participants and generate information concerning the feasibility of introducing such an approach as routine care in general practice. To this end, issues such as motivation for treatment, expectations of treatment and treatment preferences, the perceived helpfulness of the treatments received, difficulties encountered, how treatment approaches might be improved, and patients' perceptions of what has helped them most in trying to overcome their eating disorder will be investigated.

The study hypothesis is that there will be no serious disadvantage in outcome for women with bulimia nervosa randomised to receive a self-help intervention in general practice compared to those receiving specialist out-patient clinic care. The study findings should have both theoretical and practical implications for future clinical practice and treatment research with patients with bulimia nervosa.

The thesis is set out as follows. Chapter One focuses on bulimia nervosa: the criteria used for diagnostic purposes; clinical features of the disorder; its epidemiology and aetiology; and the nature of co-morbid psychiatric problems seen in individuals suffering from bulimia nervosa. The implications for the conduct of treatment trials of the multi-symptomatic nature of bulimia nervosa and of its associated psychiatric co-morbidity are highlighted throughout. A review of treatment focused research, particularly that concerned with cognitive behaviour therapy, anti-depressant medication and self-help interventions, is presented in Chapter Two. Evidence to support the argument that GPs can be effective in managing mental health problems in general practice is also presented, as is the limited, existing body of research on the management of bulimia nervosa in general practice. Chapter Three focuses on the theory and practice of randomised controlled trials, including the concept of efficacy and effectiveness trials. The chapter also includes brief sections on the ethics of trials; economic analyses and trials; the conduct of trials in general practice; and the merits of combining qualitative research methods with randomised controlled trial methodology. The methods employed in the current study are the focus of Chapter Four. The descriptive findings and the quantitative outcomes of the randomised controlled trial are described in Chapter Five. Chapter Six focuses on the findings of the GP surveys, and findings concerning patients' subjective views and experiences are presented in Chapter Seven. The study findings and their implications for future policy, practice, and research are discussed in Chapter Eight, as are the strengths and limitations of the current study.

The terms 'patient' and 'participant' are used interchangeably throughout the thesis. The terms 'primary care' and 'general practice' are also used interchangeably to refer to the general practice setting. The abbreviation 'BN' will be used throughout to refer to bulimia nervosa.

CHAPTER ONE:

BULIMIA NERVOSA: THE NATURE OF THE DISORDER

1.1 INTRODUCTION

The term 'bulimia' derives from the combination of the Greek word 'limos', meaning hunger, and the prefix 'bou' or 'bous' (steer, ox, cow). While descriptions of bulimia or 'bulimos' go back to the fourth century BC (Ziolko, 1996), modern authors such as Vandereycken (1994) date the formal recognition of 'bulimia nervosa' (BN) as a distinct disorder to the publication of Gerald Russell's article '*Bulimia nervosa: An ominous variant of anorexia nervosa*' in 1979. Diagnostic criteria have since been delineated and revised several times, the clinical features of BN have been widely described, and a considerable amount of epidemiological and treatment-focused research has been undertaken. The behavioural aspects of BN (i.e., binge-eating and purging) are generally perceived as its defining features. However, both empirical research and clinical observation attest to the fact that BN is essentially a multi-symptomatic disorder, potentially affecting many aspects of the individual's life, including his/her social and psychological functioning. Furthermore, affective, personality or addictive disorders are seen in a sizeable proportion of those seeking treatment for BN (e.g., Wilson, 1993; Bushnell *et al*, 1994; Carroll *et al*, 1996). The multi-symptomatic nature of the disorder and the psychiatric co-morbidity associated with it have implications for the conduct of treatment trials (e.g., in terms of defining inclusion and exclusion criteria) and for the scope and nature of outcome assessed in intervention studies. For example, while BN treatment trials still focus primarily on the eating disorder symptoms (especially bingeing and purging), the past decade has seen researchers broaden the concept of outcome in trials to include the assessment of depression, self-esteem, social adjustment or other aspects of the general psychopathology commonly associated with BN.

The purpose of this chapter is, firstly, to outline the development of the classificatory systems used to diagnose BN, and to describe its clinical features and relationship to other eating disorders. Secondly, the epidemiology and aetiology of

BN will be considered briefly. The remainder of the chapter will focus on the general psychopathology and co-morbid problems commonly seen in individuals seeking treatment for BN and on the relevance of these problems to treatment-focused research.

1.2 THE EVOLUTION OF DIAGNOSTIC AND CLASSIFICATORY SYSTEMS

In the 1970s clinicians began describing binge-eating and purging behaviours that did not fit the clinical picture of anorexia nervosa (AN) and which sometimes occurred in normal weight women (Vandereycken, 1994). Russell (1979) described the features of this overeating ‘symptom’, which he termed ‘bulimia nervosa’, in a series of 30 patients seen over a six and a half year period at the Royal Free Hospital in London. He suggested that there were three important aspects to BN:

- “1. the patients suffer from powerful and intractable urges to overeat;
2. they seek to avoid the ‘fattening’ effects of food by inducing vomiting, abusing purgatives or both; and,
3. they have a morbid fear of becoming fat (p. 445).”

The disorder entered the American Psychiatric Association’s (APA) Diagnostic and Statistical Manual of Mental Disorders (DSM III) in 1980 as ‘bulimia’ (Figure 1.1), but differed from Russell’s definition in a number of respects (Fairburn, 1986). The term was used in DSM-III to describe both a behaviour (overeating) and a syndrome. Weight control behaviours were not stipulated as a necessary diagnostic criterion, and concerns about weight and shape were not included, while neurotic symptoms were (Fairburn, 1986).

The disorder was re-named ‘bulimia nervosa’ in DSM-III-R (APA, 1987) (Figure 1.2). Over-concern with body weight and shape was added as an essential criterion, along with a frequency component, resulting in a more restrictive diagnosis.

Figure 1.1: APA (1980) DSM-III criteria for Bulimia

- A. *Recurrent episodes of binge-eating (rapid consumption of a large amount of food in a discrete period of time, usually less than two hours)*
- B. *At least three of the following:*
 - 1 *Consumption of high-calorie, easily ingested food during a binge*
 - 2 *Inconspicuous eating during a binge*
 - 3 *Termination of such eating episodes by abdominal pain, sleep, social interruption or self-induced vomiting*
 - 4 *Repeated attempts to lose weight by severely restrictive diets, self-induced vomiting, or use of cathartics or diuretics*
 - 5 *Frequent weight fluctuations greater than ten pounds due to alternating binges and fasts*
- C. *Awareness that the eating pattern is abnormal and fear of not being able to stop eating voluntarily*
- D. *Depressed mood and self-deprecating thoughts following eating binges*
- E. *The bulimic episodes are not due to Anorexia Nervosa or any known physical disorder*

Figure 1.2: APA (1987) DSM-III-R criteria for Bulimia Nervosa

- A. *Recurrent episodes of binge eating (rapid consumption of a large amount of food in a discrete period of time)*
- B. *A feeling of lack of control over eating behaviour during the eating binges*
- C. *The person regularly engages in either self-induced vomiting, use of laxatives or diuretics, strict dieting or fasting, or vigorous exercise in order to prevent weight gain*
- D. *A minimum average of two binge eating episodes a week for at least three months*
- E. *Persistent over-concern with body shape and weight*

The diagnosis was made even more restrictive in DSM-IV (APA, 1994) (Figure 1.3). The importance of weight and shape in terms of self-evaluation was refined and the centrality of the fear of fatness in leading to weight controlling behaviours emphasised. However, it has been argued that body image involves both self-perceptual and affective components, and that DSM-IV does not tap into the affective component, body dissatisfaction (Garfinkel *et al*, 1995 a).

Figure 1.3: APA (1994) DSM-IV criteria for Bulimia Nervosa

- A. Recurrent episodes of binge eating. An episode of binge eating is characterised by both of the following:*
- 1. Eating in a discrete period of time (e.g., within any two hour period) an amount of food that is definitely larger than most people would eat during a similar period of time and under similar circumstances.*
 - 2. A sense of lack of control over eating during the episode (e.g., a feeling that one cannot stop eating or control what or how much one is eating.)*
- B. Recurrent inappropriate compensatory behaviours in order to prevent weight gain, such as: self-induced vomiting; misuse of laxatives, diuretics, enemas or other medications; fasting; or excessive exercise.*
- C. The binge eating and inappropriate compensatory behaviours both occur, on average, at least twice a week for three months.*
- D. Self-evaluation is unduly influenced by body shape and weight.*
- E. The disturbance does not occur exclusively during episodes of anorexia nervosa.*
- Purging type: During the current episode of bulimia nervosa, the person has regularly engaged in self-induced vomiting or the misuse of laxatives, diuretics or enemas.*
- Non-purging type: During the current episode of bulimia nervosa, the person has used other inappropriate compensatory behaviours, such as fasting or excessive exercise, but has not regularly engaged in self-induced vomiting or the misuse of laxatives, diuretics or enemas.*

DSM-IV still concentrates on bingeing behaviour and the frequency of binges rather than on the *urge* to binge, and Garfinkel *et al* (1995 a) suggest that the definition of what constitutes a binge (i.e., in terms of quantity of food consumed) and the minimum required frequency of binges need further consideration. Empirical research suggests that individuals who fail to meet the current twice weekly binge criterion do not differ in terms of general psychopathology or eating disorder features from those who binge more frequently (e.g., Wilson and Eldredge, 1991; Garfinkel, 1995 b; Hay and Fairburn, 1998). The fluctuating nature of the disorder also requires consideration so that the frequency of binges can be averaged over time (Garfinkel *et al*, 1995 a). DSM-IV also delineated subtypes of the disorder on the basis of purging behaviours. This subdivision is beneficial in that purging may constitute an indicator of increased pathology and severity (e.g.,

Johnson *et al*, 1989); purging behaviours are quantifiable; and there is some evidence to suggest a differing course of illness in purgers and non-purgers (e.g., Garfinkel *et al*, 1995 a). DSM-IV also distinguishes BN from Binge Eating Disorder (BED).

While the DSM-IV classification has advantages over previous versions, Fairburn *et al* (1999) have suggested that the “central diagnostic features of “binge-eating” and “overconcern about shape and weight” are difficult to demarcate from simple overeating and normative dissatisfaction with appearance respectively (p. 354).” Regardless of its limitations, however, a DSM-IV diagnosis is now widely used as an inclusion criterion in recruiting individuals with BN into treatment trials. The use of standard diagnostic systems and assessment measures facilitates the comparison of sample characteristics and treatment outcomes across studies.

1.3 CLINICAL FEATURES

BN usually begins in late adolescence or early adulthood (e.g., Lacey, 1993; Hoek *et al*, 1995; Turnbull *et al*, 1996) and the course of the disorder may be chronic or intermittent.

Binges generally occur in secret, are often described as ‘frenetic’ (Cooper, 1993), and can involve depersonalisation experiences (APA, 1994). Long-term sufferers may experience behavioural indicators of impaired control such as difficulty resisting eating or stopping once started rather than an acute loss of control during bingeing (APA, 1994). Furthermore, loss of control is not absolute in that individuals can stop eating if, for example, they are unexpectedly interrupted. Estimates of the average number of calories consumed in binges range from between 1,500 and 3,500 (Cooper, 1993) to 4,800 (Johnson *et al*, 1982). It has been suggested that binge-eating is characterised more by an abnormality in the amount of food consumed rather by a craving for a particular type of nutrient (APA, 1994). However, a well-designed study of patients seeking treatment for BN or BED found that while the calorific intake of both groups was the same, those with BN consumed more carbohydrates and sugars (Fitzgibbon and Blackman, 2000). Binges tend to be triggered by three broad categories of events or experiences: those concerned with eating and food, such as breaking a dietary rule; those

associated with concerns about body weight or shape; and, negative mood states (e.g., Abraham and Beumont, 1982; Cooper, 1993; Mitchell *et al*, 1999). Binges are generally followed by feelings of shame, disgust, guilt (Cooper, 1993), physical illness, anxiety and depression (Mitchell *et al*, 1999).

Approximately 80-90% of treatment-seekers report making themselves vomit after bingeing. Indeed, vomiting can become a goal in itself (APA, 1994). Roughly one-fifth (Cooper, 1993) to one-third (APA, 1994) of sufferers take laxatives. For example, a study of 275 patients with DSM-III bulimia found that 88% vomited, 61% took laxatives and 33% used diuretics as a means of purging (Mitchell *et al*, 1985).

The immediate physical effects of bingeing include abdominal pain, discomfort, and bloatedness as well as tiredness, headaches and dizziness (Abraham and Beumont, 1982). Repeated vomiting can lead to dental enamel erosion, swollen parotid glands, and throat infections. Fluid or electrolyte imbalances are seen in about half of those seeking treatment (Cooper, 1993). Frequent vomiting may produce a metabolic alkalosis while frequent use of laxatives may result in metabolic acidosis (APA, 1994). Laxative abuse can also lead to dependence, rebound constipation and fluid retention. Gastric rupture, oesophageal tears and cardiac arrhythmia are among the rare but fatal complications (APA, 1994). Women suffering from BN are usually within the normal body weight range for their age and height. However, it is estimated that between 45% and 95% of those not using oral contraceptives are affected by menstrual irregularities or amenorrhea (King, 1989).

Men suffering from BN are more likely to develop the disorder at a later age, to have a higher prevalence of pre-morbid obesity, to be less concerned with strict weight control, and to exercise vigorously rather than purge or vomit (King, 1993). For these reasons, and because far fewer men suffer from BN, they are rarely included in treatment trials.

1.4 BULIMIA NERVOSA AND OTHER EATING DISORDERS

While anorexia nervosa (AN) and BN share the common feature of a drive for thinness or morbid fear of fatness, the primary differentiating feature is that anorectic patients fail to maintain their weight at a level that would be minimally normal for their age and height. A diagnosis of purging BN can only be made when purging AN has been ruled out. DSM-IV (APA, 1994) lists BED as a new disorder. It is found in approximately 1.5-2% of non-clinical populations and 30% of obese people seeking treatment (Garfinkel *et al*, 1995 a). BED sufferers do not exhibit the compensatory weight control mechanisms central to BN. The boundaries between BED and non-purging BN are not well defined at present, and it has been suggested that the two diagnostic categories may simply consist of the same people at different phases of their eating disorder (Garfinkel *et al*, 1995 a). However, empirical research suggests that the distinction between BN and BED is a valid one (e.g., Hay and Fairburn, 1998; Mitchell *et al*, 1999).

1.5 EPIDEMIOLOGY

BN occurs with similar frequencies in all industrialised countries. The prevalence rate among adolescent and young adult women is approximately 1-3% (APA, 1994) while the female to male ratio is approximately 1: 10-20. As is the case for any newly recognised disorder, epidemiological research on BN has focused on its distribution. However, prevalence surveys have often been conducted with convenience samples, focused on narrow age bands of young women, and failed to establish caseness. Furthermore, when different classificatory systems are applied to the same data, prevalence rates alter substantially (Fairburn and Beglin, 1990).

Studies with the soundest methodologies suggest a point prevalence of between 0.5% and 1% for adolescent and young adult women, although this may be an underestimate of the true rates of BN in the population (Fairburn *et al*, 1993 a). A postal survey of a representative sample of Norwegian women revealed a lifetime prevalence of 1.6% for BN and a point prevalence of 0.7% (Gotestam and Agras, 1995), while a Canadian community survey found a lifetime prevalence of 1.1% in females aged from 15 to 65 years, and of 0.1% for males (Garfinkel *et al*, 1995 b). Two two-stage studies have investigated the point prevalence of BN in general practice attenders in the United Kingdom (UK). King (1989) found that 1% of

women screened and then interviewed at four London surgeries had full syndrome BN, while a further 3% were suffering from a partial syndrome. Whitehouse *et al* (1992) found a point prevalence of 1.5% for BN and 5.4% for partial syndrome among a consecutive series of 540 female attenders, aged 16-35, at three Cambridge general practices.

Some studies of contacts with specialist treatment services have suggested an increasing incidence of BN (e.g., Lacey, 1992; Joergesen, 1992), while others have not (e.g., Soundy *et al*, 1995). Turnbull *et al* (1996) reported a three-fold increase between 1988 and 1993 in the recording of cases of BN by GPs. However, apparent increases in incidence may simply reflect greater recognition and referral to specialist services by primary care doctors and other specialists (Fombonne, 1996). Hoek *et al* (1995) reported that the highest risk group for BN is the 20-24 year age group. Soundy *et al* (1995), however, found the highest incidence in 15-19 year olds. Turnbull *et al* (1996) reported that females aged 20-39 present to GPs with BN at a rate of 56.7 per 100,000, while those aged 10-19 present at a rate of 41 per 100,000.

Given that the evidence suggests that between 1% to 5% of women attending general practices in the UK may be suffering from full or partial syndrome BN, the issue of the recognition and management of these patients by GPs is therefore one of considerable clinical and financial importance.

1.6 AETIOLOGY AND MODELS OF BULIMIA NERVOSA

There is currently a climate of “intellectual agnosticism” (Hsu, 1997, p. 509) regarding the aetiology of eating disorders. A number of related questions have occupied those interested in this issue, at both the theoretical and empirical levels. The first is concerned with why disturbed eating attitudes and frank eating disorders have figured so prominently in western cultures towards the end of the twentieth century. The second concerns the issue of why women appear to be more vulnerable to eating disorders than men. Attempts to answer these questions remain largely speculative.

As noted earlier, descriptions of bulimia go back many centuries (Ziolko, 1996), as do those of self-imposed starvation by young women. Stunkard (1993) reports however that AN is likely to be a socially conditioned disorder that first appeared in the 1800s, and BN an even newer disorder dating from the early 1900s. It has been postulated that both appeared in the context of changing medical concerns about obesity throughout the latter half of the nineteenth century which culminated in societal derogation of obesity after the second World War (Stunkard, 1993). Despite case reports, however, consensus regarding the central features of AN was only reached in the 1960s (Stunkard, 1993) and the symptoms of BN were not formally categorised until 1979 (Russell, 1979). BED was recognised by the APA as recently as 1994. Whether the various eating disorders have always existed but have simply not received clinical recognition and classification until recently or whether the psychopathology of eating (for whatever reason) has been undergoing changes, resulting in new disorders and increasing prevalence rates, is open to speculation.

In examining relationships between classificatory systems and the people who are classified, Hacking (1999, 2002a) asks how new classifications open or close possibilities for human action, how classifications affect those classified, and how the behaviours of those who are classified feed back and change classification systems – so-called ‘classificatory looping’. Employing the concept of ‘dynamic nominalism’ he proposes that “categories of people come into being at the same time as kinds of people come into being to fit those categories” (Hacking, 2002 a, p. 48) and that there is a two-way, dynamic relationship between these processes. He suggests that social change generates new categories of people, and that each category has its own history and a non-generalisable story. He also suggests that the process of counting brings new ways of being or motives for action into existence. Elsewhere, Hacking (2002 b) argues that some mental illnesses may be ‘transcient’, appearing in a particular place at a particular point in history, affecting particular social classes or genders (e.g., hysteria), only to disappear again. Such illnesses provoke debates about whether they are ‘real’ or ‘socially constructed’. While noting the obvious suffering of patients with AN and BN, Hacking questions whether we are talking about behaviours produced by stereotypes of beauty combined with rebellion against parents, or “real mental disorder”. He suggests

that cynics might compose a list of current disorders including anorexia and chronic fatigue syndrome that may in time prove to be transient.

Eating disorders are viewed as a phenomenon of developed, western societies, to the extent that they have been categorised as culture-bound syndromes (King, 1993). They are reportedly rare in developing countries, although this may simply reflect a deficit in the research. Empirical evidence, however, suggests that eating disorders may be acquired by non-white populations who settle in western countries and that when aspects of western culture are adopted by non-western societies reports of disordered eating and eating disorders increase (e.g., King, 1993; Stice, 2002)

It is widely assumed that the modern preoccupation with slimness and dieting which appears to have accelerated in the past three decades, especially among women, is directly implicated in the pathogenesis of AN and BN (King, 1993). The changing role of women in western society since the 1960s has also been said to be central to the development of these disorders (e.g., Orbach, 1978; Wolf, 1991). Wolf (1991), for example, argues that the pressures placed on modern women to achieve the 'thin-ideal', with resultant body image and eating disturbances, represent a societal and institutional backlash against women's emerging equality and release from domesticity. While women have more financial independence, power, education, sexual autonomy and legal recognition than ever before, she argues that they have also been made feel more impoverished, out of control and sexually insecure in their bodies. Why the struggle for equality has resulted in today's successful women suffering from eating disorders rather than other forms of mental health problems is, however, still unclear (King, 1993).

Socio-cultural pressures regarding the idealisation of thinness and physical fitness are believed to originate from the mass media, family and peers and work on individuals through processes such as social reinforcement, social comparison and modelling (Stice, 2002). There is correlational, prospective and experimental evidence that the mass media promotes eating and body image disturbances, though the effects are often small in magnitude. Content analyses of magazines, for example, show that the body dimensions of female models, actresses and other female cultural icons have become progressively thinner, to the extent that a quarter

of those appearing in some magazines would satisfy the weight criteria for AN (Stice, 2002). There is also increasing correlational and prospective (but, importantly, not experimental) evidence that family and peer influences can contribute to disturbances in body image and eating. King (1993) argues that there are few clues as to the reasons for the marked sex differential in eating disorders, but that it has been claimed that men are subjected to less cultural pressures for thinness. To date, however, as Stice (2002) notes, there has been relatively little work on what renders some individuals vulnerable and others relatively immune to socio-cultural influences.

While findings of research on the aetiological risk factors for AN have sometimes been generalised to BN, little research has focused on the aetiology of BN *per se*. Existing studies have focused on clinical populations, failed to employ psychiatric controls, explored a narrow range of potential aetiological factors, and have not investigated the timing of the operation of these factors (Fairburn *et al*, 1993 a). Research in this area has of necessity been largely correlational in nature. Risk factors that have been implicated in the aetiology of BN specifically include a family history of affective disorders, substance abuse, obesity or eating disorders (e.g., Lilenfeld *et al*, 1997; Fairburn *et al*, 1993 a). A personal history of sexual abuse, diabetes, affective disorders or obesity has also been implicated (Fairburn *et al*, 1993 a), as have adverse childhood experiences, poor parenting, dieting, a prior history of AN, poor self esteem, and personality characteristics such as impulsivity (Fairburn and Cooper, 1984; Fairburn *et al*, 1993 a; Hsu, 1997; Fairburn *et al*, 1999). However, it has been argued that these aetiological risk factors should be regarded as putative rather than definite at present (Fairburn *et al*, 1993 a).

A variety of models have been proposed to explain binge-eating, including the addictions, conditioning, affective disorders/regulation, escape, dieting and biopsychosocial models (Polivy and Herman, 1993). To one extent or another, all postulate a range of precursors, triggering factors and maintaining mechanisms. The most-widely cited and influential model of BN is the cognitive behavioural model which posits that dysfunctional attitudes towards weight and shape lie at the core of the disorder (e.g., Fairburn, 1985). Patients evaluate their self-worth in terms of these attributes and engage in extreme dietary restriction, which eventually results in loss of control, bingeing and compensatory purging, excessive exercise and

dieting (the so-called 'binge-purge' cycle). Factors relevant to the maintenance of the binge-purge cycle include the physical (e.g., the physiological pressure to eat), the psychological (e.g., damage to self-esteem following binges) and the social (e.g., pressure to be thin) (Cooper, 1993). As will be discussed in Chapter Two, cognitive behaviour therapy has been tailored to, and widely used in, the treatment of BN.

1.7 PSYCHOLOGICAL AND SOCIAL ADJUSTMENT

As noted earlier, measures of self-esteem and social functioning or adjustment have increasingly been included as secondary outcomes in BN treatment trials in recent years (e.g., Agras *et al*, 2000 a). The rationale for this is that low self-esteem and poor social functioning/adjustment have consistently been found to be associated with BN.

Low self-esteem is reported to be associated with dieting, binge-eating and body-image dissatisfaction. Both BN sufferers and dieters appear to have low self-esteem (Polivy and Herman, 1993). It is argued that loss of self-esteem in eating disordered patients is linked specifically to the fear of fatness and normal body weight, and to loss of control over eating (Garfinkel *et al*, 1995 a). Joiner (1999) speculated that poor self-esteem in women with BN may result in their having a tendency to elicit negative feedback in interpersonal situations, which serves to perpetuate their bulimic symptoms. However, the correlational nature of the existing data does not allow for the deciphering of whether poor self-esteem is a cause/pre-condition for dieting, or whether it is an outcome of binge-eating and failed dieting (Polivy and Herman, 1993).

BN sufferers have been reported to have higher levels of social maladjustment in a variety of life domains compared to those with no history of an eating disorder (Garfinkel *et al*, 1995 b; Rorty *et al*, 1999). The former are also more likely to report conflictual relationships and the lack of a warm confiding relationship with another adult (Garfinkel *et al*, 1995 b). Almost 70% of those interviewed by Mitchell *et al* (1985) reported problems in interpersonal relationships, while 61% reported family problems, 53% financial problems, and 50% work-related impairment. However, neither a psychiatric nor normal control group was included

in the study. A study by Fairburn *et al* (1996) found that although the demographic characteristics, general levels of psychiatric problems, and duration of eating problems of clinic patients were similar to those of a community-ascertained sample, the former had more severe eating disorder symptomology and greater impairment in their social functioning. Hay and Fairburn (1998) reported that a community-ascertained sample of women with BN had significantly greater impairment in social functioning, higher levels of psychiatric symptoms and lower levels of self-esteem than women with BED. An association has also been found between decreased bulimic symptoms and higher social functioning (Rorty *et al*, 1999), with actively bulimic women displaying poorer overall social functioning than remitted bulimic women or women without a history of eating disorders. As with the studies of self-esteem, however, studies of social adjustment and functioning generally fail to shed light on whether poor social functioning and/or adjustment precedes BN or vice versa.

Given the hypothesised centrality of maladaptive self-evaluations and perceptions to BN, it is clinically relevant to assess the impact of treatment interventions for BN on these aspects of functioning and psychological wellbeing, and to investigate whether or not self-esteem and/or social functioning or adjustment constitute predictors of treatment outcome. As will be reported in the following chapter, a variety of interventions for BN have been found to impact positively on both self-esteem and social functioning (e.g. Agras *et al*, 2000 a).

1.8 BULIMIA NERVOSA AND CO-MORBIDITY

Individuals suffering from BN may also present with affective disorders, substance abuse problems, or personality and impulsivity disorders. Researchers conducting treatment trials have been concerned with assessing co-morbidity for a number of reasons. Co-morbid problems may potentially have an impact on treatment outcome, and may need to be controlled for in the randomisation procedure and analysis, or considered in relation to the clinical application of findings. It is also clinically relevant to establish whether a treatment intervention has an impact on patients' co-morbid problems or characteristics as well as their eating disorder symptoms. Furthermore, co-morbid problems such as dependence on psychoactive drugs or alcohol, or suicidal intent, are regularly employed as exclusion criteria in

treatment trials. However, the nature of the association between psychiatric co-morbidity and BN remains largely unresolved. Studies of co-morbidity have generally involved clinic samples and high levels of co-morbidity in such samples may reflect the fact that people are more likely to seek help if suffering from two disorders (e.g., Garfinkel *et al* 1995 b; Fairburn *et al*, 1996). Studies have also often failed to include psychiatric or general population control groups. Furthermore, differing definitions and diagnostic tools employed in such studies may lead to widely varying estimates of co-morbidity.

1.8.1 Affective disorders

Empirical research suggests that high rates of major depression, anxiety disorders, and dysthymia are found in patients suffering from BN (Garfinkel *et al*, 1995 b). Depressive symptoms are often as severe as those seen in patients suffering from a primary depressive disorder (Cooper and Fairburn, 1986).

In a study of in-patients with BN, Braun *et al* (1994) found that 45% had a lifetime history of major depression. In another group who had a history of AN prior to BN, the rate rose to 67%. In an out-patient BN sample three-quarters met criteria for lifetime mood disorder; two-thirds for at least one anxiety disorder; and half for drug and alcohol dependence (Sullivan *et al*, 1996). Bushnell *et al* (1994) compared co-morbidity rates in clinic cases with community ascertained BN sufferers and general population controls. Eighty percent of the clinic sample reported a lifetime history of depression while one-third met the criteria for alcohol disorder and one-third for drug problems, four to five times the rates of these disorders found in the general population sample. Rates of co-morbidity for affective disorders and substance abuse in the BN community sample were two to three times higher than those in the general population. Similarly, Garfinkel *et al* (1995 b) reported a three-fold increase in the lifetime occurrence of major depression and a doubling of the rate for anxiety disorders in a non-clinical population of Canadian women suffering from full- or partial-syndrome BN, compared to community controls who did not have an eating disorder. Current rates of depression and anxiety disorders were even higher. Women with the full syndrome had significantly higher rates of phobias (both simple and social), agoraphobia, panic disorder and generalised anxiety disorder than comparison subjects. The two bulimic groups were not found to differ significantly on any one co-morbid diagnosis.

Affective disturbances have also been studied in general practice attenders suffering from BN. For example, King (1989) found that women who had full or partial syndrome BN or who were dieting obsessively, were more likely to have current psychological problems, generally a depressive neurosis, than were women randomly selected from the same general practice sample who did not have eating problems. Whitehouse *et al* (1992) reported that women with full BN had higher scores on a standardised measure of depression than those with partial syndrome. However, a non-psychiatric control group was not included. Patients in the partial syndrome group who fulfilled all DSM-III-R criteria apart from the twice weekly frequency criterion were closest in mean depression scores to those with the full syndrome.

It has been argued that the diagnosis of co-morbid depression in patients with BN is difficult as the affective and somatic features of the eating disorder may be similar to those of depression (Kennedy *et al*, 1994; Fichter *et al*, 1994). Cooper and Fairburn (1986), however, found that while a community-ascertained sample of patients with BN were similar in terms of the severity of their depression to community-ascertained patients suffering from a major depressive disorder, the former displayed a greater frequency of obsessional rumination and anxiety, and the latter a greater frequency of depressed mood, suicidal ideation and apparent sadness. It has also been suggested that anxiety and depression are generally likely to be secondary to BN (Johnson-Sabine *et al*, 1984; Cooper and Fairburn, 1986). King (1989) reported that general practice attenders viewed their distress as secondary to their eating problems. However, Braun *et al* (1994) have argued that major depressive disorders can precede, coincide with or follow the onset of BN: only 33% of those in their in-patient study, for example, reported the eating disorder as their first Axis I disorder. Bushnell *et al* (1994) suggest that rather than arguing that one disorder leads to another, it may be more appropriate to speculate that “vulnerability factors predisposing to one disorder may also lead to the development of a second, or that the experience of any one disorder increases vulnerability to another (p. 611).”

Based on the evidence suggesting that high levels of affective disorders are associated with BN, BN patients being recruited to treatment trials are routinely

assessed for depression. This is done, firstly, to exclude those who are severely depressed or suicidal and who therefore should not be included for clinical or ethical reasons. Secondly, severity of depression is frequently employed as a secondary outcome measure in treatment trials. Thirdly, investigators may wish to assess severity of depression as a predictor of treatment outcome (see Chapter Two).

1.8.2 Alcohol and substance abuse

Rates of lifetime co-morbidity between binge-eating and substance abuse have been found to range from 9% to 55% in clinic populations (Wilson, 1993). However, such wide-ranging estimates may be due to the fact that drug and alcohol dependence have been categorised together as a single problem in some studies and that substance/alcohol *abuse* and *dependence* have not been differentiated (Dansky *et al*, 2000).

Lifetime histories of alcohol problems or abuse have been reported in 47% of clinic (Bulik *et al*, 1997) and 31% community-ascertained samples of women with BN (Garfinkel *et al*, 1995 b), compared with 5% of community-ascertained non-eating disordered controls (Garfinkel *et al*, 1995 b). In a national survey of women in the US, approximately one-third of those who reported a history of BN also reported a history of alcohol abuse (Dansky *et al*, 2000). However, similar rates were found in women with major depressive disorder and posttraumatic stress disorder, suggesting that the risk of alcohol abuse/dependence in women with BN is similar to that in women with other psychiatric disorders. After controlling for age and severity of eating disorder symptoms, Wiederman and Pryor (1996) found that outpatient clinic attenders with BN were more likely than those with AN to have used alcohol and a variety of drugs (amphetamines, barbiturates, marijuana, tranquillisers, cocaine). However, no comparator psychiatric or non-psychiatric control groups were employed in the study. Higher lifetime prevalence rates of alcohol dependence have also been found in women with BN who purge than in those who do not (e.g., Garfinkel *et al*, 1996).

In terms of current substance abuse problems, Lacey (1993) reported that a quarter of his clinic sample consumed over 36 units of alcohol a week in the month prior to assessment. Patients' consumption was considerably more than that reported in a

general survey of women's drinking habits where the demography of the two populations was similar. Twenty-eight percent of Lacey's sample regularly abused 'street' drugs, including amphetamines, marijuana, and unprescribed tranquillisers. Drug abuse and repeated overdosing were found to be significantly associated with alcohol abuse, while repeated self-harm, in the form of cutting, was significantly associated with both alcohol and drug abuse. A community-based study found a significantly higher proportion of smokers among women with BN than among psychiatric (affective/anxiety disorders) and normal controls (Welch and Fairburn, 1998). Daily consumption levels did not differ between the smokers in the first two groups. A higher lifetime prevalence of smoking has also been reported in women with BN who have alcohol problems than in those who do not (Dansky *et al*, 2000).

In general, higher rates of psychiatric co-morbidity, including Axis II disorders, have been found in women who have BN and a substance abuse problem/dependence than in those without substance abuse problems (e.g., Hatsukami *et al*, 1986; Lilenfeld *et al*, 1997), although severity of eating disorder symptomology has generally not differed between the two groups. It has been suggested that BN patients with alcohol problems develop their alcohol problems through their initial problems with food (Lacey and Moureli, 1986). However, it has also been posited that there may be causal relationships between sexual abuse, BN and substance abuse. A higher rate of sexual abuse has been reported in women with BN who have substance abuse problems compared to those who do not, and compared to anorectic and non-eating disordered controls (Deep *et al*, 1999).

As yet the nature of the relationship between BN and substance abuse has not been resolved. However, women with current drug and alcohol problems are frequently excluded from BN treatment trials (Mitchell *et al*, 1997) for clinical, ethical and methodological reasons. Treatment for substance abuse problems may need to take priority over treatment for the eating disorder (Wilson, 1998), and the presence of such problems might potentially confound eating disorder treatment outcome.

1.8.3 Personality disorders and impulsivity

Studies conducted in the 1980s and early 1990s found prevalence rates of personality disorders of between 50% and 63% in bulimic populations (Carroll *et*

al, 1996). Even when the full range of personality disorders are assessed with standardised diagnostic interviews, the percentage of individuals with DSM-III-R BN reported to have at least one personality disorder has varied between 28% and 77% (Braun *et al*, 1994). Many studies do not involve comparison groups, or are otherwise methodologically flawed, and fail to control for the possible confounding effects of co-morbid depression (Carroll *et al*, 1996). Carroll *et al* (1996) reported prevalence rates of personality disorders of 47% in depressed BN patients, 33% in non-depressed BN patients and 7% in non-psychiatric controls (with no history of eating disorders). The patients suffering from BN were most frequently assigned atypical (20%), borderline (10%) and avoidant (10%) personality disorder Axis II diagnoses. Thirty-one percent of in-patients with BN assessed by Braun *et al* (1994) had Cluster B disorders, with one-quarter of the sample meeting the criteria for borderline personality. Patients who had a history of AN were significantly more likely than the sample as a whole to have two or more personality disorders.

Lacey (1993) reported that 80% of an out-patient clinic sample who reported self-damaging and addictive behaviours gave a history of three or more behaviours together. These included a core group who drank at least 36 units of alcohol a week, were severe, regular 'cutters', had taken heroin, LSD, or amphetamines, or bought 'street' tranquillisers on four occasions in the previous year, and in the same time period had stolen at least 10 times and taken at least one overdose. They were likely to be older, and less likely to be employed, married or in a stable relationship than rest of the sample. They were also more likely to report a history of sex abuse, and to have an alcohol-abusing partner or come from a family with an alcohol abuse history. It has been suggested that patients like this core group suffer from a 'multi-impulsive personality disorder' (Lacey and Evans, 1986; Lacey, 1993). Lacey (1993) suggests that the multi-impulsive patient differs from the majority of BN sufferers who do not appear to have personality disturbances, but argues that it still remains to be established whether the disturbance seen in individuals with multi-impulsive BN is simply a variant of borderline personality disorder.

Multi-impulsive BN may be associated with higher levels of parasuicide and poorer outcome (Lacey and Evans, 1986; Fichter *et al*, 1994; Keel and Mitchell, 1997). Lacey (1993) reported that 23% of the out-patients in his study had taken at least one overdose, while 40% of those assessed by Fichter *et al* (1994) reported a

lifetime incidence of attempted suicide, and 24% reported self-mutilating or auto-aggressive behaviours. Generally cutting is described not as a suicidal gesture or attempt, but rather as a means of self-punishment or releasing tension (e.g., Lacey, 1993). Fifteen percent of Lacey's sample reported cutting themselves; however, only 8% were regular 'cutters'. Forty-one percent of the sample studied by Lacey (1993) and 35% of those in Fichter *et al*'s (1994) study reported a history of stealing. Lacey argues that stealing and overdosing are markers of severity and that they do not occur in isolation, but in the presence of one another or of substance abuse. While definitions of 'promiscuity' are arguably culture and age specific, Lacey and Evans (1986) and Fichter *et al* (1994) have reported lifetime histories of 'promiscuity' in 37% and 20% of their clinic samples respectively.

Researchers conducting treatment trials involving BN patients have sometimes assessed personality using standardised measures, in order to exclude those with personality disorders or, alternatively, to test the predictive power of personality disorders vis-à-vis outcome. Where formal personality measures cannot be included in a trial (e.g., for fear of patient overload in terms of assessment) it has been suggested (personal communication: Dr. Bridget Dolan, St. George's Hospital, London) that questions concerning drug and alcohol abuse, sexual relationships, stealing and self-harm should be included as a proxy measure in patient assessments.

1.9 CONCLUSIONS

BN has only been recognised as a distinct eating disorder in the past 20 or so years. While diagnostic systems have been refined, questions still exist concerning aspects of the criteria currently used to diagnose BN. As a disorder of clinical severity BN affects 1-3% of women, while many more may suffer from sub-clinical forms of the disorder. Far fewer men are affected. As yet, the causes remain speculative. The physical, psychological and social consequences of BN can be profound, and there appear to be high levels of psychiatric co-morbidity (particularly Axis I disorders) in individuals suffering from BN. Whether the observed patterns of co-morbidity are specific to BN, however, is open to debate. What is clear, though, is that the multi-symptomatic nature of BN needs to be taken into account by researchers conducting treatment trials and reflected in the outcome measures they employ. The

following chapter reviews the research evidence concerning effective treatments for BN, as well as assessing what is known about the potential for treating patients with BN in the general practice setting.

CHAPTER TWO:

BULIMIA NERVOSA: TREATMENT AND OUTCOME

2.1 INTRODUCTION

A stepped approach to the treatment of BN, with the least intensive interventions taking place in general practice or non-specialist settings has been advocated (e.g., the Royal College of Psychiatrists, 1992). The most recent report from the Royal College (2000) also advocates a role for primary care services in the detection of eating disorders and the management of less severe cases. To date, however, in the UK, treatment for BN has been largely concentrated in specialist eating disorder units, with patients generally seen on an out-patient basis. Cognitive behaviour therapy (CBT) is recommended as the choice of treatment for BN (e.g., Royal College of Psychiatrists, 1992; APA, 1993; Wilson, 1999; Agras *et al*, 2000 a). Its effectiveness has been widely assessed in specialist settings and it has been found to be more effective than other forms of psychotherapy, at least in the short-term (e.g., Fairburn *et al*, 1986; Fairburn *et al*, 1991; Agras *et al*, 2000 a). Its use in combination with anti-depressant medication has also been found to be more effective than medication alone (e.g., Mitchell *et al*, 1990; Walsh *et al*, 1997). Recently, cognitive behaviour principles have been incorporated into self-help manuals for BN and the use of such manuals has been the focus of a growing body of research in specialist settings. Findings lend support to the hypothesis that less intensive approaches to treatment may be appropriate for at least some patients with BN (e.g., Treasure *et al*, 1994; Cooper *et al*, 1996; Thiels *et al*, 1998; Palmer *et al*, 2002).

It is estimated that roughly one-quarter of those attending general practice are suffering from a mental health problem (Goldberg and Lecrubier, 1995). At present in the UK, the majority of people with mental health or psychological problems are treated in general practice or community settings, with only approximately 9% referred to specialist services (Department of Health, 1999). The past ten to fifteen years have seen a proliferation of studies of non-intensive, general practice based interventions for a range of mental health, psychological and addiction problems. The

findings of such studies suggest that problems formerly managed only in specialist settings may be treated effectively in general practice (e.g., Drummond *et al*, 1990; Kupshik and Fletcher, 1999).

The widespread management of common mental health problems in general practice, the growing body of research evidence to support this management approach, along with the finding that less intensive approaches may be effective in the treatment of BN, suggest that a general practice based intervention for BN warrants empirical investigation.

The aim of the current chapter is therefore to review literature from a number of areas in support of this suggestion. The objectives are, firstly, to briefly review the evidence concerning the effectiveness of CBT generally as a treatment for BN. Studies comparing therapist-led CBT in turn with no therapy, other forms of psychotherapy and with medication will be reviewed. Secondly, evidence concerning the effectiveness of employing cognitive behaviour self-help manuals in the treatment of BN will be reviewed in detail, while the use of self-help interventions in the mental health field generally will be considered briefly. Thirdly, predictors of treatment outcome will be considered. Fourthly, this chapter will focus briefly on studies designed to evaluate the management of mental health problems other than eating disorders with non-intensive or brief intervention techniques in general practice. Finally, the limited existing literature on the detection and management of BN in general practice will be considered.

2.2 THERAPEUTIC APPROACHES TO TREATING BULIMIA NERVOSA

2.2.1 Cognitive Behaviour Theory and Therapy

Cognitive theory proposes that individuals' behaviours and emotions are determined largely by the ways in which they structure the world (Beck *et al*, 1979). It is not an event per se, but rather the way in which an individual interprets or assesses it, that leads to his emotional and behavioural reactions to it (Lam and Gale, 2000). Enright (1997) employs Beck's original model of depression (Beck, 1976) to illustrate the

link between dysfunctional patterns of thought and behaviour and psychological problems. Beck proposed that the negative thinking evident in people suffering from depression is based on attitudes and assumptions arising from early life experiences; assumptions which may be extreme, rigid and resistant to change. Events that contradict an individual's goals and beliefs (e.g., a failure experience for the individual who believes that self worth is dependent on success) may lead to the production of negative automatic thoughts, which lower mood and increase the likelihood of further negative thinking. A set of cognitive distortions (the so-called 'cognitive triad' of negative view of self, current experience and the future) and other information processing biases reinforce the depression while behavioural factors (e.g., reduced activity levels) exacerbate it (Enright, 1997). While it is not proposed that negative thinking and abnormal behaviour cause depression, cognitive behaviour theory does predict that these factors exacerbate and maintain emotional disturbance (Enright, 1997).

As outlined in the previous chapter, the cognitive model of BN suggests that patients' dysfunctional beliefs concerning the importance of weight and shape lie at the heart of the disorder. Social pressures lead some women to overvalue weight and shape and to restrict their diets in an extreme manner. Control over eating is eventually lost and a pattern of bingeing and purging develops (Wilson, 1999). It has been suggested that if faulty beliefs and values about weight and shape are seen as central to the disorder, then all the other symptoms and psychopathology associated with BN become comprehensible (Fairburn, 1985).

CBT is designed to help patients change both their cognitions and behaviours by encouraging them to collect evidence to support/refute their beliefs and to re-evaluate their beliefs in the light of this evidence. Garner and Bemis (1985), cited by Freeman (1995), note that the core features of CBT are as follows: it has a theoretical basis shaped by empirical findings; it focuses on conscious experience and views meanings and cognitions as mediating variables accounting for negative or maladaptive emotions and feelings; it uses questioning as a therapeutic device; and the CBT therapist is actively involved in the treatment process.

CBT is usually brief, and individual therapy is most common. A review of the clinical applications of CBT (Enright, 1997) highlighted its use in the treatment of a wide range of mental health and psychiatric problems (e.g., panic disorders and agoraphobia, anxiety disorders, obsessive-compulsive disorder, psychosis and schizophrenia, and psychosexual problems). Formulated by Fairburn (1981), CBT for BN is directed at reducing dietary restraint, establishing normal eating patterns, developing skills for dealing with situations that trigger binges and purging behaviours, and modifying dysfunctional attitudes about the importance of shape and weight (Wilson, 1999). There are three stages to CBT for BN, each focusing on a specific problem area (e.g., Fairburn, 1985; Fairburn *et al*, 1986). The first stage, which is largely behavioural, is concerned with establishing control over eating. The second, which is cognitive in its orientation, focuses on the identification of dysfunctional cognitions, belief and value systems, and attempts to modify them. Training in problem solving and the use of cognitive restructuring techniques is an integral part of this stage. The third stage concentrates on the maintenance of change and measures to reduce the risk of relapse.

2.2.2 Other therapeutic approaches

As well as CBT, a range of short-term psychotherapies such as ‘Interpersonal Therapy’ (IPT), supportive psychotherapy, or focal psychotherapy, are routinely used to treat patients with BN. These therapies have sometimes been adapted specifically for use with BN patients from their more generic forms, particularly in the research context (e.g., Fairburn *et al*, 1986). This has led to the evolution of slightly differing forms of therapy being given the same general label (e.g., IPT as described by Fairburn *et al* (1986) and Agras *et al* (2000a)). Regardless of this, however, the central tenet of all these therapies is that BN constitutes a symptom of, maladaptive response to, or way of coping with, underlying conflicts or interpersonal difficulties. Furthermore the patient may not even be fully aware of the nature of these difficulties (e.g., Fairburn *et al*, 1986; Walsh *et al*, 1997). The aim of the psychotherapy is to help her identify and explore her difficulties, conflicts or problems; find ways of resolving or coping appropriately with them; and, to experience a sense of self-knowledge, self-acceptance and emotional growth. The objective is also to encourage her to develop personal resources and strategies for facing future difficulties or crises, without resorting to disordered eating behaviours.

Short-term psychotherapies generally place less importance on the patient's presenting eating disorder symptoms and related behaviours *per se* than does CBT for BN. Instead they focus more on the context in which the eating disorder developed, the particular factors that led to its development and/or the factors that are maintaining it. Greater emphasis is placed on exploring issues such as the patient's developmental history, family history and dynamics, interpersonal relationships, and current emotional concerns, conflicts and anxieties than in CBT. However, as with CBT, in the early stages of therapy patients are sometimes asked to describe the onset of their eating disorder and to monitor their binge-purge behaviours in order to help them develop an awareness of, and insight into, factors that precipitate and maintain their BN. These factors may then become the focus of therapy. Patients may also be provided with psycho-educational material concerning the potentially harmful effects of bingeing and purging (e.g. Fairburn *et al*, 1986; Garner *et al*, 1993).

As noted above, the CBT therapist, along with the patient, plays an active role in the therapeutic process; for example, by using direct questioning techniques to help the patient to interpret her behaviours, and examine her belief systems and perceptions. Therapists employing short-term psychotherapies, on the other hand, tend to play a less directive role, and, for example, to reflect a patient's questions or statements back at her. This is done in order to encourage her to recognise her difficulties herself and develop confidence in her own opinions, feelings and needs. The therapist's role is not to provide specific advice (e.g., Garner *et al*, 1993) or make specific suggestions.

Where therapies such as IPT have been used as comparator interventions to CBT in treatment trials they have generally been manual-based, and structured in the sense that distinct stages can be described in the course of therapy. The intensity of treatment, in terms of the number and length of therapy sessions, has generally been designed to parallel that of CBT.

2.3 TREATMENT RESEARCH

The search for an effective treatment for BN has been the focus of a considerable amount of work by clinicians and researchers alike over the past 20 years. Studies have taken the form of open trials, controlled trials comparing two or three individual treatments, trials comparing individual treatment interventions with combination therapies, and sequential trials. To date, only patient-preference trials have not appeared in the literature. CBT, other forms of psychotherapy, and anti-depressant medication have all been studied as possible treatment interventions: however, the study of the impact of CBT on BN has probably received most research attention. Individual, group and self-help applications of CBT and the sequencing of treatment with CBT included as a component of therapy have all been the subject of investigation.

There are a number of limitations to the trials conducted to assess the efficacy of various forms of treatment for BN; one of the most important being that treatment studies have tended to evaluate eating disorder symptom outcome simply in terms of frequency of bingeing and purging. Earlier studies in particular failed to clarify if patients were still dieting and whether or not they retained their concerns vis-a-vis weight and shape (Fairburn, 1991). Success criteria vary from study to study, with some studies reporting a specified decrease in bingeing/purging as a mark of success while others focus on the proportions of patients ceasing these activities entirely. A wide range of assessment tools is used to measure eating pathology. In addition, varying lengths of follow-up (where follow-up occurs beyond the end of the treatment intervention), differing methods of patient ascertainment and varied inclusion and exclusion criteria (where described), including the definition of what constitutes BN itself, make comparisons across studies problematic. The approach to data analysis has also differed from study to study with some studies employing a pragmatic or intention-to-treat approach, where data from everyone recruited into the study is included, and others using only data from subjects who have completed treatment. Furthermore, less recent studies do not include power calculations, making it difficult to gauge whether they are large enough to produce meaningful results. It has also been argued that care should be exercised in generalising from the findings of individual treatment trials. Mitchell *et al* (1996), for example, suggest that the standard of care provided in treatment trials is unrealistic compared to that provided

in routine clinic settings, and that psychotherapies are in fact shown to work under very high level conditions. Wilson (1998), however, argues that major trials often include patients with levels of eating disturbance and the multiple associated problems seen in clinical populations, and that, essentially, the level of generalisability permissible depends on the individual study and the clinical service settings to which its findings are being generalised.

2.3.1 Therapist-led Cognitive Behaviour Therapy: Empirical findings

2.3.1.1 Treatment with Cognitive Behaviour Therapy compared to no treatment

One of the most fundamental questions facing clinicians treating any disorder is whether a particular treatment intervention is more beneficial than no treatment at all. In treatment trials, waiting list or 'no treatment' controls have typically been used to answer this question. In terms of BN, little is known about the prognosis of untreated bulimic patients (APA, 1993). Studies conducted in the 1980s suggested that over 1-2 years sufferers experience a degree of spontaneous improvement (e.g., Yager *et al* 1987). However, early studies employing waiting list controls reported minimal change in those in waiting list conditions (e.g., Lacey, 1983) and more recent research confirms this (e.g., Treasure *et al*, 1994). A number of early controlled studies, such as those conducted by Wilson *et al* (1986) and Freeman *et al* (1988), found CBT to be more effective in the treatment of BN than no treatment at all (Bloiun *et al*, 1994). Given the existence of treatments known to be relatively effective, as well as the fact that the evidence suggests no significant change in waiting list controls, the use of control populations receiving *no treatment at all* for BN is not widespread, with the exception of trials of anti-depressant medications (e.g., Fluoxetine Bulimia Nervosa Collaborative Study Group, 1992). However, waiting list controls have been employed in recent studies focusing on the treatment of BED (e.g., Carter and Fairburn, 1998) as well as in some of the BN treatment trials reported below. Hay and Bacaltchuk (2001) report that the results of two systematic reviews and one large RCT reveal that, compared to remaining on a waiting list, treatment with CBT reduces both the specific and non-specific symptoms of BN.

2.3.1.2 Therapist-led ‘full’ Cognitive Behaviour Therapy compared to other psychological therapies

Studies conducted in the UK comparing CBT with alternative psychotherapies or with anti-depressant medication have tended to be single-site studies with small numbers of participants (e.g., Fairburn *et al*, 1986). Larger multi-site studies have been undertaken in the United States (US) (e.g., Agras *et al*, 2000 a). This difference may in part reflect the ways in which healthcare is funded and delivered in the two countries. BN patients are generally recruited to studies in the UK from specialist centres and through GP and psychiatric referrals, whereas a combination of recruitment methods (with participants recruited to the same study from treatment centres and through media advertisements) is widely used in the US. The difference in study size may also reflect resources available for conducting eating disorders research in the two countries. Regardless of these differences, however, studies conducted in both countries have shown favourable outcomes for therapist-led CBT compared to other forms of treatment.

CBT for BN was designed to be therapist-led with patients seen on an out-patient basis (e.g., Fairburn *et al*, 1986). Studies of therapist-led CBT have generally either employed the manual employed in Fairburn’s studies (e.g., Fairburn *et al*, 1991) or devised study-specific manuals based on it. Patients taking part in studies are usually offered between 16 and 20 CBT sessions (e.g., Fairburn *et al*, 1991; Agras *et al*, 2000 a; Wilson *et al*, 2000). Where CBT for BN has been compared with another form of psychotherapy, the comparison has most often been made with IPT. However, in the research context in particular, what constitutes IPT and the degree to which it differs from CBT may not always be readily apparent. For example, Fairburn *et al* (1986) describe the form of IPT delivered in their study as *differing* from CBT *apart from* the monitoring of eating habits, provision of information about BN and discussion of the circumstances under which overeating occurred. Agras *et al* (2000 a), on the other hand, state that the form of IPT employed by them does not focus on eating habits or weight/shape attitudes, contain any behavioural or cognitive procedures specific to CBT, or involve self-monitoring.

CBT has generally been found to be more effective than IPT in reducing specific eating disorder symptomology. However, the evidence suggests that CBT may be

more immediate in its impact, and that differences in the efficacy of the two types of therapy disappear over time. Both CBT and IPT have also been found to have a positive impact on general psychiatric symptoms, depression, self-esteem and social adjustment.

In a randomised controlled trial designed to compare the efficacy of CBT with a form of IPT (focal psychotherapy) patients in both groups were found to improve significantly (post-treatment) in terms of their overall clinical status, binge eating and vomiting, and on measures of general psychopathology, with improvements maintained over a 12 month period (Fairburn *et al*, 1986). Where significant differences occurred they favoured the CBT approach. However, the study was limited by its size, difficulties in interpreting the non-significant group differences, multiple outcomes, and an analysis based on treatment completers only. A larger study found no difference in outcome, assessed at the end of therapy, and again based on a treatment completer only analysis, between CBT, behaviour therapy (BT) and IPT in terms of bingeing behaviour, or severity of psychiatric symptoms, all of which improved significantly (Fairburn *et al*, 1991). CBT was, however, more efficacious than either BT or IPT in modifying attitudes to shape, weight and extreme dieting. A 12-month follow-up analysis including data for every patient revealed that differences between CBT and IPT disappeared over the follow-up period (Fairburn *et al*, 1993 b). CBT was superior to BT, but no different from IPT, in increasing the likelihood of a good outcome (abstinence rates for CBT and IPT being 36% and 44% respectively). Both CBT and IPT had equally significant effects on attitudinal disturbances and resulted in lasting decreases in severity of general psychiatric symptoms and depression. The differing nature of the analyses conducted at the end of treatment and at the 12-month follow-up, however, makes interpretation of these findings difficult.

Stronger evidence for the short-term superiority of CBT over IPT comes from a large two-centre study involving 220 (DSM-III-R) BN patients (Agras *et al*, 2000 a). An intention-to-treat analysis revealed CBT to be significantly superior to IPT at post-treatment assessment for proportion of patients recovered (29% versus 6%), remitted (48% versus 28%) and meeting community norms for eating behaviours and attitudes (41% versus 27%). However, the two treatments did not differ on eating disorder

specific outcome measures at any follow-up point in the 12 months after treatment. A completer-only analysis echoed these results. In addition, no differences were found between the treatments in terms of their impact on improvement in weight and shape concerns, self-esteem and interpersonal functioning. Agras *et al* concluded that CBT produces more rapid improvement than IPT and should be considered the preferred choice of treatment for BN.

In order to assess the longer-term impact of CBT, BT and IPT, Fairburn *et al* (1995) interviewed 89 of the 99 participants in their two earlier trials some four to six years later (range 3-11 years). When all the forms of eating disorders were considered, differential treatment effects were found. Eighty-six percent of the patients who had received BT had an eating disorder diagnosis at follow-up, compared to 37% and 28% of CBT and IPT patients respectively. However, caution is needed in drawing conclusions from what is essentially a cohort study of two incomplete study samples, including individuals who may have had multiple treatment interventions since taking part in the initial trials.

CBT has also been reported to as effective as, or superior to, psychotherapies other than IPT, at least in the short-term. For example, it has been found to be moderately more effective than Supportive Expressive Therapy in reducing eating disorder symptoms and improving mood and psychosocial functioning (Garner *et al*, 1993), and superior to group psychoeducation in reducing frequency of purging, but not binge-eating (Olmstead *et al*, 1991). Abstinence rates from both bingeing and purging were 30% and 17% for CBT and group psychoeducation respectively (Olmstead *et al*, 1991). However, an intermediate report on a trial designed to compare the effectiveness of three treatment approaches (Motivational Enhancement Therapy (MET) followed by group or individual CBT, and individual CBT followed by group CBT) reported no difference in outcome from the first phase of treatment (4 weeks individual CBT or MET) in terms of reductions in binge-eating, vomiting and laxative abuse between CBT and MET (Treasure *et al*, 1999).

In the real-world clinical setting, clinicians may potentially use a combination of psychotherapeutic approaches when treating a patient with BN, or when one treatment does not achieve its desired outcome, they are likely to try another. Clinical

experience may also lead some to believe that maximum benefit is to be derived from an intervention known to be effective if a patient is 'prepared' for said intervention by means of an initial, alternative /less intensive approach. Furthermore, financial imperatives may dictate that a less intensive treatment is tried first. In an attempt to mirror clinical reality, recent empirical research has begun to focus on the potential of a sequential approach to the psychotherapeutic manual-based management of BN (e.g., Treasure *et al*, 1999; Davis *et al*, 1999). Such trials may serve as useful indicators of which combinations of therapies work well together and of the added value (if any) to be gained from employing various therapies in sequence. A study by Davis *et al* (1999) illustrates this point. Participants who completed a 6-week course of brief group psychoeducation (PE) were subsequently randomised to receive either no further treatment or between 12 and 20 sessions of individual CBT over a 16-week period. PE followed by CBT produced significantly greater reductions in bingeing and purging and significantly higher remission rates (43.2% versus 10.5%) post-treatment than PE alone. Improvements were maintained over a four-month follow-up period. There were no differential treatment effects in terms of non-specific psychopathology. The authors concluded that the trial provided limited support for offering CBT to patients following PE. Tellingly, however, they noted that the remission rates obtained from sequencing the two approaches are similar to those obtained in trials assessing the impact of CBT alone. From both the clinical and financial viewpoints, one might argue therefore that the delivery of PE as a precursor to CBT is unwarranted.

Based on a review of 18 controlled studies of psychotherapies used to treat BN, including some of those referenced above, Mitchell *et al* (2001) concluded that CBT and IPT are perhaps the most useful psychological therapies available. The efficacy of CBT (and of IPT in the longer term) in the treatment of BN have most recently been supported by the findings of a meta-analysis of 34 psychotherapy trials (Hay and Bacaltchuk, 2003). Like Wilson (1999), Mitchell *et al* (2001) noted that intensive psychotherapeutic treatment may produce abstinence rates of approximately 50%. However, they also noted that many professionals treating patients with eating disorders are not trained to provide CBT or other structured psychotherapies and that drug therapy with anti-depressants may be seen by some as a useful alternative.

2.3.1.3 ‘Full’ Cognitive Behaviour Therapy compared to medication/medication combined with psychotherapy

Indeed, despite psychological therapies having received much research attention, the use of antidepressants in the treatment of BN has also been widely studied. A certain amount of caution has to be exercised in reporting and evaluating the findings of drug studies. It should be borne in mind that such studies are often funded or part-funded by the manufacturers of the drugs under investigation, whose primary objective may be to obtain drug licences for treating a wider range of mental health conditions. Many drug studies involve short-term intervention periods (e.g., eight weeks) with outcome analyses based on end of treatment data rather than on outcome data collected at longer-term follow-up points. They are therefore generally only concerned with the short-term impact of pharmacotherapy. Over 15 placebo-controlled studies since 1979 have attested to superior outcome, at least in the short-term, in patients receiving the active drug (Walsh *et al*, 1997). A meta-analysis of 16 RCTs, including 1300 BN patients, the aim of which was to compare the effectiveness, acceptability and tolerability of various classes of antidepressants compared to placebo, found that short-term remission in bulimic symptoms was significantly more likely for antidepressants, and that there were no differential effects for efficacy and tolerability among the different classes of antidepressants (Bacaltchuk *et al*, 2000a). Hay and Bacaltchuk (2001) also report that two systematic reviews and four additional RCTs found that antidepressants reduced bulimic symptoms compared to placebo. The results of double-blind, placebo controlled, outpatient studies of tricyclic antidepressants, monoamine oxidase inhibitors, or atypical antidepressants indicate a mean reduction in binge-eating frequencies ranging from 22% to 91% (typically 50% to 70%) and abstinence rates at the end of treatment ranging from 0% to 68% (Mitchell *et al*, 2001). However, Mitchell *et al* (2001) caution that although antidepressants may dramatically reduce eating disorder symptoms, in reality the number of people free of symptoms at the end of treatment is generally low, and the existing evidence suggests that some of these will relapse even when maintained on the antidepressant. For example, a study by Walsh *et al* (1991) cited by Agras (2001) found that between 25% to 35% of BN patients treated with anti-depressants relapsed over a 1-2 year period.

Outcome has also been shown to be related to the dosage of active drug administered. The findings of a multi-centre, eight-week double-blind trial indicated that fluoxetine hydrochloride at 60 mg/d was significantly superior to placebo in reducing both weekly binge-eating and vomiting while a 20mg dose was superior to placebo in reducing vomiting only (Fluoxetine Bulimia Nervosa Collaborative Study Group, 1992). Fluoxetine was also superior to placebo in reducing pathological eating attitudes, carbohydrate craving and depression, with the higher dose providing stronger results.

Having established that both psychotherapeutic (particularly CBT) and psychopharmacological approaches may be used with a certain degree of success in the treatment of BN, the question of the relative efficacy of these approaches, and of the possible merit to be derived from combining the two, acquires theoretical, clinical and financial significance. A number of studies have investigated these issues. Generally the results have indicated that while CBT is more powerful than medication in reducing symptoms, there may be some advantages to combining the two in terms of improvements in eating disorder symptoms and pathological attitudes, and mood (Mitchell *et al*, 2001).

In the first study of its kind, the relative impact of imipramine hydrochloride, placebo, or intensive group out-patient treatment (incorporating many aspects of CBT) combined with imipramine or placebo was investigated and all of the active treatments found to be superior to placebo at follow-up, in terms of eating disorder symptoms and mood (Mitchell *et al*, 1990). Therapy combined with placebo was superior to imipramine alone in terms of modifying eating disorder symptoms (reductions in bingeing and purging behaviours) and reducing depression. The combination of therapy and medication was superior to therapy and placebo with regard to depression and anxiety but not eating disorder symptoms per se. In a similar study, CBT on its own or combined with desipramine was found to be superior to desipramine alone (Agras *et al*, 1992). However, the combination of CBT and medication was superior to CBT alone only on dietary restraint. In a study designed to address the question of whether a two-stage medication intervention (desipramine followed by fluoxetine if necessary) adds to the effects of manual-based psychological treatment, 120 participants were randomised to receive CBT and anti-

depressant or placebo, supportive psychotherapy (SPT) and anti-depressant or placebo, or active medication (Walsh *et al*, 1997). Seventy-four percent of eligible participants were prescribed fluoxetine. An intention-to-treat analysis revealed significant clinical improvement in all groups over time. However, CBT was found to have a significantly greater impact on binge-eating and vomiting than SPT, although there were no differences in the impact of the two on mood. The combination of psychological treatment and medication had a greater impact on binge-eating and mood than the psychological treatment and placebo. CBT and medication was found to be superior to medication alone: however, SPT and medication was not. The findings also revealed a trend favouring CBT in terms of reductions in dietary restraint and abnormal concerns about weight and shape. Walsh *et al* concluded that CBT is the treatment of choice for BN and that the addition of medication confers modest benefit to that of psychological therapies. However, as the study did not include a psychotherapy only group, the conclusion that medication adds to psychotherapy rests on the assumption, which is open to question, that psychotherapy and placebo is the same as psychotherapy alone (Walsh *et al*, 1997).

Two meta-analyses of trials (n=12) comparing single antidepressant treatment versus the combination of antidepressant and psychological therapy and single psychological approaches versus the combination of antidepressant and psychological therapy also found combined treatment to be superior in terms of remission rates than single approaches (Bacaltchuk *et al*, 2000 b). However, the acceptability of psychological treatment was found to be significantly reduced when antidepressants were combined with therapy.

The question of whether medication may prove beneficial to patients who have a poor response to psychological therapies has been addressed by Walsh *et al* (2000). Twenty-two women who had not responded to, or subsequently relapsed after, treatment with either CBT or IPT were randomly assigned to receive either fluoxetine (60mg/d) or placebo for eight weeks. A post-treatment analysis revealed that the median frequency of bingeing and purging declined in the active treatment group while increasing in the placebo group. The authors suggested that fluoxetine might be a useful intervention for patients who do not respond to psychological treatments, but acknowledged that the study's small sample size and lack of follow-up beyond the

end of treatment limit the generalisability of the findings. Furthermore, it has been suggested that individuals suffering from BN may not wish to take anti-depressant medication for a variety of reasons, including fear of side effects (e.g., Wilson and Fairburn, 1998; Walsh *et al*, 2000). A more recent study by Mitchell *et al* (2002) in which 62 patients who had been treated unsuccessfully with CBT were subsequently randomised to receive either medication or IPT found no difference between the two forms of treatment in terms of outcome. However, high drop-out rates and low abstinence rates (10% in the medication group and 16% in the IPT group) led the authors to conclude that offering lengthy treatments following CBT may have little value.

2.3.1.4 Financial costs of treatment: Empirical findings

In treating any disorder, clinicians and health service providers are concerned not only with the clinical impact but also with the cost implications of treatment interventions. The costs of treating BN generally, and the relative cost-effectiveness of different treatments for BN, have received little research attention (Agras, 2001). Based on US health insurance claims data examined by Streigel-Moore *et al* (2000), Agras (2001) reported that the average costs of treatment for BN per individual were significantly less than those for schizophrenia, but significantly more than those for obsessive compulsive disorder over a one-year period. The results of a study comparing the relative costs of desipramine and CBT suggest that although medication may appear cheaper in the short-term, costs begin to exceed those for CBT after two years of treatment (Agras, 2001).

2.3.1.5 Conclusions

The empirical evidence concerning therapist-led CBT suggests that it should be seen as the treatment of choice for BN for a number of reasons. Firstly, it appears to be more clinically effective than other psychological treatments, although its short-term superiority over IPT may disappear with time. Its impact has been attested to in both explanatory and pragmatic trials. Secondly, improvements achieved through the use of CBT appear to be maintained at least during the year following treatment. Thirdly, CBT has been found to have a significant impact on both the specific symptoms of BN and associated pathological attitudes and disturbances in mood, self-esteem and social functioning. Fourthly, it appears to be more effective than anti-depressant

medication and combining medication with CBT seems to confer only modest benefit to the impact of CBT on its own. CBT may also be more acceptable than medication to patients as a form of treatment for BN. Finally, the small amount of evidence that exists suggests that CBT may be less expensive than medication in the longer term.

2.3.2 The self-help manual approach to the treatment of Bulimia Nervosa: Empirical findings

2.3.2.1 Background

In spite of the fact that it may be seen as the treatment of choice for BN, individual, therapist-led CBT is limited in its effectiveness, in that only approximately 50% of BN patients cease binge-eating and purging. It is also relatively expensive (Agras, 2001), not widely available (e.g., Cooper *et al*, 1996; Loeb *et al*, 2000), and it has been suggested that clinicians may not be convinced about the generalisability of the findings from large randomised controlled trials to diverse clinical settings (e.g., Wilson, 1998, 1999). While a survey conducted by the Royal College of Psychiatrists (2000) reported that 93% of 57 eating disorders services surveyed said they provided CBT for patients with eating disorders, no information was provided concerning the number of professionals trained to deliver CBT or the type/ level of CBT provided. Similarly, a recent postal survey of a random selection of licensed doctoral level psychologists in an upper mid-western US state revealed that although respondents reported that they were frequently using CBT techniques with eating disordered patients, the majority had not received training in the use of manual-based treatment approaches (Pederson Mussell *et al*, 2000). In addition, the evidence suggests that many patients with BN do not seek treatment, possibly because of lack of access to psychotherapy or because they feel embarrassed about the nature of their illness (Loeb *et al*, 2000). Welch and Fairburn (1994), for example, estimated that 90% of individuals suffering from the disorder were not in treatment.

The imperative in recent years has therefore been to provide less expensive and less intensive forms of treatment that are more readily accessible to patients. As noted earlier, the use of a stepped approach to the management of BN, with supervised self-help being employed as a first-line intervention, has been advocated in the past decade. Cooper *et al* (1996) argued that CBT, because of its incremental nature, lends

itself easily to the self-help format. Furthermore, the 1990s saw a proliferation in the publication of self-help manuals for a variety of mental health and lifestyle problems or issues, and several manuals for BN became available in bookshops (e.g., Peter Cooper's (1993) *'Bulimia Nervosa; A Guide to Recovery'* and *'Getting Better Bit(e) by Bit(e)'* by Ulrike Schmidt and Janet Treasure (1993)).

Self-help interventions for disorders like BN have a number of potential advantages over specialist interventions. They are less costly and less time consuming than intensive therapies (Cooper *et al*, 1996; Wilson *et al*, 2000). They also provide an alternative for patients who do not wish to attend specialist treatment centres; they are more immediately accessible to patients; and they may be more disseminable among professionals treating individuals with eating disorders than intensive forms of therapy (Wilson *et al*, 2000). In 'pure' or 'unguided' self-help patients use a manual on their own without professional guidance or support: in 'supported' or 'guided' self-help they use the manual in conjunction with support from a professional. Self-help manuals may also be used as an adjunct to specialist treatment or drug therapy.

Since the early 1990s self-help approaches to BN have been studied empirically in open trials (e.g., Schmidt *et al*, 1993; Cooper *et al*, 1996); in controlled trials with comparator treatments (e.g., Treasure *et al*, 1994; Thiels *et al*, 1998; Mitchell *et al*, 2001), and as part of a sequential approach to treatment (e.g., Treasure *et al*, 1996). The study designs employed, and the nature of the questions trials of self-help have sought to address, therefore mirror those of the studies of full CBT. A number of self-help manuals have been used for research purposes. However, all have in common the fact that they provide information about the nature of binge-eating and compensatory behaviours and that they include strategies and techniques based largely on cognitive behaviour principles for dealing with binge-eating. Without exception, studies have been based in specialist centres although they may have involved non-specialists in supporting patients using the manuals. In terms of generating empirical evidence, however, it has perhaps been most appropriate to establish the efficaciousness of self-help manuals initially in specialist settings. Evaluations can then be conducted in non-specialist settings, to ascertain whether results will translate to these settings.

2.3.2.2 Open trials involving the use of self-help manuals

Open trials are useful in testing the feasibility and potential clinical impact of a new procedure or intervention. While in strict scientific terms, the evidence generated by using the pre-and post-intervention design of the open trial may not be as strong as that produced by conducting a randomised controlled trial, open trials are often invaluable indicators of whether a full, controlled trial is warranted. In research on the treatment of BN, open trials have been employed not only to establish the potential efficacy of the self-help approach, but also to assess patients' impressions of the self-help manuals and general approach.

The first open trial involved 28 patients (ICD-10 or atypical BN) who worked through a self-help handbook on their own for 4-6 weeks (Schmidt *et al*, 1993). Post-treatment, the 26 patients assessed were found to have improved on all *clinician-rated measures* of severity of eating behaviour and attitudes, apart from body shape concerns. Twelve were deemed to be very much or much improved; 15 were abstinent from vomiting or laxative abuse (five had been prior to treatment), while seven had a 75-100% reduction in binge frequency. The authors acknowledged that the uniform improvement seen on clinician-rated scales is open to the accusation of bias, and that as patients were chronic BN sufferers, their response to the manual might have been the result of previously learned skills. However, they argued that the findings provided preliminary evidence for the efficacy of a self-help treatment approach and suggested that, if validated, this approach would be potentially applicable to non-specialist settings including general practice. In addition, Schmidt *et al* (1993) reported that, in general, patients commented positively on the self-help manual, stating for example that it strengthened their resolve not to binge and increased their motivation to change.

Open trials of supported self-help have also produced promising results. Cooper *et al* (1994) reported that approximately half of the 18 patients (DSM-III-R BN) who used a structured cognitive behaviour self-help manual with support from a non-specialist social worker were in remission after 4-6 months. A study of patients using a different manual found that 10 out of 17 experienced improvements in eating disorder symptoms over the 16-week trial period (Grave, 1997). The results of a trial

involving 82 women (DSM-III-R BN), again aided by a non-specialist social worker, and assessed by means of a shortened version of a standardised, structured clinical interview schedule and self-report measures, supported the pattern of findings in the two smaller studies (Cooper *et al*, 1996). Sixty-seven patients ‘persisted’ with the self-help programme, attended support sessions (mode 8; range 4-13), and were re-assessed after 4-6 months. The frequency of bingeing and self-induced vomiting decreased, on average, by 80% and 79% respectively: 51% of the treatment completers ceased having binges, 45% vomiting, and 33% experienced neither event in the previous month. There were also significant improvements in concerns about shape and weight, and depression, but less in terms of body shape dissatisfaction and dietary restraint. Clinical improvements were maintained in participants followed up approximately a year after commencing treatment (n=50). In the absence of a control group, the researchers compared their findings with those of Fairburn *et al* (1991), and found full CBT to be superior to the self-help version. Nonetheless, they concluded that the study findings support the use of supervised cognitive behavioural self-help as a first line intervention for BN. Participants highlighted the structured nature of the manual and the provision of support as important features of the approach. Cooper *et al* suggested that support could be provided by any sympathetic person, and recommended that this approach to treating BN be studied in the general practice setting.

The evidence from the four open trials reported in the literature therefore suggests that the self-help approach is a feasible one and that it may be of benefit to at least some individuals suffering from BN. However, it is important not only to establish that the approach results in clinical improvement in patients, but also to establish its efficacy in comparison to standard treatments (Schmidt *et al*, 1993; Cooper *et al*, 1996). A handful of controlled trials have addressed this issue.

2.3.2.3 Controlled trials involving the use of self-help manuals

A trial involving 110 (ICD-10 bulimia or atypical bulimia) patients (81 of whom completed two assessments), and designed to assess the efficacy of eight weeks of unguided self-help, compared to the first eight sessions of a CBT programme, and a waiting list control, found that patients in the self-help and CBT conditions improved significantly in terms of their eating disorder symptoms, while those on the waiting

list remained unchanged (Treasure *et al*, 1994). There was no difference in total change in symptoms between the CBT and manual groups; both did significantly better than the waiting list control group. However, the dietary pattern of patients receiving CBT improved more than that of the other two groups. In terms of abstinence from bingeing, vomiting and other weight-control behaviours, the manual was found to be intermediate between CBT and waiting list in its impact (22% compared to 24% and 11% respectively). Treasure *et al* suggested that the findings provided preliminary evidence that a self-help manual may be a useful first phase in the treatment process. They speculated that the manual might be more effective in treating patients with milder forms of BN and that patients might benefit from some support in using it. An intention-to-treat analysis was not undertaken as the trial was designed to be explanatory in nature. It is impossible therefore to tell whether the findings would have been more conservative had data from every patient (including the 29 who dropped out) been included.

In a continuation of the study described above and in order to test their hypothesis that sequential treatment involving an initial self-help component would be as effective as standard CBT, Treasure *et al* (1996) randomly allocated patients (ICD-10 bulimia or atypical bulimia) to unguided self-help for eight weeks followed by up to eight sessions of CBT (if symptomatic), or to 16 weekly sessions of CBT (55 assigned to each treatment arm). After the initial eight weeks, patients in the sequential condition received a median number of three CBT sessions (of the 41 assessed, 16 were deemed no longer symptomatic at eight weeks and a further nine did not take up the CBT). Drop-out from treatment did not differ between the groups. A post-treatment completer analysis at 16 weeks revealed that 30% of participants in each group were symptom free. At 18-month follow-up, 40% and 41% of those in the sequential and CBT conditions respectively were free from symptoms. The results therefore suggest that initial use of a self-help manual can help to reduce the amount of therapist involvement in treatment, while at the same time producing results similar to that of full CBT. Perhaps not surprisingly, compliance with the self-help manual was found to predict outcome (Troop *et al*, 1996) in that 40% of 'high' compliers achieved full remission after eight weeks compared to 5% of 'low' compliers. However, only 57% of the participants reported reading more than half the manual. Patients with greater levels of concern about weight and shape were less

likely to use the manual, while those who had had their illness for longer were more likely to do so.

The effectiveness of 'guided self-change', in the form of the self-help manual combined with eight fortnightly sessions of CBT, has also been compared with that of standard 16-session CBT (Thiels *et al*, 1998). Thirty-one patients (DSM-III-R), whose eating disorder symptoms were assessed by means of a standardised clinical interview and self-report measures, were allocated to each condition. Drop-out was higher, but not significantly so, from the guided self-change condition (29.0% versus 12.9%) over the course of treatment. Post-treatment, an intention-to-treat analysis revealed abstinence rates from bingeing and vomiting of 54.8% and 12.9% in the CBT and guided self-change participants respectively. Improvements were also seen in both groups in terms of depression and self-esteem. Analysis of a follow-up assessment conducted an average of 43 weeks (range 13-123) after the end of treatment, and involving 77% of the sample, revealed abstinence rates of 71% (bingeing and vomiting) and 70% (bingeing) and 61% (vomiting) in the CBT and self-change groups respectively. Sixty-one percent of the self-change group had stopped both bingeing and vomiting. The authors concluded that, in the longer term, guided self-care may be as effective as standard CBT and argued that improvements seen over the follow-up period were not the result of additional treatment received during this time. However, while the findings appear very encouraging, caution must be exercised in extrapolating from the high abstinence rates seen in this study as they are based only on the week prior to assessment, and not on the previous month as in many outcome studies.

The relative efficacy of a self-help manual (unguided use) and fluoxetine was investigated in a recently reported trial by Mitchell *et al* (2001), in which 91 women received a placebo, fluoxetine, or a combination of self-help manual and fluoxetine or placebo over a 16-week period. A post-treatment completer analysis found abstinence rates from bingeing and vomiting of 16% in participants who received fluoxetine, and of 24% and 26% in those who received the manual/placebo and manual/fluoxetine combinations respectively. The authors concluded that patients receiving pharmacotherapy for BN may benefit from using a self-help manual in addition to their medication.

2.3.2.4 Studies involving the use of self-help manuals by patients with Binge Eating Disorder

Additional evidence to support the use of a self-help intervention based on cognitive behaviour principles in the treatment of individuals who binge-eat comes from the findings of recent studies involving participants with either BED or a range of bulimic-type illnesses treated with self-help manuals. For example, a feasibility study of telephone support (from a non-specialist) for BED sufferers using a self-help manual over a two-month period reported improvements in eating and general psychiatric symptoms (Wells *et al*, 1997). Participants assigned to receive pure self-help or guided self-help (6-8 support sessions with a non-specialist) in a 12-week effectiveness trial were found to fare significantly better in terms of ceasing binge-eating at the end of treatment (43% and 50% respectively) than those assigned to a waiting list control condition (8%) (Carter and Fairburn, 1998). Furthermore, Loeb *et al* (2000) found guided self-help (six, 30-minute, support sessions with a clinically trained study therapist, over a 10-week period) to be superior to unguided self-help with regard to binge frequency, and associated symptomology and attitudes, in a study of 40 women, 82.5% of whom had BED. While participants in BED trials have generally tended to be recruited through media advertisements, a study by Palmer *et al* (2002) involved 121 patients referred to specialist services (59% BN; 23% BED; and 18% an Eating Disorder not Otherwise Specified) who were randomised to one of three self-help interventions (minimal; telephone supported (4 calls); and face-to-face (4 sessions)) or to a waiting list control group. Telephone and face-to-face support was provided by nurse specialists. At four months, an intention-to-treat analysis revealed at least some improvement (25%-75% reduction in key symptoms) in 36% and 50% of those in the telephone and face-to-face groups respectively, compared to 25% and 19% of those in the minimal guidance and waiting list control group respectively. Face-to-face guidance was significantly better than the other forms of intervention. While full remission rates were low in each of the three self-help groups and non-existent in the waiting list group, the majority of those who achieved remission maintained it at 12 months without further treatment. Palmer *et al* (2002) concluded that the results provide evidence for the effectiveness of self-help with face-to-face guidance and suggest that telephone guidance may be promising. The authors also suggested that support could be provided by non-

specialists and that primary care may be the optimal setting for the provision of self-help interventions. Collectively, the findings of these studies support the suggestion that the self-help approach to treating binge-eating is a valid one and that individuals who are not specialists in eating disorders can support patients with eating disorders using self-help manuals.

2.3.2.5 Conclusions

Studies focusing on the self-help approach to BN suffer from many of the methodological problems pertaining to trials of full CBT. Follow-up periods have generally been short, intention-to-treat analyses have not been widely undertaken, levels of compliance with manuals have been unreported, and a broad range of assessment tools have been employed, making comparison across studies difficult. Small samples have also been employed. Nonetheless, the evidence accumulating from studies involving either BN or BED sufferers does suggest that the self-help approach is a feasible one in practical terms, and that it appears to benefit at least some patients who binge-eat. Both open and controlled studies have reported significant reductions in frequencies of bingeing and purging in trial participants using self-help manuals, as well as abstinence rates from these behaviours ranging from 10% to over 30% post-treatment. Improvements are also seen in general psychiatric symptoms. While too few studies have been conducted as yet to draw any firm conclusions regarding the effectiveness of self-help (or self-help combined with a reduced number of CBT sessions) compared to full CBT, the early indications are that comparable rates of success may be achieved. Studies following patients beyond the intervention period report that improvements seen post-treatment are maintained over time. Both unguided and guided forms of self-help appear to have merit. However, it has appears that patients may benefit from being supported in their use of self-help manuals and that they value such support. Furthermore, the evidence suggests that non-specialists can provide the type of support required. Finally, there also appears to be general agreement among the researchers who have undertaken the self-help trials to date that the approach could potentially be utilised as a first-line treatment in non-specialist settings.

2.4 SELF-HELP INTERVENTIONS FOR OTHER COMMON MENTAL HEALTH PROBLEMS

Evaluations of the impact of self-help interventions have not been confined to studies involving patients suffering from BN and BED. Indeed there is a long tradition of the use of brief interventions or self-help in psychiatry. The latter has been used as a treatment or component of treatment for common mental health problems such as depression, panic disorder, generalised anxiety disorder, and obsessive compulsive disorder, as well as eating disorders (Lewis *et al*, 2003). Marks (2002), for example, notes that in anxiety disorders, the emphasis has shifted towards self-exposure and away from therapist-accompanied exposure. He reports that self-exposure is effective for anxiety disorders when guided by a therapist face-to-face or on the phone, or by postal manual. Self-help treatment by manual has also helped people suffering from chronic fatigue (Marks, 2002).

A recent search of the literature on self-help for common mental health and psychiatric conditions by Lewis *et al* (2003) revealed some 1159 studies on the issue, including RCTs, observational studies and qualitative research. The purpose of Lewis *et al*'s study was to systematically identify and review information on self-help interventions for mental health problems; describe and classify English-language self-help interventions for such problems; and review the literature on the evaluation of self-help interventions in relation to outcomes on clinical symptoms, costs, quality of life and acceptability to users. Lewis *et al* report (2003) that in spite of the number of studies identified many of them were limited or poorly conducted. They found that most self-help interventions are delivered in written format, that is, books and workbooks, and that the better quality evidence concerning self-help books comes from studies where the interventions included in these books are based on CBT approaches. While they reported increasing interest in the use of computer administered CBT orientated self-help packages, Lewis *et al* reported that the evidence in their favour was not sufficient to recommend their widespread usage. Most of the studies included in their review reported a significant benefit from CBT-based self-help interventions for depression, anxiety, BN and BED. However, the authors concluded that self-help interventions should probably be advocated only when based on evaluated methods (e.g., CBT), used under the supervision of a health professional, and in situations where there is access to alternative therapeutic

interventions should the self-help package prove to be ineffective or unacceptable. They also recommended that further research be undertaken on self-help interventions, given the increasing scope to use such interventions as a means of empowering patients, providing more accessible interventions and employing professionals' time more efficiently in both primary care and specialist settings.

2.5 PREDICTORS OF OUTCOME

The study of predictors of treatment outcome is important in that it can potentially indicate not only who is likely to benefit from treatment generally but also, more specifically, who will benefit from which type of treatment. Such information could both reduce the cost of treatment and lead to improvements in the types of treatments being offered (Agras *et al*, 2000 b). The empirical investigation of time course of change during treatment also has theoretical and practical value (Wilson *et al*, 1999). To date, however, reliable predictors of response to treatment with anti-depressant medication or CBT have not been identified (e.g., Wilson and Fairburn, 1998) and prognostic factors remain “poorly understood ” (Keel and Mitchell, 1997, p. 320). Contradictory findings regarding predictors of outcome and attrition in studies of BN may be the result of differing methodologies, populations, modes of delivery of therapy, assessment methods and definitions of success, as well as of studies having insufficient power to accurately identify predictors of outcome (Agras *et al*, 2000 b).

In a paper summarising much of the research in this area, Keel and Mitchell (1997) reviewed outcome and predictors of outcome in 60 of 88 identified studies that followed up women with BN for between 6 months and 10 years following presentation (56 cohorts consisting of 2,198 individuals). Only studies not confounded by the inclusion of patients with other types of eating disorders were included in the review. To examine remission rates, the authors divided studies into follow-up (both naturalistic and selected samples) and treatment outcome studies. Estimates of remission were calculated separately for both types, and as a percentage of the numbers of patients assessed at follow-up rather than at baseline. While patients in treatment studies initially had significantly higher rates of remission and lower rates of full BN at follow-up, the differences were not pronounced in those studies which had a five year or longer follow-up. The findings suggested that by five

to ten years following presentation approximately 50% of the patients have recovered fully while 20% still meet the criteria for full BN. However, as ascertainment rates were often quite low at follow-up, this picture may be a distorted one (Keel and Mitchell, 1997). Findings from both types of study were combined when assessing mortality, relapse, crossover to other eating disorders and prognostic factors, because of limited numbers. A crude mortality rate of 0.3% due to all causes of death in individuals with BN is, according to the review authors, likely to be an underestimation resulting from low follow-up ascertainment rates and short follow-up periods. Studies focusing on relapse suggested that approximately one-third of those who improve will subsequently relapse. Reported rates of crossover to another eating disorder were generally lower than seven percent.

In terms of prognostic indicators, Keel and Mitchell noted that many of the studies lacked the power to identify significant indicators, and that negative indicators may be associated with attrition. Their findings suggest that the presence of co-morbid Axis I disorders (including clinical depression, or a history of alcohol/substance abuse) at presentation is not predictive of outcome. However, only a few studies were involved, and as treatment studies tend to exclude patients with co-morbid disorders, this may confound any study of predictors. Although acknowledging contradictory findings, Keel and Mitchell suggested that personality traits such as impulsivity may be indicative of a poorer outcome. However they cautioned that overlaps between Axis II disorders, depression and substance abuse should be considered a possible explanation for contradictory results. A history of AN was not found to be predictive of outcome, and findings concerning age at onset or presentation revealed no clear pattern of association with outcome. There were also mixed results in terms of severity and duration of symptoms as predictors of outcome. More studies found severity to be unrelated to outcome, while slightly more found greater duration to be predictive of negative outcome than found it to be insignificant. Bulimic cognitions or attitudes were not studied as predictors of outcome, but this may be due to a paucity of studies assessing these features. Based on the studies reviewed, Keel and Mitchell suggested that treatment interventions may speed the recovery of women who would eventually recover in 5 to 10 years in any case.

Wilson *et al* (1999), in an extension of the Walsh *et al* (1997) study described earlier, investigated not only predictive factors, but also therapeutic alliance and the time course of change throughout treatment. They found that the higher the perceived relevance of the patient's assigned treatment at the first session the more likely she was to remain in the study. Therapy assignment was found to be the only predictor of remission: CBT increased the likelihood of remission occurring. High baseline frequencies of bingeing and vomiting, and a positive history of substance abuse/dependence were found to be negative predictors of outcome. Greater perceived therapeutic alliance was found to increase the likelihood of remission across the whole sample. However, the authors suggested that symptom change during treatment may have as much impact on ratings of alliance as the opposite. Survival analyses, employed to evaluate the time course of action of the different therapeutic approaches in terms of reductions in binge-eating and vomiting frequencies, revealed that CBT had a significantly faster impact than SPT, and that the more depressed the patient was at baseline, the quicker the effects of CBT were on vomiting frequency, compared to SPT. The findings did not reveal any treatment specific predictors that might shed light on the issue of patient-treatment matching. Limitations of the study include the fact that Axis II diagnoses were not included and outcome was measured at end of treatment. Wilson *et al* concluded that further research and larger studies are required to investigate the question of when to decide that individual patients will not respond to treatment, and to establish the characteristics of early responders.

The issue of response to treatment has also been investigated by Agras *et al* (2000 b) who used signal detection analyses to differentiate between treatment drop-outs, non-recovered and recovered patients in a study designed to determine clinically meaningful cut-off points that would be predictive of attrition and abstinence. The study involved 194 women treated with CBT. Those who dropped out were found to have higher levels of bulimic cognitions, greater impulsivity, and greater concerns about weight and shape than those who completed treatment. However, it was not possible to delineate any clinically useful predictors of drop-out. When the recovered patients were compared with the non-recovered patients (minus those who had dropped out), the latter were found to be more likely to have a low BMI, poor social adjustment and to have reported current depression. Signal detection analyses

revealed that those who had reduced their purging by less than 70% by session six of treatment were more likely to be treatment non-responders. The authors concluded that a cut-off point based on a reduction in purging will usefully differentiate potential treatment responders from non-responders, and that early progress in therapy may be the best predictor of outcome. Early progress in CBT treatment (in the form of reduced dietary restraint) has also been reported by Wilson *et al* (2002) to mediate post-treatment improvement in terms of bingeing and vomiting behaviours.

Predictors of outcome have not been widely investigated in trials of self-help for BN. Cooper *et al*, based on an analysis of data from all 82 women recruited to their 1996 trial, found that those who fared less well were more than twice as likely to have had a previous diagnosis of AN, and slightly more had an Axis II diagnosis. As noted earlier, compliance with the self-help manual has also been found to be predictive of outcome (Troop *et al*, 1996).

In summary, the study of predictors of outcome in BN has not yet yielded conclusive results, partly because of a paucity of long-term follow-up studies. The indications are that personality characteristics such as impulsivity may be indicative of a poorer outcome and that treatment interventions may speed up eventual recovery. It has also been suggested that patients' perceptions of the saliency to them of the particular treatment they are receiving and early improvements during a course of CBT are possible positive indicators of outcome. At present, however, it is not possible to predict who is most likely to benefit from self-help interventions for BN.

2.6 INTERVENTIONS FOR MENTAL HEALTH PROBLEMS IN GENERAL PRACTICE

The evidence reviewed thus far in the present chapter suggests that not only is full therapist-led CBT an effective treatment for BN, but that self-help manuals based on CBT principles can also be an effective approach to treatment for at least some patients with BN. To date, however, studies of the use of self-help manuals have taken place in specialist settings. The question then is, can the self-help approach be transferred to the general practice setting, and what evidence is there to suggest that GPs might be an appropriate professional to support patients using manuals?

It is estimated that 98% of people in the UK are registered with a GP (Fuhrer, 1992) and that approximately 70% visit their GP in a given year (Goldberg, 1991). Goldberg and Lecrubier (1995), in a 14-country study, found that 24% of general practice attenders met ICD-10 criteria for a current mental disorder, while another 9% had a sub-threshold disorder. The Department of Health (1999) has reported that at any given time, approximately one in six individuals of working age will be suffering from a mental health problem. Murray and Jones (1998) report that up to 40% of general practice attenders may be suffering from mental health problems. The majority of these are not in contact with specialist services; indeed it is estimated that for every 100 people who consult their GP with a mental health problem, only nine will be referred to specialist services (Department of Health, 1999). There is therefore great scope for intervention in general practice. Depression, eating disorders and anxiety disorders are the most common mental health problems (Department of Health, 1999).

Standard Two of the *Modern Standards and Service Models National Service Frameworks: Mental Health* (Department of Health, 1999) states that

“ Any service user who contacts their primary health care team with a common mental health problem should:

- have their mental health needs identified and assessed
- be offered effective treatments, including referral to specialist services for further assessment, treatment and care if they require it (p. 28).”

The past decade has seen a proliferation of trials of interventions in general practice for problems that have traditionally been the remit of specialist mental health professionals. These studies have generally focused on the impact of ‘brief’ interventions by GPs, the use of assisted bibliotherapy in the primary care setting, and the comparison of general practice care with specialist care. Many have taken the form of randomised controlled trials.

Empirical research has shown that GPs can successfully implement brief interventions designed to prevent the development of potential mental health or

addiction-related problems in their patients. Controlled studies conducted with 'at risk' drinkers in general practice, for example, have found that brief advice from GPs (with accompanying information, drinking diaries or self-help booklets) can result in significant reductions in consumption and /or in the proportion of patients 'at risk' over a 12-month period (Wallace *et al*, 1988; Anderson and Scott, 1992). Existing evidence suggests that brief interventions conducted by GPs can also have a beneficial effect on patients with already established problems. Bashir *et al* (1994) found that a significantly greater reduction in benzodiazepine prescribing was recorded for chronic users who received GP advice and a self-help booklet compared with patients who received routine care. GP support and the self-help booklet were perceived as helpful by 81% and 65% respectively of those who reduced their intake. The intervention did not result in psychological distress or increased consultation rates among patients.

Assisted bibliotherapy similar to the guided self-help for BN and BED reported earlier has also been used successfully in the general practice setting to treat patients with mental health problems. For example, general practice attenders suffering from mild-moderate anxiety who were randomised to receive bibliotherapy (a booklet based on cognitive behaviour principles) and one of three levels of support over a six-week period (telephone contact, or fortnightly or weekly meetings with a nurse) experienced clinically significant improvements (Kupshik and Fletcher, 1999). Greater contact increased the proportion of patients who showed a significant improvement in symptoms. Improvements were sustained at three-month follow-up and the approach was seen as acceptable by patients (Kupshik and Fletcher, 1999).

Finally, evidence emerging in the past decade or so suggests that GPs may be no less effective in managing patients with mental health or addiction-related problems than mental health professionals. In a study designed to examine the effectiveness of general practice treatment for individuals with established drinking problems, Drummond *et al* (1990) randomly allocated problem drinkers to receive either GP or specialist clinic care. Six months later both groups displayed significant reductions in alcohol consumption and alcohol-related problems and did not differ significantly from one another on these outcome measures. More recently, Friedli *et al* (1997) randomly assigned general practice attenders with emotional difficulties, mainly

depression, to receive either general practice based psychotherapy from a trained counsellor or routine GP care over a 12-week period. They found that while both groups improved significantly over time, there was no difference in outcome between them at three- or nine-month follow-up.

Taken together, the findings of the studies reported here and of others like them demonstrate not only that the general practice setting is an appropriate one in which to manage a range of mental health concerns, but also that GPs and other primary care professionals employing non-intensive interventions or routine care strategies many have a beneficial impact on patients' potential or established mental health problems. Furthermore, patients appear to find such interventions by their GPs both acceptable and helpful. The evidence therefore suggests that it is timely to investigate the potential for managing patients with BN in the general practice setting.

2.7 THE DIAGNOSIS AND MANAGEMENT OF BULIMIA NERVOSA IN GENERAL PRACTICE

GPs are the source of the majority of referrals to specialist eating disorder services in the UK. While there has been some epidemiologically based work looking at the prevalence of eating disorders in general practice (e.g., King, 1989), few studies have looked at the detection, diagnosis and management of patients with eating disorders by primary care professionals.

It has been suggested that patients with eating disorders attend general practice with greater frequency than controls. In a retrospective case note study of 100 consecutive patients referred to the Southern General Hospital, Glasgow, for eating disorders, Ogg *et al* (1997) found that in the five years prior to referral, patients consulted their GPs significantly more frequently than did controls matched for age, sex, social class and marital status. Seventy-one percent of the eating disordered patients consulted more than four times during the five years prior to referral while only 18% of the controls consulted with this frequency.

Existing evidence also suggests that GPs fail to detect eating disorders in their patients and that there may be quite a high level of hidden eating pathology in general

practice attenders. Whitehouse *et al* (1992) found that only half of the eight cases of BN identified in their epidemiological study conducted in Cambridge were known to the patients' GPs while a further two patients had been referred to specialists for treatment of secondary features of the disorder. Of 29 patients suffering from a partial form of the disorder only seven had discussed their eating problems with their GP. The authors do not explicitly report findings of patient note searches. King (1989) identified six cases of full BN as well as cases of sub-clinical BN in his study of general practice attenders in London, none of whom had been identified by GPs, although one patient had been referred to a gynaecologist for investigation of amenorrhoea. In the Ogg *et al* (1997) study reported above, hospital case notes revealed that prior to diagnosis and referral to the Southern General Hospital 18 patients had been referred to gynaecologists, 15 to internal medicine specialists, four to surgeons and 17 to other psychologists or psychiatrists. This suggests that even if health problems associated with eating disorders are detected by GPs, inappropriate referrals may follow. As noted in the previous chapter, Turnbull *et al* (1996), using the General Practice Research Database in the UK, found a three-fold increase between 1988 and 1993 in the recording of cases of BN by GPs. A questionnaire sent to GPs for a random sample of 25 cases achieved a 100% response rate. Data obtained indicated that 60% of detected cases were referred to psychiatric services for specialist care. The study findings also indicated that patients had generally suffered from eating problems for several years before the problem was detected by their GPs, and that over a quarter of the cases had been prescribed laxatives or diuretics by their GPs at some point. The authors concluded that there is a need for GPs to know more about BN, and for more effective management of the disorder in general practice.

Only one study to date has investigated the management of BN patients in the general practice setting: this was an open pilot study conducted by Waller and colleagues (1996) in two general practices in Oxfordshire. Waller *et al* designed an abbreviated and simplified version of manual-based CBT (no more than eight weekly 20-minute sessions) which was administered by four GPs and a practice nurse (who received two three-hour training sessions, the step-by-step manual, monitoring and information sheets). Eleven consecutive female patients who presented with DSM-IV BN at the practices participated. The results indicated that six patients (55%) improved considerably, in terms of the frequency of reported bingeing and vomiting,

decreased severity of concerns about weight and shape, and improved mood. The remaining five did not benefit (two of these had major coexistent psychiatric problems). Follow-up assessments appear to have been conducted at one and three months although this is not entirely clear from the article. The authors concluded that CBT can be simplified for use in primary care and that it may benefit a significant percentage of cases seen in this setting. They also suggested that there might be a better way of delivering brief CBT, such as through the use of self-help manuals.

2.8 CONCLUSIONS

The empirical research reviewed in this chapter suggests that CBT in its full form is generally more effective than other forms of psychotherapy for BN, at least in the short-term. It is also more effective than anti-depressant medication. However, CBT is expensive and not widely available, and the imperative in the past decade has been to develop less intensive and more accessible forms of treatment. Studies of the use of self-help manuals suggest that the self-help approach may be effective for at least some individuals suffering from BN, and that guided self-help may be even more beneficial than unsupported self-help. At present, however, there is little reliable evidence to suggest who will benefit most from CBT, and even less to indicate the types of BN patients likely to improve using a self-help manual.

To date studies of the self-help approach to treatment for BN have taken place in specialist settings. However, it has been suggested that this approach might be applicable to, and should be studied in, the general practice setting. Studies employing non-specialists to support patients using manuals have had positive outcomes. Research findings have also indicated that GPs can effectively employ non-intensive interventions in general practice that benefit patients with a variety of mental health problems. As yet, however, no research has been undertaken to evaluate the effectiveness of a general practice based self-help approach to the treatment of BN compared to that of specialist treatment. The objective of the present study is to fill this gap. The next chapter focuses on randomised controlled trials and on the pragmatic trial methodology employed in studies seeking to evaluate the effectiveness of therapeutic interventions in routine clinical settings such as the general practice setting.

CHAPTER THREE:

RANDOMISED CONTROLLED TRIALS: THEORY AND PRACTICE

3.1 INTRODUCTION

Limited funds available for healthcare compel those who finance health services to pay close attention to outcome and value for money (St. Leger *et al*, 1992). Consequently, clinicians are under increasing pressure to ensure that they provide services that have a firm evidence-base. Randomised controlled trials (RCTs) have been advocated as the ‘gold standard’, or at least as ‘more golden’ than other research designs (Hotopf *et al* 1999), for evaluating or comparing different treatments or interventions. Unlike other research designs, RCTs allow for the inference of cause and effect. They are therefore preferable to observational studies, for example, when definitive answers about therapeutic effectiveness are required (Fahey, 1995). The relatively tiny cost of running RCTs may serve to reduce wastage in financial and clinical resources if effective treatments are established. For ethical and clinical reasons, RCTs should only be undertaken where is equipoise, or genuine doubt, about whether one intervention or course of action is better than another (e.g., Muir Grey, 1997). It is argued that to maximise their value to clinicians, RCTs should be applied to important, real-life clinical questions, and carried out, whenever feasible, under usual service conditions (Hotopf *et al*, 1999).

Originally, RCTs were developed in agriculture to study different treatments of soils or plants, with the methodology being adopted by medical researchers in the 1940s (Altman, 1996 a). Today they are employed to study issues ranging from the efficacy of new drugs to the effectiveness of entire services. In recent decades, and as evidenced by the studies reviewed in the previous chapter, RCTs have been increasingly employed in psychiatry to evaluate the impact of psychotherapies and/or psychotropic medications on mental health problems. Concerns about deficiencies in the ways that trials were being reported in the literature led to the publication of the CONSORT statement by Begg *et al* in the *Journal of the American Medical Association* in 1996. This statement listed 21 items that should be mentioned (e.g., regarding random allocation and blinding) as well

as a flowchart describing how participants have progressed through a trial. The statement was adopted by the *British Medical Journal* (Altman, 1996 b) and most other leading medical journals around the world. As a consequence, recent reports of trials of psychotherapies for BN are more detailed than earlier ones.

The purpose of this chapter is not to provide a comprehensive review of the theory and methods of RCTs, but rather to highlight issues pertinent to the current study. Thus, the concept of efficacy and effectiveness trials will be considered, and some of the features of RCTs employed to control threats to internal and external validity will be briefly outlined. The chapter will also include brief sections on sample size calculation, the ethics of RCTs, economic analyses and trials, conducting RCTs in primary care, and the use of multiple data collection methods to supplement the findings of RCTs. Finally, the rationale for employing a pragmatic RCT design in the current study will be considered.

3.2 EFFICACY AND EFFECTIVENESS TRIALS

Internal validity is the “basic minimum without which any experiment is uninterpretable” (Campbell and Stanley, p. 5, 1966). It is concerned with the question of whether the experimental intervention or manipulation made the difference in a given experimental trial. External validity concerns the potential generalisability of the trial findings. While both factors are obviously very important, the maximisation of one may jeopardise the other (Campbell and Stanley, 1966). The internal validity of a study is said to be more important than its generalisability, as it is always inappropriate to extrapolate from the findings of an invalid study (Mant *et al*, 1995). However, if clinical practice is to benefit, then empirical findings must be applicable and generalisable to the clinical setting. As noted in the previous chapter, one of the criticisms of RCTs of psychotherapies for BN has been that they do not evaluate therapies as they are practised in reality, but rather under ideal conditions involving specially trained therapists and highly selected patients who may not be typical of those seen in everyday practice (e.g., Mitchell *et al*, 1996). As a result, clinicians have been sceptical about the relevance of trial findings to their practices and patients (e.g., Wilson, 1998, 1999). There is therefore a need to study the applicability to routine circumstances of therapies found to be efficacious under optimum conditions.

A distinction is increasingly being drawn between efficacy (explanatory) and effectiveness (pragmatic) trials (Wilson, 1998). Efficacy trials are designed to establish the causal effects of specific treatments under controlled conditions, and the emphasis is on establishing internal validity by eliminating other alternative explanations for the results. In effectiveness, or pragmatic, trials, the emphasis is more on external validity and on establishing the effects of treatments under more routine conditions (Wilson, 1998). This is not to suggest that pragmatic trials are less methodologically rigorous or less concerned with internal validity than explanatory trials or that the results of the latter cannot be generalised to clinical settings. It is simply that the emphasis in efficacy/explanatory and effectiveness/pragmatic trials is slightly different. As Torgerson *et al* (1996, p. 194) note, "... a pragmatic trial seeks information not on the basic therapeutic efficacy of an intervention, but on its practical effectiveness, which combines efficacy and other effects" Pragmatic trials are designed to address *clinically relevant* questions, tend to be less controlled in terms of the exclusion criteria employed and involve the use of an intention-to-treat approach to data analysis. They should ideally involve the comparison of new treatments with existing ones which represent good practice and include clinically relevant, easy to measure outcomes (Hotopf *et al*, 1999). Where possible there should be one major criterion of success (Newell, 1992). In addition, study interventions and populations should be clearly defined if trials are to provide a sound basis for clinical decision-making (Britton *et al*, 1998). Furthermore, the less complex the treatments involved, the more generalisable the findings will be to practitioners in general (Wilson, 1998).

Efficacy studies generally precede those concerned with effectiveness. For example, while earlier trials were generally designed to establish the therapeutic efficacy of CBT for BN, recent trials have tended to be slightly more pragmatic in nature, particularly in terms of the approach taken to data analysis. Having established the efficacy of the self-help approach to treating BN in the specialist setting, the researchers involved (e.g., Schmidt *et al*, 1993; Cooper *et al*, 1996) have advocated that it should now be evaluated in non-specialist settings in order to test its applicability to, and effectiveness in, such settings.

3.3 CONTROLLING FOR BIAS AND THREATS TO INTERNAL AND EXTERNAL VALIDITY

3.3.1 Design features, advantages and threats

RCTs are prospective experiments designed to compare two or more forms of treatment. The key idea is to compare two groups of participants who differ only in respect of the treatment they receive (Altman, 1996 a). All known and unknown confounders between treatment and outcome will be balanced between the randomised arms. The main features of the RCT, as a 'true' experiment, include the fact that the researcher has control over the manipulation of the experimental variable (the interventions or treatments), that participants are randomly allocated to intervention, and that pre- and post-intervention testing of participants is undertaken using appropriate assessment tools in order to measure the effects of the interventions (Bowling, 1997). The fundamental advantage of the RCT over other designs (e.g., observational methods) used in healthcare research is that, in principle, it can yield causal results. RCTs are therefore seen by many as the choice of method for comparing the effectiveness of different healthcare interventions. However, there are situations where RCTs may be neither feasible nor appropriate. For example, they may be inappropriate for assessing rare outcomes (e.g., suicide) where the sample sizes required would be prohibitive; for assessing long-term outcomes; or where there are medical, political or legal objections to randomisation (Black, 1996, cited by Hotopf *et al*, 1999).

A variety of factors, if not controlled for, can threaten the internal and external validity of trials. These include selection and participation biases, imbalance in known and unknown extraneous confounders (such as participants' demographic or disease characteristics), time-related threats such as history and maturation, lack of blinding and observer biases, and participant attrition. The following sub-sections (3.3.1.1 to 3.3.1.5) consider threats to validity and the methods used in trials to address them.

3.3.1.1 Randomisation

A criticism of non-randomised treatment studies is that the groups being compared may differ on characteristics that are of prognostic importance (Britton *et al*, 1998). This is particularly important where large numbers of factors, a good many of which may be

unknown, could contribute to outcome, thereby confounding the effects of the treatments being evaluated and reducing the internal validity of the study. The purposes of randomisation are to control for selection biases and confounding by known or unknown extraneous variables (Hotopf *et al*, 1999).

Selection biases occur when allocation to treatment is influenced by factors that might affect outcome (Mant *et al*, 1995). For example, a clinician might allocate all of the older patients to one study treatment and all of the younger ones to the other, and age might have an important effect on outcome (e.g., in a physiotherapy trial). Randomisation eliminates the potential for this type of allocation bias. In addition, researchers are often unaware of important confounders, or such confounders may be impossible to measure (Hotopf *et al*, 1999). In RCTs these unpredicted or unmeasurable confounders are randomly allocated between groups, thereby ensuring that “variation among participants which might affect their response to treatment will on average be the same in the different treatment groups” (Altman, 1996 a p.88). This is a power unique to RCTs. Bowling (1997) notes that randomisation controls not only for group-related threats, but also for time-related ones (e.g., those related to history and maturation).

Various randomisation techniques can be used to allocate individuals to the different arms of a trial, varying from simple randomisation (e.g., the toss of a coin) to more restricted procedures (e.g., minimisation). Key prognostic variables or characteristics known to be related to outcome (e.g., disease severity) can be controlled for by using stratification procedures whereby different subgroups (e.g., mild and severe) are randomised separately (Altman, 1996 a). However, this is usually unnecessary in large trials where participants are likely to be balanced on prognostic indicators at baseline. Block designs can be used where the aim is to ensure that there will be roughly equal numbers of participants in each trial arm (Bowling, 1997). Altman (1996 a) recommends that blocking should always be used in conjunction with stratification; otherwise stratification will confer no benefit over simple randomisation. Ideally in RCTs the randomisation procedure should be kept independent from treatment allocation, with the individual conducting the initial study assessment contacting independent randomisation personnel to be given the participant’s treatment allocation.

The use of a stratified block randomisation procedure (based on scores on a standardised

measure of BN) may be advisable in a pragmatic trial designed to evaluate the effectiveness of a general practice based self-help intervention for BN compared to specialist out-patient treatment, given the heterogeneity of symptoms seen in BN patients and the mixed research findings concerning severity of BN as a possible predictor of treatment outcome.

3.3.1.2 Blinding

Biases can arise in trials as a result of the expectations of the participants, researchers, and individuals providing treatments, when they know which study intervention has been administered. For example, patients may benefit psychologically by knowing that they are receiving a new ‘wonder’ treatment, and this could affect outcome regardless of the treatment’s actual efficacy (Pocock, 1983; St. Leger *et al*, 1992). Similarly, the knowledge that the standard treatment is being administered may cause them to feel disadvantaged, thereby adversely affecting compliance and outcome. Conversely, individuals may feel reassured to receive the standard treatment, or concerned about receiving new, experimental ones (Pocock, 1983). Those providing study interventions may also respond differently to participants known to be receiving new or standard treatments (over and above any actual differences prescribed in the study protocol) and in so doing inadvertently affect study outcome. Another key concern in trials is to ensure that those assessing outcome remain objective (Pocock, 1983). Where an assessor is aware of treatment allocation and where clinical judgement is involved, then there is potential for bias regardless of how objective the assessor intends to be (Pocock, 1983). Pocock (1983) suggests that these aspects of bias will vary depending on the type of trial being conducted: for example, where the treatments being compared are quite similar and outcome is clear-cut then bias will be minimal.

‘Blinding’ is used in trials in order to control for potential biases of this nature. In a *single-blind* trial participants are unaware of which treatment is being administered. The same is also true of the individuals providing the interventions, and assessors in *double-blind* trials. *Triple-blind* trials exist when even the investigator analysing the data is unaware of which treatment was the active one (St. Leger *et al*, 1992), or where only the investigators are aware that the trial is happening.

However, blinding is generally only feasible in situations such as trials where the study

interventions can be ‘packaged’ to look identical (e.g., drugs, ECT and acupuncture). The situation is more complicated where individuals are required to be active participants in treatment, and are aware of their treatment allocation. Participant motivation and preferences for treatments are considered in Section 3.3.1.4 below. In order to try to overcome potential therapist biases where psychological therapies are being evaluated, as in the trials of psychotherapies for BN, researchers often ensure that the same clinician does not deliver more than one type of therapy. Similarly, clinicians running trials should not deliver the study therapies themselves. Potential assessor biases are sometimes addressed by employing independent investigators to conduct outcome assessments. However, participants may inadvertently reveal the nature of the treatment experienced, and research funding often does not allow for extra study personnel. An alternative approach involves the use of standardised self-report outcome measures. While they may not always assess psychopathology with the same degree of accuracy as clinician-rated interviews, self-report measures are not open to the potential of assessor biasing and they are likely to be able to detect changes in psychopathology over time (Hotopf *et al*, 1999). For this reason, and as noted in the previous chapter, trials of treatments for BN often involve the use of both self-report and interviewer-rated assessment measures. However, self-report measures may be vulnerable to patients’ expectancies in trials that are not ‘blind’.

3.3.1.3 Inclusion and exclusion criteria

The population to be included in a trial must be carefully defined, both in terms of a diagnosis for inclusion and specified exclusion criteria (Newell, 1992), in order to determine to whom its findings can be generalised. The use of specific inclusion and exclusion criteria helps to ensure that the sample being treated is relatively homogenous and that for any given patient the treatment being offered is both reasonable and appropriate (Mitchell *et al*, 1997). Broad exclusion criteria may help to increase the power and precision of the study findings and to minimise threats to internal validity (e.g., by excluding patients likely to be non-compliant or to drop out) (Britton *et al*, 1998). However, it is argued that long lists of exclusion criteria should be avoided in pragmatic trials (Hotopf *et al*, 1999). In general, participants should reflect the demographic and disease-relevant characteristics of the population from which they have been drawn (Hunninghake *et al*, 1987). Multiple exclusion criteria reduce the possibility of studying heterogeneity of treatment response and may lead to recruitment

difficulties (Hotopf *et al*, 1999), unjustified extrapolation of results, denial of effective treatment to patients who might benefit, and delays in obtaining definitive results because of inadequate study sample sizes (Britton *et al*, 1998). However it will always be necessary to exclude some patients on medical or ethical grounds. It would be inadvisable, for example, to include those who are suicidal, dependent on drugs or alcohol, or psychotic, in BN treatment trials as the primary goal of treatment should be to address these problems initially (Wilson, 1998).

Defining the population for inclusion in a treatment trial for BN may be problematic. Mitchell *et al* (1996) examined 21 BN psychotherapy studies and found that eight different sets of criteria had been used for defining the eating disorder diagnosis (i.e., in terms of frequency criteria for bingeing and with respect to purging behaviour requirements). Few included atypical cases or patients with co-morbid disorders. A further study of 41 treatment trials for BN (Mitchell *et al*, 1997) revealed that approximately half excluded patients under 18, and /or had upper age limits, weight exclusion criteria, and exclusion criteria related to alcohol problems, medication or risk of suicide. Using the example of 51 patients who spontaneously presented for treatment to their clinic, Mitchell *et al* argued that many of them would have been excluded from the trials examined. They concluded that patients who may be more difficult to treat are excluded from treatment trials, and that this may lead to an inflated view of the efficacy of specific treatments. However, as noted in the previous chapter, it has also been argued (Wilson, 1998) that the types of exclusion criteria employed in BN treatment trials do not mean that only patients free from the multiple problems seen in clinic samples are included and, furthermore, that major RCTs have included patients with characteristics known to be linked to poorer outcome. The heterogeneity among women diagnosed with BN, in terms of their eating disorder symptoms, also increases the generalisability of trial findings (Wilson, 1998).

The crucial question in evaluating how generalisable trial findings are to service settings concerns how closely the study population and interventions resemble those existing in the settings to which one wants to generalise. Discussions of the generalisability of findings from trials often fail to note the heterogeneity of the clinical settings to which the findings are being generalised (Wilson, 1998). Given that it will never be possible or advisable to generalise from RCTs to all treatment settings, researchers should attempt

to ensure that pragmatic trials include patients (and therapies and settings) who are as representative as possible of those to whom they want to generalise their individual study findings. In conducting a trial comparing the effectiveness of a GP supported self-help intervention for BN with that of routine specialist treatment, it could be argued that one needs to recruit patients identified by GPs in the general practice setting. Given the evidence highlighted in Chapter Two that GPs have difficulties detecting eating disorders and require education in their management, it is likely that in most instances identification may coincide with referral to secondary services, and that this is possibly the best time to recruit patients to a trial. Furthermore, it might be argued that exclusion criteria should be kept to a minimum in order to recruit a sample that reflects the types of patients identified and referred by GPs.

3.3.1.4 Participant recruitment, motivation and attrition

Participant recruitment, motivation, treatment preferences and attrition may all potentially impact on the conduct, internal and external validity, and outcome of trials.

A review of recruitment in clinical trials (Hunninghake *et al*, 1987) suggested that recruitment is generally more difficult than anticipated. Most of the studies reviewed reported extending their recruitment time period, changing their entry criteria, using additional recruitment strategies, or in extreme cases terminating the study. Consequences of recruitment delays or failures include increased financial costs, extended duration of trials, potential reductions in study power, difficulties in predicting how changes to recruitment procedures will impact on study outcome, and adverse effects on participants and study staff (Hunninghake *et al*, 1987). Reasons for accrual problems include the lack of published information regarding recruitment for different disorders and population groups, and misconceptions about recruitment. Unwillingness to participate and exclusion criteria, for example, may reduce the actual recruited population to 10% of that originally expected (Hunninghake *et al*, 1987). In the 1980s only 2% of eligible breast cancer patients were entering treatment trials (Britton *et al*, 1998). Mitchell *et al* (1996) suggest that, although estimates vary widely, the number of individuals suffering from BN who will eventually enter a study is generally less than half of those who initially contact trial organisers. Other factors that may impact on recruitment rates include the sources from which participants are being recruited, and the attitudes of clinicians and patients to trials (see also Section 3.8 below).

Participation biases may occur when eligible service providers or patients who take part in trials differ from those who refuse to do so (Britton *et al*, 1998). Some commentators argue that differences will generally be found between research participants and non-participants (Britton *et al*, 1998). However, little is known about the characteristics of people who do or do not take part in trials (Mitchell *et al*, 1996; Britton *et al*, 1998). For example, it is unclear whether individuals who are willing to undergo the assessments and screening involved in RCTs are more motivated and compliant than those who are not (Wilson, 1998). It is not always possible to collect data on people who refuse to participate in trials, but in order to address questions concerning the generalisability of one's findings it may be advisable to collect pertinent socio-demographic or clinical status data, where feasible, for comparison purposes.

The nature of the therapy on offer may also affect recruitment. Patients may self-select for a treatment trial of a therapy they would prefer or refuse randomisation where they have strong preferences for one of the trial therapies. Recent years have seen a growing interest in the notion of patient preferences in trials. In normal clinical practice treatment depends to a large extent on patient motivation and compliance. In RCTs, however, participants are assigned to treatments irrespective of their preferences or ability to comply with the treatment regimen. The possibility therefore exists that allocation to a preferred treatment will enhance its therapeutic effect while allocation to a non-preferred one may dilute it (e.g., Torgeson and Sibbald, 1998), particularly where 'blinding' is not possible (McPherson *et al*, 1997). The attributable therapeutic effects of preferences are currently poorly understood (McPherson *et al*, 1997; Britton *et al*, 1998). Patient-preference trials (Brewin and Bradley, 1989), in which participants who have a strong preference receive their preferred treatment while those who do not are randomly allocated to treatment and outcome is assessed on the basis of allocation method, have been used to investigate the impact of preferences. However these trials have limitations (Torgeson and Sibbald, 1998; Hotopf *et al*, 1999). Comparisons involving the patient preference arms may be unreliable due to unknown confounders. They involve an assumption that patients seen in clinical settings are offered a choice of treatments, and recruitment to the randomised arms of these trials may be slower, making them more expensive. As noted in the previous chapter, patient preference trials have not been reported in the eating disorders research literature to date, and whether preferences have

been assessed is not reported either. Some studies have assessed participants' perceptions of the suitability and expected effectiveness of, or satisfaction with, their allocated treatment (e.g., Agras *et al*, 2000 a). It has been suggested that treatment preferences should be measured even in fully randomised trials to allow for the assessment of possible interactions between preferences and outcome at the analysis stage and to improve the external validity of studies (e.g., Torgerson *et al*, 1996; Torgerson and Sibbald, 1998).

Patients dropping out of a trial and being unavailable for follow-up assessments can affect its internal and external validity. There is also the possibility that patients will drop out of treatment but complete follow-up assessments. Such events are almost inevitable in research. Attrition from trials may occur for a variety of clinical, social or practical reasons. For example, if the assessment burden in trials is high, it may encourage drop out (Mitchell *et al*, 1996). Difficulties in conducting follow-up assessments in BN studies may include the fact that patients are often young, mobile, and do not have permanent addresses. Agras *et al* (2000 b) cited an average drop-out figure of 20% (range: 0%-35%) of participants in trials of CBT for BN, while Thiels *et al* (1998) reported that 22.6% of the initial study group in their guided self-change study were not assessed at follow-up. In the 21 studies reviewed by Mitchell *et al* (1996), only nine conducted follow-up assessments beyond the end of the treatment intervention. Long-term follow-up is often omitted for practical or financial reasons. Follow-ups can be expensive and time consuming; monitoring patients intensively may alter their behaviours; and follow-up assessments tend to be cross-sectional, brief and limited in scope (Mitchell *et al*, 1996). However, they are essential if the longer-term impacts of therapy are to be established. For those designing trials, the difficulty lies in balancing an appropriately long follow-up period and the number and nature of assessments required, with anticipated difficulties in following up specific study populations. Additionally, there may be some uncertainty in follow-up beyond treatment, when essentially the trial is no longer controlled.

3.3.1.5 Explanatory and pragmatic approaches to data analysis

As noted above, some patients will almost invariably drop out of treatment trials, or they will fail to comply with the treatment regimens being evaluated, with subsequent consequences for the internal and external validity of trials. In analysing trial data a

decision has to be made about whether to include only data from those who have completed the trial according to its protocol, or from everybody who was originally randomised to take part in the trial. If one wants to know whether or not a treatment works (efficacy trials), then only data from those who have actually received and complied with it should be included; a strategy that Pocock (1983) refers to as the ‘explanatory approach’ to data analysis. As reported in the previous chapter, many of the trials of treatments for BN have used this approach.

However, analyses based on completers or compliers are known to produce results which maximise differences between treatments (e.g., Hotopf *et al*, 1999). Furthermore they are based on data from groups which are no longer the original, randomised ones and therefore arguably no longer comparable. As a result, such analyses may be confounded by a variety of unknown factors. In addition, defining completers in control groups (e.g., when the control group is receiving routine care) or in experimental groups (where the new treatment is not defined in terms of set number of treatment sessions) can be difficult. Pocock (1983) argues that where possible, data from all randomised patients should be included in the analysis of trial results. This pragmatic approach to data analysis (also known as analysis on an ‘intention-to-treat’ basis) provides a more valid assessment of treatment effectiveness as it relates to real-life practice (Pocock, 1983). Such analyses are less biased because they retain the full benefits of the original randomisation (Hotopf *et al*, 1999). The pragmatic approach reflects the reality of clinical practice where patients offered treatment can sometimes be non-compliant, drop out or seek treatment elsewhere. Effectiveness or pragmatic trials tend to prioritise the ‘intention-to-treat’ approach to data analysis, their interest being in how effective treatments are when offered to people under conditions that reflect reality as far as possible. In addition, where issues of cost effectiveness are to be considered, such an approach is warranted (Mitchell *et al*, 1996). Some of the more recent BN trials reviewed in the last chapter have reported findings based on intention-to-treat analyses (e.g., Thiels *et al*, 1998; Agras *et al*, 2000 a). A few have even reported both completer only and intention-to-treat analyses for comparison purposes (e.g., Agras *et al*, 2000 a). While various statistical techniques have been used to impute values for missing data in trials (e.g., based on the mean of other participants’ scores or on regression techniques to estimate scores), the last observed value has typically been carried forward for inclusion in analyses in BN trials (e.g., Thiels *et al*, 1998).

3.4 SAMPLE SIZE AND POWER

The power of a study is the likelihood that a difference in outcome between treatment and control groups will be detected if such a difference exists. A growing awareness during the 1970s that many trials were too small to detect important clinical differences (Muir Grey, 1997) has led to the current, widespread use by researchers of a standard statistical approach (the power calculation) to estimate the sample size required in order to reduce the likelihood of a trial committing a Type II error (i.e., failing to detect a difference in treatments, where one exists, because the study sample size is too small).

In order to determine sample size researchers need to estimate the magnitude of random error in the study and decide on the main outcome measure and the smallest observed difference between the study groups that would be of interest. They also need to assess the clinical consequences of erroneously rejecting (Type I error) or accepting (Type II error) a null hypothesis, and consider the costs of the study in relation to various assumptions about study size. The size of the minimum difference to be detected, the significance level and the required power can then be entered into an appropriate statistical formula for calculating sample size (St. Leger *et al*, 1992; Bowling, 1997). Various computer packages and sets of published tables (e.g., Machin and Campbell, 1987) are available for the purposes of sample size estimation. The general convention among researchers is to take the 0.05 level of significance and a power of 0.8 or above; the latter implying a 20% chance or less of failing to detect a true difference (Bowling, 1997). Power calculations should always be conducted before a study commences, but may also be calculated retrospectively to assess how much chance a study's results (once analysed) had of detecting a significant difference (Bowling, 1997).

One of the difficulties in calculating power prior to undertaking a trial relates to estimating the expected differences in outcome between the study groups (Hotopf *et al*, 1999). Such estimates are generally based on pilot studies or previous research in the field. Where these do not exist, researchers may have to use predictions based on clinical experience, or an 'educated' guess. Although heavily dependent on the variance of the main outcome measure, in general the smaller the expected effect or difference, the larger the sample needed to detect it (Muir Grey, 1997). Pocock (1983) observed that

researchers are often surprised by the sizes of samples required in trials: equivalence trials in particular require substantial numbers of participants as these trial are essentially attempting to detect very small differences in outcome. However, he suggested that statistical methods for calculating power can only be used as a guideline and that practical matters such as the availability of patients and resources, and the need to prevent patients from receiving inferior treatments in clinical settings, should also be taken into account. Furthermore, sample attrition and the importance of conducting sub-group analyses need to be considered when calculating sample size (Bowling, 1997).

As noted in the previous chapter, many of the early BN treatment trials did not report power calculations, thereby making it difficult to interpret non-significant results. Possibly as a result of the CONSORT statement (Begg *et al*, 1996), recent trials have more often reported this information. As also noted in the previous chapter, BN trials tend not to be very large (with the exception of some of the American studies), with the result that they generally do not have sufficient power to allow for reliable sub-group analyses or to reliably identify predictors of outcome.

3.5 OUTCOME IN TRIALS

As noted earlier, it has been suggested (e.g., Hotopf *et al*, 1999) that trials should include clinically meaningful and easy-to-measure outcomes. Ideally, in assessing the impact of a new treatment there should be only one major criterion of its success (Newell, 1992), and this outcome measure, on which the power calculation is based, should be closely related to the study's hypothesis. The rigorous approach of focusing only on one specific outcome works well in medical settings where outcome (e.g., death or coronary events) is obvious. Keeping outcome simple has the benefit of improving follow-up rates and consequently the internal validity of a study (Hotopf *et al*, 1999).

However, there is rarely only one outcome of an effective treatment (Muir Grey, 1997), and in policy related or mental health research, the use of a single outcome measure may be unachievable and inappropriate (e.g., Newell, 1992). Furthermore, as Altman (1996 a) notes, in most clinical trials many variables are employed to gather information about treatment effects. The task of those conducting trials is to decide on the primary outcome of interest in advance and to treat all other measured outcomes as secondary in nature.

Where a mental health problem or psychiatric disorder has multiple impacts on the individual's health, life and functioning, this task may be a difficult one. In treatment trials in psychiatry, disorder-specific symptoms are usually chosen as the primary outcome while other outcomes, which may be highly clinically relevant (e.g., quality of life, ability to return to work) but not germane to the main study hypothesis, are measured as secondary outcomes.

The inclusion or exclusion of secondary outcomes in psychiatry trials can lead to a tension between researchers and clinicians. If only one outcome (symptoms) is included, clinicians may argue that the results of the trials are too narrow to be of value to them in their clinical practice. On the other hand, if a wide range of secondary outcomes are included, then researchers are open to criticism on methodological grounds because, as Altman (1996 a) notes, the results of significance tests may be invalidated by multiple testing. Altman suggests, however, that secondary variables can and should be analysed in trials, but that findings should be treated with caution rather than being considered definitive. As highlighted in the previous two chapters, the multi-symptomatic nature of BN and the observed levels of psychiatric co-morbidity associated with it, have led to the broadening of the concept of outcome beyond that of bingeing and purging in BN treatment trials. Measures of depression, social adjustment, and self-esteem are regularly included as secondary outcomes in such trials. Their inclusion is justified on the grounds that if trial findings are to be relevant to routine practice then it is important to assess the impact of treatment on not only the eating disorder-specific features of BN but also on the other features (e.g., depression) commonly associated with it.

3.6 ETHICAL ISSUES

The basic ethical principles governing research are that individuals should give their informed consent to participate and that they should not be harmed as a result of their participation (Bowling, 1997).

Clinical uncertainty is a requisite for undertaking RCTs. Where there is good exiting evidence and clinical consensus that a particular treatment works then a trial is unwarranted. Where clinicians are faced with uncertainty about the most effective treatment for a specific disorder then the random allocation of patients to one treatment

or another in a trial becomes an ethical option (Hotopf *et al*, 1999). While RCTs should only be conducted where there is equipoise (e.g., Muir Grey), empirical research suggests that personal equipoise may be difficult to achieve in practice (Edwards *et al*, 1998). This may, however, simply reflect ignorance of the benefits of interventions, and personal, non-evidence based biases. Equipoise is therefore perhaps best conceptualised as operating at a societal level.

The notion of collective versus individual benefit is also central to the ethics of clinical trials (Pocock, 1983). Pocock (1983) suggests that the primary motivation for conducting trials is to establish which therapies are most effective so that they can be used for the collective benefit of future patients. However, collective benefit has to be balanced with the right of the individual currently requiring treatment to receive that which is thought most likely to benefit him/her. When balancing individual versus collective considerations, Pocock suggests that account needs to be taken of the importance of a trial in resolving a clinical question, prior knowledge of the therapies under investigation, and the level of risk and inconvenience involved for participants. Newell (1992) argues that individuals should only be included in trials where either of the treatments would be appropriate for them.

It has also been argued that trials should not be undertaken where there is a likelihood that they will be of insufficient size to detect a better treatment (e.g., Newell, 1992). This is based on the premise that it is unethical to recruit patients into a study and allow them to undergo procedures that may be uncomfortable or non-routine when neither they nor future patients are likely to benefit. However, it is often difficult to predict problems in recruitment at the design or early stages of a trial.

Individuals should be included in a trial only after they have given their informed, written consent, having been provided with full information about the study. They should be made aware of its purpose and the implications of participating (e.g., regarding procedures, confidentiality etc.) (Bowling, 1997). Researchers should also ensure that participants have an understanding of the concept of random allocation. Finally, individuals need to be made aware that their participation is entirely voluntary and that declining to take part in, or withdrawing from, a trial will not affect their future medical care. For ethical, clinical and social reasons withdrawal criteria, and allowance

for cross-over to the standard treatment, may be necessary in trials where a new treatment is being compared with a standard one known to be effective. Where potentially life-saving treatments have been made available only in trials, there has been concern that patients may feel compelled to consent (Edwards *et al*, 1998). A related issue has pertained to some of the BN treatment trials conducted in the US where individuals have volunteered to participate in order to (potentially) receive treatments that would ordinarily only be available to them at great financial expense. This does not apply in the UK where NHS treatment is available free to everyone at the point of contact, and individuals with BN do not have to take part in research in order to receive treatment.

3.7 ECONOMIC EVALUATIONS AND RANDOMISED CONTROLLED TRIALS

Health service demands exceed supply (St. Leger *et al*, 1992). Evidence of value for money is therefore becoming increasingly important to health service decision-makers. RCTs provide an opportunity for the collection of economic data concerning new and standard interventions. However, three factors need to be considered by those designing and conducting trials (Drummond, 1994). The first concerns the economic importance of the question a trial is seeking to address. Where there is uncertainty about the relative costs of interventions or where a large cost difference is not anticipated, but the resource consequences could be important if the treatments were frequently employed, then an economic analysis may be justified (Drummond, 1994). The second factor concerns the practical relevance of the study design. Trials conducted under optimum conditions, and including assessments / procedures not typical of routine practice, may generate costs that are not generalisable. Pragmatic trials comparing new therapies with standard ones delivered in settings that resemble normal practice are the best candidates for economic analysis (e.g., Drummond, 1994; Hotopf *et al*, 1999). The third factor requiring consideration concerns the fact that economic data collection may require lengthy interviews that overburden participants, contradict the call for simple outcomes, and substantially increase the costs of trials (Drummond, 1994; Hotopf *et al*, 1999).

The main category of costs to be considered in relation to healthcare interventions are the *direct costs* of the intervention themselves (Drummond, 1994). These pertain mainly

to the health service (e.g., clinician time, medications, equipment etc), but also to other agencies (e.g., Social Services), patients and their families. An intervention may also incur *indirect costs*, such as losses in production resulting from the patient taking time off work to receive treatment. The three main consequences of healthcare interventions are: their impact on the individual's health; direct benefits in terms of savings in other healthcare resources if the individual improves; and indirect benefits such as increases in productivity if he/she returns to work (Drummond, 1994).

The most appropriate type of economic analysis for any given trial will depend to an extent on the nature of the illness and interventions being studied, as well as the hypothesis being tested and the outcome of the study. Drummond (1994) suggests that if two treatments are predicted to be equivalent in their effects, then a *cost-minimisation exercise* involving the calculation of costs only will suffice. However, as he notes, most trials are designed to ascertain whether or not a new treatment is better than an existing one. A *cost-effectiveness analysis* is appropriate where outcome along one main dimension (e.g., life extension) is being assessed and differences in costs between the study interventions can be compared in relation to differences in outcome on this dimension. Where interventions are likely to affect many aspects of quality of life a *cost-utility analysis* that employs an overall index of health gain such as the 'quality adjusted life year' (QALY) may be required (Drummond, 1994). The broadest form of economic evaluation is the *cost-benefit analysis* (St. Leger *et al*, 1992). Here the costs and consequences of interventions are valued in monetary terms, the results of the evaluation expressed in terms of net economic benefit, and an assessment made of whether the value of the extra benefits of one intervention over another exceeds any extra costs involved (Drummond, 1994). Drummond (1994) notes that many economic evaluations do not fit neatly into one of the four types outlined. Given that the type of analysis eventually performed will depend partly on the outcome of the trial, he suggests that any economic analysis plans made in relation to RCTs need to be flexible. Hotopf *et al* (1999) caution that economic data are frequently skewed by a minority of patients consuming far more healthcare than the average patient, which may lead to unstable estimates of cost and effect. This increased variance also means that sample sizes needed for analyses of cost-effectiveness may greatly exceed those needed for examination of clinical effectiveness (Briggs, 2000). Hotopf *et al* (1999) also note that deciding on economic endpoints in the measurement of indirect costs and benefits is fraught with

difficulties.

It is estimated that roughly £12million is spent on extra-contractual referrals alone for the treatment of eating disorders in the UK (Royal College of Psychiatrists, 2000) and that 1-5% of women attending general practice may be suffering from full or partial BN. However, as noted in the previous chapter, little research has been conducted on the costs of different types of treatments for BN. As suggested above, pragmatic trials that aim to evaluate interventions as they would be delivered in routine settings, may provide an opportunity to estimate at least some of the main direct costs involved in the provision of the interventions in question. To date, however, economic evaluations of study interventions have not been reported in the BN psychotherapy trials literature.

3.8 CONDUCTING RANDOMISED CONTROLLED TRIALS IN GENERAL PRACTICE

There is an increasing demand for high quality research in primary care (Foy *et al*, 1998). The Royal College of General Practitioners (RCGP) actively encourages GPs and their primary care teams to participate in research with initiatives such as its research fellowship awards, and practice accreditation scheme. Recent Department of Health policies and funding initiatives have also focused increasingly on raising the profile of research in primary care. For example, Primary Care Research Networks, funded in part to provide research-related advice and support to general practice based professionals, are now active throughout the country. With over 90% of NHS contacts taking place in general practice (Elwyn *et al*, 2001), there are persuasive arguments for the importance and relevance of conducting research in this setting. General practice staff can potentially become involved in research by, for example, conducting funded or 'own account' research, collecting data for research council funded studies, or undertaking interventions with their patients as part of studies which are designed and evaluated by external researchers.

Hungin (2001) reports that some academics and clinicians argue that conventional research methods such as RCTs are not readily applicable to the study of general practice or the types of problems encountered there. However, as the evidence presented in Chapter Two suggests, RCTs can indeed be carried out successfully in the primary

care setting, particularly when they are pragmatic in nature, address questions of interest and relevance to GPs and involve either GPs or their staff in conducting the study interventions. Nonetheless, conducting research in the general practice setting, as in any other healthcare setting, has its difficulties.

Research may not be top of their list of priorities for the many GPs who feel overwhelmed by high workloads and government accountability frameworks (Elwyn *et al*, 2001). They may be unwilling to participate in trials that have no immediate impact on their patients and disrupt the routine delivery of care (Pringle and Churchill, 1995). Practitioners who participate in trials may be atypical, making the extrapolation of findings problematic (Foy *et al*, 1998). Maintaining motivation may also be difficult in practices involved in long-term studies (Pringle and Churchill, 1995). GPs may be unwilling to recruit patients to trials for a number of reasons: participation in a trial may disrupt the normal interaction between GP and patient; GPs may experience a conflict of interest between their role in maintaining a patient's autonomy and their desire to recruit him/her to a trial; and they may have ethical concerns about patients feeling coerced to participate. General practice patients too may have concerns about participating in trials (e.g., concerning issues of confidentiality, risks of the intervention, or apparent disadvantages to being randomised to the control group) (Pringle and Churchill, 1995).

It has been suggested that the trials most likely to succeed in general practice are those which involve minimal disruption of normal working practices and which compensate GPs for their additional time commitment (Pringle and Churchill, 1995). While monetary incentives appear to work for large pharmaceutical companies who wish to recruit general practice patients to trials, such incentives are controversial because they may, for example, lead to the recruitment of atypical patients (Foy *et al*, 1998). Ward *et al* (1999) suggest that the introduction of a new service as part of a trial offers an incentive for practices to participate. Other possible incentives that might be offered to GPs include study-related training opportunities or provision of the study materials (e.g., handbooks), both of which may be of use to them in their routine practice after the study has concluded. Whatever the incentive, the introduction of an RCT into general practice should not disrupt the culture of primary care to such an extent that the findings will not reflect reality in general practice (Pringle and Churchill, 1995).

Mant *et al* (1995) suggest that the problems involved in carrying out RCTs in general practice are very much the same as those involved in carrying out RCTs in any clinical setting. They maintain that while generalisability is always a problem with RCTs, even more of a problem arises when the results of studies performed in secondary care are generalised to general practice. They suggest that the solution to this problem lies in conducting more RCTs in general practice. If, as the Royal College of Psychiatrists (2000) suggests, there is a role for primary care services in the management of patients with eating disorders, then such a role needs to be evaluated *in situ*. It is only by conducting a pragmatic trial of a GP supported self-help intervention for BN patients actually in the primary care setting that the effectiveness and practical realities of this approach can be fully explored and evaluated.

3.9 CONTEXTUALISING RANDOMISED CONTROLLED TRIAL FINDINGS: THE VALUE OF A MULTI-METHODS APPROACH

While the use of standardised outcome measures may provide objective evidence concerning the effectiveness or otherwise of the treatment interventions under investigation in a trial, they do not necessarily reveal anything about why a specific treatment did or did not work. Arguably, this is particularly the case when psychological therapies are involved. Essentially, the pragmatic trial approach, being concerned with answering clinical dilemmas, can lead to the conclusion that the provision of a particular treatment intervention will benefit patients, but it cannot normally say much about the ‘active’ component of that intervention (e.g., Newell, 1992; Hotopf *et al*, 1999) or its acceptability to patients (Marks, 2002). The use of survey or qualitative research methods, that is, taking a multi-methods approach, in conjunction with a trial may extend the scope of a study in this regard by addressing “questions of process” (Barbour, 1999, p. 39). Providing participants (and those providing the interventions) with opportunities to express their views of the treatment (and research) process may help to contextualise trial outcomes. Given that the ultimate aim of effectiveness studies is to try to improve routine clinical practice in the real-world setting, obtaining participants’ views may in fact be particularly important in this type of trial. Significantly, recent Department of Health policies (e.g., regarding clinical and research governance) have increasingly signalled the importance of eliciting patients’ views concerning clinical practice and research, and there has been some speculation that future health services

research may well be grounded in a multi-methods approach (e.g., Barbour, 1999). Furthermore, there have been specific calls for qualitative investigations of the perceived accessibility and benefits to patients of the self-help manuals or packages used by them (e.g., Lewis *et al*, 2003) in addition to the more traditional evaluations of the efficacy or effectiveness of these interventions.

Participants' perceptions may potentially shed light on whether there are any aspects of the treatment(s) being evaluated that are helpful or not, and what (if anything) about a treatment makes a difference. Their views of an intervention may have implications for future research programmes, clinical practice, or policy formation. Objectively, a treatment may be found to be very effective, but if perceived or experienced negatively by patients, is unlikely to prove useful in applied clinical practice. Similarly, information may be gained concerning aspects of a treatment package that if modified or emphasised would add extra benefit. The views of those providing interventions in pragmatic trials may also prove to be informative in helping to decide whether or not a successful study intervention can be realistically incorporated into routine practice. Their views may also help to establish what went 'wrong' when an intervention was less effective than predicted.

Study participants' views may perhaps be best obtained through the use of surveys or short questionnaires including open-ended questions or through brief semi-structured interviews. The concern is not to overburden participants with long, in-depth interviews and thereby potentially decrease follow-up rates, while at the same time satisfying the desire to obtain pertinent information that may help to explain outcomes and be of future benefit. The most obvious point at which to assess perceptions of treatment is the final follow-up, when participants have formed their views of an intervention and its impact on them, and when eliciting their views cannot be said to impact on treatment or reduce a study's internal validity.

Schmidt *et al* (1993) and Cooper *et al* (1996) reported on the usefulness of obtaining study participants' views of the self-help manuals and self-help approach to treatment of BN. Where a trial is the first of its type to evaluate treatments in a novel setting, then obtaining views about the treatments and settings involved may be particularly valuable. Obtaining GPs' and patients' views of the benefits and drawbacks of a general practice

based self-help approach to treating BN seems highly appropriate within the context of the present study.

3.10 CONCLUSIONS AND RATIONALE FOR USING A PRAGMATIC RANDOMISED CONTROLLED TRIAL DESIGN

The main advantage of the RCT over other research designs employed to evaluate health care interventions is that it allows for the inference of cause and effect, and can provide definitive answers to questions about the therapeutic effectiveness of specific interventions. The methods employed in RCTs (e.g., randomisation) serve to minimise bias and the impact of potential confounding variables. The review of the theory and practice of RCTs presented in the current chapter suggests that the pragmatic RCT is the optimum research design to employ when trying to evaluate the effectiveness of interventions as they would be delivered in routine clinical practice. As noted in the previous chapter, the purpose of the present study is to fill a gap in the evidence base concerning the effectiveness of a GP supported self-help approach to treating BN compared to specialist outpatient treatment. It seeks to mirror the reality of clinical practice in NHS eating disorders clinics and busy general practices. The use of a pragmatic RCT design (e.g., involving the recruitment of patients identified and referred by GPs to specialist services; employing a published self-help manual; and using an intention-to-treat approach to data analysis etc.) would therefore seem to be most appropriate to the needs of the current study. A pragmatic approach should serve not only to provide evidence concerning the therapeutic impact of the self-help approach but also to increase the generalisability and practical applicability of the results to routine clinical practice.

CONCLUSIONS FROM THE LITERATURE REVIEW AND JUSTIFICATION FOR THE CURRENT STUDY

The literature reviewed in the previous chapters has highlighted the fact that BN is a serious, chronic disorder, which in its full and sub-clinical forms may affect up to 5% of women attending general practice. It is multi-symptomatic in nature, and high levels of psychiatric co-morbidity are associated with it. Treatment for BN has largely been provided and evaluated in specialist settings. At least in the short-term, BN does not appear to improve without treatment. While full CBT has been advocated as the treatment of choice, it is expensive and not widely available. A viable, alternative approach to treatment may be the use of a cognitive behaviour, self-help manual. To date, however, the efficacy of self-help has only been tested in a limited number of studies in specialist settings, and its applicability to, or potential effectiveness in the general practice setting, are unknown. The evidence suggests though that GPs may be an appropriate professional to support patients undertaking a self-help intervention for BN.

The most appropriate way to test the effectiveness of a GP supported self-help intervention in general practice compared with that of out-patient specialist treatment is by conducting an RCT. Given the nature of the interventions involved (which, for example, do not allow for blinding), and ethical concerns about evaluating a relatively new treatment intervention in a non-specialist setting, a pragmatic trial involving willing patients and GPs, and employing a limited range of medical and social exclusion/withdrawal criteria, is warranted. A pragmatic trial constitutes a valuable means of addressing a variety of related issues relevant to clinical practice in routine settings. In the current study, not only will it provide information concerning the clinical effectiveness of the self-help approach, but, combined with qualitative methods and survey techniques, it will also allow for the other aims of the study, namely the exploration of GPs' and patients' perceptions and experiences, to be addressed.

The study hypothesis, design and methods are described in the next chapter.

CHAPTER FOUR: THE STUDY METHODS

4.1 INTRODUCTION

The design, methods, measures and procedures employed in the present study, as well as the data analysis strategy, are described in this chapter.

4.2 PURPOSE OF THE STUDY AND THE STUDY HYPOTHESIS

4.2.1 The purpose of the study

The aims of the study are threefold. It is designed to:

1. Compare in a pragmatic, randomised controlled trial the effectiveness of a general practice based self-help approach to the treatment of BN (a self-help cognitive behaviour manual with GP support) with that of specialist out-patient clinic treatment. Primary and secondary outcomes will be assessed at baseline and two follow-up points.
2. To ascertain, by means of two postal surveys, the views of GPs providing support to self-help patients about the experience of using this approach in general practice with patients suffering from BN. The objective is to highlight the advantages of, and drawbacks to, the approach as perceived by the GPs, and gather information concerning potential barriers and incentives to implementing the self-help intervention as routine practice in primary care. GPs will therefore be asked about their perceptions of the approach, the self-help manual, patient consultations, professional support requirements, and their willingness to undertake the approach with future patients.
3. Explore, using quantitative and qualitative methods, patients' views and experiences of the treatment interventions received, be they in general practice or the specialist clinic, in order to help contextualise the findings of the trial. Issues such as reasons for help-seeking, expectations of treatments and treatment preferences, the perceived

helpfulness of the treatments received, difficulties encountered, how treatment approaches might be improved, and what, if anything, has helped patients most in trying to overcome their eating disorder, will therefore be explored.

4.2.2 The experimental hypothesis

The experimental hypothesis is that there will be no serious disadvantage in outcome for women with BN randomised to receive the self-help intervention based in general practice (a self-help manual and support from the patient's GP) compared to those receiving specialist out-patient clinic care.

4.3 ETHICAL APPROVAL

Ethical approval for the trial was obtained from three ethics committees: the Royal Free Hampstead NHS Trust Ethics Sub-committee, The New River Health Authority Local Research Ethics Committee (LREC), and the Riverside Research Ethics Committee.

4.4 STUDY DESIGN

A prospective, parallel group, randomised controlled trial was undertaken. Patients were randomised to receive either the self-help intervention in general practice or attend a specialist out-patient clinic for treatment. Data were collected at baseline and two follow-up points (six and nine months). The trial was designed to be pragmatic in nature, and an intention-to-treat analysis was undertaken. Blinding was not possible as patients were required to be active participants in the treatment process and study funding did not allow for a 'blind' outcome assessor. However, steps were undertaken to reduce potential bias. Firstly, the primary outcome measure used was self-report in nature, as were the majority of the secondary measures. Secondly, the researcher and her supervisor did not work in the specialist clinics and were not involved in the provision of the treatment interventions. Thirdly, no study data were analysed before all of the data had been collected.

Two postal surveys were undertaken with the GPs supporting self-help patients during the course of the study. These took the form of brief questionnaires and included both 'open' and 'closed' questions. Both qualitative and quantitative methods were employed

to explore patients' expectations of, and views about treatment. These included the use of visual analogue scales and 'open' and 'closed' questions in self-completed questionnaires.

4.5 THE INTERVENTIONS

4.5.1 The general practice based self-help intervention

Patients randomised to the self-help arm of the trial were given a copy of the self-help manual, '*Bulimia Nervosa: A Guide to Recovery*' (Cooper, 1993), and instructed to work through it while keeping in regular contact with their GP over the following weeks/months.

A variety of manuals and self-help books for BN that were available at the time of commencement of the study, as well as any published studies involving their use, were read and reviewed by the researcher. Neither the researcher nor her supervisor had any vested academic or financial interest in promoting one manual over another. The Cooper (1993) manual was chosen for use in the study over the others for a number of reasons. Firstly, it contained a highly structured, step-by-step, self-help programme. Secondly, the programme was based on CBT principles. Thirdly, its efficacy had previously been tested in an open trial, during which BN patients were provided with support by a non-specialist social worker (Cooper *et al*, 1994). Other manuals (e.g., that of Schmidt and Treasure, 1993) had largely been studied in a 'pure', unsupported self-help format.

GPs supporting patients randomised to the self-help condition were given a copy of the manual. They were also given brief written guidelines concerning their role in supporting patients using the manual. The guidelines consisted of a short description of BN, advice about the general nature of the support and encouragement to be given to patients, a reminder to log patient visits and any medication prescribed for BN, and information about contacting the researcher. GPs were asked to contact the clinic through the researcher if they had any concerns about their patients. They were advised to familiarise themselves with the contents of the manual. However, they were not given specific training concerning the treatment of eating disorders because the trial was

designed to be pragmatic in nature and to evaluate how effective the self-help intervention would be when based in the routine general practice setting, with ordinary GPs providing support to patients. GPs were not instructed to see patients on a set number of occasions or over a specific period of time, but it was suggested that patients might benefit from regular contact as they commenced the programme.

'Bulimia Nervosa: A Guide to Recovery' is composed of two parts: the first six chapters describe BN, its potential effects, theories of causality and recommended treatment approaches. The second half of the book consists of a six-step self-help manual based on cognitive behaviour principles. Cooper (1993) recommends that individuals undertaking the programme should enlist the assistance of a helper (e.g., a GP, practice nurse or dietician). The programme is highly structured and users are instructed to follow the steps in consecutive order, completing one successfully before starting the next. The first step involves monitoring what is eaten and recording related perceptions/feelings. The second step involves the institution of a meal plan so that the individual learns to eat regularly. Strategies for creating, maintaining and monitoring meal plans are provided. The third step involves learning to prevent bingeing; the aim being to equip the individual with strategies to deal with situations and emotions that may precipitate bingeing. Both global 'forward planning' and specific 'immediate' strategies are suggested. The objective of step four, problem solving, is for the individual to identify problems that underlie her desire to binge, address them and deal with them in ways other than by overeating. Five phases involved in problem solving are outlined. The fifth step of the programme, eliminating dieting, which is designed to be undertaken when the individual is able to stick to her meal plan and not binge on most days, involves widening her diet to include previously forbidden or binge foods. A precise set of guidelines for achieving this is provided, along with suggested strategies for dealing with difficult situations. 'Changing your mind', the final step, engages the individual in questioning the importance of weight and shape in her life, and how she thinks about herself. Guidelines for professionals and others supporting someone through the programme are also included.

4.5.2 The specialist out-patient clinic intervention

Patients randomised to the clinic intervention were sent an appointment to attend the Eating Disorders Clinic to which they had initially been referred. A consultant

psychiatrist managed each clinic and staff included psychiatrists, psychologists, nurse specialists and dieticians. Trainee psychiatrists worked at each of the clinics. Each of the hospitals at which the study was undertaken had in-patient facilities for patients with eating disorders, as well as running out-patient clinics. Clinics were held at each hospital on specific days of the week, during normal office hours. Patients attending routine out-patient clinics would usually be offered appointments of between a half an hour and an hour in duration, and would be seen by a consultant psychiatrist, specialist registrar, or staff grade psychiatrist specialising in eating disorders, or a qualified therapist. They could also be seen by the clinic's dietician. Each clinic offered similar forms of therapy for BN including a combination of cognitive behaviour and interpersonal therapy approaches. Treatment at any of the clinics did not involve the use of self-help manuals. Medication, however, could be prescribed in the course of routine treatment, and patients might be seen by dieticians. As the trial was designed to be pragmatic in nature and to reflect what happens in routine NHS clinics, a set number of clinic appointments per patient was not specified. After an initial clinic assessment, patients were seen on a weekly or fortnightly basis in line with standard clinic procedures, and for as long as deemed appropriate by their individual clinician.

4.6 SAMPLE

Female patients were recruited from GP referrals for BN to three London specialist Eating Disorder Clinics. The three clinics involved were based at the Royal Free, the North Middlesex and the Gordon hospitals. Referrals to these clinics come from GPs based in North and West London. Waiting list times at the clinics were generally longer than a month at the time the study was undertaken. A number of inclusion and exclusion criteria were employed in the trial and are outlined in Figure 4.1.

Only women were recruited to the present trial because of the small number of men seen in the clinics and because, as highlighted in the literature review, the evidence suggests that BN may take a different form in men. Participants were required to be 18 years of age or over, as this is the minimum age at which patients are treated in adult psychiatry departments and the recruitment of younger patients would have necessitated obtaining parental as well as patient consent. As patients randomised to the self-help arm of the trial were to be provided with reading material in the form of the manual, only those

who were fluent in written English could be recruited to the study. Given the pragmatic nature of the trial, limited exclusion criteria were employed, and all were based on medical or ethical imperatives. As the trial involved evaluating a relatively new treatment for BN (the self-help intervention) which had only been tested in a small number of studies, withdrawal criteria were included, and an assurance was given that if patients requested to be withdrawn/were withdrawn by their GPs from the self-help arm of the trial for medical or social reasons they would be seen in the clinic to which they had been originally referred.

Figure 4.1 Study inclusion, exclusion and withdrawal criteria

Inclusion criteria:

- GP referral
- Suffering from BN, as assessed by the Eating Disorder Examination –12 (EDE) (Fairburn and Cooper, 1993)
- Aged 18 or over
- Female
- English-speaking

Exclusion criteria:

- Suffering from BN but requiring an urgent clinic assessment
- Pregnancy
- Medical disorders such as diabetes which might have implications for eating
- Substance or alcohol abuse problems
- Evidence of serious suicidal intent

Withdrawal criteria for those randomised to self-help/general practice arm:

- Where GPs felt strongly that for medical or social reasons it was no longer appropriate that patients continue in the self-help condition or if patients expressed a strong wish to be withdrawn from this arm of the trial

4.7 MEASURES

4.7.1 Primary outcome measure: Bulimic Investigatory Test Edinburgh (Henderson and Freeman, 1987)

The primary outcome measure used in the trial was the Bulimic Investigatory Test Edinburgh (BITE) (Henderson and Freeman, 1987) (Appendix 1). This measure was chosen because it is a self-report questionnaire, and would therefore not be open to

potential interviewer bias. In addition, unlike other self-report measures available at the time, it focused specifically on bulimic symptoms *per se* rather than on more general eating disorder symptoms. Furthermore, it had been used in other studies of self-help interventions for BN (e.g., Schmidt *et al*, 1993).

The BITE is a 33-item self-report measure which can be used to identify individuals with bulimia or binge-eating. It can be employed either as a screening tool in epidemiological studies or as a measure of response to treatment, as in the current study. The BITE consists of two subscales. The Symptom Scale, which measures the degree of symptoms present, consists of 30 questions and has a maximum possible score of 30 (five of the questions on this scale score one point for a 'no' answer). Scores on this scale can be divided into three groups. Scores of 20 and above indicate a highly disordered eating pattern and signal the presence of binge-eating: individuals scoring at this level are very likely to meet diagnostic criteria. Scores of 10 to 19 indicate that an individual has an unusual eating pattern, but that he/she is unlikely to fulfil full diagnostic criteria. Scores below 10 are in the normal range. Questions 6, 7, and 27 comprise the Severity Scale, which measures the severity of bingeing and purging in terms of frequency of occurrence, and has a maximum score of 39. A score of 5 or more on this scale is considered to be clinically significant. However, a high score on this scale alone may be indicative of psychogenic vomiting or laxative abuse in the absence of binge-eating. Henderson and Freeman (1987) recommend that a combined total score of 25 or above should be employed when the BITE is being used for diagnostic purposes. Where the BITE is used as a screening instrument, those completing the questionnaire should consider their feelings and behaviours over the previous three months. When, as in the current study, it is being employed as an outcome measure, only the previous month is considered.

Henderson and Freeman developed the BITE in response to the absence of a scale which focused specifically on bulimic symptoms and binge-eating. A list of questions was generated on the basis of all the symptoms and behaviours reported to be associated with binge-eating. Ambiguous items, or those open to possible misinterpretation, were deleted or re-worded following discussion with a group of normal controls and binge-eaters. Two pilot studies were conducted to test the validity of the questionnaire. In both studies the BITE successfully distinguished binge-eaters from normal controls on the

basis of their scores on the questionnaire.

Inter-item reliability co-efficients of 0.96 and 0.62 have been reported for the Symptom and Severity Scales respectively (Henderson and Freeman, 1987). The authors also report significant correlations between binge-eaters' scores on the BITE and other eating disorders measures. A pilot study involving a clinic sample found the BITE to be sensitive to change over a 15-week treatment period (mean=33.8 at baseline, and 8.3 at the end of treatment), while a study of test-retest reliability in non-case women produced a Pearson correlation co-efficient of 0.86.

Henderson and Freeman (1987) suggest that the BITE can be used as “a measure of response to treatment by both psychiatrists and GPs in outpatient work (p. 22).”

4.7.2 Secondary outcome measures

The following secondary outcome measures were employed in the study.

4.7.2.1 The Eating Disorder Examination–12 (Fairburn and Cooper, 1993) (Appendix 2).

The Eating Disorder Examination-12 (EDE) is a structured, interviewer-administered, clinical interview “devised to provide a standardised instrument for the assessment of the psychopathology of eating disorders (p. 317).” It was used in the current study both as a diagnostic tool and as a secondary outcome measure. The researcher received training in the administration of the interview schedule at Dr. Christopher Fairburn's Department at the Warneford Hospital, Oxford. Prior to the start of the study she used the interview schedule in practice sessions with five patients already attending the Royal Free Eating Disorders Clinic.

The EDE assesses a range of the psychopathological symptoms and behaviours associated with AN and BN. It is designed for use in both clinical and community settings and has been widely used in descriptive studies and as an outcome measure in treatment trials. The 12th edition of the EDE has been shortened from previous versions to include only items required to assess key behaviours, create subscales and derive eating disorder diagnoses. It assesses two key behavioural aspects of eating disorders – overeating and the use of extreme forms of weight control - and provides frequency

ratings for their occurrence. The EDE also contains four subscales: Restraint, Eating Concern, Shape Concern, and Weight Concern and allows for the generation of operationally defined eating disorder diagnoses, based on DSM-IV criteria. While most of the interview items are concerned with the previous 28 days, some require answers relating to the previous three months for diagnostic purposes. The vast majority of the individual items are rated on defined severity or frequency scales (Appendix 2).

EDE data can be presented on three descriptive levels (Fairburn and Cooper, 1993). Firstly, at the level of the individual item, the EDE provides frequency or severity ratings for key behavioural and attitudinal aspects of BN and AN. Secondly, subscale scores provide a profile of individuals in terms of the four areas of eating disorder psychopathology listed above (i.e., restraint, eating, and weight and shape concerns). Subscale scores are obtained by adding the ratings for the appropriate items together (Appendix 2) and dividing the sum by the number of items forming the subscale. Thirdly, the EDE allows for the calculation of a global score, or overall measure of eating disorder psychopathology. The subscales scores are summed and divided by four.

High levels of inter-rater reliability are reported for the EDE, and the subscales have been shown to have a high degree of internal consistency (Fairburn and Cooper, 1993). High rates of discriminant and concurrent validity have also been reported by the authors, and the interview has been shown to be sensitive to change. Norms are provided for individuals suffering from BN.

4.7.2.2 The Beck Depression Inventory (Beck and Steer, 1987) (Appendix 3)

As reported in Chapters One and Two, depression is commonly seen in patients suffering from BN, and severity of depression is usually assessed in individuals taking part in BN treatment trials. This is done for a number of reasons; namely, in order to exclude patients who may be severely depressed or suicidal, to study the role of depression as a possible predictor of treatment outcome, and/or to assess the impact of treatment interventions for BN on severity of depression. The Beck Depression Inventory (BDI) (Beck and Steer, 1987), which is commonly used in BN studies, was included in the current study for all of these reasons.

The BDI was designed to assess the severity of depression in adolescents and adults

(Beck and Steer, 1987), and is used widely for assessing the intensity of depression in psychiatric patients and for detecting depression in normal populations (although Beck and Steer recommend that it be used with caution for the latter purpose). The BDI was originally based on clinical observations and descriptions of symptoms given by depressed psychiatric patients, and the items included in the inventory were designed to assess severity of depression rather than reflect a particular theory of depression (Beck and Steer, 1987). The original version of the BDI was modified during the 1970s, resulting in the current version described by Beck and Steer in the BDI manual published in 1987. The BDI is a self-report measure, and those completing it are asked to rate the items in relation to 'the past week, including today'. The item content reflects cognitive, affective, somatic and vegetative symptoms (Appendix 3). The inventory consists of 21 groups of statements, each of which can be rated on a 4-point scale between 0 and 3, giving a total possible score of 63. Beck and Steer (1987) note that cut-off scores should be based on the clinical decisions for which the instrument is being administered. However the following cut-off scores are widely used with depressed patients: scores of 0-9 are considered to be within the normal range (asymptomatic); 10-18 indicates mild-moderate depression; scores of 19-29 suggest moderate-severe depression, and scores of 30-63 indicate extremely severe depression.

Beck and Steer (1987) report that the BDI has high internal consistency in both clinical and non-clinical populations, high test-retest reliability in non-depressed populations, and that its validity has also been shown to be high in number of respects (e.g., with regard to concurrent validity).

4.7.2.3 Self-Concept Questionnaire (Robson, 1989) (Appendix 4)

As reported in Chapter One, low self-esteem has been found to be associated with BN, although the question of whether it has a causal or maintaining role in the disorder is unclear. Improvement in self-esteem is widely seen by therapists as an important element of the treatment process (Robson, 1989). A measure of self-esteem was included in the current study in order to assess the impact of the interventions on participants' self-esteem levels. The Self-Concept Questionnaire (Robson, 1989) was chosen because it is self-completed, relatively brief and gives a global self-esteem score, while adopting a component approach to the concept of self-esteem.

Robson (1989) defines self-esteem as, “The sense of contentment and self acceptance that results from a person’s appraisal of his own worth, significance, attractiveness, competence, and ability to satisfy his aspirations (p. 514).” On the basis of the theoretical and empirical evidence, Robson suggests that there are seven components to self-esteem. The questionnaire was originally developed as the result of a card-sort exercise conducted by nine experienced psychiatrists and psychologists in which 50 trait items reflecting these components were allocated to one or other of the seven defined components on the basis of face validity. Items that did not achieve unanimous categorisation were discarded, as were those that did not perform well on test-retest reliability, produced heavily skewed responses in a normative population, or showed poor correlation with the overall mean score. A pool of 30 items were categorised as exemplars of the seven components of self-esteem: “significance (5); worthiness (5); appearance/social acceptability (5); resilience and determination (5); competence (4); control over personal destiny (4); value of existence (2) (p. 514).”

A Likert scale ranging from 0 to 7 is used for scoring items (some are reverse scored), giving a possible total global score of 210. Four anchor points are included (ranging from ‘completely disagree’ to ‘completely agree’) and individuals completing the scale are asked to respond to the questionnaire items in terms of how they ‘typically feel most of the time’ (Appendix 4).

Robson reports a mean global score of 137 (standard error=2.41) in a non-psychiatric population and of 100.5 (+or-25) in a patient group suffering from anxiety. High levels of reliability (split-half, Cronbach’s Co-efficient Alpha, and test-retest) and convergent, clinical, and discriminant validity are reported for the questionnaire.

4.7.2.4 The Work, Leisure and Family Life Questionnaire (Cooper *et al*, 1982) (Appendix 5).

As noted in Chapter One, poor social adjustment has been reported in women suffering from BN. As with self-esteem, it is difficult to ascertain whether poor social adjustment is a precursor or maintaining factor in BN. The Work, Leisure and Family Life Questionnaire (Cooper *et al*, 1982), which is a British self-report adaptation of the **Social Adjustment Scale** (Weissman and Pajek, 1974), was used in the current study for two purposes: to assess the impact of the interventions on social adjustment and to

investigate the possible role of social adjustment as a predictor of treatment outcome. This particular questionnaire was chosen because it is self-report in format, was developed using UK population study samples, and the authors suggest that it is suitable for application in psychiatric research.

The Work, Leisure and Family Life Questionnaire is a 45-item questionnaire (Appendix 5), covering adjustment in the following areas: work outside the home; housework; social and leisure activities; extended family; marital; parental; and family unit. Individuals are asked to rate the items in terms of how they have been feeling in the previous two weeks. Items are rated on a five-point scale ('not at all' to 'all the time' or variants of this format), and higher scores are indicative of poorer social adjustment. The individual's ratings on the questionnaire can be interpreted in three ways; in terms of their functioning in each of the six role areas; in terms of four descriptive categories (Performance, Interpersonal behaviour, Friction, and Feelings); and in terms of a single score for all items, an Overall Adjustment Score (Cooper *et al*, 1982). Only the latter was used in the current study.

Cooper *et al* (1982) modified the US version of the scale by adapting the wording of some of the items to reflect UK idioms, and by changing the rating scale used. The reliability and validity of the scale was then assessed in two studies, the first involving a group of mothers with one-year old babies, and the second women undergoing elective sterilisation. A high level of agreement was found between women's self-ratings on the questionnaire, and ratings made a psychiatrist using the interview version of the Social Adjustment Scale, and between subjects' own ratings and those made of them by their husbands. Self-ratings and ratings of mental state were also found to be highly correlated. In addition, the instrument was shown to be sensitive to change in the women undergoing surgery.

Cooper *et al* (1982) suggest that the Work, Leisure and Family Life Questionnaire is suitable for measuring changes in social adjustment over time, examining differences between various patient groups, and exploring the relationship between social functioning and other psychological or social variables.

4.7.2.5 Self-rated severity (Appendix 6: Expectations of Treatment)

Participants rated the perceived severity of their eating problem on an 11-point visual analogue scale (0-10, with 10 representing the more severe end of the scale) (Appendices 6, 9 and 11).

4.7.3 Baseline assessment

As well as the primary and secondary outcome measures described above, the following were included in the baseline assessment:

4.7.3.1 A Social and Psychiatric History (Appendix 7):

In order to assess whether individual patients met the study's inclusion and exclusion criteria, describe the study sample, and assess possible predictors of outcome, a structured interview schedule covering issues related to patients' social and psychiatric histories was designed specifically for the study. The schedule was interviewer-administered and consisted of three sections.

The first section included demographic questions concerning the patient's age, marital status, ethnicity, employment status and the nature of her employment, educational qualifications, living arrangements, and religion. The second section consisted of questions concerning the individual's physical health, eating problems and psychiatric history. Patients were asked questions about physical illnesses, their height and weight, menstrual cycle, and use of oral contraceptives. They were asked to describe themselves in terms of their weight (very underweight, underweight, average, overweight or very overweight), about previous referrals for eating problems to specialists, nature of treatments received, any diagnosis given, the date of last contact with specialist treatment services, and the duration of their eating problems. They were then asked if anyone, apart from their GP, knew about their eating problems, and if they felt that anyone was being supportive of their efforts to overcome them. Questions about treatment received for mental health or emotional problems (e.g., depression, stress) other than eating, and about prescribed medications currently being used (name of medication, dose and duration) were also posed. The final section of the schedule concerned the health of the patient's immediate family of origin. Patients were asked if any family members were suffering from a chronic physical illness or were currently receiving/ had received treatment for anxiety, alcohol problems, depression,

schizophrenia, 'nerves' and/or eating disorders.

4.7.3.2 A Problems Questionnaire (Appendix 8):

This self-report questionnaire, which included both 'open' and 'closed' questions, was designed specifically for the study, on the basis of a suggestion by Dr. Bridget Dolan, St. George's hospital (personal communication). Where general information concerning impulsive behaviours is required, Dr. Dolan suggested that instead of conducting formal personality assessments on patients with eating disorders, patients can simply be asked about addictive and self-harming behaviours, sexual relationships, and shoplifting/stealing. Again the purpose of including this questionnaire was to assess whether potential study participants met the study's inclusion/exclusion criteria, to enable the researcher to describe the study population and to gather information that might potentially be used in assessing predictors of treatment outcome.

Questions concerning smoking, alcohol consumption, drug use (cannabis, tranquillisers, amphetamines, heroin, cocaine, inhalants/solvents), and treatment for substance or alcohol abuse were included. So too were questions concerning sexual relationships (number of sexual partners in the previous two years, existence of a current relationship with a partner, and the patient's perception of her current relationship; good, unremarkable, poor, or variable). Three questions concerning self-harm were also included. Patients were asked if they had ever felt like harming themselves, ever deliberately harmed themselves, and if so, when and how. They were asked whether they had ever felt compelled to steal something even though they did not need it, and if they had ever stolen from shops, been caught shoplifting or charged with a shoplifting offence. In addition, they were asked to complete the CAGE (Ewing, 1984), which is a four-item, self-report measure widely used in general population studies to screen for alcohol problems. The four questionnaire items ask if the individual has ever felt he/she should cut down on his/her drinking; felt annoyed about others' criticism of his/her drinking; felt guilty about drinking; and, had an eye-opener drink (Appendix 8). The CAGE was originally developed in a clinical study involving 130 randomly selected medical and surgical patients, and has since been shown to reliably distinguish between alcoholics and non-alcoholics in a variety of populations (Ewing, 1984). While Ewing (1984) acknowledges that a diagnosis of alcoholism should not be made solely on the basis of responses to a questionnaire, the empirical evidence suggests that the higher the

number of positive responses to the CAGE questions the greater the likelihood that the individual concerned has a problem with alcohol and that further investigation is warranted.

4.7.3.3. An Expectations of Treatment Questionnaire (Appendix 6):

This 8-item, self-report questionnaire was again designed specifically for the study. Patients were asked to rate on 11-point (0-10) visual analogue scales the perceived severity of their eating problems (as noted above); the importance to them of overcoming their eating problems; and how confident they felt that they could stop their problem eating behaviours altogether if helped to do so. They were asked to rate how effective they would expect the self-help manual and GP to be in helping them to overcome their eating disorders if randomised to the general practice condition, and how effective they would expect the specialist clinic to be if randomised to receive treatment there. Patients were also asked to indicate which type of treatment they would prefer to receive, given a choice (clinic, self-help manual with GP support, or no preference). In addition they were asked to indicate, on a 5-point scale (bad to very good), their relationship with their GP.

As can be seen from the sections that follow, patients were asked to rate the severity of their disorder and the helpfulness of the treatment interventions throughout the course of the follow-up assessments. This was done in order to examine potential within- and between-group differences in subjective perceptions at the different time points and to provide more in-depth data than that provided by the primary outcome measure.

4.7.4 Follow-up One (6 months)

The primary and secondary outcome measures listed above were included in the first follow-up assessment. Also included were:

4.7.4.1 A Satisfaction with Treatment Questionnaire I (Appendix 9):

Patients were asked to rate on 11-point (0-10) visual analogue scales the severity of their eating problem now, the importance to them of overcoming their eating problem and how helpful they had been finding the clinic or self-help intervention. This measure was specifically designed for the study.

4.7.4.2 An Economic Evaluation and Treatment Attendance Questionnaire I (Appendix 10):

As noted in Chapter Two, little research has been conducted on the costs of treating eating disorders. The present study posed an opportunity to explore some of the costs involved in providing care for patients seeking treatment for BN. Hence, an interviewer-administered schedule was designed for the purposes of the study. Advice on economic variables was obtained from Professor Nick Bosanquet, at St. Mary's Hospital. The schedule included questions concerning any changes that had taken place in the participant's marital status, accommodation, or occupational status in the six months since commencement of treatment. Patients were asked about their financial circumstances. They were also asked about their ability to work or study during the six months prior to and after commencing treatment, and whether their eating problems had affected their ability to work/study, job choice, efficiency at work/study, promotion prospects, overtime hours worked, or having a second job. They were asked about sick leave and if they had been treated as an in- or out-patient in a general or psychiatric hospital, or in casualty, in the two years prior to and the six months post-commencement of treatment, and if so, about the nature of their illness and treatment. They were then asked whether in the two years prior to, and (separately) in the six months since commencing treatment they had received help for their eating problems or other emotional or mental health problems from any of the following: GP, eating disorders unit specialist, psychiatrist, psychologist, dietician, counsellor, therapist, practice nurse, self-help group or 'other' professional. Questions were also posed about the number of visits made. Patients were asked if they had lost pay through taking time off work to visit a professional about their eating problems (if applicable). Patients were also asked if they had been taking any medications (name of medication, dose and duration) prescribed by their GP or specialists for physical or mental health problems during the six months since they had commenced treatment. They were then asked if they had had to make childcare arrangements in order to attend their GP or the clinic, and whether friends or family members had accompanied them at clinic or GP visits and taken time off work to do so. Finally, they were asked how much money they spent per week on average on food in the six months prior to and the six months post commencement of treatment.

4.7.5 Follow-up Two (9 months)

In addition to the primary and secondary outcome measures listed above, Follow-up Two also included:

4.7.5.1 A Satisfaction with Treatment Questionnaire II (Appendix 11):

Designed specifically for the purposes of the study and self-completed by patients, this questionnaire consisted of both 'closed' and 'open' questions. Patients were asked to rate on 11-point (0-10) visual analogue scales the severity of their eating problem prior to treatment for it and now. Those participants in the self-help/general practice arm of the trial were asked to rate on 11-point (0-10) visual analogue scales the perceived helpfulness of the self-help manual and their GP. They were asked to indicate which stages of the self-help programme they had undertaken, and to describe which parts of the programme they had found most helpful. They were also asked about the support received from their GP. In addition, they were asked if there were any ways in which the self-help programme with GP support could be improved and whether they had read any books about eating disorders apart from the study manual. Patients who had been randomised to receive treatment at the clinics were asked to rate on an 11-point (0-10) visual analogue scale the perceived helpfulness of the clinic. They were asked to describe which parts of the clinic treatment they found most helpful and if there were any ways in which it could be improved. Those who had stopped attending were asked why this was the case. Clinic patients were also asked if they had read any books about eating disorders since commencing their treatment. Both clinic and self-help patients were asked to describe what had triggered their decision to seek help in the first place. Finally they were asked what had helped them most in trying to overcome their eating problem (be it related to the treatment intervention received or to factors external to the treatment process).

4.7.5.2 An Economic Evaluation and Treatment Attendance Questionnaire II (Appendix 12):

This measure, designed for the study, was the same as that used at the first follow-up, but focusing only the three-month period between the first and second follow-ups.

4.8 GP SURVEYS

As noted earlier, two surveys were undertaken with the GPs who were supporting self-help patients using the manual. The first (Appendix 13) was sent to each GP after s/he had been supporting his/her self-help patient for approximately three months, and consisted of both 'closed' and 'open-ended' questions. GPs were asked about contact with their patient, use of the manual, whether they were finding the manual helpful (and if so, which aspects were particularly helpful), what they thought the patient felt about the self-help programme and whether they were experiencing any problems in supporting their patient.

The second questionnaire (Appendix 14) was sent to GPs after the nine-month follow-up period was over for their patients. Like the first, it consisted of both 'closed' and 'open-ended' questions concerning patient contact, use of the manual, and whether the manual had been helpful (if so, in what way, and if not, how was it lacking?). GPs were asked to describe any difficulties they had encountered in supporting their patient in the use of the self-help programme and if the consultations had involved discussion of other problems in the patient's life apart from eating. They were also asked whether they had prescribed any medications that they felt might help the patient with her eating. Questions were also included concerning GPs' perceptions of the benefits to be gained by patients from the general practice based approach, personal benefits (for the GP) derived from taking part in the study, and whether they felt they had needed more specialist support. Finally, they were asked to describe the advantages and drawbacks of managing patients with BN in general practice, using a self-help approach, and whether they would be prepared to try the self-help approach with future patients.

4.9 POWER CALCULATION

The power calculation for the study was based on the development of the BITE, in which mean scores were 33.8 (SD 6.0) for patients with bulimia nervosa entering specialist treatment and 8.3 (SD 6.0) at the end of treatment (Henderson and Freeman, 1987). The study aimed to assess whether self-help would be no less effective than specialist treatment by two thirds of a standard deviation (moderate treatment effect). In order to detect outcome scores on the BITE at least 0.66 of a standard deviation higher in the self-help arm, it was estimated that at a significance level of 0.05 and a power of

0.8, 36 patients would be required in each arm of the trial.

4.10 RANDOMISATION

A stratified, block randomisation was used to assign patients to each trial arm. Stratification was on the basis of scores on the BITE (Henderson and Freeman, 1987) (low/high scores: high being a score of 35 or above (based on the evidence in the literature concerning mean scores on the measure and personal communication with Dr. Christopher Freeman)). A random sequence of blocks of four for each strata was constructed by a statistician (two self-help and two specialist treatment in each block). Sealed envelopes were employed. These were prepared independently of the researcher. As noted above, the researcher, who interviewed participants, was not blind to group allocation. However, as also noted, the principal outcome measure depended on participant self-report, as did the majority of the standardised instruments used in the study, thereby reducing interviewer bias.

4.11 DATA COLLECTION PROCEDURE

4.11.1 Recruitment

A letter was sent to all GPs in the catchment areas of the three hospitals to inform them that the study was about to commence in their area. Regular updates were also sent in order to remind GPs that the study was underway. Recruitment to the study began at the Royal Free hospital in January 1995, at the North Middlesex in May 1995 and at the Gordon in March 1996 and finished in June 1997. The study was explained in detail to the clinicians and clinic secretaries in each of the clinics prior to commencement. Detailed arrangements were made for logging and keeping track of referrals and of patients taking part in the study. The researcher spoke either in person or on the phone to each of the consultants at the three clinics or their clinic secretaries on a weekly basis to ascertain if any new referrals had been received which would potentially be suitable for the study. Details of each potential participant were logged in a study book (one for each clinic).

Once the researcher had received a referral letter from a clinic, the referring GP was

phoned and provided with information about the study (i.e., about its nature, rationale and methodology and the role they would have to play if a patient was randomised back to them). They were asked if they were willing to allow the researcher contact their patient with a view to recruiting her into the study. Consenting GPs were sent full written information (Appendices 15 and 16). Their patient was subsequently sent a letter and full details of the study including the fact that her GP had been contacted, a number at which she could contact the researcher should she require more information about the study and a study consent /opt out form (Appendix 17). Once written consent had been received, the researcher contacted the patient's GP to let him/her know that she was willing to take part in the study. An appointment was then arranged to conduct a baseline assessment interview with the patient at her GP's surgery.

Where GPs did not want their patients to take part in the study or patients themselves indicated that they did not wish to participate (but still wanted the referral), the appropriate clinic was informed and they were sent a routine appointment letter. Clinic secretaries were asked to ensure that such patients were given a BITE to complete at their first clinic visit so that some estimate could be made of the clinical similarity or otherwise of patients who entered the study and those who did not.

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4.11.2 Baseline assessment

All of the baseline assessment interviews with the exception of one (where the surgery was undergoing renovation and the patient was interviewed in her home) were conducted at patients' surgeries during surgery hours. Whenever possible interviews were conducted at a time when the patient's GP was present in the surgery so that the GP could be told which arm the patient had been assigned to after the baseline assessment, and he/she could be given a copy of the self-help book and study guidelines about supporting self-help patients if appropriate. The researcher introduced herself to the patient and thanked her for attending. She explained the background to the study and outlined the methods and procedures. She briefly explained the nature of the two interventions, as outlined on the information sheet, and ensured that the patient clearly understood what was meant by random allocation. Patients were assured that only study codes would be attached to questionnaires, that study data would be kept in a locked filing cabinet, and that no patient's name would appear in any report or publication. The researcher then went through the Social and Psychiatric History schedule with the

patient, followed by the EDE. The patient completed the BITE and the rest of the self-completion questionnaires. Scores on the BITE were calculated while the patient completed the self-report questionnaires. The researcher then opened the sealed envelope to reveal which the arm of the trial the patient had been allocated to.

Patients randomised to the GP/self help condition were given a copy of the self-help manual and advised to make an appointment before leaving the surgery to see their GP some time the following week (in order to give both the patient and her GP time to read through the manual prior to first appointment). Those randomised to receive clinic treatment were told that they would be sent an appointment to attend the clinic to which they had originally been referred. All of the patients were reminded that they would be contacted for follow-up interviews and asked to inform the researcher, clinic and/or GP should they change address.

If it became obvious during the assessment interview that a patient did not meet diagnostic criteria for BN or that one or other of the exclusion criteria applied, the researcher explained this to the patient. She was told that instead of participating in the study she would be sent a routine clinic appointment for the clinic to which she had been originally referred.

As noted above, where patients were allocated to the self-help arm of the trial, their GP was given a copy of the manual, which the researcher talked through with them, as well as the written study guidelines (Appendix 18). They were asked to contact the researcher if they had any queries or problems or if they felt, at any stage, that their patient needed to be withdrawn from the self-help arm of the trial and seen by a specialist.

Immediately following the baseline assessment interview the appropriate clinic secretary was informed whether a patient was to be sent a clinic appointment - either because she had been randomised to the specialist treatment arm of the trial or because she did not meet the study inclusion criteria - or if she was to be seen by the GP. This information was logged at the clinic, and in the researcher's study logbooks and charts. The clinic secretary informed the researcher of the date of a study participant's first clinic appointment.

4.11.3 Follow-up assessments

Participants were contacted by letter several weeks before their (6 or 9-month) follow-up assessment was due, and offered two possible appointment times. They were also offered the choice of being interviewed in their own home, at the researcher's office at the Royal Free or at their GP's surgery, on the premise that the easier it could be made for patients to attend follow-up the more likely they would be to do so. At the follow-up interview, patients were assessed using the measures described in Section 4.7 above. Where patients did not respond to the first letter, several attempts were made to contact them by post and/or phone (including contacting their GPs and/or the clinic to see if they could provide a new address). Where contact could not be established, questionnaires were sent to a patient's last known address. If they were not returned within a week, a second batch was sent. Patients who had moved away from London were also sent questionnaires by post and/or interviews were conducted on the phone. Where feasible the researcher travelled to see them in person.

4.11.4 Note Searches

Note searches were conducted at the GPs' surgeries and the three clinics after final follow-up assessments for data on attendance, professionals seen, prescribing of psychotropic medication (medication, dose and duration) and other interventions or referrals made by clinic or general practice staff. A pro-forma, based on suggestions made by Dr. Khaver Bashir at the Royal Free Hospital, was used for searching notes. Notes were searched for the nine-month course of the study.

4.12 DATA ANALYSIS STRATEGY

4.12.1 Data entry and general analytic strategy

Data were entered into the SPSS PC statistical package (version 9), and both versions 6 and 9 were used for analysis purposes. Coding sheets devised by the researcher were used for the Social and Psychiatric History, the Economic Evaluation and Treatment Attendance questionnaires, the EDE and for record searches to facilitate data entry. Data were cleaned by using double-entry procedures, and frequency counts. Total scores and subscale scores on the outcome measures were calculated according to published guidelines. Data were checked for normality. Parametric and non-parametric tests were

employed as appropriate. Data were not analysed on the basis of each individual clinic as the numbers involved were too small.

Descriptive statistics were employed to report on study population characteristics, mean scores on outcome measures at baseline and follow-up assessments, and issues such as attendance for treatment. The primary and secondary outcome measures were analysed for within- and between- group differences over the course of the study. Exploratory analyses were undertaken to investigate potential predictors of outcome, perceived helpfulness of treatment and economic variables. Qualitative data were explored for themes and issues concerning patients' motivations for seeking help, their views of the treatments received, difficulties encountered, how treatment approaches might be improved and what had helped them most in trying to overcome their eating problems. Similarly, data from the GP surveys were explored for themes and issues related to their experiences of supporting self-help patients.

Patient attendance for treatment during the study was calculated as follows: self-help patients' attendance at the GP was calculated using data from patient note searches. Where a note search could not be conducted (e.g., because patients refused permission, had moved practice, or notes were lost), reports from GPs obtained in the second GP survey, or patient self-reports were employed. For clinic patients, data from clinic notes searches were employed to calculate attendance at the clinic to see the eating disorders specialist. Where notes were not available/lost, patient self-reports were used. Data from general practice notes or, if unavailable, from self-reports, were employed in order to calculate the number of times that specialist clinic patients visited their GPs about their eating problems throughout the follow-up period.

As the trial was designed to be pragmatic in nature an intention-to-treat analysis was conducted in relation to primary and secondary outcomes. Where self-help patients were seen in the specialist clinic they were retained in the self-help trial arm in the analysis. Where patients could not be followed up or where follow-up data were missing, the last observed value was carried forward for inclusion in analyses. As noted in the literature review, this is the method for replacing missing data reported most commonly in the BN treatment trial literature. While it might be argued that this is a very conservative approach to coping with missing data, given the relative novelty of the self-help

intervention being evaluated, it was considered that this was an appropriate method.

4.12.2 Primary and secondary analysis

Using SPSS version 6, a repeated measures, multivariate analysis of variance and covariance was conducted on mean BITE scores for the two treatment groups, entering baseline BDI scores, age and length of illness as covariates, as these may be potential clinical predictors of outcome. The covariates were included individually initially and then together. The BDI scores at baseline and the two follow-up points were included as varying covariates in a separate analysis. Individual repeated measures analyses, using general linear modelling (GLM) techniques on SPSS version 9, were conducted to examine differences in mean scores on the BDI, EDE (total score and subscales), Work, Leisure and Family Life Questionnaire (total score), and Self-Concept Questionnaire. Significance tests results from the repeated measures analyses are reported using the F ratio equivalent of the multivariate tests (Wilks Lambda) for within- and between-subjects analyses. Patients' ratings of the severity of their eating disorder were analysed using Wilcoxon Signed Ranks Tests to investigate whether within group differences existed between baseline and follow-up scores over the study period. Mann-Whitney U Tests were employed to investigate whether the two treatment groups differed from one another in terms of their severity ratings at any of the three assessment points. Change scores for Objective Bulimic Episodes (OBEs) on the EDE (covering the 28 days prior to each assessment) were calculated for each individual by subtracting the number of episodes of OBEs recorded at follow-ups One and Two from those recorded at baseline (using last observations carried forward data). Change scores for vomiting episodes were similarly calculated for those who reported vomiting at the baseline assessment. Baseline scores and change scores for OBEs and vomiting episodes were analysed for group differences using Mann-Whitney U Tests.

The main outcome analyses and some of the secondary outcomes reported above were also conducted involving only patients for whom full data were available in order to establish whether there would be any important differences between results for those patients and the sample as a whole.

4.12.3 Exploratory analyses

4.12.3.1 Comparison of patients who did and did not take part in the study

In order to investigate whether the patients taking part in the study were similar in terms of their eating disorder characteristics to those who were potentially eligible to participate but declined to do so or whose GP declined, the BITE scores of study participants were compared with the scores of those who did not participate but attended the clinic using a T-Test for independent samples.

4.12.3.2 Perceived helpfulness of treatment

As noted above, data on the perceived helpfulness of treatment were obtained at the 6 and 9-month follow-up points. Therefore only available data were analysed (i.e., last observations were not carried forward). Mann-Whitney U tests were undertaken to investigate whether the two treatment groups differed in terms of their perceived helpfulness ratings at the 6 and 9-month follow-up points.

4.12.3.3 Predictors of treatment outcome

As noted in the literature review, there has been little consensus about predictors of treatment outcome for patients with BN, which may in part be due to the fact that sample sizes in clinical trials have often been too small to produce conclusive results. Notwithstanding the nature of the sample size in the current study, potential predictors of outcome were investigated in an effort to establish whether the findings of previous studies would be replicated. This analysis should be considered exploratory in nature. Categorical variables that had more than two levels were reduced to form two levels where possible for the analysis. Binary logistic regressions were conducted separately for each potential predictor variable with experimental condition entered as a covariate; the dependent variable being BITE scores at the 9-month follow-up (last observations carried forward data) divided into scores up to, and including, 19 and 20 and above. Potential predictor variables investigated were as follows:

- *socio-demographic characteristics*: age and marital status
- *eating disorder history variables*: duration
- *clinical status at baseline*: BITE score, BDI score, and social adjustment score

4.12.3.4 Baseline characteristics of participants who were not assessed at follow-up compared to those who were

T-tests for independent samples were undertaken in order to assess whether there were differences at baseline in the demographic characteristics and mean scores on clinical outcome measures of study participants for whom no follow-up assessment data on the primary outcome measure were available, compared to those for whom follow-up data were available.

4.12.3.5 Treatment preferences

Although this study was not designed to be a patient preference trial, as noted above, data were collected on participants' treatment preferences at baseline. An exploratory analysis was undertaken to investigate the possibility that being allocated to/not being allocated to one's preferred treatment might be predictive of outcome.

4.12.3.6 Economic data

As described in Section 4.7 above, economic data were collected at the 6 and 9-month follow-up points but not at baseline. As a result data are incomplete as they could only be collected for patients who completed either or both follow-ups. In addition, where necessary only the most pertinent economic data (e.g., regarding attendance for treatment) were collected. Furthermore, at the 6-month follow-up participants were asked about events and issues pertaining to the months before the baseline assessment for comparison with the follow-up period (e.g., regarding the impact of the eating disorder on the individual's ability to work). Ideally the information concerning the pre-baseline period would have been collected at the baseline assessment, but this was not feasible because of the length of the assessment interview. Only limited analyses were undertaken therefore using the economic data. These analyses should be regarded as very exploratory and the results presented treated with a degree of caution.

The direct costs of treatment (i.e., GP and clinic costs and the costs of the self-help manual) were calculated for the two arms of the trial, using data from *Unit Costs of Health and Social Care 2002* (Netten and Curtis, 2003, www.ukc.ac.uk/PSSRU). As noted earlier, data collected from clinic and general practice notes, GPs and patient self-report were used to calculate attendance for treatment. However, asking patients to

estimate the length of consultations with GPs did not yield high quality data, and for the self-help patients, GPs' estimates were used in the cost analysis.

The impact of the eating disorder on participants' ability to work during the pre-baseline period compared to during the period to first follow-up was explored using McNemar tests for the sample as a whole and the two treatment arms separately.

4.12.3.7 Qualitative data from GP surveys and patient treatment satisfaction questionnaire

The qualitative data from the GP surveys and the patients' responses to the satisfaction questionnaire at the second follow-up were analysed (separately) using a content analysis approach. 'Content analysis' is the approach most favoured by quantitative researchers for analysing written text (Silverman, 2000). It involves the generation of a set of categories or themes, and then counting the number of instances where the data fall into each category. The first stage in conducting a content analysis of qualitative data is to develop the categories or themes into which the data will be coded (Bowling, 1997). Where the research stems from a theory, the categories or themes should be chosen to represent the theory and the data fitted into them: however, if the aim of the research is to generate theory using the data, then the categories/themes should be generated directly from the data (Bowling, 1997). Bowling (1997), however, suggests that it is always preferable to use the latter approach of 'coding-up' from the data and to ensure that additional theoretical coded are included, and used, if appropriate. As the purpose of collecting qualitative data in the current study was to help contextualise quantitative findings, to generate information concerning the perceived advantages and drawbacks of the general practice-based intervention, and to gather information about the potential barriers and incentives to implementing a self-help approach in primary care, the 'coding-up' from the data approach was applied.

The crucial requirement of content analysis is that the categories/themes generated are precise enough to allow different coders to arrive at the same decisions regarding which categories individual 'items' of data (i.e., section of text) should be coded under (Silverman, 2000). Unlike the situation with the coding of quantitative data, however, Bowling (1997) notes that data may be coded under more than one category, if appropriate, in order to permit cross-referencing of themes and the generation of a

number of hypotheses.

Traditionally, qualitative data have been hand sorted and categorised by theme manually, although recent years have seen the use of computer programmes in the categorisation process. The advantage of the manual method, still used widely in small studies, is that the researcher maintains a close relationship with, and awareness of the raw data (Bowling, 1997). Data were analysed manually in the current study as described below.

For each question posed, all of the responses made by individual patients (or GPs in the case of the surveys) were typed into a Word file. Each question and the responses to it were analysed separately. For each question, the researcher read through the responses several times, and identified a number of broad categories or themes in the responses. Each theme was given a number and a hard copy of the data was then coded using this number scheme. Where possible, responses were placed under one theme only, but in cases where a response fell equally under two or more related themes it was coded under each. Themes were then examined for sub-themes, and where they existed, data were re-coded in terms of these sub-themes. The number of participants whose responses were coded under each individual theme or sub-theme was recorded. Verbatim quotations were used to illustrate the main themes that emerged in patients' (and GPs') responses to each question.

The study's quantitative outcomes are described in Chapter Five. Findings concerning the GPs' experiences of supporting self-help patients and concerning patients' views of treatment are presented in Chapters Six and Seven respectively.

CHAPTER FIVE:

DESCRIPTIVE AND QUANTITATIVE RESULTS

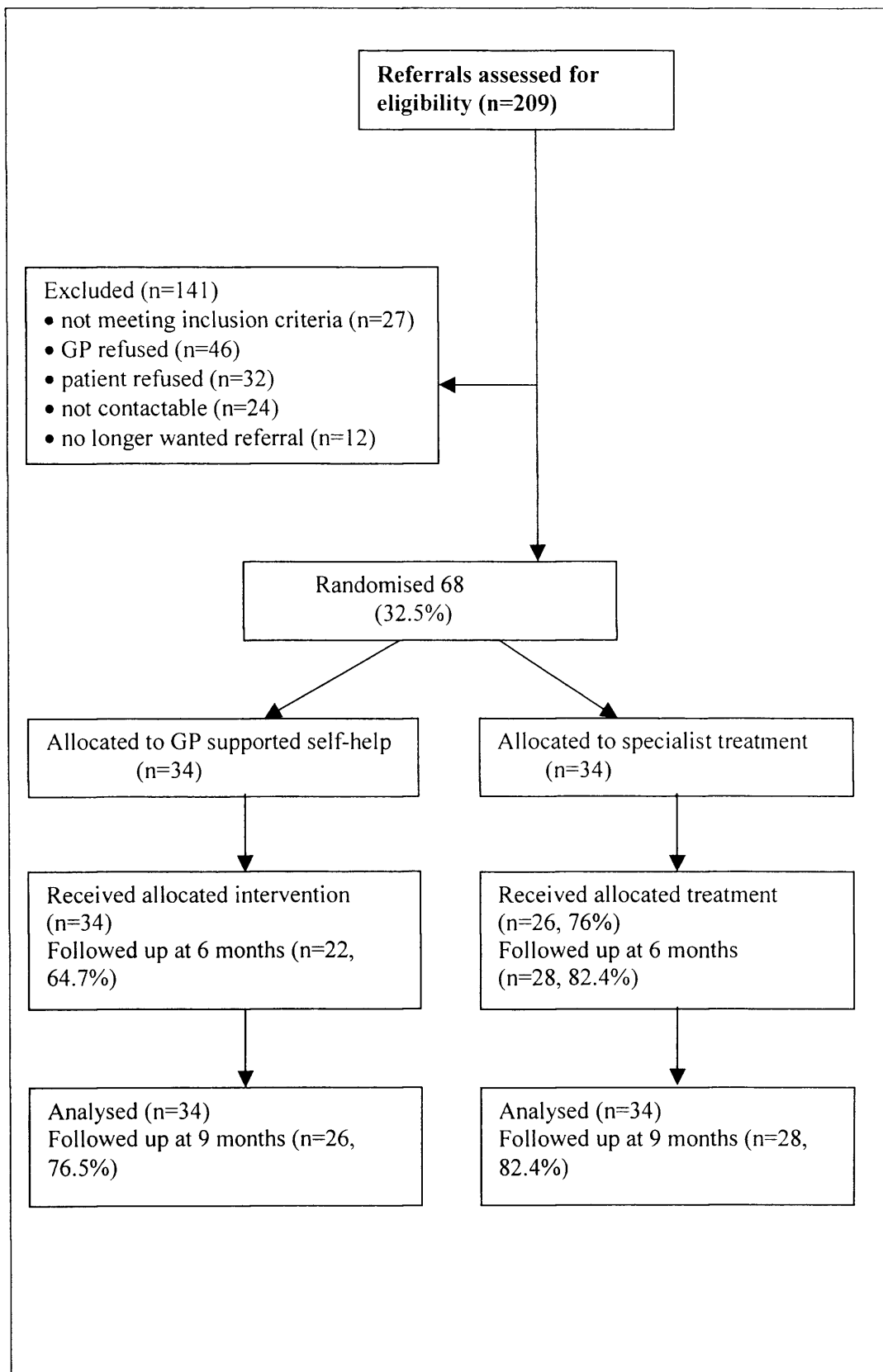
5.1 INTRODUCTION

This chapter focuses on descriptive results and the main outcomes of the trial. The results will be presented as follows:

- Recruitment and allocation to treatment arm
- Sample characteristics at baseline
- Clinical characteristics of those who did not take part in the study
- Attendance for treatment and transfer between self-help and clinic arm of the trial
- Follow-up and response rates at six and nine months
- Primary outcome (BITE)
- Secondary outcomes (BDI, EDE, social adjustment, self-esteem, and self-rated severity)
- Perceived helpfulness of treatment
- Baseline characteristics of those who could not be followed up for assessment at six and nine months
- Predictors of treatment outcome
- Economic analyses
- Conclusions

As mentioned in Chapter Three, it is recommended that researchers conducting clinical trials depict diagrammatically the recruitment and progress of participants through a trial, using the CONSORT trial flow diagram. The flow diagram for the current trial is presented below (Figure 5.1).

Figure 5.1: Trial Flow Diagram



5.2 RECRUITMENT AND ALLOCATION TO TRIAL ARMS

Patients were recruited between January 1995 and June 1997 (trial flow diagram, Figure 5.1). In total, 209 referrals by GPs to specialist clinics were considered for possible inclusion in the study, and sixty-eight patients (32.5%) were recruited into the study. Of 113 referrals from clinic one, 43 patients (38%) were recruited; of 69 referrals from the second clinic 19 (28%) were recruited, while the third clinic provided 27 referrals, of whom six (22%) were recruited.

One hundred and forty-one patients were not recruited into the trial for the following reasons (trial flow diagram, Figure 5.1):

- 1) Twenty-seven did not meet the study inclusion criteria. The majority of these were suffering from an eating disorder other than BN. Eight patients were anorexic. They were underweight, eating very little, and one was admitted as an emergency case, having been assessed by the researcher. Another seven patients were suffering from non-specific eating disorders, including four in their 40s, who were very obese but claimed to be eating little. Five were excluded because of their use of hard drugs (heroin) or because of alcohol problems for which they were either already receiving help or specifically seeking it. The remainder were excluded for reasons such as requiring urgent clinic appointments, pregnancy or having a medical illness (e.g., diabetes).
- 2) GPs, when contacted about 46 referrals, did not consent to their patients being contacted about the study (17, 21 and 8 from clinics one, two and three respectively). Many GPs gave more than one reason for this. Fifteen reported being too busy to take part in the study, citing their administrative load, or unfairness to other patients who would see even less of them were they to participate. Twenty-five saw their patient's problem as being too serious or complicated for the general practice approach, some of them describing their patients as having multiple psychological or social problems requiring specialist treatment. Other reasons for not consenting included the patient being perceived as 'difficult' (3) or not well known (3); a self-help approach having already been tried by the GP (4); and practice policy being not to participate in research (3 practices; 6 referrals).

Miscellaneous reasons provided by seven GPs included not personally wanting to take part, and having had a struggle to get patients to accept a referral in the first place.

- 3) Thirty-two patients approached about the study declined to participate. Although not specifically asked to do so, over half gave at least one reason for their decision. Four said that their problem was too severe for the self-help approach, while another four reported having already undertaken self-help programmes and now wanting specialist help. Three patients reported that they would not be able to work with their GPs as they did not like/had little confidence in them. Four patients who initially consented to take part in the study turned up for the baseline assessment but said that they had changed their minds about participating. Two had decided that they would not feel comfortable working with their GPs, if randomised to the self-help condition. The third had decided that the self-help approach would not benefit her, and the fourth said that she had discovered that the clinic was nearer and more convenient to where she lived than her GP's surgery. Other miscellaneous reasons included not wishing to take part in a trial, or having changed GP.
- 4) Twenty-four patients could not be contacted, although several letters were sent to the address given for them in the GP's referral letter and the address was checked with their GP.
- 5) Twelve patients when contacted about the study telephoned or wrote to the researcher to say that they no longer wanted the clinic referral (because they were leaving the area or London, or had sought treatment elsewhere).

Of the 68 recruited to the study, 34 were randomised to receive the self-help intervention in general practice and 34 to receive specialist out-patient clinic treatment (trial flow chart Figure 5.1).

5.3 THE STUDY SAMPLE: BASELINE CHARACTERISTICS

5.3.1 Socio-demographic characteristics

The socio-demographic characteristics of the study sample are presented in Table 5.1.

The participants in the two arms of the trial were balanced in terms of these characteristics. The majority of the participants in each arm were young, white, single, working or studying, and sharing living accommodation with family or friends. Many had obtained post-school level qualifications. Only eight participants reported having children. Of those who were working, nine participants were in secretarial or administrative jobs, while four were employed in the media/journalism, three were teachers, and six worked in marketing and sales. Four worked in banking or finance, while the remainder had occupations in professions allied to medicine, catering, childcare, the legal profession, the arts and civil service. Of those who reported having a religious affiliation, only five said that they practised their religion. Participants reported being Church of England, Roman Catholic, Jewish or Hindu.

5.3.2 General health, eating history and previous treatment for eating or psychological problems

Only 16% of the study population reported menstrual irregularities (Table 5.2). As can be seen from Table 5.2, roughly two-thirds of those in each arm of the trial perceived themselves to be overweight or very overweight. Participants' subjective evaluations of their actual weight closely matched objective measurements (the researcher weighed patients who permitted her to do so). The average Body Mass Index (BMI) in both groups of participants was in the healthy range, although it ranged between 17.7 (underweight) and 35.6 (obese) for the study population as a whole.

Table 5.1 Socio-demographic characteristics at baseline assessment

DESCRIPTOR	SELF-HELP (34)	CLINIC (34)
Age		
Mean (sd)	28.3 (6.5)	24.5 (5.2)
Marital Status		
Single	24 (71%)	24 (71%)
Married/cohabiting	5 (15%)	9 (27%)
Other	5 (15%)	1 (3%)
Ethnicity		
White	29 (85%)	30 (88%)
Black	3 (9%)	3 (9%)
Other	1 (3%)	1 (3%)
Missing	1 (3%)	0 (0%)
Employment status		
Working full or part-time	20 (59%)	16 (47%)
Unemployed- seeking work	4 (12%)	2 (6%)
Unemployed- not seeking work	4 (12%)	3 (9%)
At college / university	6 (18%)	13 (38%)
Living arrangements		
With spouse/partner or other relatives	15 (44%)	18 (53%)
Flatshare / university halls	11 (32%)	13 (38%)
Alone	8 (24%)	3 (9%)
Educational qualifications		
School:		
Yes	31 (91%)	32 (94%)
Post-school		
None	11 (32%)	18 (53%)
Degree	10 (29%)	13 (38%)
Higher degree	2 (6%)	1 (3%)
Other	11 (32%)	2 (6%)
Religious affiliation		
Yes	13 (38%)	10 (29%)

Table 5.2: General health and attitude to weight

Descriptor	SELF-HELP (34)	CLINIC (34)
Regular menstrual cycle		
Yes	27 (79%)	30 (88%)
Taking oral contraceptive		
Yes	14 (41%)	12 (35%)
Perception of current weight		
Underweight	0 (0%)	1 (3%)
Average	11 (32%)	11 (32%)
Overweight	18 (53%)	17 (50%)
Very overweight	5 (15%)	5 (15%)
Subjective wt (kgs)		
Mean (sd)	60.1 (9.6) *	62.9 (9.9) *
Subjective ht (cms)		
Mean (sd)	164.2 (6.6)	166.8 (6.9)
Objective wt (kgs)		
Mean (sd)	61.2 (9.5) **	63.0 (8.6) *
Objective ht (cms)		
Mean(sd)	164.2 (7.4) *	167.3 (8.3)
BMI		
Mean (sd)	22.9 (4.3)***	22.4 (3.3) *

* n=32 ** n=31 ***n=29

Participants reported having suffered from eating problems for between 1 and 17 years (Table 5.3). While the majority had not previously received a formal diagnosis for their eating problems (and this included the current GP referral), where one had been given it was nearly always BN (Table 5.3). Forty-six per cent (31) of the study population had been previously referred to a 'specialist' for help with eating problems (Table 5.3). However, the specialists seen were not necessarily specialists in eating disorders. They included psychiatrists, psychologists, counsellors and therapists as well specialist eating disorder clinic staff. The majority of those in both groups who had received treatment previously had done so as out-patients, and for most treatment was NHS

based. None of the participants had received treatment in specialist eating disorder clinics in the year prior to the study baseline assessment.

At the time of the initial assessment, 23.5% of the total study population reported that they were taking anti-depressant medication, generally fluoxetine, prescribed by their GPs. The majority of those taking prescribed medication for a physical illness were using inhalers for asthma. As can be seen from Table 5.3, half of the study population reported that they been treated for ‘emotional’ problems, such as depression or general distress / life problems. The types of professionals seen were GPs, psychologists, psychiatrists and counsellors/therapists.

The majority of participants reported that someone apart from their GP/ other health professionals knew about their eating problems (mainly friends, mothers and partners) and almost half said that someone was, in one way or another, being supportive of their attempts to overcome their problem (Table 5.4).

Table 5.3: Eating disorder history and treatment

DESCRIPTOR	SELF-HELP (34)	CLINIC (34)
Previous diagnosis		
None	23 (68%)	25 (74%)
AN	1 (3%)	0 (0%)
BN	9 (27%)	8 (24%)
AN/BN	1 (3%)	1 (3%)
Duration of problem (years)		
Mean (sd)	7.7 (4.6)	5.9 (3.9)
Ever referred to a 'specialist' for eating?		
Yes	18 (53%)	13 (38%)
Type of previous eating treatments		
In-patient	0 (0%)	1 (3%)
Out-patient	15 (44%)	12 (35%)
Both	3 (9%)	0 (0%)
No treatment	16 (47%)	21 (62%)
Nature of previous eating treatment		
NHS	9 (27%)	8 (24%)
Private	2 (6%)	4 (12%)
Both	5 (15%)	1 (3%)
Other	2 (6%)	0 (0%)
No treatment	16 (47%)	21 (62%)
Taking prescribed anti-depressant medication		
Yes	7 (21%)	9 (27%)
Taking prescribed medication for physical illness		
Yes	4 (12%)	8 (24%)
Ever had help for an emotional problem?		
Yes	17 (50%)	17 (50%)
Treatment for:		
Depression	9 (27%)	12 (35%)
General distress	6 (18%)	6 (18%)
Other problems	5 (15%)	7 (21%)

Table 5.4 Relatives' or friends' awareness that the participant has an eating problem

DESCRIPTOR	SELF-HELP (34)	CLINIC (34)
Anyone know about problem?		
Yes	30 (88%)	33 (97%)
Who knows?		
Mother	17 (50%)	22 (65%)
Father	12 (35%)	14 (41%)
Partner/boyfriend	14 (41%)	19 (56%)
Siblings	11 (32%)	13 (38%)
Friends	23 (68%)	19 (56%)
Anyone supportive?		
Yes	27 (79%)	25 (74%)

5.3.3 Family history of illness

Twenty-five participants (37%) reported that at least one immediate relative (family of origin) was suffering from a chronic physical illness, while 56% said that at least one relative had suffered/was suffering from a mental health problem or psychiatric illness (Table 5.5). Roughly equal numbers of participants in both arms of the trial reported that immediate relatives had received treatment for anxiety, alcohol problems, schizophrenia, 'nerves', and eating disorders (Table 5.5).

Table 5.5: Illness history: participants' immediate family members

DESCRIPTOR	SELF-HELP (34)	CLINIC (34)
Has chronic physical illness	15 (44%)	10 (29%)
Have had /has mental illness	21 (62%)	17 (50%)
Has received treatment for:		
Anxiety	9 (27%)	10 (29%)
Alcohol problems	3 (9%)	3 (9%)
Depression	10 (29%)	14 (41%)
Schizophrenia	1 (3%)	1 (3%)
'Nerves'	5 (15%)	4 (12%)
Eating disorder	7 (21%)	7 (21%)

5.3.4 Addictive and self-harming behaviours

Participants were asked about their use of addictive substances, self-harming behaviours, stealing and sexual activity.

5.3.4.1 Use of addictive substances

Reported use of cigarettes, alcohol and drugs are presented in Tables 5.6 and 5.7. Less than half the study population reported that they smoked (Table 5.6). While 17.6% (12) reported that they did not drink alcohol, 4.4% (3) reported drinking every day (Table 5.6). Over half of the study population (n=37; 54.4%) answered ‘no’ to all of the CAGE questions. Only one patient (2.9%) in each group answered affirmatively to all four CAGE questions. The participants who answered in the affirmative to ever having had an ‘eye opener’ drink said that it had not been in the recent past. None of the participants were receiving treatment for alcohol problems at the time of the baseline assessment, although three reported having done so in the past.

Table 5.6: Participants’ reported cigarette and alcohol consumption

DESCRIPTOR	SELF-HELP	CLINIC
Smokes	11 (32%)	14 (41%)
Mean (sd) (n) cigarettes smoked daily	14.9 (5.5) (10)	10.3 (5.2) (14)
Drinks	29 (85%)	27 (79%)
Drinking frequency:		
Less than once per week	10 (29%)	10 (29%)
Everyday	2 (6%)	1 (3%)
Mean units (sd) (n) per week in weeks when drinking	8.6 (10.2) (27)	11.6 (9.5) (24)
CAGE		
Affirmative responses to:		
Cut down drink	11 (32%)	16 (47%)
Annoyed with criticism	4 (12%)	11 (32%)
Guilty about drinking	10 (29%)	11 (32%)
Eyeopener drink	1 (3%)	1 (3%)

N=34 except where indicated

Cannabis was the main drug of use in the study population (Table 5.7). Even so, 43% of the population reported never having used it and only 6 participants reported being regular users. One participant reported being a ‘regular’ user of cocaine but when questioned about her use said that it was only at parties. One participant in the clinic arm of the trial had attended AA for a drug problem in the past.

Table 5.7: Participants’ reported drug use

DESCRIPTOR	SELF-HELP (34)	CLINIC (34)
Cannabis		
Never used	18 (53%)	11 (32%)
In the past, not now	10 (29%)	10 (29%)
Occasionally	3 (9%)	5 (15%)
Sometimes	1 (3%)	4 (12%)
Regularly	2 (6%)	4 (12%)
Cocaine		
Never used	26 (76%)	27 (79%)
In the past, not now	4 (12%)	3 (9%)
Occasionally	2 (6%)	0 (0%)
Sometimes	1 (3%)	3 (9%)
Regularly	0 (0%)	1 (3%)
Missing	1 (3%)	0 (0%)
Heroin		
Never	34 (100%)	33 (97%)
In the past, not now		1 (3%)
Solvents/Inhalants		
Never	32 (94%)	33 (97%)
In the past, not now	2 (6%)	1 (3%)
Non-prescription tranquillisers		
Never	32 (94%)	31 (91%)
In the past, not now	2 (6%)	3 (9%)
Amphetamines		
Never used	27 (79%)	24 (71%)
In the past, not now	4 (12%)	4 (12%)
Occasionally	0 (0%)	2 (6%)
Sometimes	2 (6%)	3 (9%)
Regularly	0 (0%)	1 (3%)
Missing	1 (3%)	0 (0%)

5.3.4.2 Sexual relationships

Asked if they had ever had a sexual relationship, 59 participants (87%) reported that they had (data missing for one participant) (Table 5.8). The majority of those in a current serious relationship described it as 'good'.

Table 5.8: Relationships

DESCRIPTOR	SELF-HELP	CLINIC
Ever had a sexual relationship? Yes	31 (91%)	28 (82%)*
Mean (sd) number of sexual partners in past two years.	N=29 participants 2.2 (1.4)	N=26 participants 2.7 (2.5)
Current serious relationship? Yes	23 (68%)	22 (65%)
Quality of current relationship: Good Poor Variable	(N=23) 15 (65%) 3 (13%) 5 (22%)	(N=22) 16 (73%) 2 (9%) 4 (18%)

* data missing for one participant

5.3.4.3 Self-harming behaviours

Forty-seven participants (69%) said that they had felt like harming themselves, and 27 (40%) reported that they had done so (Table 5.9). None reported a serious attempt at self-harm in the month prior to assessment. Among the patients in both arms of the trial who reported self-harming, the groups were equally balanced in terms of the percentage that reported overdosing. However, a greater percentage of the clinic population who self-harmed did so by cutting or punching/hitting themselves.

Table 5.9: Self-harm and stealing

DESCRIPTOR	SELF-HELP (34)	CLINIC (34)
Ever felt like self-harm?		
Yes	21 (62%)	26 (76%)
Ever self-harmed?		
Yes	11 (32%)	16 (47%)
Means of self harm:	(N=11)	(N=16)
Overdose	6 (55%)	8 (50%)
Cutting	3 (27%)	9 (56%)
Punch/hit self	1 (9%)	5 (31%)
Other	2 (18%)	1 (6%)
Ever felt like stealing?		
Yes	8 (24%)	13 (38%)
Ever stolen from shops?		
Yes	7 (21%)	13 (38%)
Ever caught shoplifting?		
Yes	3 (9%)	6 (18%)
Ever charged with shoplifting?		
Yes	0 (0%)	2 (6%)

5.3.4.4 Stealing

Almost one-third of the population reported stealing from shops (Table 5.9), although, anecdotally, some reported that this was when they were teenagers. A greater number of those in the clinic arm of the trial had engaged in shoplifting, and had been charged with the offence, but none of participants had served custodial sentences for shoplifting.

5.3.4.5 Summary

Participants in both arms of the trial were well balanced in terms of the percentage that reported smoking and drinking, and in terms of their consumption of cigarettes and alcohol. The trial arms were also balanced in terms of participants' reported drug use. Most of the study participants had four or fewer sexual partners in the two years prior to baseline interview. Slightly more of the participants in the clinic arm reported engaging in self-harming behaviours and shoplifting.

5.3.5 Expectations about treatment, and treatment preferences

Participants rated their expectations about treatment on visual analogue scales (0-10, with 10 being the positive end of the scale in each case). As can be seen from Table 5.10, participants in both arms of the study placed considerable importance on overcoming their eating disorder. Means scores for the expected effectiveness of the GP, self-help manual and clinic in helping them to overcome their eating problems were similar in the two groups.

Table 5.10: Expectations about treatment

DESCRIPTOR	SELF-HELP (34)	CLINIC (34)
How important to overcome? Mean (sd)	9.3 (1.2)	8.7 (1.8)
How confident can overcome? Mean (sd)	6.4 (3.0)	6.5 (2.8)
How helpful expect manual? Mean (sd)	5.7 (2.6)	5.9 (2.9)
How helpful expect GP? Mean (sd)	5.9 (2.7)	6.0 (2.8)
How helpful expect clinic? Mean (sd)	7.3 (2.2)	6.9 (2.2)

The majority of participants in both arms of the trial reported having at least a ‘satisfactory’ relationship with their GP. The groups were also quite well balanced with respect to their treatment preferences (Table 5.11), although slightly more of those in the self-help arm reported having no treatment preference.

Table 5.11 Quality of relationship with GP and treatment preferences

DESCRIPTOR	SELF-HELP (34)	CLINIC (34)
Relationship with GP		
Very good	5 (15%)	2 (6%)
Good	18 (53%)	13 (38%)
Satisfactory	7 (21%)	11 (32%)
Not very good	2 (6%)	4 (12%)
Bad	0 (0%)	0 (0%)
Missing	2 (6%)	4 (12%)
Treatment preference		
Eating disorder clinic	12 (35%)	14 (41%)
Self-help/GP	7 (21%)	8 (24%)
No preference	13 (38%)	9 (27%)
Missing	2 (6%)	3 (9%)

5.3.6 General summary of the study population's baseline demographic characteristics, psychiatric histories and expectations about treatment

In summary, the participants randomised to the two arms of the trial can be described as well balanced at baseline assessment in terms of their demographic characteristics and eating disorder and mental health histories. The majority of the study participants were white, single, and working or studying. At least 65% of the participants in both arms perceived themselves to be overweight at baseline. Almost half of the sample had previously been referred to specialists (but not necessarily specialists in eating disorders) for eating problems. However, only a quarter of the participants had previously received a specific eating disorder diagnosis for their problem.

Approximately half of the study population had received previous treatment for emotional problems, while 40% reported a history of self-harming behaviours, ranging from hitting themselves to overdosing, and roughly one-quarter were taking antidepressants at the time of the baseline assessment. This suggests high levels of previous emotional distress in the study sample. In addition, over half of the participants reported a history of mental health or psychiatric problems in their immediate families. The trial arms were also generally balanced in terms of participants' use of addictive substances and number of sexual relationships in the two

years prior to the study baseline assessment, although slightly more of those in the clinic arm reported self-harming behaviours and stealing.

In addition, patients in both arms of the trial were quite balanced in terms of their treatment preferences, and their expectations of how helpful the treatments being studied would be. In both groups participants placed high levels of importance on overcoming their eating problems.

5.4 CLINICAL CHARACTERISTICS OF THOSE WHO DID NOT TAKE PART IN THE STUDY

BITE scores were obtained for 47 of the potential participants who did not take part in the trial, but who attended the clinics. Three of those for whom data were collected would have been excluded from the study on the basis of their BITE scores being too low and seven questionnaires were incomplete. The mean BITE score for the remaining 37 non-participants was 37.9 (sd 7.4), which was significantly higher than for participants in the trial (mean difference=4.02, 3.01, df=103, p=0.003).

5.5 ATTENDANCE FOR TREATMENT

As noted earlier 34 patients were randomly allocated to each arm of the trial. Thirty-two GPs acted as support GPs to the patients in the self-help arm of the trial (two GPs had two patients each in the self-help arm). Three self-help patients were seen at the clinic after their GPs requested it (one after several weeks and the other two after several months). In addition two self-help patients requested clinic appointments, one of whom was seen in the clinic only once. Each of the patients in the self-help arm received a copy of the self-help manual. Over the period of the trial, patients in the self-help arm saw their GPs a mean of 4.9 times (sd 5.6; range 0-28; n=31), while those receiving specialist clinic treatment saw a clinic specialist 4.8 times (sd 6.0; range 0-25; n=34). Twenty-five self-help patients visited the GP at least once (data missing for a further three) and twenty-six clinic patients saw the specialist at least once. Participants in the clinic arm of the trial saw their GP on average 1.9 times (sd 2.7, range 0-13; n=29). Out of 48 patients for whom data are available seven clinic patients

saw a dietician at the specialist clinic and one self-help patient saw a dietician at work during the course of the study.

In terms of reporting receiving treatment that was additional to that provided within the context of the study, three self-help and four clinic patients (out of 48) reported seeing counsellors while four clinic and one self-help patient (out of 47) reported seeing a therapist during the study period.

In terms of compliance with the self-help programme, 23 patients in the self-help arm indicated which of the stages of the self-help programme they had tried (Table 5.12).

Table 5.12: Reported use of the steps of the self-help programme by those in the self-help arm of the trial who responded to the question at the 9-month follow-up (n=23)

Stages of self-help programme tried	N (% of 23)
1. Monitoring eating	18 (78%)
2. Instigating meal plan	16 (70%)
3. Learning to prevent binges	8 (35%)
4. Problem solving	6 (26%)
5. Eliminating dieting	8 (35%)
6. Changing one's mind	2 (9%)

5.6 RESPONSE RATES AT SIX AND NINE MONTH FOLLOW-UPS

At least some outcome data were collected for 74% and 80% of the study participants at the six and nine-month follow-ups respectively. Actual response rates for each outcome measure are presented in Table 5.13. As can be seen, there were slightly higher rates for those in the clinic arm of the trial at both follow-ups.

Table 5.13: Responses rates to study outcome measures at 6 and 9 months

MEASURE	6 MONTHS		9 MONTHS	
	SELF-HELP	CLINIC	SELF-HELP	CLINIC
BITE	22 (65%)	28 (82%)	26 (76%)	28 (82%)
BDI	22 (65%)	28 (82%)	22 (65%)	26 (76%)
EDE	20 (59%)	26 (76%)	20 (59%)	21 (62%)
SAQ	21 (62%)	28 (82%)	22 (65%)	24 (71%)
Self-rated severity	21 (62%)	28 (82%)	24 (71%)	25 (74%)
Self-esteem	21 (62%)	28 (82%)	22 (65%)	24 (71%)

Data concerning the perceived helpfulness of treatment were collected at the two follow-up points while the qualitative data concerning treatment were collected only at the second follow-up. As these measures are not technically *a priori* study outcome measures, response rates are reported separately below (Table 5.14).

Table 5.14: Response rates to other study measures

MEASURE	6 MONTHS		9 MONTHS	
	SELF-HELP	CLINIC	SELF-HELP	CLINIC
Perceived helpfulness of treatment	20 (59%)	23 (68%)	23 (68%)	20 (59%)
Qualitative data	N/A	N/A	23 (68%)	25 (74%)

5.7 STUDY OUTCOME

The mean scores for the 68 participants on the study measures at baseline, 6 and 9 months (with last observations carried forward as necessary) are presented in Table 5.15. Mean scores for only those participants who could be followed up at 6 and/or 9 months are presented in Table 5.16.

Table 5.15: Mean scores on outcome measures at baseline, 6 and 9 months: all participants (last observations carried forward as necessary)

MEASURE	TIME POINT	SELF-HELP (34)	CLINIC (34)	EFFECT SIZE
BITE Mean (sd)	Baseline 6 months 9 months	34.1 (6.3) 28.9 (11.3) 26.2 (12.4)	33.7 (5.9) 28.2 (9.9) 26.6 (11.4)	0.03
BDI Mean (sd)	Baseline 6 months 9 months	21.7 (9.7) 17.8 (11.7) 16.2 (9.9)	21.4 (10.7) 18.1 (10.6) 15.5 (10.8)	-0.07
Patient rated severity Mean (sd)	Baseline 6 months 9 months	7.6 (2.2) 6.6 (3.2) 5.8 (3.1)	7.1 (2.6) 6.1 (3.0) 4.8 (2.8)	-0.34
Social Adjustment (total score) Mean (sd)	Baseline 6 months 9 months	2.4 (0.4) 2.3 (0.5) 2.2 (0.4)	2.5 (0.5) 2.3 (0.5) 2.2 (0.6)	0.0
EDE (total score) Mean (sd)	Baseline 6 months 9 months	3.0 (1.0) 2.6 (1.2) 2.4 (1.2)	3.3 (0.8) 2.8 (1.0) 2.6 (1.0)	0.18
Self-esteem* Mean (sd)	Baseline 6 months 9 months	100.5 (27.0) 107.6 (29.4) 108.1 (29.9)	86.9 (30.5) 97.6 (29.9) 105.4 (39.3)	-0.08

* Higher scores on this scale represent higher self-esteem

Table 5.16: Mean scores on outcome measures at baseline, 6 and 9 months for patients who could be followed up at either / both time points

MEASURE	TIME POINT	SELF-HELP	CLINIC
BITE	Baseline	34.1 (6.3) 34	33.7 (5.9) 34
Mean (sd) (no.)	6 months	24.6 (11.9) 22	27.4 (9.9) 28
	9 months	24.7 (12.1) 26	26.4 (11.1) 28
BDI	Baseline	21.7 (9.7) 34	21.4 (10.7) 34
Mean (sd) (no.)	6 months	13.7 (11.5) 22	18.1 (10.9) 28
	9 months	13.8 (9.2) 22	14.1 (11.1) 26
Patient rated severity	Baseline	7.6 (2.2) 34	7.1 (2.6) 34
Mean (sd) (no.)	6 months	5.7 (3.5) 21	6.2 (3.0) 28
	9 months	5.1 (2.8) 24	4.5 (2.7) 25
Social Adjustment (total score)	Baseline	2.4 (0.4) 34	2.5 (0.5) 34
Mean (sd) (no.)	6 months	2.2 (0.5) 21	2.3 (0.5) 28
	9 months	2.1 (0.4) 22	2.2 (0.6) 24
EDE (total score)	Baseline	3.0 (1.0) 34	3.3 (0.8) 34
Mean (sd) (no.)	6 months	2.1 (1.0) 20	2.7 (1.0) 26
	9 months	1.9 (0.9) 20	2.3 (0.8) 21
Self-esteem	Baseline	100.5 (27.0) 34	86.9 (30.5) 34
Mean (sd) (no.)	6 months	108.6 (35.6) 21	98.1 (28.4) 28
	9 months	107.1 (33.0) 22	108.1 (40.9) 24

5.7.1 Primary outcome: Bulimic Investigatory Test, Edinburgh (BITE)

5.7.1.1 Analysis based on intention-to-treat with last observations carried forward

For BITE scores, there was a significant main effect for time ($F=18.00$ df 2,65 $p<0.001$) but not for intervention group by time ($F=0.16$ df=2,65 $p=0.850$). Both

groups improved significantly over time with no difference between them. When BDI baseline scores, age, and duration of illness were assessed individually as covariates, only the BDI baseline scores reached significance ($F=11.60$ $df=1,65$ $p=0.001$). The results were confirmed when all three covariates were entered into the analysis together ($F=4.32$ $df=1,63$ $p=0.008$). BDI scores were also incorporated into the analysis as varying covariates (baseline, 6 months and 9 months). The results confirmed the relationship between BDI and BITE scores throughout the course of the study ($F=30.06$ $df=1,65$ $p<0.001$). As BITE scores decreased over time so did BDI scores.

5.7.1.2 Analysis based on participants with full data

An analysis based on participants with full data produced the same results, with a main effect for time ($F=16.03$ $df=2,43$ $p<0.001$) but no difference between treatment groups over time ($F=0.37$ $df=2,43$, $p=0.692$). Baseline BDI scores incorporated on their own almost reached significance ($F=3.30$ $df=1,43$ $p=0.076$) and BDI scores included as varying covariates were significant ($F=9.87$, $df=1,40$ $p=0.003$), indicating a similar pattern of results to the intention-to-treat analysis. BDI scores, age and duration of illness entered into the analysis together had no significant effect as covariates ($F=1.24$, $df=1,41$ $p=0.307$).

5.7.1.3 Percentage of patients in each trial arm no longer meeting full clinical criteria at the nine-month follow-up

Using last observation carried forward data, ten self-help (29.4%) and nine clinic (26.5%) patients had a total score of less than 20 on the BITE at final follow-up, suggesting that they no longer met full clinical criteria for BN.

5.7.2 Secondary outcomes

5.7.2.1 Beck Depression Inventory (BDI)

Mean scores on the BDI are presented in Tables 5.15 and 5.16 above. An intention-to-treat analysis (repeated measures General Linear Modelling (GLM)) with last observations carried forward revealed a main effect for time ($F=14.81$, $df=2,65$, $p<0.001$), but not for treatment group by time ($F=0.13$, $df=2,65$, $p=0.878$). Depression scores therefore decreased significantly in both groups over time but the groups did not differ from one another. An analysis based on participants with full data produced the

same pattern of results, with a significant main effect for time ($F=12.60$, $df=2,40$, $p<0.001$) but not for treatment group by time ($F=0.26$, $df=2,40$, $p=0.773$). Depression therefore improved over the time course of the study, but the two groups of participants did not differ from one another over time in terms of their improvement.

5.7.2.2 Eating Disorder Examination (EDE)

Mean global scores on the EDE at baseline, 6 and 9 months are presented in Tables 5.15 and 5.16 above, while subscale means are presented in Tables 5.17 and 5.18 below along with mean frequencies of objective bulimic episodes (OBEs) and vomiting episodes in the 28 days prior to assessment.

Table 5.17: EDE subscales: mean baseline and outcome scores for all participants (last observations carried forward where necessary)

EDE SUBSCALE	TIME POINT	SELF-HELP (34)	CLINIC (34)
EDE Restraint	Baseline	3.3 (1.0)	3.4 (0.8)
Mean (sd)	6 months	2.8 (1.3)	2.6 (1.4)
	9 months	2.4 (1.4)	2.8 (1.1)
EDE Eating concern	Baseline	2.4 (1.2)	2.5 (1.0)
Mean (sd)	6 months	2.0 (1.3)	2.1 (1.3)
	9 months	1.8 (1.3)	1.9 (1.2)
EDE Weight concern	Baseline	3.1 (1.3)	3.4 (1.3)
Mean (sd)	6 months	2.6 (1.4)	3.0 (1.2)
	9 months	2.5 (1.5)	2.9 (1.3)
EDE shape concern	Baseline	3.4 (1.2)	3.9 (1.1)
Mean (sd)	6 months	2.9 (1.3)	3.3 (1.2)
	9 months	2.9 (1.3)	3.0 (1.3)
OBEs (previous 28 days)	Baseline	19.0 (15.2)	20.4 (19.6)
Mean (sd)	6 months	16.4 (17.4)	12.6 (14.2)
	9 months	15.0 (17.4)	14.9 (18.9)
Episodes of vomiting (previous 28 days)*	Baseline	35.1 (31.0)	37.8 (33.9)
Mean (sd)	6 months	25.0 (25.6)	16.5 (18.7)
	9 months	20.3 (27.0)	20.5 (23.9)

* N=48 (28 SH and 20 clinic) who reported vomiting at baseline

The median number of OBEs for those in the self-help arm of the trial at baseline, follow-up one and follow-up two was 16.0, 8.0 and 8.0 respectively, while for those in the clinic arm it was 16.5, 7.0 and 6.5 respectively. For those reported vomiting at baseline, the median number of vomiting episodes for those in the self-help arm was 28.0, 16.5, and 11.5 at baseline, and follow-up one and two respectively. For those in the clinic arm it was 29.0, 10.0 and 10.5 at baseline, follow-up one and follow-up two respectively.

Table 5.18: EDE subscales: mean baseline and outcome scores for patients who could be followed up at either/both time points

EDE SUBSCALE	TIME POINT	SELF-HELP	CLINIC
EDE Restraint (mean; sd; no.)	Baseline	3.3 (1.0) 34	3.4 (0.8) 34
	6 months	2.4 (1.3) 20	2.4 (1.4) 26
	9 months	1.9 (1.1) 20	2.6 (0.9) 21
EDE Eating Concern (mean; sd; no.)	Baseline	2.4 (1.2) 34	2.5 (1.0) 34
	6 months	1.5 (1.1) 20	2.3 (1.4) 26
	9 months	1.3 (0.9) 20	1.7 (1.0) 21
EDE Weight Concern (mean; sd; no.)	Baseline	3.1 (1.3) 34	3.4 (1.2) 34
	6 months	2.2 (1.1) 20	2.9 (1.2) 26
	9 months	2.1 (1.2) 20	2.5 (1.3) 21
EDE Shape Concern (mean; sd; no.)	Baseline	3.4 (1.2) 34	3.9 (1.1) 34
	6 months	2.3 (1.1) 20	3.3 (1.2) 26
	9 months	2.4 (1.1) 20	2.6 (1.2) 21
OBEs (previous 28 days) (mean; sd; no.)	Baseline	19.0 (15.2) 34	20.4 (19.6) 34
	6 months	12.4 (16.1) 21	10.7 (12.7) 26
	9 months	8.2 (11.4) 20	14.3 (21.1) 21
Episodes of vomiting (previous 28 days) (mean; sd; no.)	Baseline	35.1 (31.0) 34	37.8 (33.9) 34
	6 months	17.1 (19.0) 18	17.0 (20.1) 17
	9 months	12.2 (20.1) 15	20.9 (26.9) 15

A repeated measures GLM conducted on the EDE global scores on an intention-to-treat basis with last observations carried forward revealed a main effect for time ($F=18.92$, $df=2,65$, $p<0.001$) but not for treatment group by time ($F=0.07$, $df=2,65$, $p=0.930$). The same pattern was seen when only participants with full data were included in the analysis, with a main effect for time ($F=24.79$, $df=2,35$, $p<0.001$) but not for treatment group by time ($F=0.14$, $df=2,35$, $p=0.871$). There was therefore a reduction in eating pathology, as measured by the EDE total score, in both groups over time but the two intervention groups did not differ in terms of this reduction.

Each of the EDE subscales was also analysed separately on an intention-to-treat-basis, using last observations carried forward data. The results are presented in Table 5.19: the findings revealed a main effect for time on each of the four subscales but only for treatment group by time on the Restraint and Shape Concern subscales.

Table 5.19 EDE subscales: GLM results

Subscale	Main effect of time	Treatment type by time
Restraint	$F=13.853$, $df=2, 65$, $p<0.001$	$F=4.033$, $df=2,65$, $p=0.022$
Eating Concern	$F=8.288$, $df=2,65$, $p=0.001$	$F=0.041$, $df=2,65$, $p=0.960$
Weight Concern	$F=12.177$, $df=2,65$, $p<0.001$	$F=0.185$, $df=2,65$, $p=0.831$
Shape Concern	$F=16.547$, $df=2,65$, $p<.001$	$F=3.266$, $df=2,65$, $p=0.045$

Using last observation carried forward data Mann-Whitney U Tests revealed no difference between the two treatment groups in terms of OBEs at baseline (Mann-Whitney U 576.500; $Z=-0.018$; $p=0.988$); in baseline to 6 month follow-up change scores (Mann-Whitney U = 517.500; $Z=-0.757$; $p=0.449$); or in baseline to 9 month follow-up change scores (Mann-Whitney U =573.000; $Z=-0.062$; $p=0.951$). Similarly for those participants who reported vomiting at baseline, there was no differences between the two groups in terms of baseline vomiting episodes (Mann-Whitney U=263.500; $Z=-0.345$; $p=0.730$); in baseline to 6 month follow-up change scores

(Mann-Whitney $U = 234.500$; $Z = -0.964$; $p = 0.335$) or in baseline to 9 month change scores (Mann-Whitney $U = 267.500$; $Z = -0.263$; $p = 0.793$).

5.7.2.3 Social adjustment (Work, Leisure and Family Life Questionnaire)

Mean total scores on the social adjustment scale at baseline, 6 months and 9 months follow-up are presented in Tables 5.15 and 5.16 above. As noted in the method section the higher the scores the poorer the social adjustment, so a decrease in scores implies an improvement in social adjustment. A repeated measures GLM revealed a main effect for time ($F = 8.66$, $df = 2, 65$, $p < 0.001$) but not for intervention group by time ($F = 0.78$, $df = 2, 65$, $p = 0.461$). When data from participants with full data were analysed there was also a main effect for time ($F = 6.34$, $df = 2, 41$, $p = 0.004$) but not for treatment group by time ($F = 0.51$, $df = 2, 41$, $p = 0.606$). Social adjustment therefore improved over time for the sample as a whole, but the intervention groups did not differ over time in terms of their improvement in social adjustment.

5.7.2.4 Self-esteem (Self-Concept Questionnaire)

Mean scores on the self-esteem scale at baseline and for the two follow-ups are presented in Tables 5.15 and 5.16 above. As noted in the Method section, the higher the individual's score on this questionnaire the better their self-esteem. A repeated measures GLM, conducted on an intention-to-treat basis, using last observation carried forward data, revealed a main effect for time ($F = 13.11$, $df = 2, 65$, $p < 0.001$) but not for treatment group by time ($F = 1.77$, $df = 2, 65$, $p = 0.179$). The same pattern of results was obtained when only participants with full data were included in the analysis ($F = 11.54$, $df = 2, 41$, $p < 0.001$ and $F = 1.17$, $df = 2, 41$, $p = 0.321$ respectively).

5.7.2.5 Perceived severity

As noted above, study participants were asked to rate the perceived severity of their eating problems at the baseline and the two follow-up points. Where data were not available at follow-up, last observations were carried forward. The means are presented in Tables 5.15 and 5.16 above. Wilcoxon Signed Rank tests revealed within-group differences with both the self-help and clinic patients rating their disorder as less severe

at second follow-up than at baseline (Table 5.20). However, Mann-Whitney U tests revealed no differences between the self-help and specialist clinic patients in terms of their ratings of the severity of their illness at either baseline or the two follow-up points (Table 5.21).

Table 5.20: Within-group analyses: perceived severity of eating disorder (last observations carried forward as necessary)

Perceived Severity	Self- help	Clinic
Baseline vs FU1	Z=-1.871; p= 0.061	Z=-2.090; p=0.037
FU1 vs FU2	Z=-2.087; p=0.038	Z=-2.875; p=0.004
Baseline vs FU2	Z=-3.262; p=0.001	Z=-3.571; p<0.001

Table 5.21: Between-group analyses: Perceived severity of eating disorder (last observations carried forward as necessary)

Perceived severity at time points	Between-group effects
Baseline	Mann-Whitney U=526.500; Z=-.639; p=0.523
Follow-up 1	Mann-Whitney U=502.500; Z=-.934; p=0.350
Follow-up 2	Mann-Whitney U=467.000; Z=-1.372; p=0.170

When data from participants with full data only were analysed, a similar pattern emerged. However, there was not a significant within-group difference for the self-help patients between perceived severity at follow-up one and follow-up two (Z=-.1.593; p=0.111). Again there were no between-group differences at either of the two follow-up points.

The results therefore suggest that both groups perceived their illness as less severe at follow-up than at baseline. However, they did not differ from one another in terms of their severity ratings at any of the assessment points.

5.8 PERCEIVED HELPFULNESS OF TREATMENT

Patients were asked to rate how helpful they had perceived clinic or self-help treatments at the 6 and 9-month follow-up assessments. Helpfulness ratings are presented in Table 5.22. Only actual data were included in the analyses. Therefore the respondents whose data were included differed slightly at the two follow-up points.

The results of Mann-Whitney U Tests at each of the follow-up points revealed no significant differences between the two treatment groups in terms of their perceptions of the helpfulness of the treatments received (Table 5.23)

Table 5.22: Perceived helpfulness of treatment at 6 and 9 months

Perceived helpfulness if treatment at:	Self-help (Mean, sd, no.)	Clinic (Mean, sd, no.)
6 months		
Eating disorder clinic treatment	N/A	3.9 (3.3) (23)
GP and Manual	4.4 (3.6) (20)	N/A
9 months		
Eating Disorder Clinic treatment	N/A	4.7 (2.9) (20)
GP	3.9 (3.0) (23)	N/A
Manual	3.2 (3.0) (23)	N/A

Table 5.23: Perceived helpfulness of treatment at 6 and 9 months: between-group analyses

Perceived helpfulness of treatment	Between group-effects
Follow-up 1 - 6 months	
EDC or GP and manual	Mann Whitney U =214.500; Z=-.381; p=0.703
Follow-up 2 - 9 months	
EDC or GP	Mann-Whitney U= 189.500; Z=-.992; p=0.321
EDC or manual	Mann-Whitney U=163.500; Z=-1.634; p=0.102

EDC = Eating Disorders Clinic

5.9 BASELINE CHARACTERISTICS OF PARTICIPANTS WHO COULD NOT BE ASSESSED AT FOLLOW-UP COMPARED TO THOSE WHO COULD BE

The baseline scores on clinical outcome measures of patients (n=10) for whom no primary outcome follow-up data were available were compared with those for whom follow-up data were available. The two groups did not differ in terms of their mean scores on any of the measures examined: that is, BITE, BDI, or social adjustment scores. In addition, there was no difference between the two groups in terms of age or the length of time that they had had their eating problem.

5.10 PREDICTORS OF TREATMENT OUTCOME

5.10.1 Clinical and demographic characteristics

When treatment type was controlled for, only marital status (being married/ co-habiting) and having lower BITE baseline scores were found to be positive predictors of treatment outcome at the nine month follow-up point (using last observation carried forward data at this point). However, their significance is lost in the adjusted analysis. The adjusted and unadjusted odds ratios are presented in Table 5.24.

Table 5.24: Predictors of treatment outcome: clinical and demographic characteristics

Predictor Variable	Unadjusted OR	95% CI	p	Adjusted OR	95% CI	p
Socio-demographic						
Age	1.02	(0.93, 1.12)	0.69	1.05	(0.94, 1.18)	0.38
Marital status (married/ co-habiting)	0.27	(0.08, 0.94)	0.04	0.42	(0.10, 1.84)	0.26
Eating disorder history						
Duration of eating disorder	0.90	(0.79, 1.04)	0.17	0.88	(0.75, 1.05)	0.17
Clinical status at baseline						
BITE (lower)	0.91	(0.82, 1.00)	0.04	0.93	(0.83, 1.04)	0.18
BDI (lower)	0.95	(0.90, 1.01)	0.09	0.99	(0.91, 1.08)	0.75
Social adjustment	0.34	(1.10, 1.25)	0.11	0.95	(0.13, 6.67)	0.96

5.10.2 Baseline treatment preferences

Being allocated to the preferred treatment (i.e., self-help or clinic) if the patient had a preference, was not found to be predictive of outcome at the second follow-up point.

5.11 ECONOMIC ANALYSES

5.11.1 Introduction

As noted in the previous chapter, analyses undertaken with economic data should be considered exploratory in nature, and treated with caution.

5.11.2 Direct costs of treatment

As detailed in Chapter Four, patient records at the clinics and GP surgeries, as well as self-report data were used to calculate attendance rates at clinics and surgeries for treatment over the follow-up period of the studies. Data relating to the *number* of

clinic/surgery visits can therefore be considered quite reliable. Asking patients to estimate the *amount of time* they spent with a GP during a consultation, however, proved far more difficult, with the typical response being “the usual time”. For this reason, data obtained from GPs (see Chapter Six), which are also open to the criticism that they may not be completely accurate, were used in generating costs. On average GPs reported that they spent 10-20 minutes with patients.

The costs presented in Table 5.25 are based on Netten and Curtis’s (www.ukc.ac.uk/PSSRU 2003) report, *Unit Costs of Health and Social Care 2002*, which estimates costs of £2.12 per minute for GP surgery time, and £136 per out-patient attendance for patients with mental health problems. They are also based on a (perhaps generous) estimation that each GP consultation with a ‘self-help’ patient lasted 20 minutes, while GP consultations with ‘clinic’ patients lasted ‘the usual 10 minutes’. On this basis the actual cost of the self-help approach for the 34 patients randomised to this arm of the trial is considerably less than the clinic costs for 34 patients randomised to receive specialist care (Table 5.25).

Again, it must be stated that these figures should be treated with some caution.

Table 5.25: Direct costs of treatment

SELF-HELP (34)		CLINIC (34)	
Total number GP visits	153	Total number GP visits	56
Cost per visit	£42.40	Cost per visit	£21.20
Total GP costs	£6487.20	Total GP costs	£1187.20
Total number clinic visits	35	Total number clinic visits	162
Cost per visit	£136	Cost per visit	£136
Total clinic costs	£4760	Total clinic costs	£22,032
Number of self-help books	34		
Cost per book	£5.99		
Total costs	£203		
GRAND TOTAL	£11,450	GRAND TOTAL	£23,219

5.11.3 Changes in marital, employment and accommodation status between commencement of treatment and the first follow-up

Two self-help patients and one clinic patient (out of 50) reported a change in their marital status in the period between commencement of treatment and the first follow-up (getting married or cohabiting with a partner), while three self-help and eight clinic patients (out of 50) reported a change of accommodation. Five self-help and seven clinic patients (out of 49) reported that they had a change in employment status between commencing treatment and follow-up one. However, none of these reported that the change was in any way related to their eating problems.

5.11.4 Impact of eating disorder on ability to work as reported at the six-month follow-up.

As noted earlier, as part of the economic evaluation, participants were asked if their ability to work, their job choice and their efficiency at work had been affected by their eating problems. At the first follow-up, participants were asked to answer these questions in relation to the six months prior to commencement of treatment, and the six months between commencement and follow-up. The responses to each of the three questions are presented in Table 5.26 below.

Table 5.26: Participants' perceptions of the impact of their eating problems on their ability to work, their job choice and their efficiency at work, as measured at Follow-up 1 (6 months).

Eating problems affected the:	6 months prior to treatment		6 months post commencement of Rx	
	Self-help	Clinic	Self-help	Clinic
Ability to work				
Yes	10 (48%)	18 (69%)	5 (24%)	13 (50%)
No	11 (52%)	7 (27%)	16 (76%)	12 (46%)
N/a	0	1 (4%)	0	1 (4%)
Total	21	26	21	26
Job choice				
Yes	5 (24%)	3 (12%)	3 (14%)	6 (23%)
No	12 (57%)	17 (65%)	13 (62%)	17 (65%)
N/a	4 (19%)	6 (24%)	5 (24%)	3 (12%)
Total	21	26	21	26
Efficiency at work				
Yes	12 (57%)	18 (69%)	6 (29%)	11 (44%)
No	8 (38%)	6 (23%)	14 (67%)	10 (40%)
N/a	1 (5%)	2 (8%)	1 (5%)	4 (16%)
Total	21	26	21	25

Of the 46 people with valid yes/no responses to the question, ‘ have your eating problems affected your ability to work?’ for both the pre-treatment period and the period between commencement of treatment and the first follow-up, 12 said that their eating problems no longer affected their ability to work during the second time period, compared to two for whom their illness became a difficulty in terms of their ability to work during this time ($p < 0.02$, McNemar Test). When data for the two intervention groups were analysed separately the results failed to reach significance. Of the 35 participants who gave a valid response to the question, ‘has your eating problem affected your job choice?’ there was no significant difference between the numbers whose job choice had been affected during the pre-treatment period and was affected during the post commencement of treatment to 6 month follow-up period. Again when data for the two intervention groups were analysed separately the results were not statistically significant. Of the participants ($n=41$) who provided a valid yes/no

response to the question 'has your efficiency at work been affected by your eating problems, 11 said that their efficiency was not affected during the period between commencement of treatment and the first follow-up, while for 1 person, it did become a problem during this period ($p=0.006$ McNemar Test). When data for the two intervention groups were analysed separately, only that for the self-help participants was significant, with 6 (out of 20 respondents with valid yes/no responses for both time periods) saying that their efficiency at work was no longer affected during the follow-up period, while no one reported that it had become a problem ($p=0.031$). The results appear to suggest therefore that fewer participants' ability to work and efficiency at work was affected by their eating disorder after treatment commenced (regardless of intervention received).

5.12 SUMMARY AND CONCLUSIONS

The results indicate that over nine months there is no difference in eating disorder outcome for patients in the two arms of the trial. This is also true of the secondary outcome measures. Patients in both arms rated their eating disorder as less severe at the second follow-up and there was no difference between the two in terms of their rating of the helpfulness of the treatments received. Taken together, the results support the hypothesis and suggest that patients offered a self-help intervention for BN in general practice are not seriously disadvantaged compared to those offered treatment in a specialist out-patient clinic.

CHAPTER SIX:

GENERAL PRACTITIONER SURVEY RESULTS

6.1 INTRODUCTION

The present chapter focuses on the results of the two postal surveys sent to GPs supporting self-help patients over the course of the trial. As noted earlier, the purpose of the surveys was to obtain the views and perceptions of these GPs about their experiences of supporting BN patients using the self-help manual.

6.2 THE THREE-MONTH SURVEY

Each of the 32 GPs supporting the 34 self-help patients was sent a one-page questionnaire after they had been supporting their individual patients on the self-help programme for approximately three months. The purpose of the questionnaire was to ascertain whether GPs and their patients were finding the self-help manual and approach useful, and if patients were making progress. Where individual GPs did not respond, a second questionnaire was sent, and a reminder phone call made to them. In total, 29 GPs supporting 30 patients responded.

Eighteen GPs reported that they had found the self-help manual helpful. It was seen as a useful source of information about BN and provided them with a framework for supporting patients.

'Good description of the condition etc. Discussed the brief outline of what the patient was meant to have done, listing foods eaten in one week..'

'useful to give an understanding of approach to eating – to talk to her about this.'

'yes, very helpful'

'interesting to read'

One GP reported that the meal plan and problem solving sections had been particularly helpful. However, another reported that while s/he had personally found the manual very

helpful, his/her patient felt that it was *'too basic/simple for someone who has reasonably good insight already into the reasons behind the bulimia nervosa.'*

Twenty-three GPs (including one who had two patients in his/her care) responded to the question, 'How do you think the patient feels about the self-help programme?' Three said that they did not know, or were not sure how their patients felt. Ten reported that their patients seemed happy with the programme and/or to be making good progress. They made comments such as:

'patient seems better. Finding programme useful.'

'I think she is keen to help herself with the use of the book.'

'She seems happy with it. Overall her bulimia is in a 'good phase' and she seems to appreciate some support, but has got a good understanding already.'

'It varies. She is mainly quite keen, although does feel dependent at times.'

Others seemed to feel that their patients were less positive about the programme, or, even if positive, were having difficulty following it or in making changes in their behaviour.

'Does not appear to believe in the programme.'

'She is bored with it as it is repetitive. She has tried hard to provide information, but finds it hard to make changes.'

'reasonably ok, but frustrated by lack of progress – encouraged to resume and practice strategies advised in the book.'

'Seems to follow it, but finding it very difficult to progress; gained lots of understanding into the disorder.'

Asked if they had any problems with the self-help approach, the main ones cited by the eleven GPs who mentioned concerns were the time commitment involved on their part and patients not attending or cancelling appointments.

'I have found it an unacceptable load on my time and feel [patient's name] has missed out on an opportunity to have proper counselling. She would have gained more.'

'focusing the consultation. Staying within the standard 10 minute consultation initially impossible....patient requires/demands much longer. This is a major drawback to this sort of supervision in primary care – depending on frequency, patient could consume a 'disproportionate' amount of doctor's time.....not saying this is not validly given to these patients, but compared to other client groups.'

'I have spent lots of time supporting my patient, which under normal circumstances is difficult in my busy practice.'

In general then, GPs found the self-help manual helpful. It served to increase their knowledge about, and understanding of, the nature of BN. It also provided them with a framework or structure on which they could base the support they gave to patients undertaking the programme. Providing GPs with information like that contained in the self-help manual used in the current study may constitute an important first step in encouraging them to consider managing patients with BN in general practice rather than simply referring them to specialist care. A sizeable proportion of GPs reported that their patients seemed to be finding the programme helpful. However some noted that lack of progress with the programme could be frustrating for patients.

How they use their limited surgery time is an ever-present consideration for GPs working in busy general practice settings. The main concern expressed about the general practice based self-help approach to treating BN was the time it consumed or could potentially consume and the implications that this would have for other patients. This is an important issue and a potential barrier that must be addressed if any attempt to introduce a self-help approach to the treatment of BN as routine practice in the primary care setting is to be successful.

6.3 THE POST-NINE-MONTH FOLLOW-UP SURVEY

Twenty-five responses were obtained from 24 GPs to a questionnaire sent to the 32 GPs after the 9-month follow-up period of the study was over for their individual patients. One GP responded about two patients in his/her care. In addition, three questionnaires were returned by practice managers, stating that the GPs in question were either on maternity leave or long-term sickness leave and therefore would not be able to respond.

As with the first survey, a second copy of the questionnaire was sent and a reminder phone call made in the case of non-responding GPs.

The questionnaire sent at this time point was designed to elicit information concerning GPs' contact with their self-help patients, their opinions of the self-help programme, whether or not they felt their patient had benefited from the approach, and if they would be willing to support future patients using the manual.

6.3.1 Use and perceived helpfulness of the self-help manual and programme

GPs were asked about their use of the self-help manual, its helpfulness or otherwise, and about any difficulties encountered in supporting patients undertaking the self-help programme.

Fourteen of the GPs reported that they had used the self-help manual with their patients during actual consultations, and the majority said that they found it helpful. Comments made by the GPs in general about the manual echoed those made in response to the first survey. Again the two principal themes which emerged were that the manual led to increased knowledge and understanding of BN, and that it provided them with a useful structure or starting point for helping the patients to help themselves. Essentially, it made it easier for the GPs to talk to patients about their disorder.

'helped my limited understanding of eating disorders'

'increased my understanding of bulimia'

'structure of help, insight into mechanisms of problem, and how to help'

'easy to follow, good way to categorise management and putting it over to patient on discussion.'

'focal point for discussion'

Only one GP had something negative to say about the manual. S/he felt that it was *'very limited; very focused on eating disorders only which isn't always the case for the patient.'* Although in general GPs were positive about the self-help *manual*, twelve reported that they encountered difficulties in supporting their patient in the use of the

self-help *programme* generally. These were mainly due to patients failing to attend for appointments, not engaging with the programme, or because of the time commitment involved (from both GP and patient).

'her reluctance to commit time.'

'She did not consult regularly.'

'failure to attend surgery'

'At times I felt I lacked the knowledge to move further. What saved the situation was my good relationship with the patient over a long time.'

6.3.2 The perceived benefits to patients of the self-help approach

For GPs to be convinced that a self-help approach is worth trying with BN patients, they must be able to see their patients benefiting from its use. They were therefore asked about the ways, if any, in which they felt their patients derived benefit from the approach. Two GPs reported that they did not feel that their patients had gained much. However, as in response to the first survey, others highlighted the actual progress made, or insight gained, by their patients.

'focus on the problem allowed her to understand why she was bulimic and revealed the underlying problem'

'no longer using laxatives, much more positive and much less bingeing.'

'she developed good insight..'

'I think it gave her guidance to get to grips with things. She was a very well motivated patient anyway and it helped her to think things through, but also things were settling in her life anyway. She still has the problem but I think knows how to deal with it better and is more aware.'

Some GPs also acknowledged the value of their own input in terms of the interest and support they showed their patients. They clearly felt that this helped patients and was appreciated by them.

'I think she found the contact supportive'

'Regular GP/therapist contact in a supportive role and medication.'

'....I think she found me supportive and interested..'

It is perhaps not surprising, given the multi-symptomatic nature of BN and the co-morbidity associated with it, that twelve GPs reported that during their self-help consultations patients discussed other problems as well as BN. The types of problems discussed included stress, social isolation, marital, family and work-related problems, self-esteem, underlying concerns and other long-standing psychological problems.

'discussed work, home, hobbies, life expectations etc'

'self-esteem, new underlying issues, parental divorce'

'social isolation, unhappy in job'

It would appear therefore that GPs felt that BN patients benefited in a number of ways from the primary care based self-help intervention, and that the effort that they as GPs were making to support patients was valued. Furthermore, the findings suggest that patients felt sufficiently comfortable during self-help consultations to raise problems associated with, or separate from, their BN.

6.3.3 Perceived benefits to GPs from the experience of participating in the study

Asked if they felt that they had benefited themselves from taking part in the study, nine GPs commented on the benefits of participation. Yet again the gains mentioned were largely related to the knowledge and skills acquired, and to the fact that the programme provided them with a starting point for talking to patients and supporting them in their efforts to help themselves. As noted earlier, this finding highlights the importance of providing GPs with information about BN.

'yes, increased my knowledge'

'I feel I know more about bulimia.'

'yes, useful approach for the patients; have loaned the book to other patients.'

'yes, been able to start with basic advice on sensible eating and explain some of the mechanisms'

'yes, good reading material, easier to talk to patients about it now'

One GP reported that although s/he felt that taking part in the study increased his/her knowledge, it also made him/her aware that as a GP s/he had very little time to give to his/her patient in the face of all the other demands made on his/her time.

Six GPs said that they had not benefited from participating in the study (one because s/he already felt confident about treating patients with eating disorders, and another because s/he had done a year of psychiatry).

6.3.4 GPs' support needs

Asked about their support needs, seven GPs reported that they felt that specialist involvement would be helpful to GPs working with patients using a self-help intervention for BN in general practice. One said that s/he would like to have had group discussions (presumably concerning the management of these patients) while another would like to have had the support of a dietician. This finding suggests that there might be merit in developing shared care arrangements and in providing peer support to GPs working with this patient group. Potential ways in which GPs might be provided with support will be discussed in Chapter Eight.

6.3.5 Perceived advantages and disadvantages of managing bulimia nervosa patients in the primary care setting using the self-help approach to treatment

The reported advantages of the primary care based self-help approach included the fact that patients suffering from BN can be seen locally by someone they already know and that they may feel more in control with this type of approach to the treatment of their problem.

'patient felt comfortable in familiar surroundings. Easy access to GP.'

'They see someone locally that they know and (hopefully) trust.'

'..patient feels in control of programme.'

'The patient can feel more in control and take things at own pace.'

'I suppose it could be useful with narrower problems.'

As in the responses to the earlier survey, the main disadvantages identified by GPs to treating BN patients in the general practice setting using the self-help approach were the existing time constraints and demands in general practice, and the fact that patients are not getting in-depth counselling. While the majority of GPs said that they spent ten to twenty minutes with their self-help patient per visit, one GP reported that s/he gave the patient up to forty minutes per consultation. In general, GPs reported that most of their self-help patient's consultations had taken place in the first couple of months following allocation to the self-help condition. However, seven of them reported seeing their patients regularly over at least a four-month period and a number of these were still supporting their patient at nine months. The dilemma for GPs may be that in providing support to BN patients they see themselves as short-changing other patient groups who have just as much need of, and right to, their time. As noted above, GPs' fears about time consumption and extra workloads, if not addressed, may constitute a barrier to implementing the self-help approach as routine practice in primary care.

'I honestly don't think at present a GP can provide the service: in the last two years there has been such an increase in demand and pressure, that I would not be able to offer such service at present.'

'saves secondary care time but increases work in primary care.'

'very time consuming in general practice'

'Time! To do it properly takes a large chunk of GP time and we are constantly being asked to manage more disorders in general practice.'

'...limited appointment lengths make it difficult to become properly involved.'

In addition, some GPs were concerned, quite understandably, that a self-help intervention based in the primary care setting might not be appropriate for all BN patients.

'...may be sufficient for mild/recent cases but reserve judgement.'

'time required; patients don't get in-depth counselling'

'I feel that they may be better managed by specialists.'

In spite of their concerns, including those about the potential time commitment involved, eleven GPs (including one who had supported two patients) said that they would be prepared to support patients undertaking the self-help approach in the future. Of the six who gave reasons why they would not be prepared to support another patient, the majority said that this was because of time constraints, existing demands or other interests. One said s/he felt the approach did not work.

'I can't cope with the work as it stands. It sounds pathetic but our stress has increased to such an extent that we are learning to say no to any extra work.'

6.4 SUMMARY OF FINDINGS

In summary, the responses to the two surveys suggest that many GPs found the self-help manual helpful/useful, primarily because it led to an increased knowledge and understanding of BN on their part, but also because it provided them with a framework for helping their patients to help themselves. As generalists, the majority of GPs working in routine primary care settings cannot by definition be expected to have specialist knowledge or skills concerning the treatment of BN or other eating disorders. However, as noted earlier, simply providing them with basic information about BN, and a structure to help them focus consultations and provide support to patients undertaking a self-help programme may encourage them to consider managing more BN patients in the primary care setting and increase their confidence about doing so. The educational and training needs of GPs concerning eating disorders and their management in primary care will be considered in Chapter Eight.

The main concerns expressed by GPs about the self-help approach related to the demands it made or could make on them in terms of the potential time commitment and extra workload involved. Some expressed, or at least implied, a fear that this would have negative consequences for other patient groups in their care. Other difficulties

encountered included patients not turning up for appointments, failing to engage fully with the self-help approach, or having trouble making progress. A few were also concerned about the fact that patients were not receiving in-depth counselling or that the approach might not be appropriate for all. However, GPs who responded to the surveys could also see merit in the approach, for example, in terms of continuity of care for patients from a professional known to them. Furthermore, they were able to report specific improvements in patients, particularly in terms of increased insight and reduced symptoms. While some GPs suggested a need for specialist support in managing patients with BN in the general practice setting, a sizeable proportion of participating GPs said that they would be willing to try the approach again with other patients.

The indications from the survey findings are that having had the experience, participating GPs are not completely averse to the idea of supporting patients undertaking self-help interventions for BN in general practice. The climate may therefore be favourable for encouraging GPs in general to become more involved than at present in the provision of non-intensive interventions to patients who present to them in general practice with the symptoms of BN. Strategies designed to maximise the likelihood of their involvement (e.g., educational and training initiatives, peer support and shared care arrangements) and to address potential barriers to their involvement (e.g., concerns about the time commitment and workload involved) will be discussed in Chapter Eight.

CHAPTER SEVEN: PATIENTS' VIEWS OF TREATMENT: A QUALITATIVE PERSPECTIVE

7.1 INTRODUCTION

As noted in Chapter Four, at the second follow-up assessment study participants were asked 'open-ended' questions about their views and experiences of the treatment process. This chapter focuses on their responses. Firstly, the factors that motivated patients to seek treatment will be reported, followed by the views of patients randomised to the self-help arm of the trial concerning the general practice based self-help intervention. Clinic patients' perceptions of the treatment they received at the specialist out-patient clinics will then be reported. Finally, the chapter will focus on participants' perceptions of what had helped them most in trying to overcome their eating problems.

7.2 DECIDING TO SEEK TREATMENT

Participants were asked what had triggered their decision to seek help from their GPs for their eating problems at the point when they had done so prior to their recruitment into the study. Forty-eight participants responded to the question, with the majority citing more than one triggering factor. A number of themes emerged. Some of these are inter-related and /or overlapping. The triggering factors mentioned were common to patients in both arms of the trial.

7.2.1 The patient's life is overwhelmed by her eating problem

Firstly, the feeling that their lives were being taken over by their eating problem caused 22 patients to seek help. These women reported, for example, a sense of loss of control over their lives, or a feeling of being overwhelmed by their eating problem. To some it had become almost an obsession or addiction that they realised had to be overcome.

'Its absolute control over me - increasing downward spiral. Unable to help myself. Bulimia affecting all areas of my life.'

'...my bulimia was at a level where I could get on with my life and still binge - this is frightening - it was a controllable obsession which I wanted to get rid of altogether.'

'Felt like it was getting ridiculous: it was taking over my life.'

'I became aware that I had another addiction that needed treatment.'

'Dependency on food and thinking bingeing was the solution to everything. Total preoccupation with food and consequent appearance.'

Participants described their eating disorder and its impact on them as frightening, crippling, draining and socially isolating. They reported that their eating problems affected their capacity to function on a day-to-day basis, and to carry out their normal tasks and roles. For some this created a sense that they were missing out on life and social relationships.

'I didn't want to be obsessive. I was too fed up and felt drained. Too restrictive for me on my social life...'

'I felt afraid of my disorder. I felt crippled by it and needed help.'

'..it became so prominent in my life that I couldn't work or socialise normally, and was very depressed....'

'My second year at university - I failed exams due to being too ill.'

'Simply the build up of interference with everyday life and my dissatisfaction with that.'

'Could not carry out day-to-day activities normally.'

'...felt out of things and lonely.'

'felt very unhappy and I was becoming increasingly isolated from other people and I had started university and I had no friends to talk to.'

One woman remarked on her growing awareness of the abnormality of her situation:

'I felt physically and emotionally exhausted and realised that what I was doing was far from natural/'normal'.'

7.2.2 Hitting ‘rock bottom’

Feelings of being low, depressed, suicidal or of having hit ‘rock bottom’ were cited by 21 of the participants as reasons for seeking help for their eating problems. It would appear that for some the mental distress they were suffering had become too much to cope with, and they sought professional help out of necessity.

‘I suppose it was guilt, depression and lack of any diet working, so it was desperation...’

‘I was too fed up and felt drained.’

‘when I felt very depressed/suicidal and began cutting myself’

‘From time to time it all just becomes too much and I can’t bear the fact that I’m ruining my chance of being happy.’

‘I was depressed and suicidal and the eating disorder was an important symptom of this and possibly a causative influence at this time.’

‘I was very depressed about everything in my life and I felt it was wise to seek help for one of my biggest problems, the eating, in order to start sorting out my world.’

‘I felt that I couldn’t carry on living with things how they were and this was my last chance to try and change my life.’

7.2.3 Other people influence the individual’s decision to seek help

Eleven women reported that their decision to seek help was influenced by other people, either because they encouraged the patient to seek help or insisted that she did so, or because the patient felt she was upsetting or harming them as a result of her behaviour or problems. For instance, being a bad example to one’s child(ren) or not being able to care properly for one’s child(ren) were cited as triggering factors to help-seeking. In yet other cases a health professional had suggested to the individual that she needed help for her eating when she had sought treatment for related physical or emotional problems.

‘I was encouraged by a close friend and my husband to get help – this was the first time I had told anyone about it.’

‘My second year at university I failed my exams due to being too ill. My parents insisted I seek help again.’

‘didn’t want my children growing up doing the same thing.’

'...would often end up upsetting people close to me with my neurotic behaviour.'

'I was very depressed and couldn't really care for my son properly.'

'The nurse wanted me to see the doctor about not having periods and I had to explain.'

7.2.4 Impact on physical health

Eight patients sought professional help at least partly because their physical health had begun to suffer. Their reported problems ranged from not looking or feeling well to suffering from internal bleeding.

'..losing hair, ageing skin, and feeling tired and rundown.'

'made me look and feel awful...'

'Lack of concentration, sleep, general feeling of lethargy, emotional distress finally got the better of me and I realised I couldn't work this through alone and needed to seek help.'

'I fainted, it worried me.'

'because I started bleeding internally and knew it wasn't doing me any good...'

7.2.5 Symptoms getting worse

Seven participants cited the fact that their eating disorder-related symptoms and behaviours were long-standing or getting worse as a reason for seeking professional help.

'It had been going on for too long.'

'I started to depend more on laxatives, taking them became a daily event, and I would take about 20 at one time. I also became worried about my health and the amount of money I was spending on the laxatives.'

'felt very low, trouble studying for exams, crying a lot. Felt I'd be fat forever after every diet failing and an increasing number of binges.'

'I had been treated for anorexia 6 years ago but developed bulimia as a result. Last year things were at the worst they'd ever been. Felt really down, out of control, as though things would never be 'right'.'

7.2.6 Recognising that professional help is needed

Six women mentioned their recognition of their need to talk to a professional, or their acceptance of the fact that they could not defeat their eating disorder on their own as a reason for seeking treatment.

'I just needed someone to talk to.'

'Lack of concentration, sleep, general feeling of lethargy, emotional distress finally got the better of me and I realised I couldn't work through this alone and needed to seek help.'

'I saw no other way out but by reaching out to a professional. I had talked about it to friends/family for too long.'

The failure of previous attempts at recovery was noted by two of these individuals.

'It had been going on too long. I've sought help in the past but nothing had any effect.'

7.2.7 Desire to recover

Finally, a specific and positive desire to recover and to improve the quality of their lives or give themselves a chance of happiness in life was mentioned by five women as a reason for seeking help with their eating problems.

'Something inside me just told me that it was time to seek help, especially as I had a future with a wonderful man and I wanted to give my new married life the best chance possible without any secrets.'

'...I can't bear the fact that I'm ruining my chance to be happy.'

'wanting to get back into work and social life like everyone else.'

'...continued very strong desire to recover...'

7.2.8 Summary

Participants' responses to the question about triggers to help seeking provide an insight into the profound and detrimental impact of BN on the physical and emotional wellbeing of sufferers, as well as on their day-to-day functioning and working, social and family lives. As such they serve to reinforce the need to establish and provide effective and accessible treatments for BN.

Evidence presented in the literature review chapters suggests that although patients with eating disorders are frequent users of health services, BN sufferers may not seek help for their problem, possibly out of embarrassment. The frequency with which the themes mentioned in Sections 7.2.1 and 7.2.2 above (feeling overwhelmed by, or hitting 'rock bottom' because of, one's eating disorder) emerged as triggers to help seeking suggests that, for some BN sufferers at least, help is not sought until they can no longer cope with the impact of their eating problems on their lives. Seeking professional help is then seen as the only option available to them if they are to regain control of the situation. Improving the eating disorder detection and management skills of GPs and other primary care professionals might potentially lead to earlier intervention with such patients so that they do not have to reach a crisis point before they can bring themselves to ask for help.

Other important triggers to help seeking were worsening symptoms, the impact of the eating problems on the individual's physical health and the influence of other people. Several people mentioned being motivated by a specific desire to recover. While many of the triggers mentioned might be seen as 'negative' motivators, a sense also emerges in the responses that patients actively want to overcome or deal with their eating problem. It is therefore important that the first professional they turn to for help, which in the vast majority of cases is likely to be their GP, is ready and able to provide appropriate help.

7.3 SELF-HELP PATIENTS' PERCEPTIONS OF THE GENERAL PRACTICE BASED SELF-HELP APPROACH TO TREATMENT

Patients in the self-help arm of the trial were asked about their views of the self-help programme itself, the support provided by their GPs, and about the ways (if any) in which the self-help intervention in general practice might be improved.

7.3.1 Perceptions of the self-help programme

Patients were asked to describe which parts, if any, of the self-help programme they had found most helpful. For seven of them it was the behaviourally focused early stages of the programme; that is, learning to establish a meal plan or monitoring what they were eating.

'The menu planning was useful.'

'Monitoring food and my feelings associated with it.'

One patient noted that writing the meal plan and using the monitoring sheets had given her some structure. For others, the section on eliminating dieting was seen as useful.

'The effect it has on your health. I found eliminating dieting helped me.'

The problem solving section was also reported to be helpful. For four participants, the mere fact of having a programme to follow or someone to talk to had been perceived as useful.

'Actually talking to people about my eating problems and my feelings.'

One patient said of the programme generally: *The positive approach was helpful – to realise there is light at the end of the tunnel.'*

It would appear therefore that patients found that having a specific structure to follow was useful. The practical suggestions made in the early stages of the programme gave them something to work with and specific goals to attain.

However, five patients said that they had found none of the steps of the self-help programme particularly helpful. Six participants reported experiencing difficulties associated with the discipline and time involved in keeping to the programme; with not seeing immediate effects of undertaking the programme; or with being forced to think too much about their eating problem because they were monitoring their eating and feelings. Difficulties in using the programme resulted in some patients eventually abandoning it.

'I found it difficult to write down what my binges contained and the discipline involved was daunting. Motivation was a problem.'

'I just gave up. I found that it took all my time up. I was having to think about eating constantly. It made me feel horrible. Hated myself more.'

'Drifted from constant use, due to being on my own and even though my GP was helpful and understanding she did not go through the different stages in the book.'

'Felt guilty about not following the plan – didn't want to feel guilty.'

In addition, one patient reported that the programme:

'...doesn't get to the root of the problem. It treats the disorder as a 'diet' that's gone wrong and not a symptom of deeper problems.'

For some participants the very idea of change was difficult.

'...Also I subconsciously worry that if I confront this problem, I will overcome it, but will end up being a fat person, of which I'm terrified.'

'I didn't find it (the self-help programme) helpful because eliminating dieting put me off the whole idea as I couldn't bear to stay the same size. I needed to be smaller.'

'Lethargy. Not really wanting to confront this problem. Pushing it to the back of my mind or pretending that there are other reasons for this behaviour.'

'I find it very hard to stop dieting/ changing my attitude towards my body and food.'

In summary then, while patients found various aspects of the self-help programme helpful, its use was not entirely unproblematic. It was perceived as time-consuming and as requiring a lot of discipline. More fundamentally, however, some patients alluded to the fact that for them the very concept of change was difficult. This suggests that BN patients undertaking a self-help approach to their treatment may need to be given support and encouragement as they try to help themselves.

7.3.2 Perceptions of GP support

When asked about their GPs and the support provided by them, patients made general remarks about their GPs being 'helpful' or 'understanding'. However, a number of

concerns were also expressed about the ability of GPs to support patients undertaking the self-help programme.

For example, seven women spoke about time constraints on their individual GP, which they had perceived as affecting his/her ability to support them in their use of the manual. Patients reported feeling either that GPs did not have enough time to give them or that they were wasting the GP's valuable time and should not be bothering him/her. There was a concern, for example, that 'ill' people were waiting to see him/her.

'I didn't find that the GP had the time to give me that I needed.'

'I felt that I was rushing with the GP as other people were waiting who were sick or unwell.'

One patient got the impression that the GP was too busy because once he had asked how things were and she had reported that they were OK, he did not probe any further. She said that she could easily have lied to him. Another patient expressed the view that she felt she could not give the GP the results he wanted (i.e., improvement) and consequently she felt that she was wasting his time. In contrast, a patient who reported that she got more than the standard ten-minute appointment said she found the lengthier appointments very helpful.

The finding that some patients feel that GPs are too busy to support them fully as they undertake the self-help programme or feel that they are wasting GPs' valuable time is potentially a significant one. If patients starting a self-help intervention sense that the professional supporting them does not have enough time for them, their motivation to continue with the programme, particularly if they encounter difficulties with it, may flag. As reported in Chapter Six, the time involved, or potentially involved, in supporting self-help patients was also of concern to some GPs. Concerns about time (using too much or receiving too little, from the viewpoints of the GPs and patients respectively) constitute a potential barrier to the implementation of a self-help approach to treating BN as routine practice in primary care. However, it is not an insurmountable barrier, as will be discussed in Chapter Eight.

Fear of disappointing their GP was a concern for two patients, while another felt ashamed telling her GP about her binges:

'I only saw my GP for just over a month. As soon as he asked for a record of my eating I was too ashamed and didn't return.'

Another theme that emerged in the data was that of the appropriateness of having GPs treat patients with eating disorders (see also section 7.3.3 below). Some patients expressed the opinion that GPs are not experts and require more training in treating eating disorders (e.g., in terms of asking probing questions), a view also expressed by some of the GPs themselves, who felt that they could do with more specialist support.

'have gone occasionally, but obviously my GP is learning about eating problems at the same time.'

'It should be stressed that your GP and another person should help (where possible).'

One patient suggested that having one's GP as the supportive professional when undertaking the self-help programme was not a good idea, as she perceived the GP to be someone you went to when you were ill. She suggested that practice nurses might be more appropriate as they would have different priorities and could spend more time with individual patients.

In summary, while GPs were perceived to be positive and interested, some patients were concerned that they did not have enough time to support them because they were too busy or had other ill patients waiting to be seen. Some were also concerned about their individual GP's level of expertise and experience in managing eating disorders. These are concerns also expressed by GPs supporting self-help patients; concerns that need to be addressed if attempts are to be made to introduce the self-help approach as routine practice in primary care. GPs need to feel that they have the expertise and confidence to support self-help patients without spending an inordinate amount of time with them, while BN patients using the self-help approach need to feel fully supported by their GPs.

7.3.3 Views about how the self-help programme with GP support might be improved

When asked about ways, if any, in which the self help-programme with GP support might be improved, sixteen patients made suggestions. In addition, several others said that they had nothing to say; one because she felt that the self-help programme was not a very good one to start with.

Reflecting concerns that GPs are not experts in eating disorder treatment, two patients called for increased training for GPs supporting patients using self-help programmes.

'...GPs on the whole do not seem to have particular expertise/understanding of eating disorders – they ought to go on a specialist training beforehand.'

The involvement of other professionals instead of, or in addition to, the GP was mentioned by four people.

'It should be stressed that your GP and another person should help (where possible).'

..suggest alternate reading. Have extra support from a dietician.'

'I feel somebody apart from a GP – ie., dietician, practice nurse, would be more helpful.'

One patient suggested that the programme should be run like a general practice clinic: *'a clinic like baby weighing etc.'*

Several patients made comments that suggested that they would like to have seen their GPs playing a traditional 'management' or prescriptive role in their care.

'a more structured plan with the GP.'

'More impetus from the GP (ie., setting up a series of meetings in advance).'

'Set appointments with Drs so that a routine is established.'

'If the GP could give a weekly meal plan for a month for example (which included calorific values for peace of mind).'

Two patients said that they would have liked longer GP appointments.

'... regular weekly meeting, for about half an hour.'

'A longer more relaxed meeting.'

Two patients called for contact with other patients with similar problems.

'contact with self-help group.'

'Personally, I felt stupid and as though I was wasting his time, one of the reasons I stopped seeing him. Maybe meeting up with others on the self-help programme.'

In summary then, some of the self-help patients felt that the self-help intervention in general practice might benefit from more GP training, more consultation time for patients and more direct management /input from GPs. All of these issues have implications for clinical practice in routine primary care settings and will be addressed in Chapter Eight.

7.4 CLINIC PATIENTS' PERCEPTIONS OF THE SPECIALIST OUT-PATIENT TREATMENT

Clinic patients were also asked which aspects, if any, of the clinic treatment they had found most helpful, and about any difficulties they had experienced.

7.4.1 Views about the clinic treatment

Twelve patients mentioned the fact that they had been able to 'talk to someone' or discuss their problem as the most helpful aspect of the clinic treatment. Clinic staff were perceived as being 'experts', and people who 'understood' and could 'reassure'.

'talking to someone who understands and puts things in perspective.'

'Being able to talk to someone not personally involved with me who I could be honest with and not feel I had to please helped me address my problems in a wider context than just the eating disorder and did have a beneficial effect on the eating disorder.'

'speaking to someone who understood and told me it would be ok.'

'talking it over with an expert..'

Other aspects of the treatment at the clinic which individual patients valued included being warned of the dangers of laxative abuse, and being able to talk about personal or emotional problems other than the eating disorder per se.

When asked about clinic attendance, including reasons for stopping / not attending, patients reported difficulties related to the fact that appointment times had clashed with their working hours or other unavoidable commitments (e.g., university lectures).

'....I was at full-time college and could not make the appointments.'

Two patients reported being concerned that their employers should not find out about their clinic appointments as they feared the possible consequences for their jobs /job prospects. One patient reported a fear of meeting people she knew at the hospital, while for another the hospital brought back bad memories. In addition, three people reported that clinic treatment had not lived up to their expectations.

'no psychotherapy offered - symptoms treated but not their reasons for being. Waste of time.'

'I didn't feel it would help me – not what I expected.'

Yet two other patients reported that a change in therapist during their treatment had not helped.

'Both doctors left. I felt we were going nowhere fast.'

In summary then, the most beneficial aspect to receiving clinic treatment appears to have been the opportunity to discuss the eating problem with a professional perceived to be an 'expert' in eating disorders. This is in contrast to the views of some self-help patients who questioned the expertise of their GPs in treating eating disorders, and suggested that they required more training in this area of patient care, or that other primary care professionals might be more qualified to help them. Perceived drawbacks and difficulties of the clinic treatment related to the timing of clinic appointments and to personal concerns which patients had about attending a specialist clinic for treatment. Interestingly, some GPs supporting self-help patients noted that continuity of care with support from a professional known to them was one of the main advantages to primary care based interventions for BN patients. Attending her general practice for help might provoke less concerns or anxieties for the BN patient about her employers or others

finding out about her eating disorder, and as some of the GPs noted, might help her to feel more in control of her treatment.

7.4.2 Views about the ways in which the clinic treatment might be improved

Participants were asked if there were any ways in which the clinic treatment might be improved. As with the self-help patients, five clinic patients wanted more frequent sessions, more sessions in total, and/or longer sessions with the professional treating them.

'long-term one-to-one regular psychotherapy sessions.'

'A longer appointment time would be useful.'

'More regular counselling.'

Two further patients suggested that meeting other patients in a group situation might be helpful.

'More time to spend with other patients – maybe once every three months an open forum.'

'maybe group discussions or do a combination of people to see rather than just one.'

The latter quote came from a patient who had experienced group therapy for eating problems as a teenager. She expressed the view that people can learn a lot from one another in these situations.

More active participation on the part of therapists was suggested by four patients, who reported that they would like to have had more feedback or practical suggestions about things that they could do to help themselves.

'if the psychologist asked more questions / made more suggestions about the problems I have instead of just listening.'

'more information on self-help'

One patient suggested that out-of-work-hours clinics might be helpful. Two others called for shorter waiting list times at clinics.

Like the self-help patients then, some of those who attended the clinic believed that improvements could be made to the treatment they had received, in the form of longer/more consultations and greater direction or more structured help to patients from therapists.

7.5 PERCEPTIONS OF WHAT HELPED PARTICIPANTS MOST IN TRYING TO OVERCOME THEIR EATING PROBLEM

Forty-one patients responded to a question asking them what they thought had helped them most in trying to overcome their eating problems. They were told that they could mention factors related to the treatment they had received and/or factors or events external to treatment. Many cited multiple factors. Three broad inter-related themes emerged in the responses: factors related to treatment or eating disorder symptoms; factors external to treatment; and what might loosely be termed ‘psychological’ factors related to motivation, or improved coping, awareness and self-esteem. There were no apparent differences between participants in the self-help condition and those in the clinic condition in terms of what they felt had made a difference to them in trying to overcome their eating problem.

7.5.1 Factors related to treatment

Twelve people mentioned aspects of the treatment itself or the fact that talking about their problems had helped.

‘the support of my GP’

the treatment in itself’

‘learning ways to divert a full-scale binge, although I still feel that I have an eating disorder’

‘Finally being able to tell someone that the problem existed; follow-up appointments kept me wanting to get better, even though it didn’t always work.’

'...Sustained effort on eating sensibly has been helped by reading the manual (part of it) and discussing things.'

'The book gave me hope that it was possible to overcome it.'

Seven patients listed changes in their attitudes to eating, and/or improvements in their symptoms or their ability to control symptoms as significant helping factors.

'I haven't overcome it, but have suppressed the symptoms, so that I can almost forget it exists.'

'getting an extra job, buying new larger (but slim looking) clothes for when I have put on weight, buying a weeks worth of food at the beginning of the week.'

'...establishing a regular eating pattern...'

For three participants, the anti-depressant medication they had received was mentioned as a factor in helping them to try to overcome their problem.

'Getting a new job/ and establishing a regular eating pattern and counselling – combination of all, and significantly, PROZAC – stabilising mood.'

7.5.2 Factors / events external to treatment

Many of the issues listed by participants as helping them to try to overcome their eating problems appear to be unrelated to treatment. Fourteen individuals mentioned a new job, an academic achievement, a change in career, or a promotion at work.

'getting a job and going out with someone who cares about me are the main factors.'

'starting university again – I feel I have some direction and new ambitions...'

In addition, eight participants mentioned being busier or having a better social life.

'new job, active social life, moving away from London'

The support, understanding or encouragement of partners, or the start of a new relationship were cited as important by nine participants.

'Stable job, very happy at home. My husband knows about the problem and tries to help out. Realising that there is always tomorrow to have some more to eat.'

'getting married is the main one – looking forward to starting a family'

'getting a job and going out with someone who cares about me are the main factors.'

The support of family and friends was seen as valuable by five participants.

'steady job – more settled. Good friends – support from friends and family.'

Three people mentioned exercise or going to the gym as being important in helping them to overcome their eating problems, while two people reported that moving out of London had been beneficial.

7.5.3 'Psychological' factors

Finally, nine participants mentioned factors related to increased insight into the potential damage caused by their eating disorder, motivation to recover, improved psychological wellbeing or coping ability.

'realising that my intake of laxatives was controlling my life.'

'dealing with the problem in the context of my life in general which helped me to get a new job and altered other aspects of my life which I was unhappy with.'

'Motivation to get better; e.g., in order to go travelling.'

'Really wanting to do it for myself – wanting to get a normal life together.'

'...better self-esteem.'

In summary then, while factors related to the treatment process are perceived as important by patients in helping them to overcome their eating problems, factors which they perceive to be outside or apparently unrelated to treatment may be just as important in their conceptions of what helps them.

7.6 SUMMARY OF FINDINGS

Perhaps not surprisingly participants reported a wide range of factors or events as triggers to their decision to seek help for their eating problems. However, for a significant proportion, it was the increasingly negative impact or consequences of the eating disorder that triggered help seeking behaviour. The main motivators included the fact that patients felt that their lives were being taken over by their eating problem, or that they had hit a particularly low point. The empirical investigation of incentives to help seeking is important. Not only do the factors involved in triggering help seeking behaviour provide an insight into the impact of BN on the individual's life, but they could also have implications for clinical practice, for example in terms of the types of treatments that patients may be willing to try.

While some of the self-help patients felt that aspects of the self-help programme were helpful and attributed improvement to it, others reported difficulties in using it. For some of the latter, however, their difficulties may have been more to do with a general fear of change. While self-help patients also reported that their GPs had been helpful or understanding, concern was expressed that GPs did not appear to have enough time to fully support them in the face of other demands on their time, and that they were not experts in treating eating disorders. On the whole, however, patients, like the GPs supporting them, did not seem to be averse to using a self-help approach to treating BN in primary care, which augurs well for any attempt to introduce such an approach as routine practice. However, potential barriers to the uptake of this form of treatment in routine general practice settings such as concerns about time and the perceived lack of skill or expertise of GPs supporting patients would need to be addressed. Possible ways of overcoming such barriers will be discussed in Chapter Eight. Patients attending the clinic reported that it was speaking to a professional, perceived by them to be an expert, about their problems that had been the most helpful aspect to their treatment.

There were several areas of similarity in the views expressed by the self-help and clinic patients concerning their treatment experiences. For example, some participants in both groups either implied or stated that they wanted more time from those helping them. In addition, patients in both arms of the trial called for more 'managed' or 'directive' support and treatment. There were also areas of marked contrast. For example, while some of the self-help patients expressed concern that their GP was not an expert in

eating disorders, or that GPs needed training in the management of eating disorders, the perceived expertise of the clinic staff was what patients attending the clinic seemed to appreciate most. Furthermore, there was agreement between some of self-help patients and some of the GPs involved in supporting such patients on issues to do with time and expertise.

Finally, patients in both arms of the trial, when asked what had helped them most in trying to overcome their eating problems, mentioned factors related to the treatment process itself, life events and what might be termed ‘psychological growth’ factors. For many, events unrelated to treatment were perceived as being among the most important factors in helping them to overcome their eating problems.

Just as the study’s objective outcomes have implications for policy and clinical practice, so too do the findings of the GP surveys, and the patients’ subjective views of the self-help intervention presented here, along with the findings concerning GPs and patients who declined to participate in the study (Chapter Five). The outcomes and findings of the various strands of the study and their implications for future policy development, clinical practice and research will be addressed in Chapter Eight.

CHAPTER EIGHT: DISCUSSION

8.1 INTRODUCTION

The present study was designed to compare the effectiveness of a general practice based self-help approach to treating BN with that of specialist clinic out-patient treatment; to investigate GPs' experiences of supporting patients using the self-help manual; and to explore patients' expectations, views, and experiences of treatment. In addition, predictors of outcome were explored, as were some of the financial aspects of treating patients with BN in general practice and clinic settings.

The aims of the current chapter are several. Firstly, the objective is to briefly describe the findings of the three main strands of the research and, setting them in the context of previous research, to highlight how they contribute to the knowledge base in this area of patient care. Secondly, the strengths and limitations of the study will be outlined. Thirdly, the implications of the research findings for policy initiatives, service development and clinical practice will be described. Fourthly, the findings indicate that further research is required in a number of areas and topics for potential future studies, as well as the methods that might be employed in undertaking them, will be suggested. The chapter will finish with general conclusions and recommendations.

8.2 MAIN STUDY FINDINGS AND THEIR CONTRIBUTION TO THE KNOWLEDGE BASE

8.2.1 The randomised controlled trial

As far as the researcher is aware, this is the first clinical trial in general practice of a self-help package for patients with BN in which GPs provided added support. The aim of the RCT was to establish the effectiveness of a self-help approach in general practice compared to specialist clinic out-patient treatment, the hypothesis being that

there would be no serious disadvantage in outcome for patients randomised to receive the self-help treatment compared to those receiving specialist care.

The results indicate that over nine months there is no difference in eating disorder outcome, as assessed by the BITE, for patients receiving self-help or specialist care. The BITE scores of participants at the second follow-up suggested that a similar percentage of patients in both arms of the trial no longer met full clinical criteria for the eating disorder at this point. In addition, assessment of eating disorder pathology with a structured clinical tool (EDE) revealed no differences between the groups in the secondary analyses. This is also true of the other secondary outcome measures of depressive symptoms, social adjustment and self-esteem. Patients in both groups rated their eating disorder as less severe at the final follow-up than at baseline, and there was no difference between the two groups in terms of their rating of the perceived helpfulness of the treatment interventions received. Finding no differences in the secondary outcomes suggests that there is little difference in impact between the two forms of management. In support of the findings for the primary and secondary outcomes was the lack of any serious difficulty arising for patients in the self-help arm and the low numbers of self-help patients seeking specialist attention at the clinics during the trial. Furthermore, low numbers of patients in both arms sought additional help from therapists or counsellors external to the trial over the course of the study follow-up period. Taken together, the results of the RCT therefore support the study hypothesis.

Only an equivalence trial would definitely address the question of no difference between the treatment arms. However, it would require very large numbers of participants and could not be justified as either feasible or necessary. The current study sought only to investigate whether there was any definite disadvantage in outcome for patients receiving general practice based self-help with GP support. McAlister and Sackett (2001) have proposed criteria to judge clinical trials where the aim is to show that the new intervention is not inferior to the established control. The criteria that apply to the present study are that there is already evidence for the effectiveness of the established treatment (which consisted of a combination of CBT and IPT approaches), and therefore it cannot be claimed that both the clinic and self-help treatments are ineffective; that the patients involved in a study were of the type

normally seen in the established service; and that the magnitude of difference that would be accepted for the general practice based approach to be regarded as inferior was specified *a priori*.

Exploratory analyses indicated that treatment preferences assessed at baseline did not predict outcome at the second follow-up. The number of participants in the study did not allow for the investigation of a broad range of possible predictors of outcome, and therefore only some of the variables found to be predictive of outcome in previous studies were investigated. The current findings suggest that lower BITE scores at baseline and being married/cohabiting with a partner may be positive predictors of outcome, regardless of treatment received. As noted in Chapter Two, findings concerning predictors of treatment outcome for patients with BN have been very variable (e.g., Keel and Mitchell, 1997), and while the current findings do concur with those of some of the earlier studies they should nonetheless be treated with caution. Larger studies than the present one are required to reliably identify the demographic and clinical characteristics of women suffering from BN who would benefit most by receiving self-help treatment in primary care.

To date, apart from Agras (2001), little research attention has been paid to the financial costs of treating BN patients. The current study did not involve a full economic evaluation, and, as noted earlier, there were limitations to the analyses undertaken. However, the findings suggest that financial benefit would be gained even if only a percentage of BN patients were to be managed in primary care. These findings, added to those concerning clinical outcome, suggest that the primary care approach is a cost-effective one and that the idea of introducing the self-help approach as routine practice in primary care merits serious consideration.

Previous trials have found that the self-help approach is efficacious (e.g., Schmidt *et al*, 1993; Cooper *et al*, 1996; Palmer *et al*, 2002) and that as a component of treatment, self-help appears to work as well as other interventions (e.g., Treasure *et al*, 1996; Thiels *et al*, 1998). They have also demonstrated improvements in the co-morbid pathology associated with BN (e.g., depression and self-esteem) in patients using self-help manuals (e.g., Cooper *et al*, 1996; Thiels *et al*, 1998). In addition they have indicated that non-specialists can play a part in managing BN patients (e.g.,

Cooper *et al*, 1996; Waller *et al*, 1996). The uniqueness of the current RCT findings lies in the fact that they suggest that it is feasible to take a self-help approach to the treatment of BN out of the specialist setting and apply it in primary care, without seriously disadvantaging patients across a range of outcomes. They also suggest that GPs are capable of providing support to patients undertaking a self-help approach in general practice. The implication is therefore that GPs could reasonably consider employing a self-help approach when patients first present to them with BN. Referral to specialist services should not be viewed as the only treatment option available.

On a more general level, the findings add to the increasing body of evidence (e.g., that reviewed by Lewis *et al*, 2003) which suggests that self-help interventions have an important place in the treatment of common mental health problems, regardless of the setting in which they are delivered.

8.2.2 The GP postal surveys and patient qualitative data

Arguably, just as important as the clinical outcomes of trials are the perceptions of participants concerning the interventions being evaluated. Of themselves, RCT findings cannot reveal much about the active components of treatments, or their perceived acceptability to recipients or providers. The chances of a novel treatment which proves effective under experimental conditions becoming routine clinical practice are limited if it proves unacceptable to recipients or providers. Perceptions about treatment may be particularly important when patients and professionals alike are required to play an active role in a treatment intervention. Marks (2002) has observed that while brief or less intensive therapies are known to be effective, for example, in the treatment of depression and anxiety disorders, far less is known about their mode of action or active components, and about their acceptability or cost-effectiveness. Lewis *et al* (2003) have called for qualitative studies which examine how accessible and beneficial patients with mental health problems who use self-help materials find these materials. The use of qualitative methods to examine participants' perceptions and experiences can help to add context to trial outcomes as well as indicating areas in which treatments might be modified or improved, and suggesting issues for future research.

In the eating disorders field, the past decade has seen the steady accumulation of evidence concerning the efficacy and effectiveness of self-help manual interventions for BN and BED. Far less is known about how these interventions are perceived by providers and recipients, and about potential barriers to implementing them, or about factors that might facilitate their implementation, outside the confines of a clinical trial. The surveys and qualitative component of the current study constitute an initial step towards filling this information gap.

8.2.2.1 GP surveys

As reported earlier, there is a paucity of research on the management by GPs of patients with eating disorders. The themes that emerge from the existing literature are that there is a role for primary care professionals in the management of such patients (e.g., Royal College of Psychiatrists, 1992, 2000); that GPs are not skilled at detecting eating disorders (e.g., Whitehouse *et al*, 1992; King, 1989); and that GPs should be provided with more training in the detection and management of eating disordered patients (e.g., King, 1989; Turnbull *et al*, 1996). The present study increases the knowledge base by providing an insight into GPs' experiences of actually supporting BN patients in the primary care setting.

The survey findings revealed that GPs generally found the self-help manual used in the study informative and helpful, both in terms of increasing their understanding of BN and as a framework for providing support to their patients. Perceived improvements in patients included improved general wellbeing, reduced symptoms and increased insight into their eating problems. Some patients discussed other mental health or life problems as well as their BN with GPs. However, a few GPs reported that their patients were bored or frustrated with the self-help programme. GPs saw the benefits of the approach as including continuity of care, with patients being seen locally and supported by someone known to them. Perceived disadvantages of the approach included time constraints, and the fact that patients were not receiving full counselling. Problems reported by GPs included a lack of time to devote to BN patients because of other (equally important) demands on their time, and patients failing to turn up for appointments or to engage fully with the self-help programme. A not-insignificant number of GPs reported that more specialist

input and support would benefit GPs undertaking the approach with their BN patients. Very encouragingly, a sizeable proportion of participating GPs indicated a willingness to use the approach again, or were already doing so with other patients.

While GPs felt that patients might benefit from receiving treatment in the primary care setting therefore, and were willing to undertake the intervention with future patients, the potential of the approach for time consumption was a cause for concern. This concern and the expressed desire for more specialist support, combined with the information derived from GPs who declined to participate in the study for reasons such as lack of expertise, must be addressed in any attempt to persuade GPs generally to consider using a self-help approach with patients with BN (see Section 8.4 below). As noted in Chapter Two, the empirical evidence suggests that GPs can successfully support and manage patients with a range of mental health problems. However, they may have reservations about treating such patients. It is known, for example, that GPs' concerns about treating patients with established alcohol problems revolve around questions of case definition, role legitimacy, treatment success, the time consuming nature of the therapeutic input required and confidence concerning their skills and expertise (e.g., Durand, 1994). The current findings suggest that such concerns may apply too to GPs involved in supporting patients with BN. The policy- and practice-related implications of these findings will be considered below (Section 8.4).

8.2.2.2 Participants' views of treatment

Participants in previous BN treatment trials have occasionally been asked to rate the appropriateness of the treatment to which they have been assigned (e.g., Agras *et al*, 2000 a). Studies of self-help have assessed compliance with the manual used (e.g., Troop *et al*, 1996), or have reported that patients have been positive about manuals, or the professionals supporting them (e.g., Cooper *et al*, 1996). However, as Jarman and Walsh (1999) note, there is a paucity of studies in the eating disorders field concerning patients' views about treatment outcome. The data generated by both the quantitative methods employed and the open-ended questions posed in the present study provide an insight into patients' views of the treatment process, and suggest reasons for some of the objective outcomes as well indicating the types of issues that

would require consideration were the self-help approach to be implemented in practice.

8.2.2.2.1 Seeking help

As noted in Chapter Two, previous research suggests that patients with BN may not seek help for their problems, possibly because of embarrassment about their symptoms (e.g., Loeb *et al*, 2000). Furthermore, such patients often go undetected in general practice (e.g., Whitehouse *et al*, 1992), although they are likely to consult with greater frequency than matched controls (e.g., Ogg *et al*, 1997). The findings of the current study suggest that many of the participants may not have asked their GPs for help with BN until they had hit ‘rock bottom’. This finding is not entirely surprising. The general literature on concepts of health and illness suggests that one of the criteria that women commonly apply when deciding that they have a (health) problem is an inability to carry out daily tasks and roles (e.g., Blaxter and Patterson, 1982). Furthermore, studies investigating motivation for treatment in women with alcohol problems have found that the impact of drinking on their health, pressure from others and fear of losing relationships and children motivate such women to seek help (e.g., Thom, 1987), and that treatment entry is seen as the product of a number of changes or events rather than of a single life crisis. In a similar vein, the women in the current study repeatedly mentioned the increasingly negative effect of BN on their daily lives as a primary trigger to help seeking. Their lives were being overwhelmed by it, and their mental and /or physical health had begun to suffer. The intervention of other people prompted some participants to seek help, while some reported that they had arrived at a realisation themselves that professional help was necessary. Such findings suggest that commonalities exist between help seeking for eating disorders and other mental health problems. While the current study explored help seeking at only a superficial level, the findings may serve as a useful starting point for future investigations. Theoretically, triggers to help seeking may have implications for patients’ readiness/ willingness to engage in particular types of treatment (and treatment research) and for treatment outcome. One might speculate, for example, that if BN patients are detected and offered self-help interventions in primary care before they hit ‘rock bottom’ they might be more willing to engage in such approaches and might derive most benefit from them. The same patients offered specialist help might find it too great an undertaking. For example, a pilot study by

Durand *et al* (1999, unpublished report to the Royal College of General Practitioners) designed to assess the impact of non-intensive interventions (a postal self-help booklet, a brief intervention by a practice nurse, or routine GP care) on female general practice attenders with abnormal eating attitudes, found that such women were willing to engage with the interventions offered in primary care.

8.2.2.2.2 Perceptions of treatment

In terms of the specific interventions received, patients in the self-help arm of the trial reported finding various aspects of the self-help programme helpful and attributed improvements to the programme generally. However, several reported difficulties in using it; saying, for example, that it was time consuming or forced them to think constantly about their problems. While GPs were perceived as helpful or understanding, concern was expressed about time constraints on them and their lack of expertise in treating patients with eating disorders. Patients attending the specialist clinic reported that being able to *talk to* a professional (perceived to be an ‘expert’) with an understanding of eating problems had been the most helpful aspect of treatment. However, some patients reported difficulties in attending the clinic. These related principally to clinic appointment times clashing with work and other commitments. In addition, a few felt that the clinic did not live up to their expectations.

As noted above, patients in both arms of the trial rated their symptoms as less severe at the second follow-up than at baseline. When asked what had helped them most in trying to overcome their eating problems, study participants mentioned factors related to aspects of the treatment process itself, factors external to treatment, and what might be termed ‘psychological growth’ factors. There were no apparent differences between patients in the two arms of the trial in this respect. For many, events or issues unrelated to the treatment interventions received (e.g., new jobs or relationships) were viewed as important. Previous studies in the eating disorders field have indicated that receiving treatment is generally described as being ‘a little’ helpful (e.g., Yager *et al*, 1989; Rorty *et al*, 1993) in terms of outcome. However, as in the present study, a wide range of other factors are also implicated in symptom improvement (e.g., Rorty *et al*, 1993). Collings and King (1994), in a 10 year follow-up study of patients treated for BN, found that they generally perceived hospital

treatment negatively and that many felt that they had matured out of their disorder using their own resources, with occasional help from therapists of their own choosing. While it is of interest to note that patients ascribe improvements to factors such as new relationships rather than imputing a possible causal link between receiving treatment, symptom improvement and consequent improvements in other aspects of their lives, it is difficult to interpret these findings and to draw any valid conclusions from them. One could perhaps speculate that it is easier to see the benefits of a positive life event such as getting a new job than to focus on a therapeutic process which in itself may have been psychologically difficult at times.

8.2.2.2.3 Perceptions of how treatment might be improved

When asked about how the treatment interventions might be improved, a number of common themes emerged in the views expressed by the self-help and clinic patients. Firstly, some patients in both treatment arms wanted longer/more frequent appointments with the professionals treating them. Secondly, both self-help and clinic patients wanted the professionals treating them to play a more ‘active’ role in their treatment. For the self-help patients, this meant GPs providing them with more structure (e.g., in the form of set appointments and meal plans), while for the clinic patients it took the form of a desire for specialists to provide them with more structured information or feedback. Thirdly, a number of patients in both groups reported that they would like to meet other patients receiving the same treatment for eating disorders. Given these similarities, it is perhaps not surprising that patients in the two arms of the trial did not differ in terms of their ratings of the helpfulness of the treatment received. It appears that regardless of the nature of the treatment intervention patients have similar ‘complaints’.

However, the self-help and clinic patients also expressed a number of contrasting perceptions about treatment. While some of the self-help patients had concerns about GPs’ lack of training and expertise in treating patients with BN, it was the perceived *expertise* of the clinic staff that some of the clinic patients appeared to value most. In addition, while some of the self-help patients reported difficulties in using the manual, which may actually have reflected a general fear of change on their part, none of the clinic patients made comments about a fear of change. One can only speculate about why such a difference should exist: perhaps the use of a written

manual serves to focus patients' thoughts more consciously on the need for personal change than does the more 'verbal' therapy received at the clinic. The self-help patients may have a more heightened awareness of having to find solutions within themselves.

The importance to patients of receiving what they perceive to be appropriate and expert help is a theme that has emerged in other eating disorder studies. A magazine survey in the US (Yager *et al*, 1989) found that patients treated for eating disorders rated professionals perceived to be experts in eating disorders as more efficacious than those not seen as experts. Furthermore, as in the current study, patients participating in Drummond *et al*'s (1990) study comparing specialist and general practice treatment for alcohol problems, expressed concerns about their GP's professional ability to help them, even when they perceived the GP to be positive and interested (Thom *et al*, 1992). Again, the main concerns expressed were that GPs did not enough time to support them, did not have an understanding of alcohol problems and were not experienced in managing patients with alcohol problems. As highlighted, studies such as those of Palmer *et al* (2002) have found supported self-help to be more effective than pure self-help. Patients have reported finding support helpful, even where the supporting professional is not specially trained in treating eating disorders, for example as in Cooper *et al*'s (1996) study. However, the current findings suggest that even if there appears to be no difference in clinical outcome between a general practice based treatment and a specialist one, patients' concerns about the appropriateness and expertise of the professional helping them would need to be addressed were an attempt to be made to introduce the former as routine practice in primary care.

8.2.2.2.4 Areas of agreement between GPs' and self-help patients' perceptions

The study findings revealed two areas of agreement between the self-help patients and GPs in terms of their views about the general practice based approach to treatment. The main area on which there was consensus concerned the time pressure on GPs. As reported above, some self-help patients felt that they were not getting enough time from their GPs or that they were wasting his/her time when he/she should be treating 'sick' people, while GPs reported that lack of time was one of the biggest difficulties they encountered in trying to support patients. The other issue on

which there was agreement concerned the perceived need for GP training and professional support in this area of patient care. As noted above, some of the GPs felt that they would have liked more specialist input or support, while some patients called for more GP training in treating eating disorders or for the involvement of other professionals as well as GPs in their treatment in the general practice setting. Again, the emergence of such commonalties is of significance both for those conducting research in this area of patient care and for attempts to introduce as routine practice in primary care a self-help package for patients with BN.

8.2.2.3 Conclusions

The GP surveys and qualitative aspects of the current study represented an attempt to contextualise the trial outcomes. All too often in treatment trials clinical outcomes appear to be viewed as the only outcomes worth focusing on or reporting, and little attention is paid to the views of participants or those providing the treatment interventions. The multi-methods approach taken here highlights the added value to be gained by focusing on subjective experience. It revealed that both similarities and differences exist in the views of treatment expressed by patients in the two arms of the trial, and that while both self-help patients and the GPs supporting them are positive about the self-help programme, they also have concerns about it. Valuable information has been gleaned concerning the potential barriers and incentives to introducing a self-help approach in general practice. The findings of the study's survey and qualitative components have implications for future policy, practice and research which will be discussed in Sections 8.4 and 8.5 below.

8.3 STRENGTHS AND LIMITATIONS OF THE CURRENT STUDY

The present study has, like any research endeavour, strengths and limitations. While some difficulties were encountered in carrying out the study, and while it can be criticised on a number of grounds, it was largely successful in achieving its stated aims. Valuable insights have been gleaned both about undertaking pragmatic research of this nature and about the realities that are likely to be involved in trying to implement a general practice based self-help intervention for patients with BN.

8.3.1 Strengths

The strengths of the study will be outlined in Sections 8.3.1.1 to 8.3.1.8 below.

8.3.1.1 Strong empirical foundations

Although the first study of its kind to be undertaken in general practice involving GPs supporting patients using a self-help manual, the present study had strong empirical foundations and precedents. Full CBT had been shown to be as effective as (if not more effective than) other psychotherapies or anti-depressant medication in the treatment of BN (e.g., Fairburn *et al*, 1991). The efficacy of cognitive behaviour orientated self-help had previously been tested (e.g., Schmidt *et al*, 1993; Cooper *et al*, 1994); non-specialists had been found to be capable of providing support to patients using self-help manuals (e.g., Cooper *et al*, 1994); and the specific manual employed, which was closely based on full manual-CBT, had been found to be efficacious (Cooper *et al*, 1994). In addition, empirical research undertaken with GPs had found them to be capable of treating, supporting or managing patients with a variety of mental health or addictions problems (e.g., Drummond *et al*, 1990). Furthermore, having found the self-help approach to be efficacious in the specialist setting, researchers and clinicians (e.g., Schmidt *et al*, 1993) had called for it to be tested in the general practice setting. The study was therefore designed to build on existing knowledge and to answer the applied questions that had emerged from previous research.

8.3.1.2 Safeguards employed

BN is a serious eating disorder which has to date largely been treated and researched in specialist eating disorder clinics. In spite of the empirical evidence supporting the use of less intensive self-help approaches to treating the disorder in specialist settings, conducting a trial in the general practice setting was not something that was undertaken lightly. It was anticipated that the study might be a challenging one, mainly because of the ‘unknowns’ that can arise when a trial is the first to be undertaken in a novel setting. It was difficult to predict, for example, how willing GPs would be to participate; whether patients, having been referred to a specialist clinic, would wish to participate in a study that might involve receiving treatment in primary care; or whether self-help patients would need to be seen in the specialist clinics in large numbers. However, clinical, policy-relevant and ethical imperatives,

as well as the existing research evidence, suggested that a pragmatic trial comparing treatment in general practice and specialist out-patient clinics was merited. For ethical and medical reasons and in order to ensure the safety of participants, a number of safeguards were built into the study. For example, GPs were told that they could, at any time, withdraw their patients from the self-help arm of the trial for medical or social reasons, and that they would be seen at the clinic. It was also emphasised that GPs could contact the clinic if they had concerns about a patient that they wished to discuss with a specialist. In addition, self-help patients were informed that they would be seen by a specialist if they felt this was necessary. The fact that patients were recruited, randomised, received either the self-help or clinic treatment, and were followed up, with their consent and the agreement of their GPs, and that no discrepancies were found in terms of safety between the two groups over the course of the study should be taken as a positive indication that trials of this nature involving BN patients can be conducted outside specialist settings.

8.3.1.3 Pragmatic nature of the trial

One of the strongest features of the present study lies in the fact that it was a pragmatic trial designed to mirror what happens in busy surgeries and clinics. As reported earlier, a criticism of BN treatment trials, and trials of psychotherapies generally, has been that they evaluate such therapies under ideal experimental conditions, recruit highly selected patients and employ therapists who are specially trained (e.g., Mitchell *et al*, 1996; Hotopf *et al*, 1999), leading to scepticism among clinicians about the relevance of their findings to routine practice (e.g., Wilson, 1998, 1999). In the current study participating GPs, although provided with brief guidelines concerning the study as well as the self-help manual, were not given specific training in managing patients with BN and were not given instructions to see their patients for a specified number of sessions. In the same vein, routine clinic procedures and treatments were not modified in any respect for the purposes of the study. Participants were recruited only from GP referrals to specialist clinics, so that the probability that they would reflect the kinds of patients presenting to routine general practices would be maximised. Furthermore, exclusion criteria were kept to a minimum, but with full cognisance of appropriate medical and ethical considerations for patients with BN. The trial findings therefore reflect the reality of the situations as they exist, and provide a strong indication of what would happen if the self-help

approach were actually to be introduced as routine practice in the primary care setting. As a result it can be argued that they are more generalisable and applicable to routine practice in primary care than would be those of less pragmatic trials. As Hotopf *et al* (1999) have argued, the closer the research question, interventions and settings in trials are to ‘real-life’ the more valuable they are to clinicians.

8.3.1.4 Use of a multi-methods approach

While many previous studies of potential treatments for BN have concentrated solely on evaluating treatment outcomes in terms of participants’ scores on standard outcome measures, the present study represents a broader ranging, multi-methods approach to the evaluation of a general practice based intervention for BN. The inclusion of GP surveys and the collection of qualitative data from participants has, as outlined above, generated applied, practical information about a number of treatment-relevant issues that an RCT on its own could not have provided. Participants’ views of the self-help and clinic approaches have been established and consequently inferences can be drawn about the types of barriers (both attitudinal and practical) that would need to be addressed and the incentives that would require strengthening were an attempt to be made to introduce the self-help approach as routine practice. For example, as noted above, time concerns and training-related issues have emerged as pertinent to the implementation of a general practice based treatment approach. The multi-methods approach therefore provides a more rounded view not only of the effectiveness, but also of the acceptability and feasibility of the self-help approach being evaluated. Consequently, it should be viewed as an important strength of the study as well as a useful model for future studies. Marks (2002) has argued that we are still quite some way from understanding the mechanisms by which therapies work, but that the task of unravelling what works within a given treatment package is a worthwhile one. Similarly, Jarman and Walsh (1999) have argued that further work is required to elucidate patients’ views of treatment outcome and recovery in evaluative research. Lewis *et al* (2003) recommend the use of qualitative as well as quantitative methods in the study of patients’ use of self-help interventions. On a more general level, Barbour (1999) has suggested that a whole new generation of health services research initiatives may be grounded in the use of a multi-methods approach. Only by applying such an approach in conjunction with traditional RCT methods, as in the present study, can

researchers begin to address important clinical issues, and add context to the outcomes of trials.

8.3.1.5 Controlling for potential biases

Yet another strength of the study lies in the fact that attempts were made throughout to control for potential biases or confounders. Firstly, the power calculation was conducted in advance of the study and based on previous work that had been undertaken (Henderson and Freeman, 1987) using the BITE, the study's main outcome measure. Secondly, in order to control for the possible prognostic influence of eating disorder status at baseline, a stratified randomisation procedure was employed to assign patients to the trial arms, with the stratification based on BITE scores. While a randomisation strategy involving a centralised computer system at the first assessment might in general be preferable to the use of sealed envelopes this was not possible in the present study for practical reasons, and the latter had the advantage that patients could be told at the assessment which arm of the trial they had been allocated to. Thirdly, although the study was not 'blind', the study's main outcome measure and the majority of the secondary outcome measures were self-report in nature in order to minimise the possibility of interviewer bias. In addition, the main outcome measure was determined in advance and was closely related to the research hypothesis. Fourthly, the researcher and her academic supervisor were not involved in the provision of the treatment interventions, either at the clinics or in general practice. Nor had they any vested interest in the promotion of the specific self-help manual employed in the study. Fifthly, as noted above, in an attempt to maximise the generalisability of findings to routine general practice, patients were recruited from among GP referrals only and exclusion criteria were kept to a minimum. In addition, in order to ascertain how typical of clinic attenders the population was, the baseline BITE scores of the study sample were compared with those of patients who were considered for inclusion in the trial, but who declined to take part or whose GPs declined to do so, and who subsequently attended the clinic. Finally, given the pragmatic nature of the trial, data were analysed on an intention-to-treat basis, as recommended by Pocock (1983) and Hotopf *et al* (1999).

8.3.1.6 Multi-axial assessment of recovery

A further positive feature of the current study concerns the fact that a multi-axial assessment of recovery was undertaken. Previous studies have been criticised on the grounds that they have focused exclusively on bingeing and purging (Fairburn, 1991). However, in the current study, the primary (BITE) and one of the secondary outcome measures (EDE) employed were designed to assess the eating pathology associated with BN across a spectrum of symptoms, behaviours and attitudes. In addition, measures of depression, self-esteem and social adjustment were included as secondary outcomes, as co-morbidity in these areas is known to be associated with BN. As well as the standardised measures used, patients were asked to rate the perceived severity of their disorder at baseline and at the two follow-up assessments. Furthermore, exploratory analyses were undertaken to investigate possible predictors of outcome, and to explore the potential impact of stated pre-treatment treatment preferences on outcome. In addition, participants were followed over a nine-month period in order to assess the long term impact of the interventions.

8.3.1.7 Economic analysis conducted

As noted earlier, there has been little empirical investigation to date of the costs of the interventions typically used to treat patients with BN either in treatment trials or as part of routine clinical practice. Although the economic analysis undertaken in conjunction with the current study was very limited in nature, it does represent an initial attempt to ascertain the relative costs of two different treatment approaches. The findings lend support to the argument that there is financial as well as clinical merit in exploring the possibility of introducing a self-help approach to treating BN as routine practice in primary care.

8.3.1.8 Summary

In summary then, the strengths of the current study include the fact that it has solid empirical underpinnings; that it overcame challenges involved in focusing on a difficult area of patient care and was carried out successfully; that a three-pronged, multi-methods approach was employed; that attempts were made to control for possible biases; that a multi-axial assessment of recovery was undertaken; and that an economic component was included in the study.

8.3.2 Difficulties and limitations

As noted above, the present study has, like any other study of its type, limitations in terms of its methodology and findings, and like most studies a number of difficulties were encountered in undertaking it. These are described in Sections 8.3.2.1 to 8.3.2.7 below.

8.3.2.1 Recruitment

Although comparable in size to some of the other BN treatment trials that have been conducted in the UK, the current study is probably weakest in terms of its size and the magnitude of difference that could be detected to define the GP approach as disadvantageous. The better the recruitment rates in a trial, the greater the power of the study. As noted in Chapter Three, recruitment to clinical trials is often difficult, and less than half of potential participants are usually recruited to BN treatment trials (Mitchell *et al*, 1996). The current trial was no exception with approximately one-third of those considered for inclusion eventually recruited. Unlike trials where patients are recruited directly by research or clinical staff during their first visit to a specialist clinic, recruitment was less straightforward in the present study as GPs' agreement was required before patients could be approached about it. In almost a quarter of the cases this was not given and potential participants could not be contacted. In addition, patients declined to participate in the study, were uncontactable or when contacted had decided not to take up the clinic referral.

However, the study should not be seen as a failed one in terms of recruitment. Some GPs will never wish to participate in research for the very reasons given by those in the current study (lack of time, unfairness to other patients, heavy administrative loads and practice policies concerning research). As noted in Chapter Three, research may not be a priority for GPs who already feel overwhelmed by high workloads and accountability (Elwyn *et al*, 2001). Fairhurst and Dowrick (1996), for example, found that failure to recruit patients to a study designed to evaluate the effectiveness of counselling for minor psychiatric morbidity in general practice, was largely due to fundamental difficulties concerning GPs' professional responsibilities and their attitudes to research. Furthermore, the lack of willingness on the part of some GPs to participate or allow their patients to participate reflects the reality of clinical practice

in primary care where the type of self-help intervention being evaluated would not appeal to all. Some GPs will never wish to treat patients with eating disorders (or indeed other common mental health problems) viewing them as too time-consuming or because they have the types of legitimate concerns expressed by GPs in the current study about the severity or complexity of some patients' problems and the need for specialist care which they feel that they themselves cannot provide. Indeed, it was very encouraging that in over three-quarters of the cases, GPs contacted by the researcher were willing to participate in research that would potentially involve them supporting patients undertaking a self-help treatment in primary care. As noted earlier, patients were not asked specifically to say why they chose not to participate, but many volunteered reasons, such as the fact that they had already tried self-help, felt their problems were too severe for the approach, or would not be comfortable working with their GP. Again, these are legitimate, real-world reasons that might be expressed by any patient offered a self-help intervention by her GP as part of routine practice. It would undoubtedly be a valuable exercise for researchers undertaking future pragmatic trials in this area to attempt to elicit this type of information in order to increase the all-round applicability of their studies and the outcomes of such studies to routine practice.

It might be argued that a general practice intervention would have greatest success were it to occur earlier in the course of the eating disorder symptoms, before the requirement for specialist treatment, and that when conducting a trial of the effectiveness of such an approach it would be most appropriate to recruit patients directly from among general practice attenders before they have been given expectations of receiving specialist treatment. It might be argued further that such a strategy would improve the all round generalisability of the findings of any such study. However, as noted above, GPs are not skilled in the detection of eating disorders. Thus it was felt that a pragmatic trial would require the recruitment of patients at the point where they are recognised by GPs and for many this is the point of referral. It is questionable whether recruitment to BN trials like the current one would be more successful if recruitment were undertaken in general practice itself, perhaps by screening consecutive attenders. GPs would still have to agree to participate in the study and would probably be reluctant to take on too many patients in any one practice. Furthermore, patients identified purely for research purposes

through screening might not wish to receive help for their eating problem, much less to take part in a treatment trial. In addition, the time and costs involved in screening consecutive attenders and recruiting directly to the study would be prohibitive in a trial like the present one. For example, Durand *et al* (1999, unpublished report to the Royal College of General Practitioners) found that they had to screen over 1050 women in six general practices in order to recruit 70 eligible and consenting *women with abnormal eating attitudes* (as opposed to a full-blown eating disorder) to their pilot study mentioned above. Hence it is doubtful that recruitment rates would be improved by using other recruitment strategies or that study outcomes would more accurately reflect the impact of the self-help intervention than they do with the recruitment strategy and the methods employed in the current study.

It might also be argued that less severe cases were recruited into the study, based on the fact that those who did not enter the trial but who were assessed when they attended the clinic had a higher mean BITE score. However, the evidence suggests that the patients who participated in this trial were clinically very similar at baseline assessment to other study populations described in the literature on treatment trials. In addition, even if less severe cases were successfully recruited into the study they do not negate the findings as they stand as it is likely that, in routine practice, GPs would be more inclined to try the self-help intervention with less severe cases in any event.

8.3.2.2 Follow-up rates

Another limitation of the study relates to follow-up rates. Empirical evidence suggests that some study participants will always be lost to follow-up in trials. The present study is no exception, with follow-up rates broadly in line with those of previous studies. Attrition from studies has implications for internal and external validity in trials, particularly when they are designed to be explanatory in nature. In the current study, an intention-to-treat approach was adopted in order to try to reflect the nature of clinical reality where patients do drop out of treatment, fail to attend for follow-up appointments, move or otherwise ‘disappear’.

One can only speculate about the reasons why patients were lost to the present study. Findings suggest that there were no differences in terms of their baseline clinical

characteristics between those for whom follow-up data could be collected and those for whom it could not. Some patients may have felt better and not have wished to be reminded of their problem by attending a research assessment; conversely, they may have felt that they had not been helped and therefore unmotivated to continue to take part in the research. The current study sample was a relatively young and mobile one, and a number of participants were known to have moved abroad or to other parts of the UK during the course of the study. While some of these were successfully followed up, others could not be. Follow-up rates were slightly higher for participants in the clinic arm of the trial at both follow-ups. Again, one can only speculate about the reasons for this. Clinic patients may have been less likely to be inconvenienced by a study interview than self-help patients, as the researcher could see them when they attended for treatment. In previous studies specialists or non-specialists based in clinics supported patients who received self-help interventions and details of changes of address may therefore have been easier to obtain. The majority of the self-help patients in the current study had no contact with the clinic, and were often harder to find if they had changed address, simply because (anecdotally) they did not think to tell their GP (or the researcher) that they had changed address. While the benefits of conducting a multi-axial assessment of outcome have been outlined above, and constitute a strength of the study, one also has to consider the possibility that lengthy outcome assessments may not appeal to every participant. One of the difficulties with RCTs is that as researchers we often cannot tell why people agree or refuse to participate in trials in the first place, or why participants choose to drop out of treatments and/ or follow-up assessments. While we can look for possible reasons based, for example, on clinical characteristics, we rarely examine or measure the potentially more important issues such as motivation and readiness to change.

8.3.2.3 Nature of the specialist out-patient clinic treatment

Yet another potential criticism that might be levelled at the current study is that the specialist out-patient treatment involved differs in nature and intensity from the specialist treatments compared with self-help interventions in previous studies (where patients in the specialist treatment arm have generally received a set number of approximately eight to twenty sessions of full manual-based CBT). In this study there was considerable variation in the number of clinic sessions patients attended. The evidence suggests that full CBT is the treatment of choice for BN and, by

implication, would constitute best practice in specialist clinics. However, while the Royal College of Psychiatrists (2000) reported that 93% of 57 clinics surveyed said they offered CBT, it should not be assumed that the provision of full CBT is *standard* practice in UK clinics. Indeed previous studies comparing self-help interventions and CBT have not specifically identified the latter as routine specialist clinic treatment. Furthermore, the purpose of this pragmatic study was to compare the self-help intervention with *usual specialist clinic care* rather than with CBT as the specialist treatment of choice. The specialist treatment studied in the current trial (which consisted of a combination of cognitive behaviour and interpersonal therapy approaches) represented standard, routine practice in the three busy London clinics participating in the study at the time of participation. The fact that patients in the clinic arm may not have received full manual based CBT should therefore not detract from the study's findings. Evidence from Pederson Mussell *et al*'s (2000) study suggests that in the US even though doctoral psychologists may list CBT as primary mode of treatment for patients with eating disorders in reality they often use an eclectic approach to treatment. A study by Crow *et al* (1999) of patients presenting for treatment or follow-up studies (cited by Wilson *et al*, 2000) revealed that of the 61% who had received some form of previous treatment, only 7% reported receiving CBT. There is a need for more studies that evaluate the standard interventions received by patients attending specialist services rather than interventions offered in those clinics solely for the purposes of trials. The closer the treatments being evaluated in trials are to those that exist in practice, the more generalisable to routine practice those found to be effective in treatment trials will be.

8.3.2.4 Clinical outcome

Reports of recovery and abstinence rates achieved in treatment trials for BN have varied considerably from study to study. It might be argued that patients in both arms of the current study did not do as well clinically over the course of the study as those participating in some of the other studies reviewed in the literature section and that the effect sizes are not as great as those found in some other studies. There are two possible reasons for this. The first relates to the aforementioned criticism of trials of psychotherapy for BN that they are often conducted under highly experimental conditions (e.g., Mitchell *et al*, 1996). The current study was pragmatic in nature and data were analysed on an intention-to-treat basis. As such the findings may be more

reflective of outcome in routine practice than the outcomes of previous studies have been. Secondly, some of the studies that have produced the most powerful results (both in terms of full CBT and self-help) have reported only post-treatment results, results over a short follow-up period, or assess BN symptoms in relation to a very limited time period (e.g., a week) prior to assessment. The present study followed patients for nine months and considered symptoms over the month prior to follow-up assessment.

8.3.2.5 Outcome measures employed

A further potential limitation of the study relates to the fact that its principal outcome was limited to scores on a self-report measure of symptoms and behaviours related to BN. As noted above, the purpose of using the BITE was to reduce the potential for interviewer bias as funding did not allow for independent assessments of outcome and the researcher was not blind to treatment allocation. As such this was a perfectly valid undertaking. However, while clinical self-report measures are used widely in treatment trials and are likely to be able to detect changes in psychopathology over time with some accuracy (e.g., Hotopf *et al*, 1999), they are not on the whole as satisfactory as full interviewer-rated clinical assessments. In the current study EDE-related findings mirrored those on the BITE thereby validating the use of the latter as the primary outcome measure. Generally, however, where funding does allow for independent assessors at follow-up, the use of an interview schedule such as the EDE (and composed of sub-scales covering a wide range of the symptoms and attitudes associated with BN) as the study's principal outcome measure would be considered preferable.

8.3.2.6 GP surveys

Valuable information was gleaned from the GP postal surveys. The main reason for conducting surveys was to inconvenience busy GPs as little as possible and to encourage a high response rate. However, even more information about the extent to which the GPs made use of the manual or drew on their own clinical experience, and about the level of support they felt patients needed might have been gained by conducting in-depth interviews with them. Were the current study to be replicated or a similar one undertaken the use of the in-depth approach should be given serious consideration. On a related issue, it was impossible to achieve a 100% response rate

to the GP surveys or to obtain qualitative data from every patient. A degree of caution must therefore be exercised in suggesting that the views expressed are those of the study population and participating GPs as a whole. However, a range of views (from the positive to the negative) were expressed, and certain themes emerged repeatedly, suggesting that a representative sample of opinions had been gauged.

8.3.2.7 Summary

In summary, the difficulties encountered in undertaking the current study and the limitations that apply to its findings are similar to those of many trials involving the evaluation of interventions for patients with BN. The difficulties and limitations outlined are however balanced by its strengths, and both the former and the latter, as well as the study outcomes, can usefully be employed to inform future policy, practice and research (see below).

8.4 IMPLICATIONS FOR POLICY AND PRACTICE

The term ‘research and development’ is one that is much bandied about in the healthcare field. However, there is a tendency not to move beyond research findings to the ‘development’ and implementation stages, possibly because of the philosophical and practical gaps that exist between the worlds of academic research and clinical practice. It might be argued that there is little point in conducting research in the first place if its findings are not disseminated to relevant bodies, organisations and professional groups, and, where appropriate, subsequently applied in practice. The purpose of treatment trials, regardless of the patient group involved, or the nature of the interventions being tested, essentially is (or should be) to improve patient care. This can potentially be achieved through the application of research findings to policy initiatives, service development and/or clinical practice. Arguably, the more applied the research, the greater the relevance of its findings to any attempt to improve patient care. Hence the call for more pragmatic trials to be undertaken in psychiatry (e.g., Hotopf *et al*, 1999). The findings of the current pragmatic study have implications for policy, clinical practice and service delivery.

8.4.1 Implications for policy

The study results support current policies and strategies which suggest that common mental health problems, including BN, can be managed in the primary care setting. As noted previously, up to 40% of general practice attenders suffer from common mental health problems (Murray and Jenkins, 1998); such problems constitute approximately one quarter of routine consultations; and over 90% of patients with mental health problems are treated in primary care (Department of Health, 1999). It is clear from the National Services Framework for Mental Health (NSF) (Department of Health, 1999) that the latter is likely to remain the case for the foreseeable future. One of the tenets of the NSF is the provision of high quality, effective and acceptable treatments that are accessible to patients where and when needed. This includes the general practice setting. Primary Care teams have been encouraged to agree and implement protocols for assessing and managing patients with depression, post-natal depression, eating disorders, anxiety disorders and schizophrenia, starting with depression (Department of Health, 1999). Policy-makers (e.g., the National Treatment Agency for Substance Misuse, 2002) are also promoting the development of models of shared care between primary care and specialist services for managing specific patient groups. The NSF recommends that most mild eating disorders can be treated in primary care, while individuals with severe disorders should be referred to specialist services. As reported earlier, the Royal College of Psychiatrists (1992, 2000) has advocated a stepped approach to the treatment of BN and suggested that primary care professionals have a role to play in the detection and management of patients with eating disorders. In addition, the Department of Health has commissioned the National Institute for Clinical Excellence (NICE) and the National Collaborating Centre for Mental Health (NCCMH) to provide guidelines to primary care and generalist psychiatric services on the treatment and referral of patients with eating disorders. It is anticipated that their final report will be published in January 2004 (www.nice.org.uk, 2003, and personal communication, Catherine Pettinari, NCCMH). The current policy agenda, therefore, appears to favour the involvement of general practice professionals in the provision of non-specialist forms of treatment for eating disordered patients.

Policy documents like the NSF (Department of Health, 1999) generally cite evidence to support the efficacy of the treatment interventions advocated. However, they do

not necessarily include evidence to demonstrate that the specific treatments in question have been tested and found to be effective in the setting in which their use is being recommended. Furthermore, policy has sometimes been based more on expert opinion, clinical impressions and financial imperatives than on empirical evidence. (Initiatives such as the Department of Health's Policy Research Programme should help to ensure that current and future policy-relevant decision making is informed by scientifically sound and appropriate research evidence.) In terms of the evidence base concerning the treatment of BN, previous studies have attested to the efficacy and effectiveness of self-help alone or in combination with a reduced level of CBT in *specialist settings*. They have also shown that non-specialists can support patients using a self-help package, leading to the suggestion that GPs too could provide such support. The findings of the current study provide empirical evidence to suggest that BN patients offered a self-help intervention with GP support in *primary care* are not clinically disadvantaged compared to patients offered specialist treatment. They also suggest that the approach is feasible in practical terms in routine general practices and that, generally speaking, neither patients nor GPs are strongly opposed to trying the approach. They therefore help to underpin and provide an evidence base for policy initiatives relating to the management of BN in primary care and indicate that it is appropriate for GPs to at least consider the use of a self-help or other non-intensive treatment approach when a patient presents with BN. However, further studies are needed to determine the characteristics of patients who do particularly well in this setting so that policies and guidelines can be both expanded and sharpened and existing treatments (as well as those being developed) targeted appropriately, effectively and efficiently, in both primary and secondary care settings. Practice will only advance if the policy driving it is truly underpinned by a solid empirical base. Further studies like the current one, and those suggested in Section 8.5 below, should help to achieve this. The Department of Health's Service Delivery and Organisation Research and Development Programme, the aim of which is to produce and promote research evidence regarding how services can be organised and delivered to maximise the quality and effectiveness of patient care, constitutes a potential source of funding for such research.

8.4.2 Implications for clinical practice

The most obvious implication for clinical practice of the study's main finding that patients offered a self-help approach in general practice are not clinically disadvantaged across a range of outcomes, is that GPs should consider offering the self-help approach when patients present to them with BN. The study offers a number of positive indications that the implementation of self-help interventions as routine practice in primary care is feasible in practical terms.

8.4.2.1 Positive indicators of the feasibility of implementing the self-help approach in routine general practice settings

Firstly, while only about one-third of patients considered for inclusion in the current study were eventually recruited, in only approximately one-quarter of the cases considered did GPs actually decline to participate (and for some their reasons were related to not wishing to take part in research). Equally, only just over one-quarter of the patients contacted about the study declined to participate or said they did not wish to take up the specialist referral. Some GPs and patients declined on the grounds that self-help had already been tried. In addition, when participating patients were asked about treatment preferences at baseline (prior to treatment allocation), more reported having no treatment preference or a preference for the general practice approach than expressed a definite preference for specialist clinic treatment, even though all had been referred to specialist clinics at that point. These findings suggest that patients and GPs are not averse to the notion of BN being managed in the general practice setting. The climate may therefore be favourable at present for introducing non-intensive approaches like the self-help one evaluated here; a fact that should be capitalised on by policy makers and those driving service development. Obviously, some GPs will never wish to support patients using a self-help manual for BN and some patients suffering from BN will not wish to try self-help (nor is it being suggested that such an approach would be appropriate for everyone suffering from BN). However, the NSF (Department of Health, 1999) suggests that patients with mental health problems would prefer to be treated by GPs and the primary care team. Even if only one-third of BN patients were managed in primary care the savings in terms of specialist resources would potentially be considerable. Secondly, few of the self-help patients needed to be seen in the clinics in the course of the present study, suggesting that GPs are capable of offering the support needed by patients. Thirdly,

GPs reported deriving benefit, in terms of knowledge and skills gained, through using the self-help manual to support patients. Having had just a single experience of using the approach a significant proportion reported being willing to try it again with future patients. This suggests that, given the opportunity and experience, other GPs might also be willing to incorporate the self-help approach into their routine practice. Finally, both patients and GPs saw merit in the self-help approach, with possible benefits including continuity of care for the patient and the convenience of being able to attend general practice rather than regular clinic appointments that might clash with work and other commitments. In addition, the types of ‘improvements’ called for by patients in the self-help intervention are not insurmountable. Taken together, these findings suggest that it would be feasible to attempt to put the approach used in the study into place as routine practice in regular primary care settings.

8.4.2.2 Barriers to implementing the self-help approach

However, the study findings also indicate that there are a number of potential ‘barriers’ that would require attention if attempts to implement in practice an approach such as the one used in the study are to be successful. As highlighted above, the types of barriers to implementation that emerged are both attitudinal and practical in nature. They relate to GPs’ ability to detect and diagnose patients with eating problems, their concerns about time commitments, their perceptions of their level of expertise and need for support from specialist services, and their confidence about managing patients, as well as patients’ concerns about receiving appropriate and expert treatment. Strategies to overcome barriers and to increase incentives for GPs to become more involved in the care of patients with BN should focus on improving detection rates, management techniques and service delivery, and include the provision of information, training and appropriate professional support to GPs.

8.4.2.3 Overcoming barriers to implementation

8.4.2.3.1 Dissemination of relevant study findings

As a starting point in any attempt to encourage GPs to become more involved in the care and management of patients suffering from BN, the findings of studies like the present one should be disseminated in professional journals, magazines and policy documents accessed on a regular basis by GPs and other primary care staff. For

example, the current study has been published in the *British Journal of General Practice* (Durand and King, 2003). This would lead to an increased awareness among GPs and their general practice colleagues of the potential benefits (and limitations) of using self-help materials and approaches. It would also ensure that they are aware that policy initiatives and directives are not simply based on the whims of policy makers and health service managers, but are grounded in studies involving their peers and the types of patients likely to be seen in their own practices.

8.4.2.3.2 Improving detection and diagnostic skills

Before GPs can play an effective role in the management of patients with BN they need to be able to accurately detect and diagnose the disorder. Previous research has indicated that GPs require education in the detection and diagnosis of eating disorders generally (e.g., King, 1989; Turnbull *et al*, 1996). The fact that some patients had to be excluded from the present study on the grounds that they did not suffer from BN, although referred for treatment of BN, suggests that GPs may still have problems arriving at a diagnosis of the disorder. The increasing recognition that some patients with AN report bingeing suggests that when patients present to GPs with bingeing, the nature of the reported behaviour requires more than a superficial investigation. GPs also need to be aware of the clinical differences between BN, BED and atypical eating disorders. A number of strategies might usefully be employed to help improve detection and diagnosis: namely, the provision of educational information, the development of simple screening instruments and the introduction of general training concerning the detection of psychological problems including eating disorders in general practice.

8.4.2.3.3 Dissemination of information about eating disorders

GPs reported that the self-help manual used in the study increased their knowledge and understanding of BN and gave them a structure for talking to patients about their BN. The wider dissemination of the type of information contained in this manual and others like it, including clinical descriptions of symptoms based on core DSM criteria, as well as brief descriptions of appropriate primary care interventions, would potentially improve GPs' detection and diagnostic abilities. The Royal College of Psychiatrists (1998) has produced a leaflet about eating disorders which is available to patients attending general practice, and its website (www.rcpsych.ac.uk) contains a

brief diagrammatic protocol for the identification and referral of adults with eating disorders in general practice. The World Health Organisation has also produced guidance for general practitioners and primary care staff (ICD-10 PC Chapter 5) to accompany the International Classification of Disorders-10 (World Health Organisation, 1994). The development and provision of more in-depth leaflets for GPs and primary care staff is warranted. However, merely to provide information that might aid detection and diagnosis is not enough. A concerted follow-through, in the form of evaluations of the perceived usefulness of said information to GPs, and their use of it, as well as studies of the impact of information provision on detection rates would be required.

8.4.2.3.4 Development of screening tools for use in primary care

The development of tools for screening patients for BN in general practice, like the CAGE (Ewing, 1984), which can be used to screen for potential alcohol problems, would also potentially improve the detection of eating disorders in primary care. Such instruments would need to be brief, to have proven reliability and validity in terms of case identification, and to be appropriate for use in the primary care setting by any member of the general practice team. Some work has already been undertaken in terms of developing such instruments in the US (Freund *et al*, 1993), while in the UK, King (1989) developed a ‘mini’ version of the Eating Attitudes Test (Garner and Garfinkel, 1979). However, further work is required in this area. As with screening for smoking and alcohol consumption, screening for BN and other eating disorders could potentially be incorporated into ‘new patient’ assessments. New patients are currently weighed and have their BMI calculated, and the addition of a brief screening instrument would not significantly lengthen the patient assessment. The identification of patients with BN or BN-like symptoms would not necessarily mean that those patients would be ready to accept advice or offers of treatment interventions. However, it would help GPs to flag up patients who should be monitored, and who might require treatment or be amenable to trying a self-help approach at some later stage.

An alternative, and possibly more efficient and effective, strategy to screening all new patients might be to screen high-risk populations on an opportunistic basis. This would include young women who mention concerns about weight, patients with low

BMI, those presenting with gastrointestinal or menstrual problems, and frequent attenders who appear to have undefined psychosocial problems. Such opportunistic screening when there is an increased index of suspicion would present a natural and immediate opening for GPs or other members of the primary care team to discuss potential eating problems with patients at a time when they may be generally receptive to receiving help.

8.4.2.3.5 Improving professionals' interviewing skills

The study findings suggest that women suffering from BN may not *actively seek treatment* until their symptoms and the effects of the disorder on their lives have become overwhelming. However, patients with eating disorders are known to attend general practice with greater frequency than non-eating disordered matched controls. Frequent attendance for non-specific reasons should serve as an indicator to GPs that screening for psychosocial risk factors for mental health problems might be warranted (Murray and Jenkins, 1998). Previous research has found that training programmes aimed at enhancing primary care professionals' interviewing skills have resulted in increased detection of patients' psychological problems (Murray and Jenkins, 1998). It appears that most benefit is to be gained in terms of achieving changes in their detection behavior by involving GPs in active training programmes directly related to their interviewing skills (Cooper, 2003). The development and evaluation of brief educational training packages that focus on the detection of eating disorders primary care might benefit GPs and other primary care professionals and lead to more rapid identification of patients who are suffering from BN, or who are at risk of doing so. Early detection would potentially lead to earlier intervention, and perhaps to the need for less intensive intervention. It might also mean that GPs are less likely to refer BN patients inappropriately for apparent physical complaints.

8.4.2.3.6 Focusing consultations

Apart from their poor detection and diagnostic skills, an obvious barrier to the implementation of the self-help approach in general practice is that, like those who participated in the study, GPs in general are likely to have concerns about the potential time commitment and extra workload involved in supporting patients using the approach. However, as noted above, patients with BN are high consumers of primary care services as it is. The use of self-help materials by GPs would potentially

lead to more focused consultations, and therefore to more efficient use of their time. GPs develop management plans for patients with a wide range of physical and psychological complaints as part of their everyday clinical practice. They are also continually involved in encouraging patients to think about ways in which they might best manage their own health problems. They should perhaps be encouraged to think of the use of self-help materials with BN patients as simply a slightly more 'formal' approach to what they do as a matter of course with most of their patients. They should also be encouraged to ask patients about self-help materials or any informal strategies that they might be using to try to help themselves. The increased ability of GPs to focus consultations, on the basis of using the manual, might also assuage patients' concerns about not getting enough time, wasting GP time or wanting more 'managed' or 'directed' help from GPs. The GP's role in the self-help approach is one of providing support rather than treatment or counselling per se, and it should be viewed as a time-limited activity. If progress is not being made, then referral to a specialist may be the most appropriate option for an individual patient. In general, the widespread use of manuals by GPs and their increasing knowledge and experience in managing patients should result in less frequent consultations by individual patients over time and in more efficient referral practices so that patients who do require specialist treatment can be seen more rapidly in clinics (as a result of shorter waiting lists).

8.4.2.3.7 Definitions of a successful cure

Another potential barrier to the successful implementation of the self-help approach in general practice concerns the definition of a successful cure or significant improvement in symptoms. One of the issues that has emerged in the literature on GPs' treatment of patients with alcohol problems is that GPs have concerns about definitions of 'success' and 'cure' in relation to such patients (Durand, 1994). GPs in the current study reported that they could see improvements in their patients in a number of respects (e.g., in terms of improved symptoms, or increased understanding). However, BN is a chronic disorder and if GPs only experience success in terms of abstinence from binge-eating and vomiting in a limited number of patients they may become disillusioned over time. Jarman and Walsh (1999) suggest that definitions of recovery differ considerably in trials and clinical practice. GPs managing patients in primary care may need to be encouraged to think in terms of

patients' subjective definitions of improvements rather than of 'abstinence' as success or cure. When a patient has been bulimic for years she may see even one binge-free week as an enormous step forward.

8.4.3 Implications for service delivery and development

The study findings also highlighted a number of issues relating to service development and delivery that could be addressed in order to increase the likelihood that at least some BN patients could be managed successfully in general practice. These include GP training requirements, the potential involvement of primary care professionals other than GPs in the 'delivery' of self-help interventions, and the introduction of professional support arrangements for GPs managing BN patients in primary care.

It is of little value to improve detection rates and increase the accuracy of primary care professionals' diagnostic abilities if practices do not have in place protocols for managing patients identified as suffering from BN or if GPs do not feel that they are sufficiently skilled or experienced to manage such patients. As noted earlier, not every GP will wish to manage patients suffering from BN. However, the establishment of Primary Care Trusts (PCTs) may mean that those GPs who are interested could potentially undergo brief educational training and offer services on a Trust-wide basis, resulting in a co-ordinated and economically efficient general practice approach to patient care. As is the case with GPs who manage patients with substance misuse problems in primary care, it may be appropriate for GPs with a special interest in eating disorders to assume the role of 'GP specialists'. However, rather than creating another layer of 'specialists', the primary aim of educational and training initiatives should be to raise the knowledge, skills and confidence level of GPs in general concerning eating disorders and their treatment.

Some GPs declined to participate in the current study on the grounds that they felt that they did not have the expertise required. Those who did take part were not provided with specific training in how to use the self-help manual with their patients. A number of the participating GPs subsequently reported that they would have liked more specialist involvement. Training might obviate or lessen the need for such involvement. Training for GPs would ideally be provided by specialists, at times

convenient to GPs, and constitute an accredited element of ongoing professional development. Training packages could cover issues such detection and diagnosis, appropriate use of self-help manuals and materials, strategies for supporting patients using self-help techniques, guidance on appropriate management and referral practices, and a brief introduction to cognitive behaviour theory and techniques. It should also cover the types of co-morbid problems likely to be seen in patients suffering from BN as the symptoms of BN cannot realistically be considered in isolation from the other co-morbid problems and difficulties which the patient may be experiencing. Such training initiatives would need to be subjected to evaluation and to continuous updating so that maximum use was made of emerging techniques and research evidence. Brief educational training would potentially increase GPs' confidence in supporting BN patients. Furthermore, for patients the knowledge that they would receive support from a GP who has some training/expertise in eating disorders might increase their likelihood of engaging in a self-help programme or other forms of treatment in primary care.

Related to the issue of training is that of professional support for GPs who are caring for BN patients in general practice. Potentially, support might be provided both from within the primary care team and from specialist services. Several patients in the current study suggested that practice nurses and dieticians might be ideally placed to play a role in supporting patients undertaking a self-help programme in general practice. This was partly because such professionals are seen (perhaps erroneously) as having more time to devote to individual patients than busy GPs. Practice nurses are already involved in a range of interventions related to patients' weight and eating habits in the primary care setting (e.g., Peter, 1993; Thomas and Corney, 1993; Ross *et al*, 1994). Durand *et al* (1999, unpublished report to the Royal College of General Practitioners), in their pilot study of general practice interventions for women with abnormal attitudes to eating, found that practice nurses reported few problems in providing a brief advice intervention to such women. It is likely that practice nurses would be as adept as GPs at supporting patients undertaking self-help interventions for BN. Alternatively, GPs and practice nurses might employ a shared care approach to supporting patients with the former providing medical input and the latter support with using the self-help programme. Further research involving practice nurses and

other professionals allied to primary care services is warranted (see Section 8.5 below).

The NSF (Department of Health, 1999) suggests that general practice treatment for mental health problems is more likely to be effective when there is support from specialist services and agreement on how to provide integrated care. As noted above, some of the GPs who declined to take part in the current study did so on the grounds of the severity or complexity of their patient's problems. Furthermore, some of the participating GPs reported that more specialist support would be beneficial. It must be remembered that BN is a serious eating disorder with a lot of associated psychiatric and social co-morbidity and it would be unrealistic, unethical and medically unsound to suggest that a self-help approach would be appropriate for every sufferer. In the current trial GPs were aware that specialist help was available should they need it. The same support would need to be available to GPs were the approach to be implemented in practice. Again, the advent of the PCTs and the commissioning of services by Trusts may help to ensure that specialist support would be available where and when needed and that shared care models could be developed. A shared care approach would ensure that patients whom GPs had concerns about could be given a full clinical assessment and subsequently offered appropriate primary care or specialist treatment. It would also ensure that those for whom the self-help approach did not appear to be working could be fast-tracked to specialist services, thereby setting up an integrated, stepped approach to treatment. Additionally, it would mean that if necessary the self-help approach could be combined with a limited number of appointments at specialist clinics, whereby patients could be seen for a couple of sessions by a specialist but primarily remain in the care of their GP. The availability of specialist back-up would again enhance both GP and patient confidence concerning the provision and receipt of appropriate and 'expert' treatment.

Peer and specialist support might also be provided for GPs through an internet support forum, modelled on that already available to GPs with a special interest in treating patients with substance misuse problems. 'Substance Misuse Management in General Practice' (website: www.smmgp.demon.co.uk), which is backed by the Department of Health, is an interactive forum that provides registered GPs with

online expert advice and a newsletter (among other initiatives). Web based networks and support systems for GPs with a special interest in eating disorders might be used to provide expert advice and support on policy issues and clinical practice, to disseminate evidence-based guidance, and to provide information on research, conferences, training packages, and self-help materials.

As noted earlier in the chapter, the study also highlighted aspects of routine specialist clinic care that patients felt could be improved, such as the provision of more opportunities to meet other patients suffering from BN, and more feedback from therapists. The perceived expertise of clinic staff was valued. Both clinical and research governance strategies suggest that patients should be given an opportunity to provide feedback and comments about clinical interventions received. The impact of patient involvement in this manner can only help to improve clinical practice and service delivery, regardless of whether in primary care or specialist clinic settings.

8.4.4 Summary

In summary, the study findings support current policy initiatives that indicate that at least a proportion of BN patients, like patients with other common mental health problems, could potentially be managed in primary care. They suggest that a self-help intervention like the one used in the study could be introduced as routine practice in primary care if a number of potential barriers and incentives identified in the study are attended to and capitalised on respectively.

8.5 FUTURE RESEARCH

One of the outcomes of undertaking any research endeavour is that it generates ideas for future studies, provides insights into ways in which a particular study might be improved were it to be replicated, or suggests general areas for future research. The current study is no exception, and attention has already been drawn to a number of issues that the study findings suggest require further empirical investigation.

As a general principle and where possible, future studies of self-help interventions for BN or other eating disorders should be ideally be larger than the present one and similar ones undertaken to date, so that, for example, detailed sub-group analyses

might be undertaken of potential positive predictors of treatment outcome. Where possible, as in the current study, they should be undertaken by researchers who do not have a vested commercial interest in promoting a specific self-help package or manual. Future studies in this area should also be pragmatic in nature and designed as far as possible to reflect how interventions would be delivered in routine settings. The current study findings suggest that research should be undertaken in five inter-related areas, in order to:

1. establish an accurate picture of current practice regarding BN and other eating disorders in primary care;
2. evaluate how self-help interventions might be delivered to best effect in general practice;
3. delineate the characteristics of those who will profit most from the use of self-help interventions for BN in general practice;
4. establish how self-help materials might best be packaged and what their active ingredients are; and,
5. investigate in greater detail the cost-effectiveness of self-help interventions.

8.5.1 Identifying current practice in primary care

As highlighted already, the present study identified some of the reasons why GPs and patients might not wish to provide or receive general practice based interventions for BN. It also shed light on the advantages and disadvantages of the self-help intervention, as perceived by participants. However, more research is needed to establish what constitutes current practice in primary care, so that strategies designed to facilitate the management of BN patients in this setting, and to encourage GPs to work with BN patients on a routine basis, can be targeted appropriately and effectively. Most of the existing research on the epidemiology and management of eating disorders in general practice was conducted in the late eighties and early- to mid-nineties. Since then awareness of, and concern about, eating disorders is likely to have increased among health professionals. A heightened public awareness of eating disorders is certainly evidenced by the increasing coverage given to BN and AN in newspaper and magazine articles, and on television and radio. Not only have AN and BN become major public health concerns, but so too have the issues of obesity in the population in general and eating disorders in children and young adolescents. As

noted in Chapter Two, eating disorders, along with depression and anxiety disorders, are now among the most common mental health problems seen in primary care (Department of Health, 1999). Whether this has impacted on eating disorder-related management practices in primary care is unclear.

The participants in the study had all been referred to specialist services. Research is now needed to establish not only how many patients currently present to GPs annually with BN, but also whether the demographic characteristics (e.g., age) of those seeking help for eating problems has changed in recent years in light of the growing public awareness of these disorders. It would also be interesting to establish what percentage of patients seeking help are referred on to specialist care immediately after their disorder has been identified. How are GPs currently managing patients they do not refer on? What percentage of GPs are advising their patients to use a self-help approach or using brief intervention techniques with them? In areas where access to specialist care is not readily available, do GPs do more to manage patients themselves? What, if anything, is happening vis-à-vis the provision of shared care or brief counselling interventions to BN patients in general practice? A national survey of a representative sample of GPs is required to answer these and other questions. Such a survey should inquire about actual practice but it should also tap GPs' conceptions of eating disorders (e.g., do they see them as self-limiting disorders, where referrals are not an immediate priority, or do they view them as disorders that should generally fall within the remit of specialist services?), their level of interest in managing BN patients, as well as their views of the potential barriers and incentives to caring for such patients in general practice. Furthermore, it should investigate their use of self-help or brief psychological interventions in general with people suffering from other mental health problems, and their willingness to undergo brief training in the use of self-help materials.

While a survey would help to describe important aspects of current practice, qualitative methods might be employed to examine in greater depth GPs' decision-making processes regarding referral to specialist services and to investigate possible practical and attitudinal barriers to the implementation of non-intensive approaches such as the one used in the present study. Future intervention studies should adopt the approach taken in the present study and ask the professionals and patients involved

about their perceptions of self-help approaches as a matter of course. The combined findings of such studies should provide not only an up-to-date picture of current practice, but also an indication of GPs' level of interest in BN (and other eating disorders), and useful information concerning how to maximise the likelihood of GPs providing interventions and support to BN patients as a routine undertaking in primary care. Furthermore, further studies like that of Durand *et al* (1999, unpublished report to the Royal College of General Practitioners), which focus on patients with abnormal eating attitudes, should be conducted so that the potential roles of general practice professionals in the primary prevention of eating disorders might be assessed.

8.5.2 Delivering self-help approaches to best effect

The current study having established that patients offered the self-help intervention in general practice are not seriously disadvantaged, further research is now required to evaluate how self-help interventions can be delivered to best effect in general practice. For example, a pragmatic trial like the current one might be undertaken to establish whether GPs who have received brief, formal training in the use of self-help materials with BN patients provide support more effectively than untrained ones, resulting in better outcomes for their patients. In addition, while the evidence presented in Chapter Two suggested that, where the comparison was made (e.g., Palmer *et al*, 2002), supported self-help was more effective than pure self-help, research is required to establish the optimum level of support that should be provided to patients undertaking self-help programmes in general practice. Studies employing a stepped intervention approach might be utilised to answer this question. Patients with BN would initially receive minimal support in the use of a self-help package in general practice. Those who do not improve after a specified period would then be randomised to receive more intensive support in general practice, shared care support from their GP and an eating disorders specialist in their use of the self-help materials, or specialist clinic treatment. An evaluation should also be undertaken of the use of self-help materials as part of a shared care approach between primary care and specialist services. A potential study design might involve patients referred by their GPs to specialist services who would be fully assessed in a specialist clinic, followed by one treatment session with a specialist after which they would be randomised to stay in specialist care or to undertake the self-help approach in general practice with

the support of their GP. The option of receiving a number of further clinic sessions would be available if either the self-help patient or her GP felt that she would benefit from seeing a specialist. While GPs provided support to patients in the current study, some patients suggested that other primary care professionals such as practice nurses might be better suited to supporting them. In order to test this theory a trial involving cluster randomisation techniques might be employed, whereby in some practices practice nurses supported BN patients and in others GPs played the supportive role, and patient outcomes were compared. Finally, while the self-help approach used in the current study and in others reported in Chapter Two was based on cognitive behaviour principles, it would be interesting to develop and evaluate brief interventions and self-help materials with an alternative theoretical basis (e.g., modelled on the strategies used in interpersonal or motivational therapies).

8.5.3 Establishing who will benefit most from using a self-help approach

Some findings have been reported concerning the predictors of treatment outcome for BN patients (e.g., Keel and Mitchell, 1997), and the findings of the current study suggest that lower baseline BITE scores and being married/cohabiting with a partner are positive predictors of treatment outcome. However, there is a paucity of information regarding the demographic and clinical characteristics of those who benefit most from a self-help approach to treatment. This situation is however not confined to BN patients using self-help interventions. Lewis *et al* (2003) have called for general research on the characteristics of patients in general who are willing to use and complete self-help programmes and who benefit from employing such programmes. This information is required so that professionals (be they working in a general practice or specialist setting) can ensure that self-help approaches are targeted appropriately and effectively. While a stepped approach may be advocated for the treatment of patients with BN, it would be wasteful of resources and unfair to patients to offer less intensive interventions to start with if the indications, based on their clinical presentation, were that such interventions might not benefit them much. Similarly, it would be inappropriate and uneconomical to refer to specialist care when the indications suggest that an individual patient might derive benefit from the primary care approach. Large studies are required in order to establish predictors of good outcome for patients treated for BN in general practice, so that policies and directives could provide GPs with an accurate picture of the types of patients most

likely to benefit from management in general practice. The issue of who is likely to comply fully with a self-help programme also needs to be examined in greater detail than was possible in the current study. As the number of well conducted studies of self-help grows, so too will the potential for conducting systematic reviews and meta-analyses of these studies, yielding information concerning the characteristics of those who benefit most from self-help. Research findings on the management in general practice with self-help interventions of patients experiencing other types of mental health problems may also prove to be applicable to patients with BN and should not be ignored by those conducting future research on BN and self-help. As well as examining the more traditional potential predictors of outcome, future research should also attempt to measure characteristics such as motivation or readiness to change. The latter are far more difficult to evaluate, but this should not mean that they are ignored, as they may prove to be more significant predictors of treatment outcome in the long term than, for example, demographic characteristics such as age.

8.5.4 Establishing the active ingredients of self-help treatments

As already mentioned, little is known about the active ingredients or components of brief psychotherapeutic or self-help interventions for BN and other common mental health problems. This is an issue that requires empirical investigation, as establishing which are the active components of treatments would potentially lead to the modification and improvement of said treatments, with resulting benefit to users of such interventions. Studies like those of Wilson *et al* (1999) and Agras *et al* (2000 b), reported in Chapter Two, which investigate time course of change over treatment, or which seek to establish at which stages of self-help programmes significant changes in behaviour or symptoms appear to occur, might be undertaken. Such studies might involve the randomisation of patients to receive increasingly complex stages of the self-help programme. In-depth qualitative interviews with patients who have completed a self-help programme, with or without support from a professional, may also help to elucidate the aspects of the programme thought to be most helpful and why.

On a related issue, the self-help manual employed in the current study had the size and appearance of an ordinary paperback, and could easily be carried around in patients' handbags. No negative comments were made about its appearance or about

the way in which information was presented in it. However, in order to optimise the use of self-help interventions in general practice, it may be important to investigate more closely than was possible in the present study the ways in which self-help manuals and materials should be ‘packaged’ in order to appeal to patients. Questions concerning the accessibility and user-friendliness of materials need to be examined. Younger, more computer-literate patients might prefer to receive self-help instructional packages on a CD-ROM for example. It is possible that presentation factors may have an impact both on the delivery by GPs and reception by patients of self-help interventions. Both qualitative and quantitative methods should be employed to investigate this issue.

8.5.5 The cost-effectiveness of self-help

As noted throughout, there is a paucity of research on the costs of treating patients with eating disorders including BN. While the current study made an initial attempt at examining some of the costs involved in the interventions being evaluated, and the findings of the limited investigation undertaken suggest that the self-help approach is a cost-effective one, larger studies which focus in far greater detail on the costs of self-help and other interventions for patients are required. Again the issue of establishing which patients to target with self-help interventions in order to obtain most benefit is important, in that inappropriate use of self-help materials, as well as being unfair to patients, will only increase the costs of professional involvement.

8.5.6 Summary

In conclusion, the direct and indirect outcomes of the current study, as well as the knowledge gaps identified by the literature review, suggest that there is still much research to be undertaken on the use of self-help approaches in general practice by patients with BN. Indeed, the use of self-help materials by patients suffering from a whole range of common mental health problems warrants further investigation.

8.6 CONCLUSIONS AND RECOMMENDATIONS

The findings of the present study indicate that patients with BN who are offered a self-help intervention in general practice with GP support are not seriously disadvantaged compared to those who are offered specialist out-patient clinic

treatment. Over nine months there is no difference in eating disorder outcome for those randomised to receive self-help or specialist clinic treatment. The results suggest that the self-help approach to treating BN, previously only tested in specialist settings, may be applied in general practice and that GPs could consider offering self-help interventions to patients who present to them suffering from BN. The study findings also suggest that the approach is feasible in practical terms in routine general practices and that neither GPs nor patients are strongly opposed to trying it. In addition, the findings provide valuable information about the barriers that would need to be overcome and the incentives that would need to be offered were attempts to be made to introduce the approach as a routine undertaking with BN patients in general practice.

A number of recommendations can be made on the basis of the current study and its findings:

1. GPs and other primary care professionals should be encouraged to consider the use of a self-help intervention with patients suffering from BN.
2. Policy-makers and those responsible for planning service delivery in the NHS should ensure that GPs and other primary care professionals, as well as those providing specialist eating disorders services, are made aware of the potential benefits (and limitations) of self-help approaches to managing BN.
3. GPs who wish to increase their knowledge and expertise in this area of patient care should be provided with brief training in the detection and management of eating disorders in general practice and in the use of self-help materials with other patients. Furthermore, the effectiveness of such training initiatives should be evaluated. Peer support and opportunities for implementing shared care approaches to managing BN in conjunction with eating disorders specialists should also be provided to interested GPs and members of their staff.
4. Researchers undertaking trials of self-help interventions for BN (and indeed for other common mental health problems) should consider using a multi-methods approach like the one employed in the current study. The use of such a methodological approach would help to contextualise the trial findings, assess the acceptability of the interventions to study participants, and generate information

concerning the likelihood of implementing the intervention in routine clinical settings external to the trial.

5. More research is needed to establish the nature of current primary care practices regarding patients with BN and other eating disorders; to establish how self-help interventions might be delivered to such patients to best effect, what their active ingredients are, and who benefits most from using them; and to examine in detail the cost effectiveness of self-help interventions for BN.

In conclusion, the present study adds to the general body of evidence that suggests that self-help materials and interventions may have a valuable role to play in the treatment of patients with BN or other common mental health problems. It also suggests that GPs, as general practice based professionals, should be encouraged to play a part in the delivery of such interventions.

POSTSCRIPT TO THESIS

The National Clinical Practice Guideline (CG9) on eating disorders, which was produced by the National Collaborating Centre for Mental Health (NCCMH) and commissioned by the National Institute for Clinical Excellence (NICE), and which was mentioned earlier in this Chapter was published soon after this thesis was originally submitted for examination in early 2004.

The Guideline's objective is to provide advice to service commissioners, clinicians and other professionals concerning the identification, treatment and management of AN, BN and related conditions. Guideline recommendations were formulated by a multidisciplinary group consisting of health care professionals, guideline methodologists, and patients and their representatives, after consideration of the various levels of evidence available about interventions for the treatment and management of the aforementioned disorders.

The Guideline notes that there have been no "UK-based studies of treatments that are actually provided for patients with bulimia nervosa (p. 119)", and that the research in

the US suggests that evidence-based treatments are not widely used. It suggests that there is likely to be great variation in the nature of treatments provided in this country. Throughout the thesis it was noted that little is known about the detection and management of eating disorders in primary care, and this fact is also highlighted in the Guideline, along with the suggestion that primary care professionals are ideally placed to identify patients with eating disorders.

The empirical evidence considered in formulating the Guideline's recommendations regarding BN consisted of studies comparing the following: psychological treatments versus waiting list or placebo control; psychological treatments versus other psychological treatments; antidepressants versus placebo; psychological treatments versus antidepressants; psychological treatments versus the combination of psychological treatment and antidepressants; and antidepressants versus the combination of antidepressants and psychological treatment. The following recommendations are made on the basis of high-level (Grade A or B) evidence (p. 69-70):

“As a possible first step, patients with bulimia nervosa should be encouraged to follow an evidence-based self-help programme. (B)

Health care professionals should consider providing direct encouragement and support to patients undertaking an evidence-based self-help programme as this may improve outcomes. This may be sufficient for a limited subset of patients. (B)

Cognitive behaviour therapy for bulimia nervosa (CBT-BN), a specifically adapted form of cognitive behaviour therapy, should be offered to adults with bulimia nervosa. The course of CBT-BN should normally be of 16 to 20 sessions over four to five months. (A)

When people with bulimia nervosa have not responded to or do not want CBT, other psychological treatments should be considered. (B)

Interpersonal psychotherapy should be considered as an alternative to cognitive behaviour therapy, but patients should be informed that it takes eight to 12 months to achieve results comparable to cognitive behaviour therapy. (B)

As an alternative or additional first step to using an evidence-based self-help programme, adults with bulimia nervosa may be offered a trial of an antidepressant drug. (B)

Patients should be informed that antidepressant drugs can reduce the frequency of bingeing and purging, but that the long-term effects are unknown. Any beneficial effects will be rapidly apparent. (B)

No drugs, other than antidepressants, are recommended for the treatment of bulimia nervosa. (B)”

It is recommended that health professionals should be aware of the risk to patients of experiencing physical problems as a result of the behaviours associated with BN and should be concerned with monitoring for such problems. In addition, it is suggested that the vast majority of BN patients can be treated as out-patients, and that there is a limited role for in-patient treatment, which will be concerned primarily with the management of severe self-harm or risk of suicide. It is also noted that, given the lack of available evidence, no firm conclusions can be drawn about the comparative cost-effectiveness of the differing therapeutic options for BN.

Both the conclusions of the literature review presented in this thesis and the findings of the study undertaken and described are therefore in accordance with the recommendations made in the Guideline. Importantly, the findings shed new light on the potential for primary care, and GPs in particular, to become involved in the support and management of patients with BN who are using self-help programmes.

A study by Walsh *et al* published in March 2004, after this thesis was submitted for examination, evaluated the effectiveness of fluoxetine (supplied by Eli Lilly) compared with supported self-help, with both interventions taking place in primary

care clinics in the US. Ninety-one women (76 of whom met full DSM-IV criteria for BN) were randomised to receive either fluoxetine (60mg), placebo, fluoxetine and supported self-help, or placebo and supported self-help. The participants, the majority of whom were recruited through advertisements, were specifically enrolled at two primary care clinics for the purposes of the study. After two initial visits to the prescribing physician, participants were scheduled to attend four more physician visits on a monthly basis, while self-help patients were also offered six to eight nurse appointments over this time. An end of treatment intention-to-treat analysis was conducted at four months. Compared to those in the placebo condition, participants who received fluoxetine had a greater reduction in bingeing and vomiting, experienced greater improvement in psychological symptoms, and attended more physician visits. However, there were no significant differences in the number of those remitted in the supported self-help or pill-only groups in participants receiving fluoxetine or placebo. Walsh *et al* concluded that there was no evidence of benefit from supported self-help. However, they acknowledged the limited statistical power of the study. The fact that only 31% of the study population (similar rates in all conditions) completed treatment, that a follow-up beyond the end of the intervention period was not included and that the primary care aspect of the study was in a sense ‘manufactured’ (with patients, recruited through adverts, being enrolled in two specific clinics where physicians and nurses were provided with training) all limit significantly what can be concluded from the study findings regarding the implementation of self-help interventions in routine primary care settings, where regular primary care professionals support the type of patient likely to seek help in general practice for BN. It could be argued that the study, and its findings, described in this thesis present a more realistic picture of the potential for providing patients with a primary care based self-help intervention for BN, at least in the UK.

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APPENDIX ONE: BULIMIC INVESTIGATORY TEST, EDINBURGH **(Henderson and Freeman, 1987)**

code			
date			
interview	1	2	3

BULIMIC INVESTIGATORY TEST - EDINBURGH

This questionnaire is concerned with eating behaviours and attitudes towards food and eating. All of the questions refer to your experiences in the PAST MONTH.

Please circle 'yes' or 'no' or a number for each question.

1. Do you have a regular daily eating pattern? YES NO
2. Are you a strict dieter? YES NO
3. Do you feel a failure if you break your diet once? YES NO
4. Do you count the calories of everything you eat, even when not on a diet? YES NO
5. Do you ever fast for a whole day? YES NO

6. If YES, how often is this? (circle number)

every second day 5
2-3 times a week 4
once a week 3
now and then 2
have once 1

7. Do you do any of the following to help you lose weight? (circle number)

	Never	Occasionally	Once a week	2-3 times a week	Daily	2-3 times a day	5+ times a day
Take diet pills	0	2	3	4	5	6	7
Take diuretics	0	2	3	4	5	6	7
Take laxatives	0	2	3	4	5	6	7
Make yourself vomit	0	2	3	4	5	6	7

8. Does your pattern of eating severely disrupt your life? YES NO
9. Would you say that food dominated your life? YES NO
10. Do you ever eat and eat until you are stopped by physical discomfort? YES NO
11. Are there times when all you can think about is food? YES NO

12. Do you eat sensibly in front of others and make up in private?	YES	NO
13. Can you always stop eating when you want to?	YES	NO
14. Do you ever experience <i>overpowering</i> urges to eat and eat and eat?	YES	NO
15. When you are feeling anxious do you tend to eat a lot?	YES	NO
16. Does the thought of becoming fat <i>terrify</i> you?	YES	NO
17. Do you ever eat large amounts of food rapidly (not a meal)?	YES	NO
18. Are you ashamed of your eating habits?	YES	NO
19. Do you worry that you have no control over how much you eat?	YES	NO
20. Do you turn to food for comfort?	YES	NO
21. Are you able to leave food on the plate at the end of a meal?	YES	NO
22. Do you deceive other people about how much you eat?	YES	NO
23. Does how hungry you feel determine how much you eat?	YES	NO
24. Do you ever binge on large amounts of food?	YES	NO
25.If YES, do such binges leave you feeling miserable?	YES	NO
26. If you do binge, is this only when you are alone?	YES	NO
27. If you do binge, how often is this? (circle number)		
hardly ever	1	
once a month	2	
once a week	3	
2-3 times a week	4	
Daily	5	
2-3 times a day	6	
28. Would you go to great lengths to satisfy an urge to binge?	YES	NO
29. If you overeat do you feel <i>very</i> guilty?	YES	NO
30. Do you ever eat in secret?	YES	NO
31. Are your eating habits what you would consider to be normal?	YES	NO
32. Would you consider yourself to be a compulsive eater?	YES	NO
33. Does your weight fluctuate by more than 5 pounds in a week?	YES	NO

APPENDIX TWO: EATING DISORDER EXAMINATION (EDE)

Fairburn & Cooper, 1993

The Eating Disorder Examination (12.0D)

Interview Schedule

INTRODUCTION

[Having oriented the subject to the specific time period being assessed it is best to open the interview by asking a number of introductory questions designed to obtain a general picture of the subject's eating habits. Suitable questions are suggested below.]

To begin with I should like to get a general picture of your eating habits over the last 4 weeks.

Have your eating habits varied much from day to day?

Have weekdays differed from weekends?

Have there been any days when you haven't eaten anything?

What about the previous 2 months?

PATTERN OF EATING

*** I would like to ask about your pattern of eating. Over the past 4 weeks which of these meals or snacks have you eaten on a regular basis?**

- | | |
|--|--------------------------|
| breakfast (meal eaten shortly after waking) | <input type="checkbox"/> |
| mid morning snack | <input type="checkbox"/> |
| lunch (mid day meal) | <input type="checkbox"/> |
| mid afternoon snack | <input type="checkbox"/> |
| evening meal | <input type="checkbox"/> |
| evening snack | <input type="checkbox"/> |
| nocturnal snack (ie. a snack eaten after
the subject has been to sleep) | <input type="checkbox"/> |

[Rate each meal and snack separately, usually accepting the subject's classification (within the guidelines above). Ask about weekdays and weekends separately. Meals or snacks should be rated even if they lead on to a "binge". "Brunch" should generally be classed as lunch. With this item, rate up (ie., give a higher rating) if it is difficult to choose between two ratings. Rate 8 if meals or snacks are difficult to classify (eg., due to shift work).]

- | | |
|---|--|
| 0 | Meal or snack not eaten |
| 1 | |
| 2 | Meal or snack eaten on less than half the days |
| 3 | |

- 4 Meal or snack eaten on more than half the days
- 5
- 6 Meal or snack eaten every day

RESTRAINT OVER EATING

(Restraint subscale)

*** Over the past 4 weeks have you been consciously trying to restrict what you eat, whether or not you have succeeded?**

Has this been to influence your shape or weight?

[Rate the number of days on which the subject has *consciously attempted to* restrict his or her food intake, whether or not he or she has succeeded. The restraint should have been intended to influence shape, weight, or body composition, although this may not have been the sole or main reason. It should have consisted of planned attempts at restriction, rather than spur of the moment attempts such as the decision to resist a second helping.]

- 0 No attempt at restraint
- 1
- 2 Attempted to exercise restraint on less than half the days
- 3
- 4 Attempted to exercise restraint on more than half the days
- 5
- 6 Attempted to exercise restraint every day ☐

AVOIDANCE OF EATING

(Restraint subscale)

*** Over the past 4 weeks have you gone for periods of 8 or more waking hours without eating anything?**

Has this been to influence your shape or weight?

[Rate the number of days on which there has been at least 8 hours abstinence from eating food (soup and milkshakes count as food, whereas drinks in general do not) during waking hours. It may be helpful to illustrate the length of time (eg., 9am to 5pm). The abstinence must have been at least partly *self-imposed* rather than being due to force of circumstances. It should have been intended to influence shape, weight or body composition, although this may not have been the sole or main reason.]

- 0 No such days
- 1
- 2 Avoidance on less than half the days
- 3
- 4 Avoidance on more than half the days
- 5
- 6 Avoidance every day ☐

EMPTY STOMACH

(Restraint subscale)

*** Over the past 4 weeks have you wanted your stomach to be empty?**

Has this been to influence your shape or weight?

[Rate the number of days on which the subject has had a *definite desire* to have a completely empty stomach for reasons to do with dieting, shape or weight. *This should not be confused with a desire for the stomach to feel empty or be flat.*]

- 0 No definite desire to have an empty stomach
- 1
- 2 Definite desire to have an empty stomach on less than half the days
- 3
- 4 Definite desire to have an empty stomach on more than half the days
- 5
- 6 Definite desire to have an empty stomach every day ☐

FOOD AVOIDANCE**(Restraint subscale)**

*** Over the past 4 weeks have you tried to avoid eating any foods that you like, whether or not you have succeeded?**

Has this been to influence your shape or weight?

[Rate the number of days on which the subject has actively *attempted* to avoid eating specific foods (which he or she likes) whether or not he or she succeeded. The goal should have been to avoid the foods altogether and not merely to restrict their consumption. Drinks do not count as food. The avoidance should have been intended to influence shape, weight or body composition, although this may not have been the sole or main reason.]

- 0 No attempts to avoid food
- 1
- 2 Attempted to avoid food on less than half the days
- 3
- 4 Attempted to avoid food on more than half the days
- 5
- 6 Attempted to avoid food every day ☐

DIETARY RULES**(Restraint subscale)**

*** Over the past 4 weeks have you tried to follow certain definite rules regarding your eating, for example, a calorie limit, preset quantities of food or rules about what you should eat or when you should eat?**

*** Have there been occasions when you have been aware that you have broken a dietary rule that you have set for yourself?**

How have you felt about breaking them? How would you have felt if you had broken one of your dietary rules?

What are these rules? Why have you tried to follow them? Have they been designed to influence your shape or weight?

Have they been definite rules or general principles? Examples of definite rules would be "I must not eat eggs" or "I must not eat cake", whereas you could have the general principle "I should try to eat healthy food".

[Dietary rules should be rated as present if the subject has been attempting to follow "definite" (ie, specific) dietary rules regarding his or her food intake. The rules should have been self imposed, although originally they may have been prescribed. They should have concerned what the subject should have eaten or when eating should have taken place. They might consist of a calorie limit (eg, below 1,200 kcals), not eating before a certain time of day, not eating certain types of food, or not eating at all. They should have been specific rules and not general guidelines, and there may have been distress should they have been broken. If the subject is aware that he or she has occasionally broken a personal dietary rule, this suggests that one or more specific rules has been present. In such cases the interviewer should ask in detail about the transgression in an attempt to identify the underlying rule. The rules should have been intended to influence shape, weight or body composition, although this may not have been the sole or main reason. It should be noted that "*dietary rules*" are regarded as *having been present if there have been clear attempts to obey specific dietary rules*.

Rate 0 if no dietary rule can be identified. If there has been more than one rule straddling different time periods within the 4 weeks, these periods should be summated to make the rating.]

- 0 Has not attempted to obey such rules
- 1
- 2 Attempted to obey such rules on less than half the days
- 3
- 4 Attempted to obey such rules on more than half the days
- 5
- 6 Attempted to obey such rules every day ☐

**PREOCCUPATION WITH FOOD,
subscale)
EATING OR CALORIES.**

(Eating Concern

*** Over the past 4 weeks have you spent much time between meals thinking about food, eating, or calories?**

*** Has thinking about food, eating or calories interfered with your ability to concentrate? How about concentrating on things that you are interested in, for example, reading, watching television or following a conversation?**

[Concentration is regarded as impaired if there have been *intrusive thoughts about food, eating or calories that have interfered with activities*. Rate the number of days on which this has happened, whether or not bulimic episodes occurred.]

- 0 No concentration impairment
- 1
- 2 Concentration impairment on less than half the days
- 3
- 4 Concentration impairment on more than half the days
- 5
- 6 Concentration impairment every day ☐

**FEAR OF LOSING CONTROL
OVER EATING**

(Eating Concern subscale)

*** Over the past 4 weeks have you been afraid of losing control over eating?**

[Rate the number of days on which *definite fear* has been present, irrespective of whether the subject feels he or she has been in control. "*Loss of control*" involves a *sense that one will not be able to resist or stop eating*. If the subject feels unable to answer this question because he or she has already lost control, rate 9.]

- 0 No fear of losing control
- 1
- 2 Fear of losing control present on less than half the days
- 3
- 4 Fear of losing control present on more than half the days
- 5
- 6 Fear of losing control every day ☐

BULIMIC EPISODES AND OTHER EPISODES OF OVEREATING

(Diagnostic item)

Guidelines for interviewers

[Four forms of episodic "overeating" are distinguished. The distinction is based upon the presence or absence of two characteristics.

- (i) **Loss of control** (required for both types of "bulimic episode")
- (ii) **The consumption of what would generally be regarded as a "large" amount of food** (required for "objective bulimic episodes" and "objective overeating")

The classificatory scheme is summarized in Figure 1 and key terms are defined below.

The interviewer should ask about each form of overeating. It is important to note that *the forms of overeating are not mutually exclusive*. It is possible for subjects to have had several different forms over the preceding month. With some subjects it is helpful to explain the classificatory scheme. Then, using the probe questions given below, the number of each type of episode may be determined and checked back with the subject.

Definition of key terms

"Loss of control" The interviewer should ask the subject whether he or she experienced a sense of loss of control over eating *at the time* that the episode occurred. If this is clearly described, loss of control should be rated as

present. Loss of control may be rated positively even if the episode had been planned. If the subject uses terms such as "driven to eat" or "compelled to eat", loss of control should be rated as present.

For chronic cases only: If the subject reports no sense of loss of control yet describes having not been able to stop eating once eating had started or having not been able to prevent the episode from occurring, loss of control should be rated as present. If subjects report that they are no longer trying to control their eating because overeating is inevitable, loss of control should be rated as present.

If the interviewer is in doubt, loss of control should be rated as absent.

"Large amount of food" The decision whether or not the amount eaten was large should be made by the interviewer and does not require the agreement of the subject. Large may be used to refer to the amount of any particular type of food or the overall quantity of food consumed. *The interviewer should take into account what would be the usual amount eaten under the circumstances.* This requires some knowledge of the eating habits of the subject's general (but not necessarily immediate) social group. What else was eaten during the day is not relevant to this rating. The speed of eating and whether or not the subject subsequently spits out or vomits the food are not of relevance.

If the interviewer is in doubt, the amount should not be classified as large.

The number of episodes of overeating. When calculating the number of episodes of overeating, the subject's definition of separate episodes should be accepted unless (within a period of eating) there was an hour or more when the subject was not eating. In this case the initial episode should be regarded as having been completed. When estimating the length of any gap, do not count the time spent vomiting. *Note that purging (self induced vomiting or laxative misuse) is not used to define the end of individual episodes of overeating.*

<u>Amount Eaten</u>		
	"Large" (EDE definition)	Not "large", but viewed by subject as excessive
"Loss of control"	Objective bulimic episodes	Subjective bulimic episodes
No "loss of control"	Objective overeating	Subjective overeating

Guidelines for Rating the Overeating Section

First ask the asterisked questions to identify episodes of perceived or true overeating that have occurred over the previous 28 days. Note down all the forms of overeating on the blank section of the coding sheet.

Second, obtain detailed information about each form of overeating to decide whether it involved eating large amounts of food and whether or not there was loss of control (as defined above). Then establish for each form of overeating the number of days on which it occurred and the total number of occasions. It is advisable to make comprehensive notes.

Finally check with the subject to ensure that no misunderstandings have arisen.]

QUESTIONS FOR RATING ITEMS

[The asterisked questions must be asked in every case]

Main Probe Questions

*** I would like to ask you about any episodes of overeating that you may have had over the past 4 weeks.**

*** Different people mean different things by overeating. I would like you to describe any times when you have felt that you have eaten too much in one go.**

*** Have there been any times when you have felt that you have eaten too much, but others might not agree?**

[if there has been no such times, skip to "social eating"]

[n.b. For subjective bulimic episodes to be eligible, they must have been viewed as having involved eating an excessive amount of food.]

Subsidiary Probe Questions

To assess the amount of food eaten.

**Typically what have you eaten at these times?
What were others eating at the time?**

To assess loss of control

Did you have a sense of loss of control at the time?

For chronic cases only:

**Could you have stopped eating once you had started?
Could you have prevented the episode from occurring?**

[For objective bulimic episodes, subjective bulimic episodes and episodes of objective overeating make the following two ratings.

- (1) Number of days (rate 00 if none) ☐ ☐
(ii) Number of episodes (rate 000 if none) ☐ ☐ ☐

In general, it is best to calculate the number of days first and then the number of episodes. Rate 777 if the number of episodes is so great that their frequency cannot be calculated. Episodes of subjective overeating are not rated.]

[Ask about the preceding 2 months.]

For objective bulimic episodes, rate the number of episodes over the preceding 2 months and the number of days on which they occurred. (Rate 0 if none and 9 if not asked)

Days	Month 2	<input type="checkbox"/> <input type="checkbox"/>
	Month 3	<input type="checkbox"/> <input type="checkbox"/>
Episodes	Month 2	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	Month 3	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Also rate the longest continuous period in weeks free (not due to force of circumstances) from objective bulimic episodes over the past 3 months. (Rate 99 if not asked).

☐ ☐

DIETARY RESTRICTION OUTSIDE BULIMIC EPISODES

(Diagnostic item)

[Only rate this item if there have been objective bulimic episodes over the past 3 months]

Outside these times when you have lost control over eating (refer to objective and subjective bulimic episodes), how much have you been restricting the amount that you eat?

Typically, what have you eaten?

Has this been to influence your shape or weight?

[Ask about actual food intake outside the objective and subjective bulimic episodes. Rate the *average* degree of dietary restriction. This should have been intended to influence shape, weight or body composition, although this may not have been the sole or main reason. Rate each of the past 3 months separately whether or not it included a bulimic episode. Rate 9 if not asked.]

- 0 No extreme restriction outside object bulimic episodes
- 1 Extreme restriction outside objective bulimic episodes (ie, low energy in-take < 1200 kcal) due to infrequent eating and/or consumption of low calorie foods).
- 2 No eating outside objective bulimic episodes (ie, fasting)

Month 1 ☐
Month 2 ☐
Month 3 ☐

SOCIAL EATING

(Eating Concern subscale)

*** Over the past 4 weeks have you been concerned about other people seeing you eat?**

Have you avoided such occasions?

[Rate the degree of concern about eating normal or less than normal amounts of food in front of others (eg, family) and whether this has led to avoidance. This should represent the *average* for the entire month. If the possibility of eating with others has not arisen, rate 9. *Do not consider objective bulimic episodes or episodes of objective overeating.*]

- 0 No concern about being seen eating by others and no avoidance of such occasions.
- 1
- 2 Has felt slight concern at being seen eating but no avoidance
- 3
- 4 Has felt definite concern and has avoided some such occasions
- 5
- 6 Has felt definite concern and has avoided all such occasions ☐

EATING IN SECRET

(Eating Concern subscale)

*** Over the past 4 weeks have you eaten in secret?**

[Rate the number of days on which there has been at least one episode of secret eating. Secret eating refers to eating that is furtive and which the subject wishes to conceal. Avoidance of eating in front of others should be rated under "Social eating". If the possibility of eating with others has not arisen, rate 9. *Do not consider objective bulimic episodes.*]

- 0 Has not eaten in secret
- 1
- 2 Has eaten in secret on less than half the days
- 3
- 4 Has eaten in secret on more than half the days
- 5
- 6 Has eaten in secret every day ☐

GUILT ABOUT EATING

(Eating Concern subscale)

*** Over the past 4 weeks have you felt guilty after eating?**

Have you felt that you have done something wrong? Why?

On what proportion of the times that you have eaten have you felt guilty?

[Rate the *proportion of times* on which feelings of guilt have followed eating. These feelings of guilt should relate to the effects of eating on shape, weight or body composition. *Do not consider objective bulimic episodes*, but do consider other episodes of overeating. *Distinguish guilt from regret*: Guilt refers to a feeling that one has done wrong. *n.b. This rating is based on occasions.*]

- 0 No guilt after eating
- 1
- 2 Has felt guilty after eating on less than half the *occasions*
- 3
- 4 Has felt guilty after eating on more than half the *occasions*
- 5
- 6 Has felt guilty after eating on every *occasion* ☐

SELF INDUCED VOMITING**(Diagnostic item)***** Over the past 4 weeks have you made yourself sick as a means of controlling your shape or weight?**

[Rate the number of days on which there has been one or more episodes of self induced vomiting as a means of controlling shape, weight or body composition. Rate 00 if no vomiting.]

☐ ☐

[Rate the number of discrete episodes of self induced vomiting. Accept the subject's definition of an episode. Rate 777 if the number is so great that it cannot be calculated. Rate 000 if no vomiting.]

☐ ☐ ☐

[Ask about the preceding 2 months if practising self induced vomiting to influence shape, weight or body composition]

[Rate the number of discrete episodes of self induced vomiting over each of the 2 preceding months. Rate 999 if not asked.]

Month 2 ☐ ☐ ☐

Month 3 ☐ ☐ ☐

LAXATIVE MISUSE**(Diagnostic item)***** Over the past 4 weeks have you taken laxatives as a means of controlling your shape or weight?**

[Rate the number of days on which laxatives have been taken as a means of controlling shape, weight or body composition. This should have been the *main* reason, although it may not have been the sole reason. Rate 00 if there was no laxative use or there is doubt whether the laxative taking was primarily to influence shape, weight and body composition.]

☐ ☐

[Rate the number of individual episodes of laxative misuse (as defined above). Rate 777 if the number is so great that it cannot be calculated. Rate 000 if no such laxative misuse.]

☐ ☐ ☐

[Rate the average number of laxatives taken on each occasion. Rate 999 if not applicable. Rate 777 if not quantifiable, eg, use of bran.]

☐ ☐ ☐

[Note the type of laxative taken]

[Ask about the preceding 2 months if taking laxatives to influence shape, weight or body composition.]

[Rate the number of discrete episodes of laxative misuse over each of the two preceding months. Rate 000 if no such laxative misuse. Rate 999 if not asked.]

Month 2 ☐ ☐ ☐

Month 3 ☐ ☐ ☐

DIURETIC MISUSE**(Diagnostic item)***** Over the past 4 weeks have you taken diuretics as a means of controlling your shape or weight?**

[Rate the number of days on which diuretics have been taken as a means of controlling shape, weight or body composition. This should have been the *main* reason, although it may not have been the sole reason. Rate 00 if there was no diuretic use or there is doubt whether the diuretic taking was primarily to influence shape, weight or body composition.]

☐ ☐

[Rate the number of individual episodes of diuretic misuse (as defined above). Rate 777 if the number is so great that it cannot be calculated. Rate 000 if no such diuretic misuse.]

☐ ☐ ☐

[Rate the average number of diuretics taken on each occasion. Rate 999 if not applicable. Rate 777 if not quantifiable.]

□ □ □

[Note the type of diuretic taken]

[Ask about the preceding 2 months if taking diuretics to influence shape, weight or body composition.]

[Rate the number of discrete episodes of diuretic misuse over each of the 2 preceding months. Rate 000 if no such diuretic misuse. Rate 999 if not asked.]

Month 2 □ □ □

Month 3 □ □ □

**INTENSE EXERCISING TO CONTROL
SHAPE OR WEIGHT**

(Diagnostic item)

*** Over the past 4 weeks have you exercised as a means of controlling your weight, altering your shape or amount of fat, or burning off calories?**

Typically, what form of exercise have you taken?

[Rate the number of days on which the subject has engaged in *intense* exercise that was *predominantly* intended to use calories or change shape, weight or body composition. The decision whether the exercising was "intense" should be made by the interviewer. If in doubt, the exercising should not be classed as intense. Rate 00 if no such exercising.]

□ □

[Rate the *average* amount of time (in minutes) per day spent exercising in this way. Only consider days on which the subject exercised. Rate 999 if no such exercising.]

□ □ □

[Ask about the preceding 2 months if there has been exercising of this type]

[Rate the number of days on which the subject has exercised in this manner over each of the 2 preceding months. If not asked, rate 99.]

Month 2 □ □

Month 3 □ □

**ABSTINENCE FROM EXTREME
WEIGHT-CONTROL BEHAVIOUR**

(Diagnostic item)

[Only ask this question if at least one of the key forms of weight control behaviour has been rated positively at the specified severity level of the past 3 months (see section on "eating disorder diagnoses")]

[The five forms of behaviour are as follows:

fasting
self-induced vomiting
laxative misuse
diuretic misuse
excessive exercise]

Over the past 3 months has there been a period of 2 or more weeks when you have not ...

[ask as for individual items]

[Ascertain the number of consecutive weeks over the past 3 months "free" (ie, not above threshold levels) from *all five* forms of extreme weight-control behaviour. Do not rate abstinence due to force of circumstance. Rate 99 if not applicable.] □ □

**DISSATISFACTION WITH
WEIGHT**

(Weight Concern subscale)

*** Over the past 4 weeks have you been dissatisfied with your weight?**

Have you been so dissatisfied that it has made you unhappy?

[Only rate dissatisfaction due to weight being regarded as too high. Assess the subject's attitude to his or her weight and rate accordingly. This should represent the *average* for the entire month. Only rate 4, 5 or 6 if there has been distress. Do not prompt with the terms "slight", "moderate" or "marked". Rate 9 if the subject is unaware of his or her weight.]

- 0 No dissatisfaction
- 1
- 2 Slight dissatisfaction (no associated distress)
- 3
- 4 Moderate dissatisfaction (some associated distress)
- 5
- 6 Marked dissatisfaction (extreme concern and distress, weight totally unacceptable)

DESIRE TO LOSE WEIGHT

(Weight Concern subscale)

*** Over the past 4 weeks have you wanted to lose weight?**

Have you had a strong desire to lose weight?

[Rate the number of days on which there has been a *strong desire* to lose weight.]

- 0 No strong desire to lose weight
- 1
- 2 Strong desire present on less than half the days
- 3
- 4 Strong desire present on more than half the days
- 5
- 6 Strong desire present every day ☐

DESIRED WEIGHT

*** What weight would you like to be?**

[Rate weight in kilograms. Rate 888 if the subject is not interested in his or her weight. Rate 777 if no specific weight would be low enough. Rate 666 if the subject is primarily interested in his or her shape but has some concern about weight (but not specific weight).] ☐ ☐ ☐

REACTION TO PRESCRIBED WEIGHING

(Weight Concern subscale)

*** How would you feel if you were asked to weigh yourself once each week for the next 4 weeks?**

[Rate the strength of reaction. Positive reactions should be rate 9. Check whether other aspects of the subject's life would be influenced. Ask the subject to describe in detail how he or she would react and rate accordingly. Do not prompt with the terms "slight", "moderate" or "marked". If the subject would not comply with prescribed weighing because it would be extremely disturbing, rate 6.]

- 0 No reaction
- 1
- 2 Slight reaction

- 3
4 Moderate reaction (definite reaction, but manageable).
5
6 Marked reaction (pronounced reaction which would affect other aspects of the subject's life) ☐

DISSATISFACTION WITH SHAPE

(Shape Concern subscale)

*** Over the past 4 weeks have you been dissatisfied with your shape?**

Have you been so dissatisfied that it has made you unhappy?

[Only rate dissatisfaction with shape and not that concerning body tone. Assess the subject's attitude to his or her shape and rate accordingly. This should represent the *average* for the entire month. Only rate 4, 5 or 6 if there has been associated distress. Do not prompt with the terms "slight", "moderate" or "marked".] ☐

- 0 No dissatisfaction with shape
1
2 Slight dissatisfaction with shape (no associated distress)
3
4 Moderate dissatisfaction with shape (some associated distress)
5
6 Marked dissatisfaction with shape (extreme concern and distress, shape totally unacceptable). ☐

PREOCCUPATION WITH SHAPE OR WEIGHT

(Shape Concern and
Weight Concern subscales)

*** Over the past 4 weeks have you spent much time thinking about your shape or weight?**

*** Has thinking about your shape or weight interfered with your ability to concentrate? How about concentrating on things you are interested in, for example, reading, watching television or following a conversation?**

[Concentration is regarded as impaired if there have been *intrusive thoughts about shape or weight that have interfered with activities*. Rate the number of days on which this happened.]

- 0 No concentration impairment
1
2 Concentration impairment on less than half the days
3
4 Concentration impairment on more than half the days
5
6 Concentration impairment every day ☐

IMPORTANCE OF SHAPE

(Diagnostic item)
(Shape Concern subscale)

*** Over the past 4 weeks has your shape been important influencing how you feel about (judge, think, evaluate) yourself as a person.**

*** If you imagine the things that influence how you feel about (judge, think, evaluate) yourself - such as (your performance at work, being a parent, your marriage, how you get on with other people) - and put these things in order of importance, where does your shape fit in?**

If, over the past 4 weeks, your shape had changed in any way, would this have affected how you feel about yourself?

Is it important to you that your shape does not change?

[Rate the degree of importance the subject has placed on body shape and its position in his or her scheme for *self-evaluation*. To make this rating, comparisons may be made with other aspects of the subject's life that are of importance in his or her scheme for self-evaluation (eg. quality of relationships, being a parent, performance at work or leisure activities). The rating should represent the *average* for the entire month. Do not prompt with the terms "some", "moderate" or "supreme". If the subject has regarded both shape and weight as being of equivalent

supreme importance, rate 6 on this item and on "Importance of weight".]

- 0 No importance
- 1
- 2 Some importance (definitely an aspect of self evaluation)
- 3
- 4 Moderate importance (definitely one of the main aspects of self evaluation)
- 5
- 6 Supreme importance (nothing is more important in the subject's scheme for self evaluation). ☐

[Ask about the preceding 2 months]

[Rate preceding 2 months. Rate 9 if not asked]

Month 2 ☐
Month 3 ☐

IMPORTANCE OF WEIGHT

(Diagnostic item)
(Weight Concern subscale)

*** Over the past 4 weeks has your weight been important in influencing how you feel about (judge, think, evaluate) yourself as a person?**

*** If you imagine the things that influence how you feel about (judge, think, evaluate) yourself - such as (your performance at work, being a parent, your marriage, how you get on with other people) - and put these things in order of importance, where does your weight fit in?**

If, over the past 4 weeks, your weight had changed in any way, would this have affected how you feel about yourself?

Is it important to you that your weight does not change?

[Rate the degree of importance the subject has placed on weight (ie, actual or presumed weight) and its position in his or her scheme for *self evaluation*. To make this rating, comparisons may be made with other aspects of the subject's life that are of importance in his or her scheme for self evaluation (eg, quality of relationships, being a parent, performance at work or leisure activities). The rating should represent the *average* for the entire month. Do not prompt with the terms "some", "moderate" or "supreme". If the subject has regarded both weight and shape as being of equivalent supreme importance, rate 6 on this item and on "Importance of shape".]

- 0 No importance
- 1
- 2 Some importance (definitely an aspect of self evaluation)
- 3
- 4 Moderate importance (definitely one of the main aspects of self evaluation)
- 5
- 6 Supreme importance (nothing is more important in the subject's scheme for self evaluation). ☐

[Ask about the preceding 2 months.]

[Rate preceding 2 months. Rate 9 if not asked.]

Month 2 ☐

Month 3

☐

FEAR OF WEIGHT GAIN

(Diagnostic item)
(Shape Concern subscale)

[Shorten the question if the subject is obviously overweight]

***Over the past 4 weeks have you been afraid that you might gain weight (or become fat)?**

[Rate the number of days on which a *definite fear* has been present. Exclude reactions to actual weight gain]

- 0 No definite fear of fatness or weight gain
- 1
- 2 Definite fear of fatness or weight gain present on less than half the days
- 3
- 4 Definite fear of fatness or weight gain present on more than half the days
- 5

6 Definite fear of fatness or weight gain present every day ☐

[Ask about the past 2 months]

[Rate preceding 2 months. Rate 9 if not asked]

Month 2 ☐

Month 3 ☐

DISCOMFORT SEEING BODY

(Shape Concern Subscale)

***Over the past 4 weeks have you felt uncomfortable seeing your body, for example, in the mirror, in shop window reflections, while undressing, or while taking a bath or shower?**

Have you avoided seeing your body? Why?

[The discomfort should be due to the subject's sensitivity about the overall appearance of his or her shape or figure. It should not stem from sensitivity about specific aspects of appearance (eg, acne) or from modesty.]

- 0 No discomfort about seeing body
- 1
- 2 Some discomfort about seeing body
- 3
- 4 Definite discomfort about seeing body
- 5
- 6 Definite discomfort about seeing body, and has attempted to avoid all such occasions (ie, the subject has attempted not see his or her body at all even when washing) ☐

AVOIDANCE OF EXPOSURE

(Shape Concern subscale)

*** Over the past 4 weeks have you felt uncomfortable about others seeing your body, for example, in communal changing rooms, when swimming, or when wearing clothes that show your shape? What about your partner or friends seeing your body?**

Have you avoided such situations? Why?

[The discomfort should be due to the subject's sensitivity about the overall appearance of his or her shape or figure. It should not stem from sensitivity about specific aspects of appearance (eg, acne) or from modesty. If the possibility of "exposure" has not arisen, rate 9.]

- 0 No discomfort about others seeing body
- 1
- 2 Some discomfort about others seeing body
- 3
- 4 Definite discomfort about others seeing body
- 5
- 6 Definite discomfort about others seeing body, and has attempted to avoid all such occasions. ☐

FEELINGS OF FATNESS

(Diagnostic item)
(Shape Concern subscale)

[Omit this item if the subject is obviously overweight and rate 7]

*** Over the past 4 weeks have you felt fat?**

[Rate the number of days on which the subject has "felt fat" accepting his or her use of this expression. Distinguish feeling fat from feeling bloated premenstrually, unless this is experienced as feeling fat.]

- 0 Has not felt fat
- 1
- 2 Has felt fat on less than half the days
- 3

- 4 Has felt fat on more than half the days
 5
 6 Has felt fat every day ☐

[Ask about the preceding 2 months]

[Rate preceding 2 months. Rate 9 if not asked]

Month 2 ☐

Month 3 ☐

FLAT STOMACH

(Shape Concern subscale)

[Omit this item if the subject is obviously overweight and rate 7]

Over the past 4 weeks have you had a definite desire to have a flat stomach?

[Rate the number of days on which the subject has had a *definite desire to have a flat or concave stomach*. Do not rate simply the desire to have a flatter stomach]

- 0 No definite desire to have a flat stomach
 1
 2 Definite desire to have a flat stomach on less than half the days
 3
 4 Definite desire to have a flat stomach on more than half the days
 5
 6 Definite desire to have a flat stomach every day ☐

WEIGHT AND HEIGHT

[The subject's weight and height should be measured]

Weight in kg ☐ ☐ ☐

Height in cm ☐ ☐ ☐

MAINTAINED LOW WEIGHT

(Diagnostic item)

[Rate for subjects who may be underweight]

Over the past 3 months have you been trying to lose weight?

if no: **Have you been trying to make sure that you do not gain weight?**

[If weight is low, rate presence of attempts either to lose weight or to avoid weight gain. Rate 9 if not asked]

- 0 No attempts either to lose weight or to avoid weight gain over the past 3 months
 1 Attempts either to lose weight or to avoid weight gain over the past 3 months for reasons concerning shape or weight
 2 Attempts either to lose weight or to avoid weight gain over the past 3 months for other reasons ☐

MENSTRUATION

(Diagnostic item)

Have you missed any menstrual periods over the past few months?

How many periods have you had?

Are you taking an oral contraceptive (the "pill")?

[With post menarchial females, rate number of menstrual periods over the past three expected menstrual cycles. Rate 7 if the subject is premenarchial, if she has been taking an oral contraceptive, or if she has been pregnant or breast feeding] ☐

END OF SCHEDULE

APPENDIX THREE: BECK DEPRESSION INVENTORY (Beck & Steer, 1987)

	Code			
	Date			
	Interview	1	2	3

This questionnaire consists of 21 groups of statements. After reading each group of statements carefully, circle the number (0,1,2 or 3) next to the one statement in each group which **best** describes the way you have been feeling in the **past week, including today**. If several statements within a group seem to apply equally well, circle each one. **Be sure to read all the statements in each group before making your choice.**

- | | | | | | |
|----|---|--|-----|---|--|
| 1. | 0 | I do not feel sad. | 7. | 0 | I don't feel disappointed in myself. |
| | 1 | I feel sad. | | 1 | I am disappointed in myself. |
| | 2 | I am sad all the time and I can't snap out of it. | | 2 | I am disgusted with myself. |
| | 3 | I am so sad or unhappy that I can't stand it. | | 3 | I hate myself. |
| 2. | 0 | I am not particularly discouraged about the future. | 8. | 0 | I don't feel I am any worse than anybody else. |
| | 1 | I feel discouraged about the future. | | 1 | I am critical of myself for my weaknesses or mistakes. |
| | 2 | I feel I have nothing to look forward to. | | 2 | I blame myself all the time for my faults. |
| | 3 | I feel that the future is hopeless and that things cannot improve. | | 3 | I blame myself for everything bad that happens. |
| 3. | 0 | I do not feel like a failure. | 9. | 0 | I don't have any thoughts of killing myself. |
| | 1 | I feel I have failed more than the average person. | | 1 | I have thoughts of killing myself, but I would not carry them out. |
| | 2 | As I look back on my life, all I can see is a lot of failures. | | 2 | I would like to kill myself. |
| | 3 | I feel I am a complete failure as a person. | | 3 | I would kill myself if I had the chance. |
| 4. | 0 | I get as much satisfaction out of things as I used to. | 10. | 0 | I don't cry any more than usual. |
| | 1 | I don't enjoy things the way I used to. | | 1 | I cry more now than I used to. |
| | 2 | I don't get real satisfaction out of anything anymore. | | 2 | I cry all the time now. |
| | 3 | I am dissatisfied or bored with everything | | 3 | I used to be able to cry, but now I can't cry even though I want to. |
| 5. | 0 | I don't feel particularly guilty. | 11. | 0 | I am no more irritated now than I ever am. |
| | 1 | I feel guilty a good part of the time. | | 1 | I get annoyed or irritated more easily than I used to. |
| | 2 | I feel quite guilty most of the time. | | 2 | I feel irritated all the time now. |
| | 3 | I feel guilty all of the time. | | 3 | I don't get irritated at all by the things that used to irritate me. |
| 6. | 0 | I don't feel I am being punished. | 12. | 0 | I have not lost interest in other people. |
| | 1 | I feel I may be punished. | | 1 | I am less interested in other people than I used to be. |
| | 2 | I expect to be punished. | | 2 | I have lost most of my interest in other people. |
| | 3 | I feel I am being punished. | | 3 | I have lost all of my interest in other people. |

- | | | | | | |
|-----|---|--|-----|---|--|
| 13. | 0 | I can make decisions about as well as I ever could. | 18. | 0 | My appetite is no worse than usual. |
| | 1 | I put off making decisions more than I used to. | | 1 | My appetite is not as good as it used to be. |
| | 2 | I have greater difficulty in making decisions than before. | | 2 | My appetite is much worse now. |
| | 3 | I can't make decisions at all anymore. | | 3 | I have no appetite at all anymore. |
| 14. | 0 | I don't feel I look any worse than I used to. | 19. | 0 | I haven't lost much weight, if any, lately. |
| | 1 | I am worried that I am looking old or unattractive. | | 1 | I have lost more than 5 pounds. |
| | 2 | I feel that there are permanent changes in my appearance that make me look unattractive. | | 2 | I have lost more than 10 pounds. |
| | 3 | I believe that I look ugly. | | 3 | I have lost more than 15 pounds. |
| 15. | 0 | I can work about as well as before. | | | I am purposely trying to lose weight by eating less. Yes----- No----- |
| | 1 | It takes an extra effort to get started at doing something. | | | |
| | 2 | I have to push myself very hard to do anything. | 20. | 0 | I am no more worried about my health than usual. |
| | 3 | I can't do any work at all. | | 1 | I am worried about physical problems such as aches and pains; or upset stomach; or constipation. |
| 16. | 0 | I can sleep as well as usual. | | 2 | I am very worried about my physical problems and it's hard to think of much else. |
| | 1 | I don't sleep as well as I used to. | | 3 | I am so worried about my physical problems that I cannot think about anything else. |
| | 2 | I wake up 1-2 hours earlier than usual and find it hard to get back to sleep. | | | |
| | 3 | I wake up several hours earlier than I used to and cannot get back to sleep. | 21. | 0 | I have not noticed any recent change in my interest in sex. |
| 17. | 0 | I don't get more tired than usual. | | 1 | I am less interested in sex than I used to be. |
| | 1 | I get tired more easily than I used to. | | 2 | I am much less interested in sex now. |
| | 2 | I get tired from doing almost anything. | | 3 | I have lost interest in sex completely. |
| | 3 | I am too tired to do anything. | | | |

PLEASE CHECK THAT YOU HAVE ANSWERED EVERY QUESTION BEFORE STARTING THE NEXT QUESTIONNAIRE.

APPENDIX FOUR: SELF CONCEPT QUESTIONNAIRE

code			
date			
interview	1	2	3

SELF CONCEPT QUESTIONNAIRE

This questionnaire concerns attitudes and beliefs people have about themselves.

Please indicate how much you agree or disagree with each statement by circling a single number in each answer section which best represents how you typically feel most of the time.

Since people vary so much in the opinions they hold THERE ARE NO RIGHT OR WRONG ANSWERS.

Statements	Answers							
	completely disagree		disagree		agree		completely agree	
1. I have control over my own life.	0	1	2	3	4	5	6	7
2. I'm easy to like.	0	1	2	3	4	5	6	7
3. I never feel down in the dumps for very long.	0	1	2	3	4	5	6	7
4. I can never seem to achieve anything worthwhile.	0	1	2	3	4	5	6	7
5. There are lots of things I'd change about myself if I could.	0	1	2	3	4	5	6	7
6. I'm not embarrassed to let people know my opinions.	0	1	2	3	4	5	6	7
7. I don't care what happens to me.	0	1	2	3	4	5	6	7
8. I seem to be very unlucky.	0	1	2	3	4	5	6	7
9. Most people find me reasonably attractive.	0	1	2	3	4	5	6	7
10. I'm glad I'm who I am.	0	1	2	3	4	5	6	7

<u>Statements</u>	<u>Answers</u>							
	completely disagree		disagree		agree		completely agree	
11. Most people would take advantage of me if they could.	0	1	2	3	4	5	6	7
12. I am a reliable person.	0	1	2	3	4	5	6	7
13. It would be boring if I talked about myself.	0	1	2	3	4	5	6	7
14. When I'm successful there's usually a lot of luck involved.	0	1	2	3	4	5	6	7
15. I have a pleasant personality.	0	1	2	3	4	5	6	7
16. If a task is difficult that just makes me all the more determined.	0	1	2	3	4	5	6	7
17. I often feel humiliated.	0	1	2	3	4	5	6	7
18. I can usually make my mind up and stick to it.	0	1	2	3	4	5	6	7
19. Everyone else seems much more confident and contented than me.	0	1	2	3	4	5	6	7
20. Even when I quite enjoy myself there doesn't seem much purpose to it all.	0	1	2	3	4	5	6	7
21. I often worry about what other people are thinking about me.	0	1	2	3	4	5	6	7
22. There's a lot of truth in the saying 'what will be will be'.	0	1	2	3	4	5	6	7
23. I look awful these days.	0	1	2	3	4	5	6	7

<u>Statements</u>	<u>Answers</u>							
	completely disagree		disagree		agree		completely agree	
24. If I really try I can overcome most of my problems.	0	1	2	3	4	5	6	7
25. It's pretty tough to be me.	0	1	2	3	4	5	6	7
26. I feel emotionally mature.	0	1	2	3	4	5	6	7
27. When people criticise me I often feel helpless and second rate.	0	1	2	3	4	5	6	7
28. When progress is difficult I often find myself thinking it's just not worth the effort.	0	1	2	3	4	5	6	7
29. I can like myself even when others don't.	0	1	2	3	4	5	6	7
30. Those who know me well are fond of me.	0	1	2	3	4	5	6	7

PLEASE CHECK THAT YOU HAVE RESPONDED TO EVERY STATEMENT BEFORE STARTING THE NEXT QUESTIONNAIRE.

(Robson, 1989)

APPENDIX FIVE: THE WORK, LESISURE AND FAMILY LIFE QUESTIONNAIRE

code			
date			
interview	1	2	3

Work, Leisure and Family Life Questionnaire

Instructions:

We are interested in how you have been in the **past two weeks**. We would like you to answer some questions about your work, spare time activities and your family life. Please answer the questions on the following pages by ticking the box of the answer which you think most nearly applies to you.

Work outside the home:

The following questions are about how things have been in your job (full-time or half-time).
If you do not have a job go straight on to the next section.

Over the past two weeks have you:

- | | | | | | |
|--|--|--|---|--|--|
| 1. missed any time from work? | Not at
All <input type="checkbox"/> | Occasionally
<input type="checkbox"/> | About half
the time <input type="checkbox"/> | Most of the
time <input type="checkbox"/> | All the
time <input type="checkbox"/> |
| 2. been doing your job well? | All the
time <input type="checkbox"/> | Most of the
time <input type="checkbox"/> | About half
the time <input type="checkbox"/> | Occasionally
<input type="checkbox"/> | Not at
All <input type="checkbox"/> |
| 3. felt ashamed of how you have
been doing your work? | Not at
all <input type="checkbox"/> | Occasionally
<input type="checkbox"/> | About half
the time <input type="checkbox"/> | Most of the
time <input type="checkbox"/> | Constantly
<input type="checkbox"/> |
| 4. got angry with or argued with
people at work? | Not at
all <input type="checkbox"/> | Occasionally
<input type="checkbox"/> | About half
the time <input type="checkbox"/> | Most of the
time <input type="checkbox"/> | Constantly
<input type="checkbox"/> |
| 5. felt upset, worried or uncomfortable
at work? | Not at
all <input type="checkbox"/> | Occasionally
<input type="checkbox"/> | About half
the time <input type="checkbox"/> | Most of the
time <input type="checkbox"/> | Constantly
<input type="checkbox"/> |
| 6. been finding your work interesting? | All the
time <input type="checkbox"/> | Most of the
time <input type="checkbox"/> | About half
the time <input type="checkbox"/> | Occasionally
<input type="checkbox"/> | Not at
All <input type="checkbox"/> |

Work inside the home:

The following questions are about how you have been doing your household tasks.

Over the past two weeks have you:

- | | | | | | |
|--|--|--|---|--|--|
| 7. done the necessary household tasks
each day? | All the
time <input type="checkbox"/> | Most of the
time <input type="checkbox"/> | About half
the time <input type="checkbox"/> | Occasionally
<input type="checkbox"/> | Not at
All <input type="checkbox"/> |
| 8. been doing the household tasks well? | All the
time <input type="checkbox"/> | Most of the
time <input type="checkbox"/> | About half
the time <input type="checkbox"/> | Occasionally
<input type="checkbox"/> | Not at
All <input type="checkbox"/> |
| 9. felt ashamed of how you have been
doing the household tasks? | Not at
all <input type="checkbox"/> | Occasionally
<input type="checkbox"/> | About half
the time <input type="checkbox"/> | Most of the
time <input type="checkbox"/> | Constantly
<input type="checkbox"/> |

- | | | | | | |
|---|-------------------------------------|---------------------------------------|--|---|-------------------------------------|
| 10. got angry/argued with salespeople, tradesmen or neighbours? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | Constantly <input type="checkbox"/> |
| 11. felt upset, worried or uncomfortable while doing the household tasks? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | Constantly <input type="checkbox"/> |
| 12. found the household tasks boring, unpleasant or a drudge? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | Constantly <input type="checkbox"/> |

Social and leisure activities:

The following questions are about your friends and what you have been doing in your spare time.

Over the past two weeks have you:

- | | | | | | |
|---|---------------------------------------|---|--|---|-------------------------------------|
| 13. been in touch with any of your friends? | Very often <input type="checkbox"/> | Often <input type="checkbox"/> | A few times <input type="checkbox"/> | Very rarely <input type="checkbox"/> | Not at All <input type="checkbox"/> |
| 14. been able to talk about your feelings openly with your friends? | All the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | About half the time <input type="checkbox"/> | Occasionally <input type="checkbox"/> | Not at All <input type="checkbox"/> |
| 15. done things socially with your friends(eg. visiting, entertaining, going out together)? | Very often <input type="checkbox"/> | Often <input type="checkbox"/> | A few times <input type="checkbox"/> | Very rarely <input type="checkbox"/> | Not at All <input type="checkbox"/> |
| 16. spent your available time on hobbies or spare time interests? | All the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | About half the time <input type="checkbox"/> | Occasionally <input type="checkbox"/> | Not at All <input type="checkbox"/> |
| 17. got angry with or argued with your friends? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | Constantly <input type="checkbox"/> |
| 18. been offended or had your feelings hurt by your friends? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | Constantly <input type="checkbox"/> |
| 19. felt ill at ease, tense or shy when with people? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | Constantly <input type="checkbox"/> |
| 20. felt lonely and wished for companionship? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | Constantly <input type="checkbox"/> |
| 21. felt bored in your free time? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | Constantly <input type="checkbox"/> |

Extended family:

The following questions are about your extended family, ie. parents, brothers, sisters, in-laws, and children not living at home. Please do not include your partner or children living at home.

Over the past two weeks have you:

- | | | | | | |
|---|---------------------------------------|---|--|---|---------------------------------------|
| 22. got angry with or argued with any of your relatives? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | All the time <input type="checkbox"/> |
| 23. made an effort to keep in touch with your relatives? | Very often <input type="checkbox"/> | Often <input type="checkbox"/> | A few times <input type="checkbox"/> | Very rarely <input type="checkbox"/> | Not at All <input type="checkbox"/> |
| 24. been able to talk about your feelings openly with your relatives? | All the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | About half the time <input type="checkbox"/> | Occasionally <input type="checkbox"/> | Not at All <input type="checkbox"/> |
| 25. depended on your relatives for help, advice or friendship? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | All the time <input type="checkbox"/> |
| 26. worried more than necessary about things happening to your relatives? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | All the time <input type="checkbox"/> |
| 27. been feeling that you have let your relatives down at any time? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | All the time <input type="checkbox"/> |
| 28. been feeling that your relatives have let you down at any time? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | All the time <input type="checkbox"/> |

Relationships:

The following questions are about how things have been between you and your partner. If you are NOT living with your partner or living with a person in a steady relationship, go straight to next section.

Over the past two weeks have you:

- | | | | | | |
|---|---------------------------------------|---|--|---|---------------------------------------|
| 29. got angry with each other or argued with one another? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | All the time <input type="checkbox"/> |
| 30. been able to talk about your feelings and problems with your partner? | All the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | About half the time <input type="checkbox"/> | Occasionally <input type="checkbox"/> | Not at All <input type="checkbox"/> |
| 31. been making most of the decisions at home yourself? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | All the time <input type="checkbox"/> |
| 32. tended to give in to your partner and let him/her have his/her own way when there was a disagreement? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | All the time <input type="checkbox"/> |
| 33. and your partner shared the responsibility for particular matters that have arisen? | All the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | About half the time <input type="checkbox"/> | Occasionally <input type="checkbox"/> | Not at All <input type="checkbox"/> |
| 34. had to depend on your partner to help you? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | All the time <input type="checkbox"/> |

- | | | | | | |
|--|--|---|--|---|-------------------------------------|
| 35. been feeling affectionate towards your partner? | All the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | About half the time <input type="checkbox"/> | Occasionally <input type="checkbox"/> | Not at All <input type="checkbox"/> |
| 36. and your partner had sexual relations? (About how many times?) | 4 or more times <input type="checkbox"/> | Three times <input type="checkbox"/> | Twice <input type="checkbox"/> | Once <input type="checkbox"/> | Not at All <input type="checkbox"/> |
| 37. had any problems during sexual intercourse? (eg. pain or difficulty reaching climax) | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | Every time <input type="checkbox"/> |
| 38. enjoyed your sexual relations with your partner? | Every time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | About half the time <input type="checkbox"/> | Occasionally <input type="checkbox"/> | Not at all <input type="checkbox"/> |

Parental:

The following questions are about how things have been with your children. If you do not have any children living at home go straight on to the next section.

Over the past two weeks have you:

- | | | | | | |
|--|---------------------------------------|---|--|---|-------------------------------------|
| 39. been interested in your children's activities, eg. school, friends etc.? | All the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | About half the time <input type="checkbox"/> | Occasionally <input type="checkbox"/> | Not at All <input type="checkbox"/> |
| 40. been able to talk to and listen to your children? | All the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | About half the time <input type="checkbox"/> | Occasionally <input type="checkbox"/> | Not at All <input type="checkbox"/> |
| 41. been shouting at or arguing with your children? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | Constantly <input type="checkbox"/> |
| 42. been feeling affectionate towards your children? | All the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | About half the time <input type="checkbox"/> | Occasionally <input type="checkbox"/> | Not at All <input type="checkbox"/> |

Family unit:

The following questions are about how things have been with your immediate family, that is your partner and children at home. If you do not have an immediate family please ignore this section.

Over the past two weeks have you:

- | | | | | | |
|--|-------------------------------------|---------------------------------------|--|---|---------------------------------------|
| 43. been worrying more than necessary about things happening to your family? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | All the time <input type="checkbox"/> |
| 44. been feeling that you have let your immediate family down at any time? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | All the time <input type="checkbox"/> |
| 45. been feeling that your immediate family has let you down at any time? | Not at all <input type="checkbox"/> | Occasionally <input type="checkbox"/> | About half the time <input type="checkbox"/> | Most of the time <input type="checkbox"/> | All the time <input type="checkbox"/> |

PLEASE CHECK THAT YOU HAVE ANSWERED EVERY APPLICABLE QUESTION BEFORE STARTING THE NEXT QUESTIONNAIRE.

(Cooper *et al*, 1982)

APPENDIX SIX: EXPECTATIONS OF TREATMENT QUESTIONNAIRE

code			
date			
interview	1	2	3

EXPECTATIONS ABOUT TREATMENT

People who come for treatment for an eating disorder generally have some feelings about how important it is for them to overcome their problem, as well as some expectations about the treatment they will receive. As we have explained to you, you will be randomised to receive one of the following treatments: a self-help manual with support from your GP, or treatment at the Eating Disorders Clinic. We would like to know how effective you would expect these treatments to be in helping you to overcome your eating problems.

Please answer the following questions by circling the number on each of the scales which best represents how you feel.

1. How big a problem is your eating disorder in your opinion?

Not at all a problem 0 1 2 3 4 5 6 7 8 9 10 An extremely severe problem

2. How important is it to you that you overcome your eating disorder?

Not at all important 0 1 2 3 4 5 6 7 8 9 10 Of the greatest possible importance

3. How confident do you feel that you could stop your problem eating behaviours (eg. bingeing, starving yourself, making yourself vomit, using laxatives) altogether if helped to do so?

Not at all confident 0 1 2 3 4 5 6 7 8 9 10 Extremely confident

4. If you were randomised to the general practice group, how effective would you expect the self-help manual to be in helping you overcome your eating disorder?

Not at all helpful 0 1 2 3 4 5 6 7 8 9 10 Extremely helpful

5. If you were randomised to the general practice group, how effective would you expect your GP to be in helping you overcome your eating disorder?

Not at all helpful 0 1 2 3 4 5 6 7 8 9 10 Extremely helpful

6. If you were randomised to the Eating Disorders Clinic group, how effective would you expect the clinic to be in helping you overcome your eating disorder?

Not at all helpful 0 1 2 3 4 5 6 7 8 9 10 Extremely helpful

7. If given a choice, which type of treatment would you prefer to receive?

Eating Disorders Clinic treatment	<input type="checkbox"/>
Self-help manual with support from GP	<input type="checkbox"/>
No preference	<input type="checkbox"/>

8. How would you describe your relationship with your GP?

Very good	<input type="checkbox"/>
Good	<input type="checkbox"/>
Satisfactory	<input type="checkbox"/>
Not very good	<input type="checkbox"/>
Bad	<input type="checkbox"/>

PLEASE MAKE SURE YOU HAVE ANSWERED EVERY QUESTION. THANK YOU.

APPENDIX SEVEN: SOCIAL AND PSYCHIATRIC HISTORY

code			
date			
interview	1	2	3

PERSONAL DETAILS

I am going to ask you a number of questions about yourself, your health and your family's health. The information which you give me will be treated in the strictest confidence.

Firstly, I'd like to ask you some general questions about yourself.

1. Sex: Male 1 ☐ Female 2 ☐

2. Age: _____

3a. In the 1991 Census everyone in the country said what ethnic group they belonged to. To which ethnic group do you belong?

White 1	<input type="checkbox"/>	Black Other 4	<input type="checkbox"/>	Bangladeshi 7	<input type="checkbox"/>
Black Caribbean 2	<input type="checkbox"/>	Indian 5	<input type="checkbox"/>	Chinese 8	<input type="checkbox"/>
Black African 3	<input type="checkbox"/>	Pakistani 6	<input type="checkbox"/>	Other 9	<input type="checkbox"/>

If 'Other': Please describe your ancestry _____

3b. What country were you born in? _____

4. Are you....?

single 1	<input type="checkbox"/>	divorced 4	<input type="checkbox"/>
married/cohabiting 2	<input type="checkbox"/>	widowed 5	<input type="checkbox"/>
separated 3	<input type="checkbox"/>		

5a. Do you have any children? Yes 1 ☐ No 2 ☐

5b. **If YES:** How many _____?

6a. Are you still at school? Yes 1 ☐ No 2 ☐

6b. **If NO:** How old were you when you left school?

6c. Did you obtain any qualifications at school? Yes 1 ☐ No 2 ☐

6d. **If YES:** What? _____

6e. Have you obtained any qualifications since leaving school? Yes 1 ☐ No 2 ☐

6f. **If YES:** What? _____

7. Do you live with anyone?

With your parents	1	<input type="checkbox"/>
With your spouse	2	<input type="checkbox"/>
With other relatives	3	<input type="checkbox"/>
In a hostel or hall of residence	4	<input type="checkbox"/>
With your partner (girl/boyfriend)	5	<input type="checkbox"/>
In a flatshare	6	<input type="checkbox"/>
In your own flat or lodgings	7	<input type="checkbox"/>
Other (please specify)	8	<input type="checkbox"/>

8. What about employment? Are you now....?

Working full-time	1	<input type="checkbox"/>
Working part-time	2	<input type="checkbox"/>
Unemployed and seeking work	3	<input type="checkbox"/>
Unemployed and not seeking work	4	<input type="checkbox"/>
Housewife (not seeking work outside home)	5	<input type="checkbox"/>
Student (second level)	6	<input type="checkbox"/>
Student (third level)	7	<input type="checkbox"/>
Other	8	<input type="checkbox"/>

If 'other': Please specify _____

9. **If EMPLOYED:** What is your job? _____

10. **If UNEMPLOYED:** What was your last job? _____

11. How long have you been in your current employment/unemployment? _____

12. What is your partner's job? _____

13. **If UNEMPLOYED AND LIVING WITH PARENTS:** What is the main earner's job? _____

14a Do you have a religion?	Yes 1	<input type="checkbox"/>	No 2	<input type="checkbox"/>	If YES: Which?
-----------------------------	-------	--------------------------	------	--------------------------	----------------

14b. Are you a practising (religion)... ? Yes 1 ☐ No 2 ☐

The questions which I am now going to ask you concern your general health.

15. What is your height? _____ feet _____ inches, or _____ cm

16. What is your weight? _____ stone _____ pounds, or _____ kg

17. What is the most that you have ever weighed?
_____ stone _____ pounds, or _____ kg

18. What is the least you have weighed at your present height?
_____ stone _____ pounds, or _____ kg

19. What would your ideal weight be if you could choose it?
_____ stone _____ pounds, or _____ kg

20. Do you feel yourself to be:

Very overweight 5

Overweight 4

Average 3

Underweight 2

Very underweight 1

21. Do you have regular periods?

Yes 1

☐

No 2

☐

22. Are you taking oral contraceptives?

Yes 1

☐

No 2

☐

23. Are you pregnant?

Yes 1

☐

No 2

☐

24. Have you suffered from sugar diabetes now or in the past?

Yes 1

☐

No 2

☐

25a. Have you ever before been referred to a specialist for help with eating problems?

Yes 1

☐

No 2

☐

25b. **If YES:** How long ago was this?

25c. **If YES:** Were you treated as:

An inpatient 1

An outpatient 2

Both inpatient and outpatient 3

25d. **If YES:** Were you diagnosed as suffering from:

Anorexia Nervosa 1

Bulimia Nervosa 2

Another type of eating problem 3

25e. **If YES:** Where were you seen and what treatment did you receive? _____

25f. If YES: When was your last contact with specialist treatment services? _____

26. How long have you had your current eating problems? _____

27a. Apart from your GP, does anyone know about your current eating problems? Yes 1

☐

No 2

☐

27b. If YES, who and are they helping you in any way?

Person: (relationship to patient)	Help given by person

28. Have you ever seen your GP or a psychologist, psychiatrist or counsellor for help with an emotional problem?

If YES:

Nature of problem	Date	Seen by	Out-patient Rx	In-patient Rx

29. Are you currently taking any medication prescribed by your GP/specialist for physical or mental health problems?

If YES: What medications are you on and what have they been prescribed for?

Drugs/ tablets	Prescribed for

I would now like to ask you a couple of questions about your immediate family's health. By 'immediate family' I mean your mother, father, sisters and brothers.

30a. Is anyone in your family suffering from any chronic physical illness (for more than a year)?

Yes 1

☐

No 2

☐

30b. **If YES:** Who and what are they suffering from?

Relative	Illness

31. Has anyone in your immediate family ever received treatment for:

	Family member	GP	Psychiatrist/ Psychologist/ Counsellor	Out-patient Rx at psychiatric hospital	In-patient Rx at psychiatric hospital
Anxiety					
Drinking problems					
Depression					
Schizophrenia					
Other problems with nerves					
Eating problems Specify_____					

APPENDIX EIGHT: PROBLEMS QUESTIONNAIRE

code			
date			
interview	1	2	3

PROBLEMS QUESTIONNAIRE

Some people who suffer from eating problems find that they also have difficulties in other areas of their lives apart from eating (eg. with alcohol and drug use, or in relationships with partners). We are interested in whether you are experiencing such difficulties.

Please tick the appropriate boxes or write your answers to the questions in the spaces provided.

Any information which you give us will be treated in the strictest confidence.

1. Do you smoke? Yes 1 ☐ No 2 ☐

2. If YES, how many cigarettes on average do you smoke per day? _____

3. Do you drink alcohol.....

Not at all	
Less than once a week	
1 to 2 times a week	
Most days	
Every day	

4. If you do drink, how much alcohol do you drink in an average week?

	Number
Pints of beer/lager	
Pints of cider	
Glasses of wine	
Glasses of spirits	

5. Have you ever felt you ought to cut down on your drinking?

6. Have people annoyed you by criticizing your drinking?

7. Have you ever felt bad or guilty about your drinking?

8. Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (eye-opener)?

YES	NO
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

9a. Have you ever received treatment or counselling for your drinking?

Yes 1 ☐ No 2 ☐

9b. If YES, when and where _____

10. Do you use the following drugs?

	Have never used	Occasionally use	Sometimes use	Regularly use	Not now but have used in the past
cannabis					
tranquillisers (not prescribed)					
amphetamines					
heroin					
cocaine					
inhalants/solvents					

11. Have you ever felt that you might have a drug problem?

YES	NO

12a. Have you ever received treatment for a drug problem?

12b. If YES, when and where _____

13a. Have you ever had a sexual relationship?

Yes 1

☐

No 2

☐

13b. If yes, how old were you when this /the first relationship began?

13c. If yes, how many sexual partners have you had in the past two years?

13d. Do you currently have a serious relationship with a partner?

Yes 1

☐

No 2

☐

13e. If yes, how would you describe your current relationship?

Good	1	
Unremarkable	2	
Poor	3	
Variable	4	

14a. Have you ever felt like harming yourself (eg. take an overdose or cut yourself)?

Yes 1

☐

No 2

☐

14b. If YES, have you ever tried deliberately to harm yourself?

Yes 1

☐

No 2

☐

14c. If yes, when and how? _____

15a. Some people with eating difficulties sometimes say they have compulsions to do things like stealing or shoplifting:

Have you ever felt compelled to steal something, even though you didn't need it?

Yes 1

☐

No 2

☐

15b. Have you ever stolen from shops?

Yes 1

☐

No 2

☐

15c. If YES, on how many occasions? _____

15d. Have you ever been caught shoplifting?

Yes 1

☐

No 2

☐

15e. If YES, on how many occasions? _____

15f. Have you ever been charged with a shoplifting offence?

Yes 1

☐

No 2

☐

15g. If YES, on how many occasions? _____

PLEASE CHECK THAT YOU HAVE ANSWERED EVERY APPLICABLE QUESTION BEFORE STARTING THE NEXT QUESTIONNAIRE.

APPENDIX NINE: SATISFACTION WITH TREATMENT QUESTIONNAIRE I

code			
date			
interview	1	2	3

TREATMENT QUESTIONNAIRE

The following questions concern how you feel about your eating problems and the treatment you have been receiving.

Please answer these questions by circling the number on each of the scales which best represents how you feel.

1. How big a problem is your eating disorder in your opinion?

Not at all a problem 0 1 2 3 4 5 6 7 8 9 10 An extremely severe Problem

2. How important is it to you that you overcome your eating disorder?

Not at all important 0 1 2 3 4 5 6 7 8 9 10 Of the greatest possible importance

3. How helpful have you been finding the Eating Disorders Clinic / self-help manual (with or without your GP's support)?

Not at all helpful 0 1 2 3 4 5 6 7 8 9 10 Extremely helpful

4. If you have stopped going to the Eating Disorders Clinic/ using the self-help manual (delete as appropriate) to help you overcome your eating disorder, why is this?

APPENDIX 10: ECONOMIC EVALUATION AND TREATMENT ATTENDANCE QUESTIONNAIRE I

PERSONAL DETAILS/ECONOMIC EVALUATION QUESTIONNAIRE

I'd like to ask you some questions about how things may have changed for you in the past 6 months (for example, in terms of where you live or your job) and about your use of treatment services. As part of the study we are also interested in looking at the costs of having an eating disorder as well as the costs of treatment. So I'll be asking you some questions which may seem a bit irrelevant but which in fact are necessary in order to accurately look at costs. Any information you give me will be treated in the strictest confidence.

Subject No.	Patient's initials
Study Group	D.O.B.
Hospital	Date of 1st interview
Follow-up: 1	Date of first clinic appointment
	Today's date

Marital status:

1. Has your marital status changed in the past 6 months? Yes No
 If YES, in what way?

Accommodation: social aspect

2a. Have you changed your accommodation in the past 6 months Yes No
 since starting your present treatment?

2b. If YES, new address (ask if more than one move):

 Date of move(s):-----

IF NO CHANGE OF ACCOMMODATION:

2c. Do you live with other people? Yes No

2d. If YES, what relationship do they have to you?

Relationship	age	work f-t	work p-t

IF THERE HAS BEEN A CHANGE IN ACCOMMODATION IN THE PAST 6 MONTHS:

2e. During the 6 months prior to starting your present treatment did you live....? And now?

THEN NOW

with your parents		
with your spouse		
with other relatives		
in a hostel or hall of residence		
with your partner (girl/boyfriend)		
in a flatshare		
in your own flat/lodgings		
other		

2f. If you live(d) with other people in the 6 months prior to starting your present treatment/now, what relationship did (do) they have to you?

6 months prior to treatment				Now			
Relationship	Age	Work f-t	Work p-t	Relationship	Age	Work f-t	Work p-t

Accommodation: financial

IF NO CHANGE OF ACCOMMODATION IN PAST 6 MONTHS:

2g. Is your home...

Rented

Owner/occupied

If rented, is this?

Privately	
From local authority	
Housing association	
Other (eg. room in university halls)	

2h. During the 6 months prior to starting your present treatment how much on average did you pay in rent/ mortgage per month?

£-----

2i. Has this changed during the past 6 months since starting your present treatment?

Yes

No

If YES, when did it change and what do you now pay per month?£-----

IF THERE HAS BEEN A CHANGE IN ACCOMMODATION IN THE PAST 6 MONTHS:

2j. Was your previous home...

Rented

--

Owner/occupied

--

If rented, is this?

Privately	
From local authority	
Housing association	
Other (eg. room in university halls)	

2k. How much money on average did you pay in rent/mortgage per month in your previous home?
£-----

2l. Is your present home...

Rented

--

Owner/occupied

--

If rented, is this?

Privately	
From local authority	
Housing association	
Other (eg. room in university halls)	

2m. How much money do you pay in rent/mortgage each month in your present home?
£-----

If living with PARENTS at any stage during the past 12 months:

3a. Do your parents work?

Yes No

3b. If YES, descriptions:-----

3c. Approximately how much do they earn per year (before tax):Dad -----Mum:-----

If living with SPOUSE OR PARTNER at any stage during the past 12 months:

4a. Does your partner/spouse work?

Yes No

4b. If YES, description:-----

4c. Approximately how much does he/she earn per year (before tax):-----

Employment - ability to work:

5a. In the 6 months prior to starting your present treatment, did your eating problems affect your :
Y/N

ability to work	
job choice	
efficiency at work	
promotion prospects	
overtime hours worked	
having a second job	

5b. In the past 6 months since starting your present treatment, have your eating problems affected your:

Y/N

ability to work	
job choice	
efficiency at work	
promotion prospects	
overtime hours worked	
having a second job	

Employment - financial

6a. Has your employment situation changed in the past 6 months since starting your present treatment? Yes No

6b. If YES, in what way? -----

6c. Have you been unemployed at any time during the past 6 months?

Yes No

6d. If YES, for how long?-----weeks

6e. Has this change in your employment status been in any way related to your eating disorder? Yes No

Describe:-----

During the 6 months prior to starting your present treatment:

6f. What was your total monthly income (include total pay after tax, benefits received during unemployment, student grant etc.)?

£-----

6g. Did you receive any money from family members or other people living with you? Yes No

6h. If YES, how much per month? £-----

6i. Were you unemployed at any time during the 6 months prior to starting your present treatment?

Yes No

6j. If YES, for how long?-----weeks

During the past 6 months since starting your present treatment:

6k. Has your monthly income changed in any way?

Yes No

6l. If YES, when did it change and what is your current total monthly income (include total pay after tax, benefits received during unemployment, student grant etc.)?-----

6m. Do you currently receive any money from family members or other people living with you? Yes No

6n. If YES, how much per month? £-----

Social security benefits:

7a. Did you receive any social security benefits or rent rebates in the 6 months prior to starting your present treatment ?

Yes No

7b. If YES, What types of benefits? For how many weeks? How much per week?

Benefits	No. weeks	Amount per week

7c. Have you received any social security benefits or rent rebates in the past 6 months since starting your present treatment?

Yes No

7d. If YES, What types of benefits? For how many weeks? How much per week?

Benefits	No. weeks	Amount per week

Sick Leave:

8a. Approximately how many days did you have 'off sick' from work during the 6 months prior to starting your present treatment?-----

8b. How many of these were due to your eating disorder?-----

8c. How many days have you had 'off sick' from work during the past 6 months since starting your present treatment?-----

8d. How many of these were due to your eating disorder?-----

General treatment:

During the 2 years prior to starting your present treatment:

9a. Were you treated as:

	y/n	Where	For what	When and for how long?
An in-patient in a general hospital				
An out-patient in a general hospital				
An in-patient in a psychiatric hospital				
An out-patient in a psychiatric hospital				

9b. Did you go to casualty/ A and E?

Yes No

9c. If YES, where, when and for what?

In the past 6 months since starting your present treatment:

9d. Have you been treated as:

	y/n	Where	For what	When and for how long?
An in-patient in a general hospital				
An out-patient in a general hospital				
An in-patient in a psychiatric hospital				
An out-patient in a psychiatric hospital				

9e. Have you been to casualty/ A and E?

Yes No

9f. If YES, where, when and for what?

Specific treatment:

10a. In the 2 years prior to starting your present treatment, did you see any of the following for help with your eating problems or any other emotional or mental health problems?

	Where	Nature of problem	frequency of visits + length of appt	No. of visits + dates	Cost of travel 1-way	Cost per session
GP						
EDU specialist						
Psychiatrist						
Psychologist						
Dietitian						
Counsellor						
Therapist						
Practice nurse						
Self-help group						
Other						
Other						
Other						
Other						

10b. Did you have to take time off work to go and see any of these helping agencies?

Yes No

10c. If YES, did you lose pay because of this?

Yes No

10d. If YES, approximately how much did you lose each time? £-----

10e. In the past 6 months have you seen any of the following for help with your eating problems or any other emotional or mental health problems?

	Where	Nature of problem	frequency of visits + length of appt	No. of visits + dates	Cost of travel l-way	Cost per session
GP						
EDU specialist						
psychiatrist						
psychologist						
dietitian						
counsellor						
therapist						
practice nurse						
self-help group						
Other						
Other						
Other						
Other						

10f. Did you have to take time off work to go and see any of these helping agencies?

Yes No

10g. If YES, did you lose pay because of this?

Yes No

10h. If YES, approximately how much did you lose each time? £-----

Medication:

11a. In the past 6 months have you been taking any medications prescribed by your GP/specialists for physical or mental health problems?

If YES: what medications and what have they been prescribed for?

Drugs/tablets	Prescribed by	Prescribed for

11b. Have you been using any other non-prescribed tablets or medicines?

Childcare:

12a. Have you had to make childcare arrangements while going to the Eating Disorders Clinic or to see your GP about your eating problems? Yes No

12b. If YES, details (eg. childminder, family member)-----

12c. If YES, approximately how much did this cost on each occasion? £-----

Relatives and friends:

13a. In the 6 months prior to starting your present treatment, did any of your family, your partner, the people you live with or friends take time off work because of your eating disorder? Yes No

13b. If YES, who and approximately how many days did they take off work?

13c. In the past 6 months since you started your present treatment have any of your family, your partner, the people you live with or friends taken time of work because of your eating disorder? Yes No

13d. If YES, who and approximately how many days have they taken off work?

13e. If YES, have any of your family, your partner, the people you live with or friends taken time off work to go to the clinic/ GP with you?

Yes No

13f. Details (number of times etc)-----

Food:

14a. In the 6 months prior to starting your present treatment how much money did you spend on average per week on food?

£-----

14b. In the past 6 months since starting your present treatment how much money have you spent on average per week on food?

£-----

APPENDIX 11: SATISFACTION WITH TREATMENT QUESTIONNAIRE II

Code			
Date			
Interview	1	2	3

As this is the final research interview which we will having I would like to ask you some questions about how you feel about your eating disorder and about your experiences of treatment.

Anything you write will be treated in the strictest confidence and will not be shown to either your GP or the staff at the Clinic.

Please answer the questions by circling the number on each of the scales which best represents how you feel.

1. How big a problem was your eating disorder before you started treatment for it?

Not at all a problem 0 1 2 3 4 5 6 7 8 9 10 An extremely severe problem

2. How big a problem is your eating disorder at the moment?

Not at all a problem 0 1 2 3 4 5 6 7 8 9 10 An extremely severe problem

If you are a CLINIC patient please go straight to Question 11.

If you are a SELF-HELP/PRIMARY CARE patient please answer the following questions:

SELF-HELP

3. How effective has the self-help book been in helping you with your eating disorder?

Not at all helpful 0 1 2 3 4 5 6 7 8 9 10 Extremely helpful

4. Which of the following stages in the self-help book have you attempted (please tick boxes)?

Step 1: Monitoring	
Step 2: Establishing a meal plan	
Step 3: Learning to intervene	
Step 4: Problem solving	
Step 5: Eliminating dieting	
Step 6: Changing your mind	

5. How effective has your GP been in helping you with your eating disorder?

Not at all helpful 0 1 2 3 4 5 6 7 8 9 10 Extremely helpful

6. Which part(s) of the self-help programme (with or without GP support) did/do you find most helpful?

.....
.....
.....

7. If you did not use the book/ have stopped using it before completing all the stages, why is this?

.....
.....
.....

8. If you never went to see your GP/ have stopped going to see your GP, why is this?

.....
.....
.....

9. Are there any ways in which the self-help programme with GP support could be improved?

.....
.....
.....

10. Have you read any books about eating disorders (apart from the study manual) since starting your self-help programme? If yes, please list.

.....
.....
.....

Now GO TO QUESTION 16.

CLINIC

11. How effective has the Eating Disorders Clinic been in helping you with your eating disorder?

Not at all helpful 0 1 2 3 4 5 6 7 8 9 10 Extremely helpful

12. Which part(s) of the Clinic programme did/do you find most helpful?

.....
.....
.....

13. If you never went to the Clinic/ have stopped going to the Clinic, why is this?

.....
.....
.....

14. Are there any ways in which the Clinic programme could be improved?

.....
.....
.....

15. Have you read any books about eating disorders since starting your treatment at the Clinic? If yes, please list.

.....
.....
.....

ALL PATIENTS

16. What has helped you most in trying to overcome your eating disorder (eg. it could be factors to do with treatment; getting a new job etc)?

17. Finally, we are interested in the reasons why people with eating disorders seek help when they do (eg. people sometimes say that they although they may have had eating problems for years they only sought treatment when the problem began to interfere with their work or when they felt at a really low ebb). Can you remember what thing(s) / event(s), if any, triggered your decision to seek help from your GP for your eating disorder some 10 or 11 months ago?

THANK YOU.

APPENDIX 12: ECONOMIC EVALUATION AND TREATMENT ATTENDANCE QUESTIONNAIRE II

PERSONAL DETAILS/ECONOMIC EVALUATION QUESTIONNAIRE:

FOLLOW-UP 2

I'd like to ask you some questions about how things may have changed for you (in terms of your job etc) since we last met approximately 3 months ago as well as about your recent use of treatment services. As part of the study we are also interested in looking at the costs of having an eating disorder as well as the costs of treatment. So I'll be asking you some questions which may seem a bit irrelevant but which in fact are necessary in order to accurately look at costs. Any information you give me will be treated in the strictest confidence.

Subject No.

Patient's initials

Study Group

D.O.B.

Hospital

Date of 1st interview

Date of first clinic appointment

Follow-up: 2

Date of first follow-up

Today's date

Marital status:

1. Has your marital status changed in the 3 months since we last met?

Yes No

If YES, in what way?

Accommodation: social aspect

2a. Have you changed your accommodation in the 3 months since we last met? Yes No

2b. If YES, new address (ask if more than one move):

Date of move(s):-----

IF THERE HAS BEEN A CHANGE IN ACCOMMODATION IN THE PAST 3 MONTHS:

2c. Do you live with other people?

with your parents	
with your spouse	
with other relatives	
in a hostel or hall of residence	
with your partner (girl/boyfriend)	
in a flatshare	
in your own flat/lodgings	
other	

2d. If you live with other people, what relationship do they have to you?

Relationship	age	work f-t	work p-t

Accommodation: financial

IF NO CHANGE IN ACCOMMODATION IN PAST 3 MONTHS:

2e. Has the amount of money you pay per month in rent/mortgage changed during the 3 months since we last met? If yes, describe change-----

IF THERE HAS BEEN A CHANGE IN ACCOMMODATION IN THE PAST 3 MONTHS:

2f. Is your present home...

Rented

Owner/occupied

If rented, is this?

Privately	
From local authority	
Housing association	
Other (eg. room in university halls)	

2g. How much money do you pay in rent/mortgage each month in your present home?

£-----

If living with PARENTS at any stage during the past 3 months:

3a. Do your parents work?

Yes No

3b. If YES, descriptions:-----

3c. Approximately how much do they earn per year (before tax):Dad -----Mum:-----

If living with SPOUSE OR PARTNER at any stage during the past 3 months:

4a. Does your partner/spouse work?

Yes No

4b. If YES, description:-----

4c. Approximately how much does he/she earn per year (before tax):-----

Employment - ability to work:

5. In the 3 months since we last met have your eating problems affected your:

Y/N

ability to work	
job choice	
efficiency at work	
promotion prospects	
overtime hours worked	
having a second job	

Employment - financial

6a. Has your employment situation changed in the 3 months since we last met? Yes No

6b. If YES, in what way? -----

6c. Have you been unemployed at any time during the 3 months since we last met? Yes No

6d. If YES, for how long?-----weeks

6e. Has this change in your employment status been in any way related to your eating disorder? Yes No

Describe:-----

During the 3 months since we last met:

6f. Has your monthly income changed in any way? Yes No

6g. If YES, when did it change and what is your current total monthly income (include total pay after tax, benefits received during unemployment, student grant etc.)?-----

6h. Do you currently receive any money from family members or other people living with you? Yes No

6i. If YES, how much per month? £-----

Social security benefits:

7a. Have you received any social security benefits or rent rebates in the 3 months since we last met?

Yes No

7b. If YES, What types of benefits? For how many weeks? How much per week?

Benefits	No. weeks	Amount per week

Sick Leave:

8a. Approximately how many days have you had 'off sick' from work in the 3 months since we last met?----

8b. How many of these were due to your eating disorder?-----

General treatment:

In the 3 months since we last met: 9a. Have you been treated as:

	y/n	Where	For what	When and for how long?
An in-patient in a general hospital				
An out-patient in a general hospital				
An in-patient in a psychiatric hospital				
An out-patient in a psychiatric hospital				

9b. Have you been to casualty/ A and E?

Yes No

9c. If YES, where, when and for what?

Specific treatment:

10a. In the 3 months since we last met have you seen any of the following for help with your eating problems or any other emotional or mental health problems?

	Where	Nature of problem	frequency of visits + length of appt	No. of visits + dates	Cost of travel 1-way	Cost per session
GP						
EDU specialist						
Psychiatrist						
Psychologist						
Dietitian						
Counsellor						
Therapist						
practice nurse						
self-help group						
other						
other						
other						
other						

10b. Did you have to take time off work to go and see any of these helping agencies? Yes No

10c. If YES, did you lose pay because of this? Yes No

10d. If YES, approximately how much did you lose each time? £-----

Medication:

11a. In the 3 months since we last met have you been taking any medications prescribed by your GP/specialists for physical or mental health problems?

If YES: what medications and what have they been prescribed for?

Drugs/tablets	Prescribed by	Prescribed for

11b. Have you been using any other non-prescribed tablets or medicines?

Childcare:

12a. In the 3 months since we last met, have you had to make childcare arrangements while going to the Eating Disorders Clinic or to see your GP about your eating problems?

Yes No

12b. If YES, details (eg. childminder, family member)-----

12c. If YES, approximately how much did this cost on each occasion? £-----

Relatives and friends:

13a. In the 3 months since we last met, have any members of your family, your partner, the people you live with or friends taken time off work because of your eating disorder?

Yes No

13b. If YES, who and approximately how many days did they take off work?

13c. If YES, have any of your family, your partner, the people you live with or friends taken time off work to go to the clinic/ GP with you?

Yes No

13d. Details (number of times etc)-----

Food:

14. In the 3 months since we last met, how much money have you spent on average per week on food?

£-----

APPENDIX 13: GP 3-MONTH QUESTIONNAIRE

EATING DISORDERS CLINIC STUDY GP QUESTIONNAIRE

We are interested in getting some feedback from GPs who have been supporting their patients in using the self-help manual "Bulimia Nervosa : A Guide to Recovery" by Peter Cooper. We would like to know what you think about this self-help approach to the management of patients suffering from bulimia nervosa. The information you give us will be treated in STRICT CONFIDENCE.

GP's name:
Surgery address:
Date:
Patient's name:
Patient's date of birth:
Date of initial assessment by researcher:

1. Has the patient been in contact with you about the self-help programme?

Not at all	
Once	
Occasionally	
Regularly	

2. Are you using the book with the patient?
3. Are you finding the book helpful? Is there any aspect of it which you are finding particularly helpful?
4. How do you think the patient feels about the self-help programme?
5. Have you had any problems?

Signed:
Dated:

PLEASE RETURN THIS FORM TO ME IN THE FREEPOST ENVELOPE PROVIDED. THANK YOU.

APPENDIX 14: GP POST- 9- MONTH QUESTIONNAIRE

EATING DISORDERS CLINIC STUDY GP QUESTIONNAIRE

We are interested in getting some feedback from GPs and primary care staff who have been supporting their patients in using the self-help manual "Bulimia Nervosa : A Guide to Recovery" by Peter Cooper. We would like to know what you think about this self-help approach to the management of patients suffering from bulimia nervosa. The information you give us will be treated in STRICT CONFIDENCE.

GP Name: _____ Surgery: _____
Patient Name: _____ Patient DOB: _____
First Assessment by Researcher: _____

1. Approximately how many times did your patient consult you about the self-help programme? _____
2. On average, how long did each consultation last? _____ minutes
3. Over what time period did the consultations take place (e.g. 2 weeks; 2 months; 6 months)?

4. Did you use the book when supporting your patient? Yes ☐ No ☐
- 5a. Did you find the book helpful to you in your role of supporting the patient through the self-help programme? Yes ☐ No ☐
- 5b. IF YES, in what ways was it helpful? Please describe.
- 5c. IF NO, in what ways was it lacking? Please describe.
- 6a. Did you encounter any difficulties in supporting your patient in her use of the self-help programme?
Yes ☐ No ☐
- 6b. IF YES, please describe.
- 7a. Did your consultations concern other problems in the patient's life apart from eating?
Yes ☐ No ☐
- 7b. IF YES, broadly speaking, what types of problems did you discuss?

8a. Did you prescribe any medications for your patient, either before or while she was undertaking the self-help programme, which you felt might help her with her eating?

8b. IF YES:

Medication	Dose	Length of time prescribed for
------------	------	-------------------------------

9. In what ways do you feel your patient benefitted from the self-help/primary care approach to the management of her bulimia?

10. Do you feel you benefitted from taking part in this study (e.g. did it increase your knowledge about bulimia or your confidence in managing bulimic patients)? Please describe.

11a. Did you feel you needed more specialist support? Yes ☐ No ☐

11b. IF YES, what kind of support would you have liked?

12. If your patient either did not come to see you about the self-help programme or only attended once, do you know why this was? Please describe.

13. On the basis of your experience, what do you think are the advantages to managing bulimic patients in primary care using a self-help approach like the one used in the study?

14. Are there any disadvantages to taking this management approach? Please describe.

15a. Would you be prepared to try the self-help approach with other patients? Yes ☐ No ☐

15b. IF NO, why ?

Many thanks for completing this questionnaire

Mary Alison Durand, (Research Psychologist)
University Department of Psychiatry,
Royal Free Hospital School of Medicine,
Pond Street, London NW3 2QG.

APPENDIX 15: GENERAL PRACTITIONER LETTER

HEADED NOTEPAPER

Dr.
London

Date

Dear Dr.

Re: Royal Free Hospital Academic Department of Psychiatry and Eating Disorders Clinic Bulimia Study

Further to our telephone conversation yesterday concerning your patient, **Ms (DOB)**, I enclose a brief description of our study for your information. We hope that our study will lead to rapid assessments and to a reduction in waiting list times.

I shall be contacting Ms by letter in the coming days to tell her about the study and invite her participation, and will let you know when I hear from her whether or not she wishes to participate. If she does. I shall arrange to interview her at your surgery (if possible). If she doesn't, her referral will be processed in the usual way at the Royal Free clinic.

It would really help me if, when referring patients with bulimia or suspected bulimia, you could note the patient's weight and state whether she is diabetic and/or pregnant in your referral letter. Many thanks.

Yours sincerely,

Mary Alison Durand
Research Psychologist

APPENDIX 16: STUDY INFORMATION SHEET

BULIMIA NERVOSA: A CONTROLLED TRIAL OF TREATMENT IN GENERAL PRACTICE WITH SPECIALIST CLINIC CARE

Mary Alison Durand, Michael King and Anthony Wakeling
Academic Department of Psychiatry, Royal Free Hospital

OBJECTIVE: Although the prevalence, characteristics and outcome of patients with bulimia nervosa presenting in general practice have been studied, there has been no assessment of the place of primary medical care in the management of these patients. The objective of the current study is therefore to make a controlled comparison of an intervention based in general practice with current specialist treatment.

PLAN OF INVESTIGATION: All patients with suspected bulimia nervosa referred by North London GPs to the Royal Free Eating Disorders Clinic will be eligible to take part in the study, although a number of exclusion criteria will be applied.

On receipt of referral letters at the Clinic, GPs and patients will be contacted, the study explained to them and informed consent obtained. Patients will then be interviewed by the researcher. The interview will include a full psychiatric and social history, as well as the assessment of eating pathology, depressive symptoms and social problems. After the interview patients will be randomised to receive either self-help/primary care or clinic care.

Clinic treatment: Patients randomised to the Eating Disorders Clinic will receive treatment which follows the format currently adopted in the clinic: after a detailed assessment of the patient, treatment takes a flexible approach based on cognitive-behavioural principles. Treatment usually takes place over a number of months, with patients being seen approximately 10 to 12 times.

Self-help/Primary Care treatment: Patients randomised to the Self-help/ Primary Care group will be given a self-help manual, with the instruction to work through it over the coming weeks or months, and to keep in close touch with their GP. This manual includes sections on nutritional education, self-monitoring, goal setting, assertiveness training, problem solving and strategies to avoid relapse. The researcher will provide each patient's GP with a copy of the manual and discuss the plan of self-help with him/her. The role of the GP is to provide basic support and encouragement to their patient as she works her way through the manual. Both patients and GPs in this group will be assured that specialist backup will be available if required. In cases where GP feels that a primary care based approach is no longer possible for clinical or social reasons, patients will be withdrawn from the study and reviewed in the clinic.

All patients will be re-interviewed at six and 9 months post commencement of their treatment and outcome (change) will be assessed. At 9 months patients' practice records will be searched for records of attendance, psychotropic prescribing and recorded interventions by practice staff.

APPENDIX 17: PATIENT LETTER AND CONSENT FORM

*Royal Free Hospital School of
Medicine*

*Academic Department of Psychiatry
Eating Disorders Clinic Study
Royal Free Hospital
Pond Street London NW3 2QG*

Tel:

Fax:

Dear

As you know, your GP, Dr , has recently referred you to the EATING DISORDERS CLINIC at the Royal Free Hospital. The clinic is currently undertaking a study in order to try to establish where people with eating problems are best helped. We have discussed the study with your doctor who is agreeable to your taking part.

If you agree to take part in this study I will interview you about your eating difficulties at your doctor's surgery and then you will be allocated on a random basis to receive help in **one** of the following ways:

1. General Practice Based Help: You will be given a self-help manual which contains most of the information you need to know about the treatment of eating problems. This manual includes a six-step self-help programme which has already benefitted other people with eating problems. You will be supported in using the manual by your own doctor. Specialist help will be available if needed by you or your doctor.
2. You will be given an appointment for the Eating Disorders Clinic at the Royal Free Hospital and will be seen there in due course as was already planned by your doctor.

Your progress will be assessed through interview and your medical notes at 6 and 9 months. Any information you give us will be treated in the strictest confidence.

This study is an important one which will enable us to decide on the best place to help patients with eating difficulties: we would value your cooperation. However, you are completely free to decline to take part, in which case your referral will be processed at the Royal Free in the normal way.

It is important that you complete the accompanying slip and return it to me as soon as possible in the envelope enclosed. Please do not hesitate to call me if you need any further information in making up your mind.

Yours sincerely

Mary Alison Durand
Research Psychologist

***EATING DISORDERS CLINIC STUDY
PATIENT CONSENT FORM***

I (name)

of (address)

have read the accompanying explanation sheet and agree/do not agree to take part in this study. Please contact me at the above address, or on telephone _____.

Signed:

Date:

APPENDIX 18: GENERAL PRACTITIONER STUDY GUIDELINES

ROYAL FREE HOSPITAL ACADEMIC DEPARTMENT OF PSYCHIATRY AND EATING
DISORDERS CLINIC BULIMIA STUDY

GUIDELINES FOR PRIMARY CARE STAFF INVOLVED IN SUPPORTING BULIMIC
PATIENTS WHO ARE USING THE SELF-HELP MANUAL 'BULIMIA NERVOSA; A GUIDE TO
RECOVERY'

Mary Alison Durand
(Research Psychologist)
Academic Department of Psychiatry,
The Royal Free Hospital,

What is bulimia nervosa?

Bulimia nervosa is an eating disorder which affects approximately 1-2% of young women who consult in general practice; a further 2-3% may suffer from a partial form of the syndrome. Far fewer men are affected. The average age of women suffering from bulimia nervosa is around 24 years. Onset typically occurs between the ages of 16 and 18. Individuals with bulimia nervosa are generally within the normal weight range, although some may be over- or underweight.

Central diagnostic criteria for the disorder include binge eating and recurrent inappropriate compensatory behaviours to prevent weight gain. A binge may be defined as eating in a discrete period of time an amount of food that is definitely larger than most individuals would eat under similar circumstances. The type of food eaten during a binge is typically high in calories and easily digestible. Binge eating usually occurs in secret, often at home and late in the day. Episodes of binge eating are accompanied by a sense of a loss of control. Binge eating is typically triggered by negative mood states, stressors, hunger following dietary restraint, or by thoughts or feelings related to food, or body shape or weight. Between binges, bulimic individuals have difficulties eating regular meals and generally try to restrict their caloric intake. Binges may alternate with up to several days of starving.

Inappropriate compensatory behaviours used to prevent weight gain include self-induced vomiting, extreme exercising, or the misuse of laxatives and diuretics. Some 80-90% of those who come for treatment report vomiting after periods of binge eating, while approximately one-third use laxatives. Many people employ several methods. Women who suffer from bulimia nervosa place an excessive emphasis on body weight and shape in terms of how they evaluate themselves and these factors assume great importance in determining their self-esteem.

Depressed mood is common in individuals who suffer from bulimia and there may also be an increased frequency of anxiety symptoms. These often remit following effective treatment of the eating disorder, although in some individuals depression may exist independently of bulimia and may require specific treatment. A percentage of those who suffer from bulimia nervosa also abuse alcohol or drugs or engage in self-harming behaviours. Associated physical symptoms may include electrolyte abnormalities, dental decay, enlargement of the salivary glands, and menstrual irregularity or amenorrhea.

What causes bulimia nervosa?

There is no clear answer as to what causes bulimia nervosa. It appears that the disorder arises out of an interaction

of physical, psychological and social factors. A familial tendency towards eating disorders or depressive illness may increase vulnerability, as may psychological characteristics such as a profound lack of self-esteem and a sense of ineffectiveness, or social or cultural influences which cause the individual to dwell too much on the importance of weight and shape. In addition, about one-third of those who develop bulimia nervosa do so after an episode of anorexia nervosa.

The single most important precipitating factor in the development of the disorder is a period of dieting: the majority of individuals who have bulimia nervosa can recall a period of dieting before the first occasion on which they lost control over eating (Cooper, 1993). *Indeed, it has been suggested that it is the dieting itself which causes episodes of loss of control.* In individuals who were not dieting prior to developing bulimia, overeating may constitute a response to stressful life events or negative feelings.

As Cooper suggests, it is easy to see how the individual with bulimia nervosa gets into a vicious circle of starving, bingeing and purging. A vulnerable person with low self-esteem and extreme concerns about weight and shape engages in strict dieting which, through both psychological and physiological mechanisms, leads to overeating. Binge eating in turn leads to the use of inappropriate compensatory behaviours such as vomiting. These encourage further overeating, heighten preoccupations with weight and shape and in turn serve to undermine the individual's sense of self-control and self-esteem. Feelings of ineffectiveness and concerns about weight and shape are further intensified and the cycle continues.

Which treatments are beneficial?

In recent years there has been much interest in developing and evaluating treatments for bulimia nervosa. A cognitive-behavioural approach has been shown to be at least as effective as other psychological or drug treatments. Cognitive-behaviour therapy is based on the view that a key factor which prevents individuals with bulimia nervosa from spontaneously recovering is their extreme concerns about weight and shape. Treatment aims to help people regain control over their eating and to moderate their concerns about their shape and weight. A cognitive-behavioural approach has the advantage that it can be standardised for application by non-specialists. There is also recent evidence that self-help can be an effective component of treatment (eg. Schmidt et al, 1993). Schmidt et al suggest that a self-help book may be a useful first step intervention in the treatment of patients with bulimia. Self-help is not a new concept in psychiatry: a variety of types of self-help treatments have been found to be effective in the management of anxiety states, depression, alcohol abuse and benzodiazepine withdrawal.

THE CURRENT STUDY

1. Objective:

The aim of the current study is to make a controlled comparison of an intervention based in general practice (a self-help manual and primary care staff support) with current specialist treatment.

2. Your role:

2.1. Your patient has been given a copy of the self-help manual ('Bulimia Nervosa: A guide to recovery' by Peter Cooper) which she has been told to work through over the coming weeks/months while keeping in touch with you. This manual has been used to considerable benefit by many people with bulimia nervosa. Your role is essentially to provide general support and encouragement to her as she works her way through this manual.

2.2 In order to effectively support your patient it is important that you too are familiar with the manual. The book is divided into two sections, the first of which contains general information about bulimia nervosa, its causes and treatment. The second section consists of a six-step self-help programme based on cognitive behavioural principles. The six steps are highly structured and a chapter is devoted to each. It would be helpful if you were able read through the book in order to be familiar with its contents and how the self-help programme works. As the self-help section is divided into short chapters, it should be possible before seeing your patient to skim reasonably quickly through the chapter with which she is currently concerned. (An Appendix in the book focuses on helpers - you may find this helpful.)

2.3. It is particularly important that you indicate in the patient's notes whether each consultation she has with you is primarily concerned with her eating disorder and the self-help programme. For our research purposes we need to know how many consultations a patient has with the primary care team regarding her eating problems.

The following are some questions you may have about your role:

a. How often should I see the patient?

It is probably advisable when your patient starts the six-step programme in the manual that you encourage her to visit you on a frequent, perhaps weekly or fortnightly, basis. The patient is undertaking a task which may be very difficult for her and regular support and encouragement provided even during very brief consultations will be particularly beneficial during the early weeks. As she gradually regains control over her eating, consultations can become less frequent.

b. What kind of help should I give the patient?

Cooper suggests that in working with someone who is using the manual your role is essentially one of helping her to help herself. *It is therefore not up to you to devise plans and strategies for her, but rather to encourage her to develop her own techniques for overcoming her eating difficulties.* However, it is often easier for an 'outsider' to spot patterns or details (for example, on a food monitoring sheet) that the patient herself may not see and if you feel that a useful observation or suggestion could be made then you should make it. In general, consultations should revolve around a review of progress (closely linked to the stage the patient is at in the manual) and the provision of encouragement in using the steps laid out in the manual.

c. What should I do if the patient says she is not finding the manual useful?

There are bound to be times when the patient feels despondent and frustrated. It may be that she is trying to progress too quickly or, on the other hand, that she is having difficulty moving from one step to the next. It may be important to point out progress which has been made or to encourage her to think about ways in which progress might be made, in line with the steps in the manual.

d. What should I do if the patient wants to come to the clinic?

It is important to establish her reasons for wanting to come to the clinic. It may be simply that she feels that she is making little progress and that the clinic would provide a quicker solution to her problems: in this case perhaps all she needs is a little more encouragement to keep on working with the manual. It might also be useful to tell such patients that although the doctors working at the clinic are indeed specialists in eating disorders, much of the advice and help they give the majority of the bulimic patients they see at the clinic is very similar to that given in the manual. Similarly, the kind of support and encouragement they receive at the clinic would be the same as that provided by yourself. On the other hand, there may be serious reasons why specialist help should be sought and the patient withdrawn from the study. These should be explored with specialists at the clinic and appropriate action taken.

e. What about medications?

GPs sometimes prescribe medication for patients with bulimia (eg. anti-depressants). If you or anyone in your practice prescribes medication to alleviate symptoms related to the patient's bulimia it is important for research purposes to highlight this in the patient's notes.

f. Should I recommend a counsellor?

As the objective of the study is to compare self-help (with primary care support) to specialist treatment, it is preferable that you do not send your patient to a counsellor (whether attached to or independent from your practice), as this may confound the effects of the self-help treatment.

g. Who should I contact if I feel I need the advice or help of the specialist eating disorders services?

If you contact Mary Alison Durand (Research Psychologist) at the Academic Department of Psychiatry at the RFH on (answerphone) she will liaise with the staff at the Eating Disorders Clinic for you.

Mary Alison Durand
Dr. Michael King
Professor Anthony Wakeling
January 1995