Cost effectiveness in treatment of Anorexia Nervosa

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23072

Source
NTR

Brief title
TBA

Health condition

either Anorexia Nervosa or
Other Specific Feeding and Eating Disorder (OSFED) – subtype ‘atypical anorexia nervosa’, according to DSM-5 criteria

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Remission defined as a return to a healthy body mass index (BMI>18.5).

Secondary outcome

- Remission of eating pathology as measured with the EDE-Q at 9 months and 24 months post baseline (Fairburn & Beglin,
1994, Pennings & Wojciechowski, 2004)
- Quality adjusted life year (QALY) gains cumulated over the first 12 months post baseline, as measured with the EQ-5D-5L
using Dutch tariffs (Versteegh et al, 2016) and ICECAp-A-NL (H. Al-Janabi & J. Coast, 2010).
- Cumulative costs (treatment costs, other health care costs, patients' out-of-pocket costs, and costs stemming from
productivity losses owing to absenteeism and presenteeism) over the full 24 months follow-up period as measured with the
TiC-P (Hakkaart-van Roijen et al, 2002).
- CSQ patient satisfaction

Study description

Background summary

Top-clinical care (TCC) of anorexia nervosa (AN) is associated with an average treatment duration between 12 ~ 24 months.
The treatment duration of the new time-limited psychological (TLP) treatments for AN (MANTRA, CBT-E and SSCM) is
expected to be brought down to 6~12 months. In this context we will test the following primary hypothesis:
1. TLP for AN will reduce treatment duration and hence treatment costs relative to TCC (cost-minimisation hypothesis).
In addition, the study will evaluate the following secondary hypotheses:
2. In the TLP condition 50% of the AN patients will have reached treatment response (BMI>18.5) at 9-months follow-up, but
at that time point the response rate in the TCC condition clocks 25% (cost-effectiveness hypothesis),
3. Compared to TCC, the greater speed of recovery under TLP translates into a larger health gain in terms of EQ-5D-5L
QALYs (cost-utility analysis).
Finally, the flanking implementation study will produce a well-tested implementation plan for future rollout and scale up, should
the new LTP combined with SDM be proven cost-effective.
The study will therefore produce the following deliverables:
1. Clinical evaluation of the relative speed of recovery in TLP vs TCC with regard to BMI>18.5 remission rates at t6, t9 and
t12.
2. Cost-minimisation analysis of the health care costs of TLP vs TCC over the full follow-up period of 24 months.
Cost-effectiveness analysis of the incremental costs per sustained remission over the full 24-months follow-up period.

3. Cost-utility analysis assessing the longer-term incremental cost-ultility ratio of TLP vs TCC over the full follow-up period
of 24 months.
4. A well-tested implementation plan for future rollout and scale up.

Study objective

Three new time-limited psychological (TLP) treatments for anorexia nervosa (AN) will much reduce both treatment
duration and costs relative to top-clinical care (TCC).

Study design

• Preparation 1-6
• Recruitment and baseline assessment: month 7-18
• Assessment T1: month 10-21
• Assessment T2: month 13-24
• Assessment T3: month 16-27
• Assessment T4: month 19-30
• Assessment T5: month 22-33
• Assessment T6: month 25-36
• Assessment T7: month 28-39
• Assessment T8: month 31-42
• Data analyses and dissemination of results: month 42-48

Intervention

INTERVENTIONS
MANTRA, SSCM and CBT-E have been evaluated, and proven to be equally effective. At present there are no theoretical or
empirical grounds for allocating individual patients to one of these new and effective treatments (described below). Although the
three treatment methods are different in content, the outcomes are similar in BMI and eating disorder pathology (Schmidt et al.,
2016, Zainal et al., 2016, Schmidt et al., 2015, Waterman et al., 2014, Touyz et al., 2013). Further research in to these
treatments will be needed to decide which treatment to apply for a specific patient. Until then, offering these three options gives
us the opportunity to add to further research. Perhaps more importantly, the equivalence in effectiveness of MANTRA, SSCM
and CBT-E offers an excellent opportunity for shared decision-making, where patients receive the option to choose between the
three interventions. In this context, it is worth noting that shared decision-making may strengthen the patient’s autonomous
motivation for treatment on the understanding that autonomous motivation is one of the few predictors of treatment response

(Steiger et al., 2017). To be able to allocate patients to these three treatments, we were advised by the authors of these RCTs,
all international leading clinical and scientific experts in the field of eating disorders, to employ shared decision-making to
allocate patients to one of three treatment methods. After assessment at Altrecht Eating Disorders Rintveld, patients will be
informed about the three treatment-options and asked to decide. All the three treatments are time-limited (BMI<16: 40 sessions,
BMI=17.5: 30 sessions, BMI<18.5: 25 sessions, BMI>18,5: 20 sessions) and aimed at recovery from AN. Offering these three
treatments and asking patients with AN to choose, is advised in the NICE guidelines and in the ZSES (Zorgstandaard
Eetstoornissen, 2017).

At this moment a pilot RCT is being conducted (a cooperation between the University of Utrecht and Altrecht Eating Disorders
Rintveld) to further implement protocolled shared decision-making and to evaluate its impact on autonomous motivation.
The practitioner conducting the intake will apply shared decision-making following the steps described in Stiggelbout et al.
(2015):
1. The practitioner tells the patient a decision is to be made and the patient's opinion is important.
2. The practitioner shows the video in which the options are explained, and pro's and con's are mentioned. The patient is
given a folder and a decision-tool which summarizes the information given in the video.
3. The practitioner and patient discuss the patient's preferences and the practitioner supports the patient in deliberation.
4. The practitioner and patient make or defer the decision, and discuss possible follow-up. This gives patients the
opportunity to deliberate with family or friend, prior to making the decision.

Three new treatments:
[1] MANTRA (The Maudsley Anorexia Nervosa Treatment for Adults, Schmidt et al., 2014) is an evidence-based
cognitive-interpersonal treatment of anorexia nervosa. MANTRA incorporates recent findings from the field of
neuropsychological, social cognitive and personality trait research in AN. It includes both intra- and interpersonal maintaining
factors, and proposes strategies for addressing these. It is modularized with a clear hierarchy of procedures and tailored to the
needs of the individual following a workbook (Schmidt et al., 2013). Patient and therapist describe what perpetuating aspects
maintains AN and how to intervene.
Patients are given an active role in treatment. Their personal workbook structures treatment and describes the nine modules
and homework assignments. The patient and the practitioner will meet once a week for 50

minutes in the first phase of the
treatment. Later in the course of treatment appointments can be planned less frequently.
Next to paying attention to weight gain and working towards a normal eating pattern, attention is paid to motivation for change
and the maintaining factors which are specifically important for the individual patient. These factors are described in ‘a vicious
flower’. Following this vicious flower, treatment goals are discussed. Issues that can be covered in this treatment are:
• A thinking style characterized by inflexibility, excessive attention to detail and fear of making mistakes
• Impairments in the social-emotional domain
• Positive beliefs about how AN helps the person to manage their life
• Unhelpful responses of others
At end of treatment, attention is paid to relapse-prevention.

[2] CBT-E (Cognitive Behaviour Therapy- Enhanced, Fairburn, 2008) is based on a trans-diagnostic model for eating
disorders. The aim is to identify processes that are operating in the individual patient, thus creating a tailor-made treatment that
fits the patients’ psychopathology. It is emphasized that it is better to do a few essential aspects well in changing behaviour (by
focusing on the most perpetuating behaviours), instead of doing many things suboptimal. Secondly, it is based on the idea that
people learn things by doing (it is a type of behaviour therapy).
Normalising the eating pattern and regaining weight are key-features from the start of treatment.
Maintaining factors described in the individual model and targeted in treatment can be:
• overvaluation of body and weight (in which other way may a person appreciate herself?)
• overvaluation of control over eating behaviour
• dietary restrain
• dietary rules
• being underweight
• changes in eating pattern coherent with event or mood
Patients are asked to fill in a food diary.
In the first weeks sessions (of 50 minutes) are scheduled twice a week, thereafter once a week and at the end of treatment
once in the two weeks. At end of treatment attention is being paid to relapse-prevention.

[3] SSCM (Specialist supportive clinical management, McIntosh et al., 2006) was originally developed by researchers as a
control condition to test other psychotherapeutic treatments for AN (McIntosh et al, 2006). They described what therapists
should do in their treatment sessions, which turned out to be an effective method. SSCM combines aspects of clinical
management and supportive psychotherapy within sessions emphasizing normalization of eating and restoration of weight,
specialist psychoeducation and focus on other symptoms, such as vomiting or overexercising.

The remainder of the sessions
focus on content dictated by the patient (McIntosh et al. 2010).
Sessions can be weekly or once every two weeks, depending on the patients' needs.
In this treatment, attention is paid to:
• Psychoeducation on eating disorders and food
• The history of the eating disorder
• The causes of the eating disorder
• Motivation for change and what might happen if the AN is not treated
At end of treatment attention is being paid to relapse-prevention.
When required treatment can be upscaled from outpatient care to day-care or inpatient treatment. This will be done when
outpatient treatment does not lead to weight gain or improvement of the eating pattern, or when the somatic condition requires
inpatient care. Also focused treatment for co-morbid disorders such as schema therapy and EMDR can be offered. A medical
doctor, dietician, and psychiatrist are available for consultation when needed. Treatment uptake will be closely documented.
Staff has been trained to follow the new treatment protocols. Therapists have been trained in the treatments and have to attend
inter-vision sessions to discuss their therapies. In addition, supervision will be used to ensure protocol adherence and treatment
integrity.

TREATMENT AS USUAL / COMPARISON
As comparator the best alternative treatment is used, which is offered at the top-clinical centre for eating disorders:
Rivierduinen Eating Disorders Ursula. At Ursula care is offered according the following principles: at assessment diagnoses are
made by a multidisciplinary team of experienced clinicians (psychologists and psychiatrists) specialized in eating disorders,
according to the DSM-5 criteria using questions of two standardized semi-structured interviews: the Eating Disorder
Examination and the Longitudinal Interval Follow-up Evaluation. The Dutch multidisciplinary guidelines for eating disorders are
the starting point of treatment. The guidelines offer a large range of treatments based on evidence and expert consensus, and
can be applied flexibly. Treatment is tailored to the needs of the individual patient and innovative therapies can be applied when
the guidelines are not sufficient. The vast majority of patients are treated as outpatients (95%). A minority receives intensive
(day and residential) treatment. The program consists of normalization of eating behaviours, discussion of daily problems,
goals, and evaluations. Also Cognitive Behavioural Therapy, (multi) family therapy, psycho-education, social skills training,
psychomotor therapy, and art therapy are part of the programme. Most of the therapy is conducted in groups. A medical doctor,
dietician, and psychiatrist are available for consultation when needed.

Contacts

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Eligibility criteria

Inclusion criteria

The group of eating disordered patients at the two participating centres encompasses adult (age between 18-60) patients who
are referred to secondary and tertiary treatment at the participating centers, and who have either anorexia nervosa or Other
Specific Feeding and Eating Disorder (OSFED) – subtype ‘atypical anorexia nervosa’, according to DSM-5 criteria. All three
new TLP treatments are aimed at recovery of the eating disorder pathology. Hence, patients included in the study, will be
selected on their wish to recover from their eating disorder.

Exclusion criteria

Patients treated under a legal measure will be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-01-2020
Enrollment:	166
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
We will discuss this with our legal department: we want to share our data but have to be mindful of regulations concerning patients' data

Ethics review

Positive opinion

Date:	14-11-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8162
Other	Altrecht : 852002029

Study results