

Launching a randomized controlled trial of mentalization based therapy in patients with eating disorders and borderline personality disorder traits: The NOURISHED Study

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ABSTRACT

The NOURISHED study is a treatment trial comparing two effective therapies; Mentalization Based Therapy (MBT) and Specialist Supportive Clinical Management (SSCM)

Who is it for?

Patients with Anorexia Nervosa (BMI >15), Bulimia Nervosa, Binge Eating Disorder or EDNOS and traits of Borderline Personality Disorder.

What is involved?

Randomisation into either therapy arm plus an additional 5 hours of contact with a dietician.

Assessments before treatment, at 6 months, 12 months and a follow up at 18 months.

The Therapies

MBT: Mentalization Based Therapy

A type of therapy focused on thoughts and emotions. It is used to treat patients with Borderline Personality Disorder.

It consists of one individual and one group session per week for a year.

SSCM: Specialised Supportive Clinical Management

SSCM has a supportive and educational approach to problems with eating and weight. It is used to treat patients with Anorexia Nervosa and Bulimia Nervosa

The trial provides 20 individual (no group) sessions with an SSCM therapist.

The Measures

Eating Disorders

Eating Disorder Examination (Fairburn, Cooper & O'Connor, 2008)

Borderline Personality Disorder and traits

Zanarini Rating Scale for BPD (Zanarini & Frankenburg, 2001)

Acts of Deliberate Self Harm Inventory

Mentalizing

Object Relations Interview (Diamond, Blatt, Stayner & Kalow, 1993)

Reflective Functioning Scale (Fonagy, Target, Steele & Steele, 1998)

Reading the Mind in the Eyes Test (Baron-Cohen, 2001)

Quality of Life

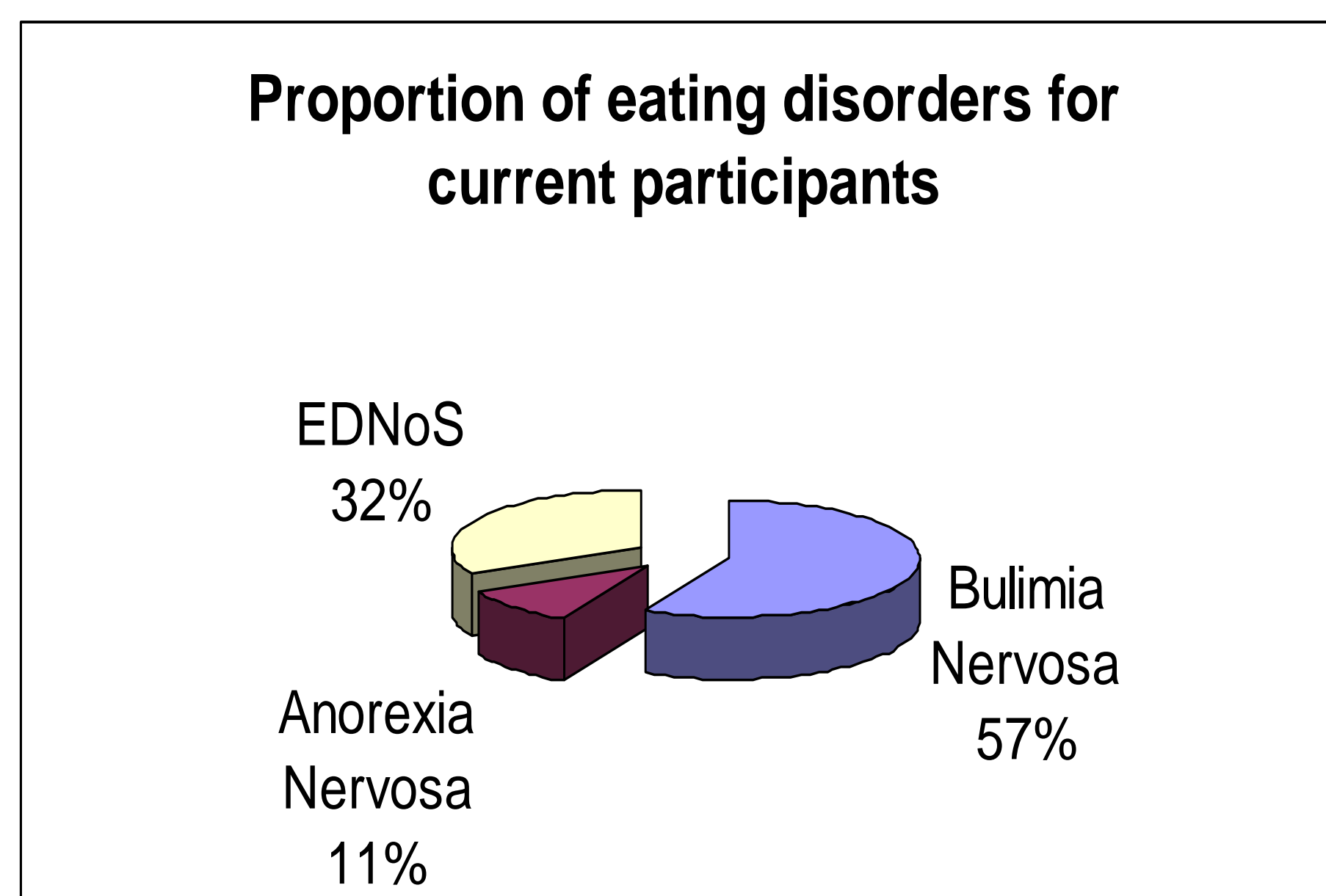
Adult Service Use Questionnaire

World Health Organisation

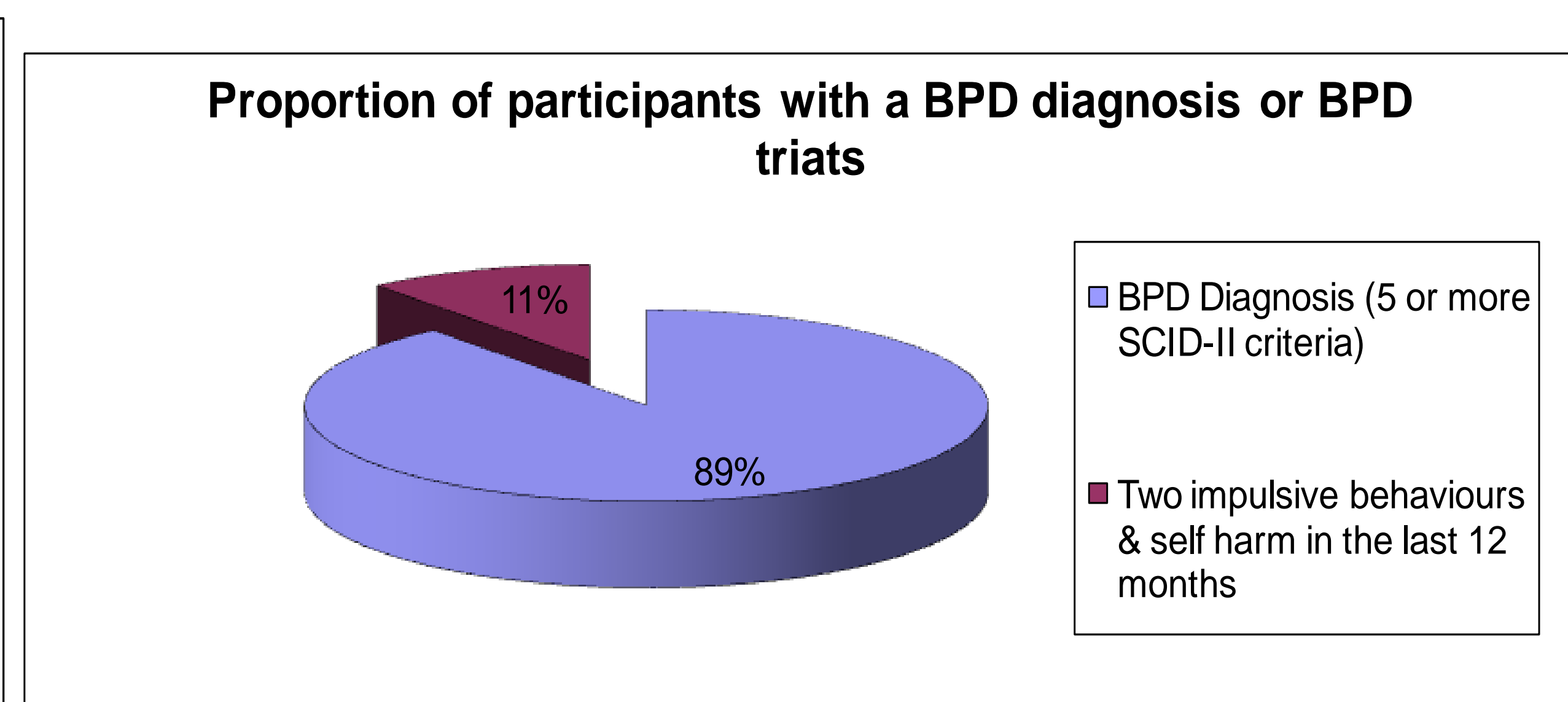
Quality of Life-BREF

Inclusion/Exclusion criteria

- 18 +
- Diagnosed with an eating disorder and has a BMI \geq 15
- Diagnosed with borderline personality disorder OR self harm/suicidal behaviour and 2 impulsive behaviours in the past 12 months
- Not an inpatient and has been discharged for at least 3 months
- Not currently receiving psychotherapy and has not had MBT in past 6 months.
- Not suffering from a psychotic illness and does not have organic brain disease.



The Participants So Far...



Overcoming obstacles associated with running a RCT

Obstacles in the initial stages:

- Unknown, new trial
- Clinicians are busy!

Solutions:

- Send out a newsletter
- Build contacts within the services you hope to receive referrals from
- We developed a simple electronic referral form for clinicians that they returned via email.

Obstacles during recruitment:

- Maintaining referral rates
- Ensuring referrals are appropriate
- Avoiding attrition

Solutions:

- Minimise the waiting time between referral and assessment and assessment and treatment.
- Be open and honest about any expected delays with participants and clinicians
- Be consistent about inclusion criteria and communicate this clearly.

Obstacles during randomisation:

- Timing
- Research workers must remain blind to treatment allocation

Solutions:

- NOURISHED uses an online system, developed by the Clinical Trials Unit at the Institute of psychiatry. This online system makes randomisation a simple automated process.
- Randomise in small block to ensure that it occurs as soon after assessment as possible

Obstacles when co-ordinating treatment pathways:

- Lack of resources- particularly lack of therapists
- Managing disappointment and complaints regarding treatment allocation
- Communication across professionals and services

Solutions:

- Motivate appropriate staff to participate by providing good supervision and emphasising professional development
- Informing participants over the telephone of their treatment arm gives them the opportunity to express any concerns and ask questions
- Liaise with care coordinators, GPs & other professional groups appropriately. Updating & monitoring online patient systems is useful.