PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Group-Based Treatment of Adolescent Female Conduct Disorders: The Central Role of Emotion Regulation

Trial Acronym

Fem-NAT-CD Intervention

URL of the trial

http://www.femnat-cd.eu

Brief Summary in Lay Language

Conduct and Oppositional Defiant Disorder (CD/ODD) is one of the most common reasons for referral to Child and Adolescent Mental Health Services and has a highly negative impact on the affected individual as well as their families, teachers, and society. Although the number of females exhibiting serious aggressive behaviours is growing, the majority of studies have focused on male subjects only. The health care delivery system as currently configured does not sufficiently meet the needs of children and adolescents with CD/ODD. There is an urgent need for effective treatment options to prevent negative development (e.g. persisting aggression problems, premature pregnancy, school breakup, drug abuse and delinquency).

In the research project, funded by the EU, the causes and treatment of CD/ODD will be investigated especially for female adolescents aged from 12-20. The aim of this subproject is to examine the effectiveness of a 12-week group-based training to improve emotion regulation for girls with CD/ODD which are living in youth welfare institutions.
Furthermore, we want to clarify if the effects are measurable in different domains: Are the girls able to apply the learned strategies? Does the brain process emotions in a better way? Therefore we examine possible changes not only with questionnaires, but also with neuroscientific methods. In addition we want to ascertain which girls benefit from the training and which not.

Brief Summary in Scientific Language

Conduct Disorder (CD) (according to DSM-IV-TR 312.8; ICD-10 F91, F92), a mental disorder of childhood and adolescence, is characterised by repeated patterns of rule-breaking, aggressive or defiant behaviour that exceeds normal age appropriate behaviour, with enormous costs to the individual and to society. Affected males and females bear a high risk of carrying the disorder into adulthood, developing persisting Antisocial Personality Disorder or other adjustment problems.
In line with ICD-10 and the NICE Guidelines (2013) oppositional defiant disorder (ODD) is subsumed under the term ‘conduct disorders’ (according to ICD-10 F91.3,

DSM-IV-TR 313.81) in order to refer to all variants of aggressive behavior and conduct problems.
The key deficit in both ODD and CD are problems in emotion regulation and have to be considered when delineating intervention programmes.

To date, treatment programmes are not widely implemented and evaluated in middle childhood and adolescence, although adolescence is one of the key periods for intervening, most notably in CD girls due to their late onset. To date, there is an internationally recognized lack of randomised controlled trials (RCTs) demonstrating efficacy of new, promising and innovative intervention programmes in female adolescents with CD.

The implementation of a cognitive-behavioral dialectical-behavioural oriented treatment programme (START NOW) for female adolescents with CD profoundly gives consideration to the repeatedly formulated necessity to develop integrative intervention approaches deriving from sound theoretical rationales, addressing core deficits of CD patients and applying gender specific strategies and materials.

The planned RCT will for the first time systematically investigate the efficacy of START NOW in terms of enhanced emotion regulation in female CD patients.

Organizational Data

- DRKS-ID: **DRKS00007524**
- Date of Registration in DRKS: **2015/12/18**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EKNZ 2014-075 , Ethikkommission Nordwest- und Zentralschweiz(EKNZ)**

Secondary IDs

Health condition or Problem studied

- ICD10: **F91 - Conduct disorders**
- Other: **DSM-IV-TR 312.8: Conduct disorder**
- ICD10: **F92 - Mixed disorders of conduct and emotions**
- Other: **DSM-IV-TR 313.81: Oppositional Defiant Disorder**
- ICD10: **F91.3 - Oppositional defiant disorder**

Interventions/Observational Groups

- Arm 1: **Intervention Programme START NOW (cognitive-behavioral, dialectical-behavioral oriented group training for the improvement of emotion regulation of female adolescents with CD) with weekly group and individual sessions within 12 weeks (group sessions: 10 x à 90 min, 2 x à 180 min at the beginning and at the end).**
- Arm 2: **Waitlist**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Pre-post treatment change in number of CD/ODD symptoms as assessed by a standardised, structured psychiatric interview on DSM-IV-TR diagnostic criteria (K-SADS-P, CD/ODD section) between baseline and post intervention (within 2 weeks after the end of the 12-week intervention) as well as between baseline and 3-month follow-up.

Secondary Outcome

Questionnaires (self-/staff-/caretaker-reported) at pre-/mid-/post-intervention and follow-up: emotion regulation, stress and behavioural problems/aggression

- Number of negative consequences received within an institution, number of unauthorized leaves at pre-/mid-/post-intervention and follow-up

- Computer tasks at pre- and post intervention: emotion regulation

- ECG (pre-/mid-/post-intervention) and MRI (pre-post-intervention): change in heart rate variability and neural functional correlates

Countries of recruitment

- CH **Switzerland**
- DE **Germany**
- NL **Netherlands**

Locations of Recruitment

- other **Jugendhilfeeinrichtungen, [---]***

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/01/14**
- Target Sample Size: **128**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **12 Years**
- Maximum Age: **20 Years**

Additional Inclusion Criteria

Current Diagnosis of CD (DSM 312.8) or ODD (DSM 313.81), sufficient writing and reading skills (German or Dutch), written informed consent and legal guardian consent (for participants <18 years) (must be available before enrollment in the trial)

Exclusion criteria

History of or current clinical diagnosis of autism spectrum disorder according to ICD-10, DSM-IV-TR or DSM-5,history of or current clinical diagnosis of Schizophrenia according to ICD-10, DSM-IV-TR or DSM-5, current clinical diagnosis of Bipolar Disorder or Mania according to ICD-10, DSM-IV-TR or DSM-5, Fetal Alcohol Syndrome (FAS) according to ICD-10, DSM-IV-TR or DSM-5, known monogenetic disorder, genetic syndrome (e.g. Fragile-X-Syndrome, Down's Syndrome, Prader-Willi-Syndrome), any chronic or acute neurological disorder, e.g. cerebral palsy, motor problems due to motor or metabolic disorder, current treatment for epilepsy, history of medium to severe traumatic brain injury (mild traumatic head injury without loss of consciousness is not an exclusion criterion), any valid indication of IQ < 70 (e.g. special education, previous test results), severe medical condition interfering with therapy, incl. suicidal ideation, concurrent group based psychotherapeutic treatment

Addresses

- **Primary Sponsor**

  University Basel Department of Child and Adolescent Psychiatry
  Ms. Prof. Dr. Dr. Chrstina Stadler
  Schanzenstrasse 13
  4056 Basel
  Switzerland

  Telephone: **+41 61 265 89 70**
  Fax: **[---]***
  E-mail: **christina.stadler at upkbs.ch**
  URL: **www.upkbs.ch**
- **Contact for Scientific Queries**

  University Basel Department of Child and Adolescent Psychiatry
  Ms. Prof. Dr. Dr. Chrstina Stadler
  Schanzenstrasse 13
  4056 Basel
  Switzerland

  Telephone: **+41 61 265 89 70**
  Fax: **[---]***
  E-mail: **christina.stadler at upkbs.ch**
  URL: **www.upkbs.ch**
- **Contact for Public Queries**

  University Basel Department of Child and Adolescent Psychiatry
  Ms. Prof. Dr. Dr. Christina Stadler
  Schnanzenstr.13
  4056 Basel
  Switzerland

  Telephone: **+41612658970**
  Fax: **[---]***
  E-mail: **christina.stadler at upkbs.ch**
  URL: **www.upkbs.ch**

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

  Directorate-General for Research and Innovation European Commission

Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)

Directorate-General for Research and Innovation European Commission
B-1049 Brussels
Belgium

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*