ISRCTN95026274 https://doi.org/10.1186/ISRCTN95026274

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

Submission date	Recruitment status	[X] Prospectively registered
25/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/12/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/01/2013	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Alan Stein

Contact details
Section of Child and Adolescent Psychiatry
University of Oxford
Warneford Hospital
Oxford
United Kingdom
OX3 7JX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
08/12/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
80

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
England

United Kingdom

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)

Sponsor details
Department of Psychiatry
Warneford Hospital
Oxford
England
United Kingdom
OX3 7JX

Sponsor type
University/education

Website
http://www.ox.ac.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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