**PB-PG-0212-27089 – NIHR Research for Patient Benefit Programme – Final report**

**Project title**: Pilot study to inform a randomised control trial protocol examining the clinical effectiveness of a modified version of Interpersonal Psychotherapy (IPT-BNm) for the treatment of bulimia nervosa


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## Plain language summary


Bulimia nervosa develops at an early stage of life and during an important developmental time for a person, profoundly disrupting their quality of life. The NICE guidelines for eating disorders recommend that patients with Bulimia nervosa should be treated with a specific type of psychotherapy specifically developed for the condition, which is called Cognitive behavioural therapy for bulimia nervosa enhanced (CBT-e). Subsequently, if patients have not responded to this treatment, the guidelines suggest that they should be offered a different type of psychological treatment, called Interpersonal psychotherapy for bulimia nervosa (IPT-BN). In spite of these recommendations, at best only half of patients who begin treatment with CBT make a full and lasting recovery. Specifically, only between 30-50% of patients cease binge eating/purging.

Fifteen years ago IPT-BN was modified further by the Leicester Eating Disorders Team. This modification of IPT-BN was named by the authors as IPT-BNm. Although the therapy has been used for more than a decade, it has only recently been manualised (Whight et al, 2012). Clinically, IPT-BNm has been found to be very successful. Recent research using IPT-BNm suggests that it works rapidly (Arcelus et al, 2009). In fact, by the middle of the treatment there is a significant reduction in bulimic symptoms, suggesting that IPT-BNm may work better than CBT-e. The aim of this project was to collect information that will help us to identify whether the development of a randomized control trial to compare IPT-BNm to standard treatment (CBT-e) is possible. As part of the project, we collected the information of suitable patients referred to the service, those who accepted participation and those who eventually dropped out of treatment, in two services using the treatment modalities described above. We aimed to compare patients' symptoms after treatment and at follow-up. This one year project found that: out of 418 people assessed by both services, 48 fulfilled the inclusion criteria and were approached to take part in the study, 2 of these declined to participate. Out of the 46 that were offered either IPT BNm or CBT-e, 22 completed therapy, meaning a dropout rate of 52.2% was experienced. Comparison of patients' symptoms was limited due to low numbers of completers. Preliminary analysis indicated that the type of therapy received made no difference to eating disorder symptoms and behaviour but did have an effect on patients rating of their anxiety.



**Keywords**

Feasibility, Eating Disorders, Bulimia nervosa, Interpersonal Psychotherapy, Cognitive Behavioural Therapy.

## Summary of research findings

### Background

Bulimia nervosa develops at an early stage of life and during an important developmental time for a person, profoundly disrupting their quality of life. The NICE guidelines for eating disorders recommend that patients with Bulimia nervosa should be treated with a specific type of psychotherapy specifically developed for the condition, which is called Cognitive behavioural therapy for bulimia nervosa enhanced (CBT-e). Subsequently, if patients have not responded to this treatment, the guidelines suggest that they should be offered a different type of psychological treatment, called Interpersonal psychotherapy for bulimia nervosa (IPT-BN). In spite of these recommendations, at best only half of patients who begin treatment with CBT make a full and lasting recovery. Specifically, only between 30-50% of patients cease binge eating/purging.

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### Aims and Objectives

Primary Aims

1. To gather information that will enable a realistic estimation of recruitment and retention rates.
2. To obtain preliminary estimates for sample size of the full trial.
3. To determine cost data appropriate for cost economics calculation in the full trial.
4. To determine acceptability to patients and clinicians of the trial comparing both psychological treatments.

Secondary Aims

1. To assess, based on the preliminary limited data, the efficacy of the modified version of Interpersonal Therapy for Bulimia Nervosa (IPT-BNm) compared to Cognitive Behavioral Therapy for Bulimia Nervosa-enhanced (CBT-e).

### Methods

*Setting*

Leicestershire Adult Eating Disorder Service (LAEDS) is a specialist NHS service for the assessment and treatment of adults aged over 18 with a clinical eating disorder which covers a population of approx. 1 million. Nottingham Eating Disorder Service (NEDS) is a specialist NHS service for the assessment and treatment of adults aged 18 and over with a clinical eating disorder which covers a population of over 600,000.

*Participants*

Inclusion criteria

1. Females aged 18 years and over with a primary diagnosis of BN or atypical BN (ICD-10) or EDNOS bulimic subtype (DSM-IV).

Exclusion criteria

1. Co-morbid major mental health disorder diagnosis such as psychosis or bipolar disorder requiring a different intervention.
2. Severe physical conditions that would interfere with treatment or eating disorder related high medical risk (e.g. severe hypokalaemia).
3. Poor understanding of spoken or written English.

*Measures*

Numbers of referrals, diagnosis and reasons for non-exclusion were recorded.

- Eating Disorders Examination Questionnaire- EDE-q (Fairburn & Beglin, 1994). The EDE-q focuses on the past 28 days and measures core elements of eating disorder psychopathology via 28 questions. It provides 4 subscale scores: Restraint, Weight Concern, Eating Concern and Shape Concern. A global score is also obtained. A high score indicates a greater level of eating disorder psychopathology.
- The Hospital Anxiety and Depression Scale - HADS (Zigmond & Snaith, 1983). HADS is a widely used 14-item self-report scale designed to briefly measure current anxiety and depressive symptomatology in non-psychiatric hospital patients. A score of 8 or above was considered to indicate depression.
- The Inventory of Interpersonal Problems - IIP-32 (Barkham, Hardy & Startup, 1996). This is a shortened version of the Inventory of Interpersonal Problems (IIP; Horowitz, Rosenberg, Baer, Ureno & Villasenor, 1988). Eight subscale scores are calculated: Hard to be assertive; Hard to be sociable; Hard to be Supportive; Hard to be involved; Too caring; Too dependent; Too aggressive; Too open, along with an overall score. High scores indicate a high degree of interpersonal problems.
- World Health Organisation Quality of Life Scale - Brief Version - WHOQOL- BREF (WHOQOL group, 1998). The WHOQOL-BREF assesses of quality of life. It consists of 26 items which measure the following broad domains: physical health, psychological health, social relationships and environment.
- Along with these, food diaries were completed by patients throughout the duration of the study. The food and purging diary was used (Fernandez-Aranda and Turon, 1998). Weekly binge-eating and purging frequency was determined by examining food diaries.

*Process*

At initial assessment, patients who potentially met eligibility criteria were identified by clinicians. Those deemed eligible were provided with a brief outline of the study and offered the option of more detailed information. Informed consent was obtained by the clinician. Following consent, patients were placed on the waiting list, as per normal practice, (in LAEDS) or went straight to therapy (in NEDS). Patients were randomised by usual clinical practice i.e. when a patient reached the top of the waiting list the intervention received was determined by which therapist was next to select from the list. When a patient reached the top of the waiting list, a set of study questionnaires and diary were issued prior to the patient starting therapy, with the expectation these would be returned at session 0. Further questionnaires were issued at end-of-therapy and 4 month post-therapy completion.

## Findings

*Primary Outcomes*

Across both centres, a total of 418 patients were screened for eligibility (n=300 at LAEDS, n=118 at NEDS). A total of 365 patients were excluded from the study (n=256 at LAEDS, n=109 at NEDS). Not meeting inclusion criteria excluded 221 of the 365 patients (primarily not fulfilling diagnostic criteria) with a similar percentage being reported at each site. At NEDS 38 patients were excluded due to staff offering different interventions in view of lack of waiting list. Other reasons for exclusion accounted for 105 patients (n=88 at LAEDS, n=17 at NEDS), these included non-attendance of appointments, non-completion of assessment and specific therapy requirements as per clinician view this was particularly the case at NEDS. Six patients in NEDS were excluded for unknown reasons. Both sites reported only 1 patient each that was eligible but declined to take part. This left a total of 46 patients to be randomised (n=44 at LAEDS, n=2 at NEDS).

Allocation led to 32 patients being randomised to receive IPT-BNm and 14 to receive CBT-BN. A total of 22 patients completed their intervention, 35.7% for CBT (n=5) and 53.1% for IPT (n=17). The main reason for non-completion of therapy was drop-out (either prior to even beginning therapy or during the course of therapy), Drop-out rates for CBT were 35.7% (n=5) and 28.1% for IPT (n=9). Other reasons included: pregnancy, relocation and change of therapy model required.

Start of therapy self-report questionnaires were received from 21 patients (n=6 for CBT, n= 15 for IPT). Of the 5 patients who completed CBT, all 5 supplied end-of-therapy questionnaires whilst 12 out of 17 patients completing IPT returned their questionnaires at end-of-therapy. All patients who completed therapy were contacted 4 months after completion, unless it was deemed clinically inappropriate by the therapist or consultant. Many patients were lost to follow-up, with only 5 returning questionnaires at follow-up (n=1 for CBT, n= 4 for IPT). It should be noted that at time of completion of this report 3 patients were still to be followed up.

*Secondary Outcomes*

Comparison of the questionnaire data was done via t-tests when comparing within groups and Mixed ANOVA's when looking between groups.

Eating disorder behaviour and psychopathology.

Comparison of the start and end EDE-q scores and frequency of bingeing and purging for the CBT (n=5) and IPT (n =10) groups showed for CBT only a significant difference on eating concern ($p<0.05$). The IPT group showed a significant reduction in binge frequency ($p<0.05$) as well as weight concern. There was not enough data to make a comparison of CBT at start and follow-up. IPT (n=4) showed significant reduction ($p<0.05$) in binge frequency, eating concern, shape concern, global score and restraint ($p<0.01$). When CBT compared to IPT no significant differences were present on any items.

Depression & Anxiety

Comparison of the start and end HADS scores for the CBT (n=4) and IPT (n=8) groups showed no significant difference for the CBT group but a significant reduction for the IPT group ($p<0.05$) on both scales. Again, not enough CBT data was available to make a follow-up comparison, but IPT analysis showed no significant difference at follow-up (n=3).

Comparison of CBT to IPT found no significant difference of therapy on depression but a significant difference on anxiety ($p<0.05$).

Interpersonal Problems

Not enough data was available for the CBT group to make comparisons within or between groups.

Quality of Life

Not enough data was available for the CBT group to make comparisons within or between groups.

## Conclusions

Whilst the required number of patients were recruited in the time period specified the majority of these came from one site.

The small number of patients declining to take part was encouraging but the large numbers of dropouts from therapy is an issue. Whilst high dropout rates are not uncommon in eating disorder therapy (Fassino, Pierò, Tomba & Abbate-Daga, 2009), this needs to be considered when calculating time to recruit and numbers required initially to obtain the correct number of completers. In view of the small number of patients who were described to have fulfilled the inclusion criteria due to the lack of diagnosis and the offer of alternative therapy in light of the lack of waiting list, future RCT studies should include more than five centres, it should review inclusion criteria and apply for funding for a therapist so there is not a competition with waiting list.

## Patient and public involvement

The study has been created in collaboration with First Steps, one of the biggest eating disorders charity services in the UK. First Steps Derbyshire was founded back in January 2004 and works closely with patients. This service is run by a group of volunteers whose lives had been affected by eating disorders and left unable to get help for their condition due to a lack of understanding and service provision.

From the beginning, the project has been discussed and reviewed by the First Steps leadership. They commented on the project protocol and the methodology. First Steps were invited to be part of several meetings with the CI's but they were unable to attend. Therefore, telephone conversations were scheduled regularly for feedback in which PPI issues were discussed, including the plan for communication of the research to those accessing support and collection of feedback.

**Data sharing statement**
See link [https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253] for the NIHR position of the sharing of research data. The NIHR strongly supports the sharing of data in the most appropriate way, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic growth in the UK. All requests for data should be directed to the award holder and managed by the award holder.

**Disclaimer**
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This project was carried out between April 2013 and March 2015. This final report has not been peer-reviewed. The report was examined by the Programme Director at the time of submission to assess completeness against the stated aims.