

**ROCKET LAUNCH**  
**Study protocol**

**Implementation and Evaluation of a Standardized Protocol for  
Treatment of Restrictive Eating Disorders With Pronounced  
Starvation During the First Month in Child Psychiatric  
Outpatient Care.**  
**The ROCKETLAUNCH Project.**

**August 13 2019**

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### Introduction

Restrictive eating disorders with pronounced starvation is one of the most acute and life-threatening conditions in child and adolescent psychiatry. The restrictive eating disorders are Anorexia Nervosa, Atypical Anorexia Nervosa and ARFID.

It is crucial that the treatment of these conditions initially focuses on the starvation and achieves a medical stabilization with weight gain for those with an underweight (1). Recent research has shown that weight gain during the first month of treatment gives a better prognosis (2-5). Family-based treatment has the best support in research to achieve weight gain for adolescents with anorexia nervosa (6). Intensive family treatment initially in treatment, which focuses on putting an end to starvation, has proven to be able to achieve sustainable results even after 30 months (7). However, only 26.4% of children and adolescents with an eating disorder in Sweden receive family therapy according to RIKSÄT, the national quality register for eating disorders (8).

The initial treatment for many young patients with an eating disorder is in-patient care, according to RIKSÄT, it is the first registered treatment for 25% of the patients. This underlines the need for a better treatment effort initially. An early-established evidence-based family therapy in outpatient care can prevent the need for hospitalization at a psychiatric clinic, and also improve the prognosis

In order to improve the treatment that patients with restrictive eating disorder and pronounced starvation within Region Skåne receive today, a working group was started in 2017 with the task of drawing up guidelines for these patients who were treated in Child and Adolescent Psychiatry in Skåne. The working group consisted of representatives from the 5 local child psychiatric units that have eating disorder teams, in Kristianstad, Lund, Ystad, Malmö and Helsingborg, as well as the regional unit at Region Skånes Center of Eating Disorders (RSÄ) in Lund.

In order to get a picture of how the initial treatment for new patients with pronounced restrictive eating disorder that comes into treatment at Child and Adolescent Psychiatry works today, the working group collected information from the units within Child and Adolescent Psychiatry in Skåne. The mapping that was done consisted of the 10 most recent patients who came into treatment before November 20, 2016. The information collected was:

- From the initial assessment: Age, waiting time from notification to the first time offered and weight and length.

- After one month: Number of visits during the first month and weight after one month.

In total, information about 60 patients was collected.

What the working group found was:

- The age is the same, 15.0 years, at start of treatment.

- How quickly you can offer time for the first visit varies between units. For three units it was around three weeks (19.6, 22.3 and 23.7 days respectively). For the other three units around two weeks (12.1, 15.1 and 15.6 days respectively). The working group has agreed that a waiting period of more than two weeks is not acceptable.

- The number of visits during the first month looks quite similar. An average of 6.2 (between 4.7 and 7.6) is just over a visit a week, which seems reasonable since it means on average more than one visit a week. Some of these visits prove to be visits within day care.

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- The weight gain for the whole group was on average 0.98 kg, but some patients had lost weight. The range was -4.2 kg – 6.0 kg. Of the patients that had a weight below 90%EBW at start of treatment 23.7% gained 2 kg or more during the first month of treatment.
- How much the patients have gained weight during the first month varied between the different units. The average weight gain varied between 0.1 kg and 1.5 kg between the units. It is lower than 2.0 kg, which is the lowest level of weight gain during the first month that international research has proven to be indication of a better prognosis.

### Aim of the project

Based on the data presented above, it became evident that there is a development work to be done regarding mainly three areas:

1. To be able to offer faster times to begin treatment.
2. Improve the treatment content by implementing the evidence-based treatment model.
3. Offer equal care regardless of where you live.

As part of this development work, the working group has drawn up basic guidelines for intensive treatment during the first month, an evidence-based treatment that focuses on helping the patient normalize eating and lifting the starvation. Treatment with a focus on normalizing the eating will of course continue even after the first month. The working group has also specified which patients should be relevant to this treatment program. Below are the guidelines developed by the working group.

### Guidelines for initial treatment of restrictive eating disorders with pronounced starvation

#### Patients

ROCKETLAUNCH treatment is applicable only to patients with an eating disorder with pronounced starvation. The patients included in ROCKETLAUNCH treatment are those who meet the weight criterion for anorexia nervosa according to DSM 5:

"Restriction of energy intake relative to requirements, leading to significantly low body weight in the context of age, sex, developmental trajectory, and physical health. Significantly low body weight is defined as a weight that is less than minimally normal or, for children and adolescents, less than that minimally expected."

For adolescents this represents a weight loss of about 85% of expected weight or lower. For prepubertal children this does not apply, since they have a more pronounced physical impact even at a minor weight loss. Previously overweight patients presenting with weight-loss, where the current weight is within the range of normal BMI, may be included in the ROCKETLAUNCH. These are patients who meet the criteria for atypical anorexia nervosa according to DSM 5:

"All of the criteria for anorexia nervosa are met, except that despite significant weight loss, the individual's weight is within or above the normal range".

Also relevant for ROCKETLAUNCH treatment are patients with Avoidant/Restrictive Food Intake Disorder (ARFID), meeting the following DSM-5 criteria:

"Persistent inability to adequately meet the body's needs for nutrients and energy"

and:

"Significant weight loss (or failure to achieve expected weight gain or faltering growth in children)"

and/or:

"Significant nutritional deficiency".

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The factor which decides if a patient should be included for ROCKETLAUNCH treatment is when pronounced starvation effects are seen at the physical examination, as outlined in the manual.

ROCKETLAUNCH treatment thus pertains to three DSM-5 diagnoses:

- Anorexia Nervosa
- Atypical Anorexia Nervosa
- Avoidant/Restrictive Food Intake Disorder

#### **First assessment:**

Whenever a young person diagnosed with an eating disorder is suspected to suffer from starvation, an assessment shall be offered promptly, normally at the latest within fourteen days. If significant cardiac symptoms are reported, assessment must be made within a few days. The treating service should be prepared to offer at least 1-2 visits a week directly at treatment start. The assessment includes the following:

- A medical assessment including a physical examination and blood tests (see national guidelines for relevant tests). An ECG should be requested in case of pronounced bradycardia. The assessment should focus on whether the patient suffers from pronounced starvation (see manual).
- Detailed background history including:
  - eating habits, including developmental trajectory
  - physical activity
  - the eating disorder's impact on family and siblings
  - parent's efforts to help their child
- Physiotherapy assessment is desirable, to assess issues pertaining to body image and excessive exercise
- Basic medical history, screening for any co-morbidity

Based on the assessment, one should primarily determine whether the patient is in starvation and ROCKETLAUNCH is applicable. If so, treatment begins instantly.

#### **Treatment during the first month.**

The treatment focusses with high intensity on medical stabilization and weight gain from the first visit. The goal of the treatment during the first month is a weight gain of at least 2 kg (exception made for atypical anorexia nervosa with a normal or high weight - where the goal is to achieve medical stabilization).

- The treatment always begins at the first visit. Both parents receive "parental allowance for a seriously ill child".
- The patient is put on sick-leave from school. It is important to reconsider this decision at every visit to minimize the time the patient is excluded from their natural social context. As soon as possible a gradual return to school should be instigated.
- At the first visit the clinician must clarify that the patient is suffering from a serious, life threatening condition, far too severe to be managed by the young person him- or herself. Then, the clinician has to charge the parents with the full responsibility for what their child should eat and to support all the meals.
- The treatment should focus on helping the parents to support each other with the difficult task of helping their child to eat.
- Parents should, if necessary, limit excessive physical activity.
- Following the first visit, a maximum of one week should pass until the second visit.
- Physical assessments should be done at least weekly.

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- If the patient has lost weight at the second visit, a family meal shall be scheduled within a few days.
- If the patient has not gained weight at the third visit, a second family meal is scheduled.
- If the patient has not reached the target weight gain during the first month, the Regional Eating Disorder Service (RSÄ) may be contacted for a case discussion.

Family meals may be arranged in day care settings, at home visits or at the outpatient clinic. The crucial element in the family meal is to help the parents to be more able support their ill child emotionally and help the child to eat food such as the parents believe their son or daughter needs. For guidelines on implementing the family meal, please see the manual.

### Standardized protocols and treatment manuals

Within the ROCKETLAUNCH project some standardized protocols and manuals have been developed:

1. Medical inclusion criteria: A manual for medical inclusion criteria has been prepared. There, it has been clearly specified what it means to be in a pronounced starvation, and how to determine how pronounced the starvation is based on the results of the assessment. It is on the basis of this assessment that one can decide whether the patient should be included in a ROCKETLAUNCH treatment.
2. Family therapy in case of restrictive eating disorder with pronounced starvation. First month. A manual in Swedish for the family therapeutic treatment based on the manuals used in the international research that showed that the best treatment method for restrictive eating disorders with severe starvation is family therapy (9,10). The manual describes how family therapy is carried out in the standardized care process, the guidelines outlines the central moments.
3. Family meal. A manual in Swedish for how to carry out a common family meal based on the manuals used in international research (9, 10).
4. Treatment course, somatic values. A standardized protocol that will be used regularly during the family sessions in order to communicate clearly how the somatic condition changes during treatment.
5. EBW%. When assessing underweight in children and adolescents with restrictive eating disorders, it is recommended to use the weight percentage calculated on the BMI value (11). In the project, the investigators have prepared a guide for how this calculation is made, where normal values for different ages are stated. This protocol is a support for the somatic assessment.
6. Blood Pressure. A compilation of blood pressure for different ages and also in relation to length, based on Swedish normal value (12). In support of the somatic assessment.
7. Pulse. A compilation of normal heart rate for different ages, based on a systematic review of current research (13).

### The importance of the project

The primary part of the project is to improve the prognosis for young newly diagnosed patients with severe restrictive eating disorders, primarily anorexia nervosa, and to reduce the need for in-patient psychiatric care. To achieve this, the project aims to spread competence and knowledge so that the Child and Adolescent Psychiatry services can offer equal care regardless of where you live. According to the national quality register RIKSÄT, only 26.4% of children and young people with eating disorders in Sweden receive the evidence-based family therapy. In addition, 25% are admitted to in-patient care as the first treatment intervention. There is a need to work more intensively to increase the accessibility of the

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treatment that is most effective and to prevent those who suffer from restrictive eating disorders has to be long times in hospitals.

### Implementation Preparation

Before the project starts, the investigators intend to make an employee survey. The purpose of the survey is to provide each clinic with a basis for planning and creating good conditions for the implementation of ROCKETLAUNCH. In the previous research (14), the areas that are affected in the survey have proved to be important for how well one can succeed in implementing new methods and way of working. In previous implementation within Child and Adolescent Psychiatry nationally within the framework of the so-called “Deplyftet”, where national guidelines for the treatment of depression were implemented, an employee survey was used to identify impeding and favorable factors. The purpose was that each unit should have knowledge of factors grouped as follows, in order to be able to design its specific implementation plan, factors such as:

1. Features of the innovation, the guideline itself and the manuals in this case.
2. Features of the user of the guideline, employees.
3. Characteristics of the target group, the patients.
4. Properties in the social environment and the organization.
5. Features in the system, economy and administration
6. How close to what is described in the guideline is the way of working today on the unit?

### Participants in the project

The project cover the Southern Healthcare Region in Sweden, and the eating disorder units in Skåne, Halland and Blekinge participate in the project. In addition, AnorexiBulimiCenter in Kalmar and Västervik are also involved in the project. This means that all patients with severe restrictive eating disorders in Skåne, Halland, Blekinge and Kalmar can be expected to participate in the project.

### Education and training

In order for the therapists to be able to work according to the guidelines developed, the investigators have to carry out training in the method. The training will be held by Ulf Wallin and Marie-Louise Majewski. What is planned so far is:

- 6 training days for all those who work with these patients, who are planned to be implemented during the first year, and will be located in Lund for those who work in Skåne. In Halmstad for those who work in Halland. In Karlskrona for those who work in Blekinge. In Kalmar for those who work in Kalmar County.
- Seminars on the guidelines in smaller groups in the workplaces, which are planned on the basis of how education and competence among the staff looks at the individual workplace.
- Training around family meals with those who work in the same workplace, and co-training with other units so the investigators can know that the patients are offered the same treatment.

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### Supervision

Supervision in the clinical work of family therapy in eating disorders will be given continuously during the three years at the various workplaces, mainly by Ulf Wallin.

### Research and evaluation

#### Scientific issues

There are four central issues regarding research and evaluation.

1. Are the prerequisites for implementing the guidelines for RAKETSTART optimal? The investigators want to make an assessment of how the clinicians who will carry out the treatment in the project will experience opportunities and difficulties.
2. Are the waiting times shortened and are the recommended treatment intensity maintained? An important part of the study is to see if the healthcare system can improve its care for these life-threatening conditions.
3. Are the patients improved in the expected extent? The amount of patients that gained 2 kg or more before the project has been 23.7% which means that a greater proportion than that of the intervention group should gain 2 kg or more during the first month of treatment. In a study of FBT 35% of the patients gained 1.8 kg during the first 4 weeks (4), which should be the proportion that the investigators aim for.

One particular issue will be to evaluate the effect of family meals that will only be offered to those patients who do not gain weight as expected. The importance of family meals has been very sparingly evaluated in international research (15).

4. Is the financial burden for family and health care reasonable in relation to the effect? Project ROCKETLAUNCH involves an intensive treatment, which places great demands on both healthcare practitioners and the patient and family. In order to safely justify that this effort is reasonable, the investigators are making a health economic evaluation.

#### Methods

##### Participants

The inclusion criteria for the patients are that they fulfill one of the three diagnoses Anorexia Nervosa, Atypical Anorexia Nervosa or ARFID and that they are in a pronounced starvation. All patients and their parents that are offered treatment within the ROCKETLAUNCH project and that fulfill the inclusion criteria will be asked to participate in the research. The treatment will take place at Child and Adolescent Psychiatry in the Southern Healthcare Region in Sweden. The Eating Disorder units in Skåne, Halland and Blekinge will participate in the project, AnorexiBulimiCenter in Kalmar and Västervik will also be involved in the project. This means that all patients with severe restrictive eating disorders in Skåne, Halland, Blekinge and Kalmar can be asked to participate in the project. In all it is 12 different out-patient clinics that will give the treatment.

At each out-patient clinic data from the 10 previous patients will be gathered in order to compare the treatment as usual with the ROCKETLAUNCH intervention.

#### Outcome

The investigators are going to evaluate:

1. The implementation, how the clinical organization and the therapists follow the treatment protocol.
2. The waiting time and the frequency of treatment sessions.

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3. Amount of in-patient care.

4. The outcome of the patient, with focus on weight gain and medical stabilization. The investigators will also look at psychological improvement, and evaluate the improvement in specific eating disorders psychopathology and improvement in general psychiatric psychopathology.

5. The health economic cost.

The main outcome variables, such as weight gain, waiting time, frequency of treatment sessions and amount of inpatient care will be compared with the patient and families that have been in treatment before the ROCKETLAUNCH project started.

### Data Collection

#### Patient that had been in treatment before ROCKETLAUNCH

Data from the patients who have been in treatment before the project started and meet the medical inclusion criteria will be collected. Data from ten patients at each participating unit on will be collected from the case records.

- The first visit: Age, waiting time from notification to the first time offered and weight and length.
- After one month: Weight. Number of visits to reception and number of visits with family meal. Amount of in-patient care. If the family and patient have been in day care or in-patient care, days of admission will be counted.
- After one year: Weight and length and diagnostic status. Amount of in-patient care.

The information about patients before the start of the project will be collected from the same time period at all units.

The data from this early group will be compared with the collected data from the group that will participate in the project.

Weight is regularly monitored in the treatment according to the protocol. These data will include 120 patients from before the project start and approximately 150 patients annually who will enter the project.

#### The intervention group.

The same data as for the former patients will be collected:

- The first visit: Age, waiting time from notification to the first time offered and weight and length.
- After one month: Weight. Number of visits to reception and number of visits with family meal. Amount of in-patient care. If the family and patient have been in day care or in-patient care, days of admission will be counted.
- After one year: Weight and length and diagnostic status. Amount of in-patient care.

The course of the eating disorder is primarily intended to be followed via the national quality register "RIKSÄT", and the additional modules that will be there. The supplement to RIKSÄT is called the FEDiCS (Feeding and Eating Disorder Clinical Support System). What is included is:

EDDA Standardized diagnostic interview based on DSM 5, which is making the interviewer able to make an eating disorder diagnosis. It can be used from the age of 12. (Prepared by RIKSÄT).

MINI kid (16). A diagnostic interview on other psychiatric conditions.

EDE-Q (Eating Disorder Examination - questionnaire) (17). A self-assessment form for eating disorder symptoms. For patients from the age of 12.

PSR (Psychiatric Status Rating Scale) (18). Clinical assessment of the severity of the eating disorder and if the eating disorder is in remission. Rating is made by the interviewer.

RCADS-C (Revised Children's Anxiety and Depression Scale and Subscales) (19, 20). A self-

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rating questionnaire which is a screening for symptoms of anxiety, obsession, compulsion and depression. For patients from the age of 12 years.

#### Health economics analysis.

In collaboration with the Department of Economics, Lund University, the investigators will carry out a health economic analysis, both with regard to cost efficiency and cost analysis. Information that will be generated to calculate the cost includes:

1. Training time for staff.
2. Number of days that patients and family are hospitalized / family treatment apartments.
3. Number of visits to the clinic for the patient and their parents, calculated for each occupational category.
5. Type of medication, their dosage, start date, end date.
6. Parent's income.
7. Parents' parental allowance.
8. Family trips to the hospital.
9. Amount of in-patient care.

Information needed to calculate the effect:

EQ-5D (EuroQol) questionnaire that measures health-related quality of life. The investigators will use two different, one for the patient (EQ-5D-Y) (21), and one for parents (EQ-5D) (22). These two questionnaires should be completed both at the start of treatment and at the conclusion of the treatment.

#### The therapists

The therapists will complete a questionnaire that follows the two family therapy manuals in order to describe the fidelity to the manual. One questionnaire for each family.

#### Timetable

During the three years, the clinical data and data from the FEDiCS will be collected. During the first year, the project will focus on training in the treatment method, and supervision. The investigators will start collecting data from the various units. During the second year the investigators will continue collecting data, and the supervision. During the third year, the clinical activities of the project and the supervision continue. Evaluation of the project becomes important during the third year, in order to compile information about this is a project that should be permanent. During this year the investigators will compile data from year 1 and year 2 and process and begin writing reports and articles.

#### Ethical consideration

The study was approved by the Swedish Ethical Review Authority Dnr 2019-01852.

#### Funding

The project has received grants from the Kamprad Family Foundation.

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