Trial Description

Title

STAR: Self-Injury: Treatment, Assessment, Recovery - Online Intervention for Adolescent Nonsuicidal Self-Injury – A randomized controlled trial

Trial Acronym

STAR

URL of the trial

http://www.star-projekt.de

Brief Summary in Lay Language

This study represents a randomized controlled trial on the efficacy of an online intervention for young people with nonsuicidal self-injury. 2000 adolescents and young adults who are recruited online will be invited to participate. Approximately 700 participants are expected to join the study and will be randomly assigned to the intervention group or the control group. In the intervention condition, an online version of a recently evaluated cognitive behavioral manual for a brief intervention (10-12 therapy sessions) will be applied. In addition the intervention group has access to fully automated psychoeducational materials online. The control condition has only access to psychoeducational materials. Access is provided for 4 months. A stronger reduction of self-injury is expected for participants of the intervention group.

Brief Summary in Scientific Language

The present project aims to develop and evaluate the first online intervention for adolescents and young adults with NSSI (Nonsuicidal self-injury disorder) based on the content of a lately evaluated face-to-face short term program for adolescents engaging in NSSI - “The Cutting Down Programme” (CDP). 2.000 youths with NSSI will be assessed and followed up by using an online platform. Out of them, 700 will participate in either an online psychoeducation only (n=350) or an additional E-treatment program (n=350). An assessment 4 months after baseline (end of treatment assessment), and follow-up evaluations 12 and 18 months after baseline (follow-ups) will be assessed. The new CDP-online intervention will be tested in a randomized controlled trial (RCT). It is hypothesized that participants receiving CDP-online report greater reduction in the frequency of NSSI after one year compared to those receiving an online psychoeducation intervention only.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00014623**
- Date of Registration in DRKS: **2018/05/22**
- 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.: **S-288/2018 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **X84.9 - [generalization X84: Intentional self-harm by unspecified means]**

Interventions/Observational Groups

- Arm 1: **The control intervention provides static online psychoeducative content on the causes, consequences, and concomitants of NSSI (Nonsuicidal self-injury). This module is available for both groups. The intensity of use is determined by the participant. The content is available for four months.**
- Arm 2: **The intervention group offers an add-on online intervention which is based on a recently evaluated cognitive behavioral manual for a brief intervention - the Cutting-Down Programme (CDP). This manualized, short-term psychotherapy is based on elements of cognitive-behavioral therapy and dialectical behavior therapy and is specifically tailored to the treatment of nonsuicidal self-injury (NSSI) in adolescents. The treatment length is 8 to 12 sessions. The manual organizes the treatment into four modules that could be expanded with optional exercises. Module 1 focused on providing knowledge about CBT (Cognitive behavioral therapy) and NSSI as well as promoting therapy motivation. The focus of module 2 was on identifying the reasons for the NSSI. In module 3, the patients tested alternative behaviors to NSSI, and module 4 comprised stabilization of the alternative behaviors. The content of the intervention is structured in a manual for participants and a separate manual for therapists that is feasible for translation into an online intervention. The modules in the manual were all developed based on a comprehensive literature review on the intervention of NSSI including associated psychological phenomena. In addition to individual online sessions, the participating adolescents will be encouraged to do certain homework, which facilitates preparation and post-processing of the online sessions in order to increase their effectiveness. Homework assignments have to be completed also online. The intervention will solely be provided over the**

internet. Participants are encouraged to complete quizzes to ensure understanding of the provided content. Within the CDP, the intervention is delivered via both personal chat as well as telephone calls with the responsible case manager and assisted by automatic content of the web-based platform. The CDP-online group will further have access to a moderated group chat facilitating exchange with other participants and providing peer support. All participants within the CDP-online group are monitored for NSSI on a weekly basis within a monitoring module. The content is available for four months.

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

The main outcome of the trial is a significant reduction in the frequency of NSSI (Nonsuicidal self-injury) within the past 3 months assessed by the NSSI Severity Questionnaire (NSSV-SG; In-Albon, Niedtfeld, & Kaess, 2017) at 1-year follow-up.

Secondary Outcome

Secondary outcome criterion is the amelioration of well-being in the KIDSCREEN-10 (Ravens-Sieberer U, Erhart M, Rajmil L, Herdman M, Auquier P, Bruil J, et al., 2010). Additionally, comorbid psychiatric disorders (e.g. BSL-23; Bohus M, Kleindienst N, Limberger MF, Stieglitz R-D, Domsalla M, Chapman AL, et al.; 2009; PHQ-A; Kroenke K, Spitzer RL, Williams JB; 2001) as well as suicidal behavior assess by the Paykel Suicide Scale (PSS, Paykel ES, Myers JK, Lindenthal JJ, Tanner J. Suicidal feelings in the general population: a prevalence study. Br J Psychiatry J Ment Sci. 1974;124:460–9.) will be evaluated.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Onlinerekrutierung, Onlinebefragung**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/11/01**
- Target Sample Size: **700**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **15 Years**
- Maximum Age: **21 Years**

Additional Inclusion Criteria

According to the criteria of the NSSI disorder (Nonsuicidal self-injury) provided by the DSM-5, eligible participants (between 15 and 21 years of age) are required to have engaged in NSSI at least five days during the previous 12 months. No current psychotherapeutic treatment. Furthermore, all participants need to provide informed consent.

Exclusion criteria

Exclusion criteria are acute symptoms and other mental states that require psychiatric care within a face-to-face setting.

Addresses

- **Primary Sponsor**

  Kinder- und Jugendpsychiatrie HeidelbergZentrum für Psychosoziale Medizin
  Mr. Prof. Dr. med. Michael Kaess
  Blumenstraße 8
  69115 Heidelberg
  Germany

  Telephone: **+49 6221 566914**
  Fax: **+49 6221 566941**
  E-mail: **Michael.Kaess at med.uni-heidelberg.de**
  URL: **http://www.klinikum.uni-heidelberg.de/Klinik-fuer-Kinder-und-Jugendpsychiatrie.2258.0.html**
- **Contact for Scientific Queries**

Contact for Scientific Queries

Kinder- und Jugendpsychiatrie HeidelbergZentrum für Psychosoziale Medizin
Mr. Prof. Dr. med. Michael Kaess
Blumenstraße 8
69115 Heidelberg
Germany

Telephone: **+49 6221 566914**
Fax: **+49 6221 566941**
E-mail: **Michael.Kaess at med.uni-heidelberg.de**
URL: **http://www.klinikum.uni-heidelberg.de/Klinik-fuer-Kinder-und-Jugendpsychiatrie.2258.0.html**

- **Contact for Public Queries**

Kinder- und Jugendpsychiatrie Heidelberg, Zentrum für Psychosoziale Medizin
Ms. M.Sc. Psych. Alexandra Edinger
Blumenstraße 8
69115 Heidelberg
Germany

Telephone: **+496221 566914**
Fax: **+496221 566941**
E-mail: **star.projekt at uniklinik-ulm.de**
URL: **http://www.klinikum.uni-heidelberg.de/Klinik-fuer-Kinder-und-Jugendpsychiatrie.2258.0.html**

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.)**

Bundesministerium für Bildung und Forschung Dienstsitz Berlin
Friedrichstraße 130 B
10117 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.bmbf.de**

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.*