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DRKS00021256

@myTabu - A placebo controlled randomized trial of a guided web-based intervention program for convicted child sexual abusers and child sexual exploitation material offenders

Organizational Data

DRKS-ID:
DRKS00021256

Recruitment Status:
Recruiting complete, study complete

Date of registration in DRKS:
2020-04-24

Last update in DRKS:
2024-10-29

Registration type:
Prospective

Acronym/abbreviation of the study

@myTabu

URL of the study

http://www.kompetenz-gegen-missbrauch.de/mytabu *(Link: http://www.kompetenz-gegen-missbrauch.de/mytabu)*

Brief summary in lay language

BACKGROUND: Sexual child abuse is one of the most harmful events for children. Treatment programs for child abusers are able to significantly reduce the risk to re-offend. In spite of some established treatment projects in primary prevention, treatment offers for child abusers conditionally released from prison are scarce – especially in rural areas. This is alarming, since most re-offences take place after release from prison. Community supervision is effective in reducing re-offenses but only with high financial effort. Online interventions provide a cost-efficient alternative and can be applied smooth in rural areas.

OBJECTIVES: The project aims to develop for the first time an online intervention for discharged child abusers during community supervision. It aims to establish an online risk assessment, which enables practitioners to assess the risk to re-offend repeatedly and efficient. It provides information on the effectiveness of the online

intervention.

METHODS: The effectiveness of the online intervention are evaluated in two federal states (Lower-Saxony and Baden-Wuerttemberg).

EXPECTED RESULTS: The project provides a cost-efficient online intervention, already integrated in community supervision of Lower-Saxony and Baden-Wuerttemberg. Legal guidelines are provided as well as an efficient way to assess the risk to re-offend online. By doing so, re-integration of child abusers into society is im-proved resulting in higher security for children.

Brief summary in scientific language

Background: There is a high demand for evidence-based and cost-effective treatment concepts for convicted child sexual abuser (CSA) and child sexual exploitation material offenders (CSEMOs) under community supervision (CS). The @myTabu-consortium developed a guided web-based intervention for convicted CSAs and CSEMOs under CS consisting of six online modules targeting psychological meaningful risk factors. The study aims to evaluate the effectiveness of this guided web-based intervention in reducing dynamic risk factors and the risk to re-offend compared to a placebo condition. Furthermore, these dynamic risk factors are measured before and after every module to evaluate their individual effectiveness to reduce the respective risk factor as well as risk to re-offend.

Methods: The methodological design is a placebo controlled randomized add-on trial (N = 582) with follow-ups at six time points. The placebo condition controls for attention and expectation effects and comprises the same amount of modules with a comparable time effort as the experimental intervention. The trial is conducted as an add-on to community supervision as usual. Primary outcomes are dynamic risk factors assessed by self-report risk assessment tools and officially recorded re-offenses.

Discussion: To the best of our knowledge, the study compares for the first time the (cost-) effectiveness of a guided web-based intervention for convicted CSAs and CSEMOs under community supervision against a placebo condition.

Health condition or problem studied

Free text:

Sexual offenders which are under community supervision (§§ 56, 57, 68 ff. StGB) because of child abuse (§§ 176, 176a, 176b StGB) or child sexual exploitation material use (§ 184b StGB).

Healthy volunteers:

No Entry

Interventions, Observational Groups

Arm 1:

The experimental condition is a web-based intervention conceptualized as a structured intervention which comprises six modules in a fixed order, each targeting different risk factors. The content is

provided online by psycho-educational blocks complemented by short videos and images. Eighteen different online exercises (e.g., fill-in-the-gap, multiple choice questions) are used to enable the user to train and to internalize the most important aspects of the psycho-educational blocks. The exercises are provided as self-guided tasks with automatic feedback and as coach-guided tasks, where the feedback is provided by online coaches. The feedback of the online coaches is manualized. Since guided web-based interventions are more effective than pure self-help programs, coach-guided exercises are one possibility to enhance the effectiveness of web-based interventions (Wild et al., 2019). Virtual participants accompany the participant, talk/narrate about their experiences and make suggestions from the perspective of someone who is also affected. Furthermore, an in-app messaging system allows the user to communicate in real-time with the online coach as well as the SO. In order to enhance the extrinsic motivation of participants, an automatic reward system is integrated based on a gamification approach. That is, participants receive coins for each finished block and virtual awards. The coins can be changed into Euros and when the participant has collected at least 20 Euros, he can request the payout online. The participant can receive a maximum compensation of 120 euros. Finally, an online first aid kit is provided for each user and filled with individual skills prepared by the user itself during the web-based intervention.

The provided content is divided into six online modules. The participant has one month to complete each module, thus the duration is 24 weeks. Each module is further divided into four sessions. Each session has a duration of about 60 minutes and the participant has one week to finish a session.

Arm 2:

The control condition is a placebo web-based intervention with the same mode, dose, and amount of support and attention by supporting online coaches as in the experimental condition - but the content of the modules is unrelated to the proposed dynamic risk factors. The content of the placebo condition comprises information on healthy living, e.g., healthy nutrition, sporting activities, or healthy sleep. The amount of exercises is the same as in the experimental condition, but exercises are specifically designed to not induce any sustainable effect.

Endpoints

Primary outcome:

Index of Desistance, IoD: The first primary endpoint is the difference in the pre-post changes of the Index of Desistance (IoD) in the experimental condition compared to the placebo condition. The IoD represents the individual risk to re-offend assessed through self-report. This composite endpoint reflects improvements with regard to psychological meaningful risk factors, offense behaviors as well as offence-related behaviors that have not been registered or convicted yet. The IoD comprises three self-report instruments, which were developed and are currently evaluated by members of the @myTabu-consortium: (1) The Acute-2007-SR is an online and self-report adaption of the Acute-2007 (hanson et al., 2013) risk-assessment tool in order to assess treatment induced short-term changes in recidivism risk factors. (2) The Checklist of Treatment Effectiveness (CTE) is developed to assess the differential treatment-induced changes in every individual treatment module. Thus, the CTE assesses the constructs that are targeted by the six modules of the invention. (3) The Checklist of Behavioral Misconduct (CMC) measures offense-related behavior as well as low- and high-level new offences. Offense-related behavior includes behaviors which are relevant for individuals previously convicted of sexual offenses prior to a new offense (e.g., recidivistic behavior like, e.g., if person convicted of sexual abuse of minors visits a playground or a school). The CMC could be seen as post-treatment deviant behavioral indicators. It is assessed pre and post each intervention module. The IoD will provide the individual risk level to re-offend by summing up the scores of the Acute-2007-SR, CTE, and CMC.

Officially recorded re-offenses in the experimental condition compared to the placebo condition are the second primary endpoint. Officially recorded re-offenses (based on the iformation of the Bundeszentralregisters, BZR) are obtained five years after last patient out.

Secondary outcome:

Pre-post difference scores of psychometric questionnaires in the experimental condition compared to the placebo condition are defined as the secondary endpoints. The questionnaires are assessed before and after each intervention module. This approach allows evaluating each web-based intervention module individually with regard to its targeted risk factors.

Corrections Victoria Treatment Readiness Questionnaire. The Corrections Victoria Treatment Readiness Questionnaire (CVTRQ Casey et al., 2007) is a self-report measure designed to assess treatment readiness in offenders who have been referred to a cognitive skills program. It comprises 20 items and consists of four scales: (1) Attitudes and motivation, (2) emotional reaction, (3) offending beliefs, and (4) efficacy. Each item has to be answered on a five-point Likert-scale. The CVTRQ shows an acceptable convergent validity, discriminant validity as well as predictive validity (Casey et al., 2007). To the best of our knowledge, there is no validated German version of the CVTRQ. @myTabu translated the CVTRQ. The translation was checked and translated back into English. Resulting differences due to adaptation were inspected and discussed in terms of item content.

Readiness to Change Questionnaire. The Readiness to Change Questionnaire (RCQ; Rollnick et al., 1992) is a 12-item questionnaire originally designed to identify the stage of change reached by an excessive drinker of alcohol. The German version (RCQ-D; Hannöver et al., 2002) was adapted within the project by changing the questions regarding drinking of alcohol in questions regarding the offences of CSAs and CSEMOs. Responses are made on a five-point Likert-scale. The RCQ-D as well as the RCQ shows good psychometric properties (Hannöver et al. 2002). Psychometric properties of the version adapted for CSAs and CSEMOs are not available yet.

Optimized Questionnaire for the Measurement of Psychological Reactance. The Questionnaire for the Measurement of Psychological Reactance (QMPR, Merz, 1983) is a questionnaire for the assessment of psychological reactance defined as the theory that people resist attempts to constrain either their thoughts or their behaviors. The Optimized Questionnaire for the Measurement of Psychological Reactance (OQMPR; Herzberg et al., 2002) is a German variant of the QMPR. The OQMPR consists of 12 statements on a five-point Likert-scale. It has a test-retest-reliability of rtt = .85 (Herzberg et al., 2002).

Social support questionnaire, short version. The seven-item short version of the Social Support Questionnaire (F-SozU K-7) is an efficient questionnaire to assess perceived social support (Dunkel et al., 2005). Each item comprises a five-point Likert-scale. Internal consistency of the original long version showed Cronbach's alpha between .81 and .93 (Sommer et al., 1989).

University of California Los Angeles Loneliness Scale. The UCLA Loneliness Scale (Russel et al., 1996) consists of 20 items in order to assess subjective feelings of loneliness. The German short version (Bilsky et al, 1989) consists of 12 items on a four-point Likert-scale. A German study with CSOs and CSEMOs demonstrated a high reliability of alpha = .92 (Neutze et al., 2012).

\paragraph{Bumby Molest Scale.} The Bumby Molest Scale (BMS; Bumby, et al., 1996) is a self-report questionnaire which assesses cognitive distortion in CSOs (German Version: Feelgood et al., 2009). It consists of 38 items on a four-point Likert-scale. The German version shows good construct validity,

internal consistency and test-retest reliability (Feelgood et al., 2009).

Social Problem-Solving Inventory Revised. The Social Problem-Solving Inventory Revised (SPSI-R; D'Zurilla et al., 2002) is a self-report questionnaire for the assessment of the five dimensions in the social problem-solving model: (1) positive problem orientation, (2) negative problem orientation, (3) rational problem solving, (4) impulsivity/carelessness style, and (5) avoidance style. The SPSI-R consists of 52 items on a five-point Likert-scale. It shows good psychometric properties for sexual offenders (Wakeling et al., 2007). The validated German version is a short form consisting of 25 items (Graf et al., 2003).

Difficulties in Emotion Regulation Scale - Sub-scale Impulsivity. The Difficulties in Emotion Regulation Scale (DERS; Gratz et al., 2004) is a self-report questionnaire to assess emotion dysregulation. The sub-scale 'impulse control difficulties' is used as outcome measure and comprises five items on a five-point Likert-scale. The German version is used, which shows a good internal consistency, construct and predictive validity (Ehring et al., 2008).

Negative Affect Repair Questionnaire. The Negative Affect Repair Questionnaire (NARQ; Scherer et al., 2013) is a self-report questionnaire to assess strategies to regulate negative affect in a systematic manner. It consists of 17 items on a five-point Likert-scale and provides a good construct validity. Reliability scores (Cronbach's alpha) for the three NARQ scales ranged between .71 and .80 (Scherer et al., 2013).

Barratt Impulsiveness Scale. The Barratt Impulsiveness Scale (BIS-11, Patton et al., 1995) is a questionnaire developed to assess the personality/behavioral construct of impulsiveness. It consists of 30 items on a four-point Likert-scale. The German short version (BIS-15, Meule et al., 2011) consisting of 15 items is used in the clinical trial. The BIS-15 is an efficient measure of impulsiveness with good internal consistency (alpha = .81; Meule et al., 2011).

Coping Using Sex Inventory. The Coping Using Sex Inventory (CUSI; Cortoni et al., 2001) is a questionnaire to assess the presence of and the degree to which sex was used to deal with problematic situations. It consists of 16 items on a five-point Likert-scale with a satisfying internal consistency (cortoni et al., 2001). The translation was checked and translated back into English by the authors. Resulting differences due to adaptation were inspected and discussed in terms of item content. For another German translation, it has been shown that the CUSI is able to assess therapy-induced changes of CSOs (Beier et al., 2015).

Hypersexual Behavior Inventory – 19. Sexual preoccupation is assessed by the Hypersexual Behavior Inventory – 19 (HBI-19; Klein et al., 2014). The HBI-19 is a three-factor measure (coping, control, and consequences) developed to assess hypersexual behaviour. The instrument consists of 19 items (e.g., “I use sex to forget sorrows of everyday life.”) answered on a scale from 1 (never) to 5 (very often). The maximum score is 95, with higher scores indicating a higher level of sexual preoccupation. The questionnaire was shown to have good reliability (alpha = .90) and validity (Klein et al., 2014).

Emotional congruence with children. Emotional congruence with children is assessed by the Questionnaire on Emotional Congruence with Children – Revised (EKK-R; Mack et al., 2012) including three factors (special relationship to children, immaturity, and emotional closeness to children). Twenty items are answered on a four-point scale. The questionnaire demonstrated good reliability (alpha = .80) and validity (Mack et al., 2012).

Specific self-efficacy for modifying sexual interest in children. Specific self-efficacy for modifying

sexual interest in children (SSIC) is assessed by the Self-Efficacy for Modifying Sexual Interest in Children Scale (SSIC-Scale; Tozdan et al., 2015). Six items on the participant's conviction regarding being able to change their sexual interest in children (e.g., "I can succeed in reducing my sexual interest in children.") were answered on a scale from 1 (do not agree at all) to 5 (totally agree). The maximum score is 30, with higher scores indicating a higher level of self-efficacy. The instrument was shown to have good reliability (alpha = .87) and validity (Tozdan et al., 2015). Four variables that were shown to be related to the SSIC (Tozdan et al., 2015, 2019) are also assessed: flexibility of sexual interest in children (three items on previous experiences concerning changes in the participants' sexual interest in children), exclusiveness of sexual interest in children (single-item question), motivation to change sexual interest in children (single-item question), and age of onset of sexual interest in children (single-item question).

Sexual interest in children. Sexual interest in children is assessed by two measurements. The Explicit Sexual Interest Questionnaire (ESIQ; Banse et al., 2010) directly assesses pedophilic interest. It consists of two scales measuring sexual behaviour (20 items, e.g., "I enjoyed orally stimulating a man.") and sexual fantasies (20 items, e.g., "I find it attractive to imagine a little boy sexually stimulating me."). All items are answered on a scale from 1 (totally disagree) to 5 (totally agree). The reliability of the instrument ranges between .86 and .97 (Banse et al., 2010). The second measurement is the Item 2a of the Sexual Outlet Inventory – Revised (SOI-R; Briken et al., 2010) which assesses the desire for sexual activity involving children on a visual analogue scale from 0 (desire is absent) to 100 (I have to act to satisfy the desire). Higher values on the scale indicate a stronger sexual interest in children (Briken et al., 2010).

Study Design

Purpose:
Treatment

Allocation:
Randomized controlled study

Control:
Placebo

Phase:
III

Study type:
Interventional

Mechanism of allocation concealment:
No Entry

Blinding:
Yes

Assignment:
Parallel

Sequence generation:
No Entry

Who is blinded:
Assessor, Data analyst, Patient/subject

Recruitment

Recruitment Status:
Recruiting complete, study complete

Reason if recruiting stopped or withdrawn:
No Entry

Recruitment Locations

Recruitment countries:
Germany

Number of study centers:
Monocenter study

Recruitment location(s):
Other community supervision Lower-Saxony, Other community supervision Baden-Wuerttemberg, Other community supervision Brandenburg, Other community supervision Rheinland-Pfalz, Other community supervision Nordrhein-Westfalen, Other community supervision Sachsen, Other community supervision Sachsen-Anhalt, Other community supervision Thüringen, Other community supervision Bayern, Other community supervision Hessen, Other community supervision Mecklenburg-Vorpommern, Other community supervision Berlin, Other community supervision Schleswig-Holstein

Recruitment period and number of participants

Planned study start date:
2021-01-01

Actual study start date:
2021-03-01

Planned study completion date:
2024-09-30

Actual Study Completion Date:
2024-09-30

Target Sample Size:
582

Final Sample Size:
369

Inclusion Criteria

Sex:
All

Minimum Age:
18 Years

Maximum Age:
no maximum age

Additional Inclusion Criteria:

(1) being under community supervision, (2) being convicted for at least one child abuse (§§ 176, 176a, 176b StGB) or child sexual exploitation material use (§ 184b StGB), and (3) being at least 18 years of age.

Exclusion Criteria

(1) a probation period shorter than six months at enrolment, (2) no access to a PC, tablet or smart phone, (3) a severe acute psychiatric disorder (e.g., acute psychosis), (4) a severe cerebro-organic disorder, (5) a severe cognitive impairment, (6) no banking account for receiving the allowance, (7) withdrawal of the informed consent, and (8) no written informed consent

Addresses

Primary Sponsor

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Investigator Sponsored/Initiated Trial (IST/IIT):
Yes

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Sources of Monetary or Material Support

Government or public funding body, financed by tax revenue (e.g. the German DFG, BMFTR)

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Ethics Committee

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Vote of leading Ethics Committee

Date of ethics committee application:
2020-01-27

Ethics committee number:
16/2/20

Vote of the Ethics Committee:
Approved

Date of the vote:
2020-02-21

Further identification numbers

Other WHO Primary Registry or Data Provider ID:
No Entry

EudraCT Number:
No Entry

UTN (Universal Trial Number):
No Entry

EUDAMED Number:
No Entry

IPD - Individual Participant Data

Do you plan to make participant-related data (IPD) available to other researchers in an anonymized form?:
No

IPD Sharing Plan:
No Entry

Study protocol and other study documents

Study protocols:
- Studienprotokoll (Version 1.0.0)

Study abstract:
No Entry

Other study documents:
No Entry

Background literature:
No Entry

Related DRKS studies:
No Entry

Publication of study results

Planned publication:
No Entry

Publications/study results:
No Entry

Date of the first journal publication of results:
No Entry

DRKS entry published for the first time with results:
No Entry

Basic reporting

Basic Reporting / Results tables:
No Entry

Brief summary of results:
No Entry