

Improving the mother-infant relationship in the context of maternal eating disorder: a randomised controlled trial

Submission date 25/09/2004	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 08/12/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/01/2013	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

050892

Study information

Scientific Title

The influence of maternal eating disorder on infant development: an intervention study

Study objectives

Maternal eating disorders have been shown to be associated with adverse effects on mother-infant interaction and infant outcome. By the infants' first birthday mothers with eating disorders are considerably more likely to be involved in major episodes of mealtime conflict with their infants and controls. This study tested whether a video-feedback treatment targeted specifically at mother-child interaction improved that interaction, especially reducing mealtime conflict, and improving infant weight and autonomy, compared to a counselling treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 09/02/2009:

1. Oxfordshire Psychiatric Research Ethics Committee gave approval on the 4th August 1999 (ref: O99.35)
2. Royal Free Hospital & Medical School Local Research Ethics Committee gave approval on the 23rd June 1998 (ref: 76-97)

Study design

Multicentre, randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bulimia nervosa

Interventions

Eighty mothers attending routine baby clinics with bulimia nervosa or a similar eating disorder (i.e. a subtype of EDNOS) of the bulimic type, with infants aged four to six months, were randomised to the following:

1. Intervention group: video-feedback interactional treatment
2. Control group: non-directive supportive counselling

Both groups also received guided cognitive behavioural self-help for their eating disorder. Each group received 13 sessions altogether.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Level of conflict during the principal main meal of the day.

Key secondary outcome(s))

1. Infant weight
2. Other mother-infant mealtime interaction variables including maternal facilitation, maternal picking up of infant to cues (verbal and non-verbal), and maternal intrusiveness
3. Infant autonomy involving self-feeding initiatives
4. Maternal eating disorder psychopathology

Completion date

01/01/2006

Eligibility

Key inclusion criteria

1. Women between 18 and 45 years of age, with infants aged between four and six months
2. Met Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM IV) diagnostic criteria for an eating disorder, either bulimia nervosa or a similar form of eating disorder of clinical severity (i.e. a subtype of Eating Disorder Not Otherwise Specified [EDNOS]) of the bulimic type
3. The inclusion criteria were:
 - 3.1. The over evaluation of body shape or weight of clinical severity
 - 3.2. Recurrent episodes of loss of control over eating (i.e. subjective or objective bulimic episodes)
 - 3.3. Secondary social impairment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

Mothers with severe co-morbid psychiatric disorders were excluded.

Date of first enrolment

08/12/2004

Date of final enrolment

01/01/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Section of Child and Adolescent Psychiatry

Oxford

United Kingdom

OX3 7JX

Sponsor information

Organisation

University of Oxford (and Royal Free and University College Medical School) (UK)

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 050892)

Funder Name

The North Central London Research Consortium (NoCLoR) (UK) supported the recruitment process in primary care.

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2006		Yes	No