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Contribution of FAMily THERApy to treat patients with anorexia nervosa (apport de la therapie familiale au traitement des patientes anorexiques mentales)

Submission date
11/05/2011

Recruitment status
No longer recruiting

Registration date
10/08/2011

Overall study status
Completed

Last Edited
23/05/2017

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Anorexia is a serious eating disorder where a person keeps their body weight as low as possible by eating less food, making themselves vomit, and exercising excessively. Anorexia can also have a big impact on the patient's family. Family therapy is therefore an important part of treatment for young people with anorexia. It involves the family discussing how anorexia has affected them, and can also help the family understand the condition and how they can help. The aim of this study is to find out whether family therapy, when added to the treatments traditionally used following hospitalisation (individual consultations and joint consultations with parents), leads to a more rapid recovery and fewer re-hospitalisations.

Who can participate?
Female patients aged 13 to 21 with anorexia

What does the study involve?
Participants are randomly allocated to one of two groups. The first group receives the "traditional" treatment program for anorexia, which includes individual consultations, regular interviews involving the parents, and, if required, individual psychotherapy with another therapist. The second group receives the "traditional" program plus family therapy, which consists of a monthly session conducted by two family therapists and including the patient and her siblings and parents.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Mutualist Montsouris Institute (France)

When is the study starting and how long is it expected to run for?
January 1999 to July 2002

Who is funding the study?
1. French Ministry of Health (France)
2. Public Assistance Hospitals of Paris (France)

Who is the main contact?
Dr Nathalie Godart

Contact information

Type(s)
Scientific

Contact name
Dr Nathalie Godart

Contact details
Psychiatry Service
Mutualist Montsouris Institute
42 Boulevard Jourdan
Paris
France
75014

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
aom97133

Study information

Scientific Title
Comparison of adjunctive FAMily THERApy and treatment as usual following inpatient treatment for anorexia nervosa in adolescents: a single-centre randomised controlled trial

Acronym
THERAFAM

Study objectives
The adjunction of family therapy intervention, focusing on the improvement of the intra-familial dynamics, would be associated with a better outcome than that of the usual multi-dimensional treatment program alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
Advisory Committee on Protection of Persons in Biomedical Research (Comité Consultatif de Protection des Personnes dans la Recherche Biomédicale) (CCPRB), 02/10/1998

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Anorexia nervosa

Interventions
Treatment program as usual versus adjunctive family therapy

Treatment as usual (TAU) : consisted in ambulatory care initiated before hospital discharge and was tailored according to the mental and physical state of the patient. It included individual consultations, regular interviews involving the parents, and, if required, individual psychotherapy with another therapist.

At each appointment, the psychiatrist conducted clinical investigation of the patients mental state, eating habits, medical condition, and psychosocial environment. In addition, the psychiatrist provided support, coordinated services (e.g., general practitioner, psychotherapist, dietician or nutritionist, social worker, and school), prescribed medication as necessary, and offered parental support and guidance regarding conflicts they had with their daughter. Parents were advised to be supportive but to leave decisions about food to the adolescent and to discuss the difficulties they observed not directly with their daughter during or after the meal, but at the time of the consultations with the psychiatrist and their daughter. In addition, nutritional/dietetic advice was provided to the patients who were not gaining weight or not gaining sufficient weight.

Family therapy (FT) : was designed by our team as one component of a multi-dimensional outpatient care program. We considered AN as a disorder resulting from multidimensional

pathways. In interaction with premorbid personality or predispositions, the intra-familial dynamic was conceptualised as potentially influencing the occurrence and maintenance of the patients eating problems.
The main aims of FT were :
1. To construct and maintain the therapeutic alliance
2. To identify areas of individual responsibility and clarify inter-generational boundaries
3. To promote abilities to protect, contain and provide support to the family
4. To enable appropriate expression and management of conflict
5. To enable the family to rediscover its own resources and strengths
6. To restore a collective sense of family identity
7. To develop the patients autonomy

Accordingly, FT focused not only on issues in the here-and-now, but also on unresolved issues from the past, as well as on expectations of how these might impact the future. Sessions focused on the familial dynamic as a whole and did not address eating behaviors directly (which were addressed by the reference psychiatrist). The sessions included the patient, her parents, and her siblings if they were over the age of 6 and living in the home. They lasted approximately 1h 30min and took place every three or four weeks. To optimise outcome, the frequency of sessions was flexible. FT continued for a period of 18 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Morgan and Russell outcome category (good or intermediate outcome versus poor outcome) measured at 18 months

Secondary outcome measures
1. Global Outcome Assessment Scale (GOAS) total score
2. AN symptoms or their consequences [body mass index (BMI), amenorrhoea, Eating Disorder Inventory (EDI) scores]
3. Social adjustment and the number of hospitalisations in the course of follow-up

Overall study start date
30/01/1999

Completion date
31/07/2002

Eligibility

Key inclusion criteria
1. 13 to 21 year old females
2. Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) diagnosis of anorexia nervosa (AN)
3. Aged under 19 at illness onset
4. AN duration more than 3 years at admission to the hospital
5. Hospitalised in inpatient unit for AN

6. Living in the Paris metropolitan area
7. Have never received family therapy (FT) (the patient could receive appropriate medication)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
60: 30 in each arm

Key exclusion criteria
1. Inability to speak or read French and/or understand the interview questions
2. Any metabolic pathology interfering with eating or digestion (e.g., diabetes) or psychotic disorder
3. This criterion also concerned the patient's parents

Date of first enrolment
30/01/1999

Date of final enrolment
31/07/2002

Locations

Countries of recruitment
France

Study participating centre
Mutualist Montsouris Institute
Paris
France
75014

Sponsor information

Organisation
Public Assistance Hospitals of Paris (France)

Sponsor details

c/o Mr Christophe Aucan
DRCD Hôpital Saint Louis
Carré Historique - Secteur gris - porte 23
1 Avenue Claude Vellefaux
Cedex 10
Paris
France
75475

Sponsor type
Hospital/treatment centre

Website
http://rechercheclinique.aphp.fr/-Notre-equipe-.html?rubrique

ROR
https://ror.org/00pg5jh14

Funder(s)

Funder type
Government

Funder Name
French Ministry of Health (France) (CRC 97012)

Funder Name
Assistance Publique - Hôpitaux de Paris (aom97133)

Alternative Name(s)
Assistance Publique Hôpitaux de Paris, Assistance Publique–Hôpitaux de Paris, AP-HP

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
France

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?
Protocol article	protocol	01/12/2006		Yes	No
Results article	results	01/12/2012		Yes	No