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Prevent it: Can internet-delivered psychotherapy reduce usage of online child sexual abuse material?

Submission date
03/01/2020

Recruitment status
No longer recruiting

Registration date
23/01/2020

Overall study status
Completed

Last Edited
28/12/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English Summary
Background and study aims
Child sexual exploitationis a major global health concern. The spread of child sexual material (CSAM) is rapidly increasing globally via online channels. This occurs frequently on the perpetrator forums located within the encrypted part of the internet called the 'darknet'. Despite technical, political and justice system initiatives to prevent online child sexual exploitation, there are no interventions with scientific research to support that they work.
The aim of this study is to evaluate if internet-delivered cognitive behavioral therapy (CBT) for users of CSAM is effective in reducing online sexual abusive behavior against children. CBT focuses on behavioral change. The therapy engages the participant to do home assignments and engage in specific actions to change their behavior. To know whether it is the therapy or just individual motivation and unspecific interaction with a therapist that is helpful, the intervention is compared to a psychological placebo.

Who can participate?
Study participants will be recruited globally via adverts on the internet, primarily on darknet websites. Anonymous adults wishing to stop using child sexual abuse material can participate.

What does the study involve?
The participants will be randomly allocated to one of two groups. Both groups will receive a program of 8 modules. Each module includes a short film, a homework assignment and individual feedback from a therapist. One group will receive a program based on CBT, the other will receive a psychological program that does not use CBT techniques, but includes similar films and interaction with the therapist.

What are the possible benefits and risks of participating?
If the therapy is effective, this benefit both the participants and victims of CSAM. Participants whose abusive behavior is not reduced may experience the study as distressing. To ensure the project acknowledges the interest of children, the researchers have collaborated not only with patient representatives but also with child rights advisors in designing the study.

Where is the study run from?
ANOVA clinic, Karolinska University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
April 2018 to December 2021

Who is funding the study?
World Childhood Foundation (Sweden), Karolinska University Hospital (Sweden) and the Swedish Medical Association

Who is the main contact?
Dr Christoffer Rahm, christoffer.rahm@ki.se

Study website
http://www.preventit.iterapi.se

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Prevent it: A single-blinded, randomized placebo-controlled trial of an internet-delivered cognitive behavioral therapy (CBT) for reducing usage of child sexual abuse material

Acronym
PRIOTAB-CBT (Pedophilia at Risk, Investigations of Treatment and Biomarkers – Cognitive Behavioral Therapy)

Study hypothesis
Treatment with the CBT manual "Prevent it", therapist-assisted internet-delivered psychotherapy, decreases the time spent on using child sexual abuse material (CSAM, also called 'child pornography'), as compared to a passive, equally long psychological placebo intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/03/2019, Överklagandenämnden för etikprövning [Ethics Review Appeals Board] (Vetenskapsrådet Box 1035, 101 38 Stockholm, Sweden; +46 08-524 870 00; kansli@stockholm.epm.se), ref: Dnr Ö 1-2019

Study design
A single-centre, single-blinded (participants), psychological placebo-controlled RCT of an online cognitive behavioral psychotherapy

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Condition
Usage of online child sexual abuse material (CSAM) in help-seeking adults

Interventions
The study participants are being randomized into two different arms after an assessment interview where inclusion criteria are being evaluated. Block-wise randomization is to be carried out by the study monitor Karolinska Trial Alliance (KTA).

The study has two arms:
Prevent It:
The intervention is delivered via internet and requires access to a computer or smartphone. It consists of eight modules, each addressing a specific theme, planned to be completed in about 1 week. Duration of therapy therefore is 2 months. The participant may progress at the time they choose, i.e. they can complete the modules faster or slower than in 1 week. They are requested to begin the first module within a week. At most, the participant has 2 months to complete the therapy. If not, therapy is terminated, even if the participant has uncompleted modules.
The therapy utilizes classical CBT. Common techniques are used to look at thoughts and feelings related to the problematic behavior, including home assignments in each module that are reported to the therapist, who then gives personal feedback. Feedback aims to reinforce positive behavioral change and present practical suggestions on complementary exercises, based on the participants' report.
Templates for answers are taken from a therapist manual but are individualized. Therapy is activating, non-judgmental and delivered with empathy and interest in the participant.
Each module consists of a 2- to 10-min film that the participant may watch as many times he or she likes, a home assignment and feedback on the assignment via message function in the platform.

Psychological placebo:
The psychological placebo is delivered in the same structure as the active intervention. This includes module format, length, and therapist interaction. The psychological placebo is designed to be perceived as therapy by a layman, while an expert would conclude it doesn't have CBT-specific content. Naturally, unspecific effects on behavior may be exerted by the empathy and interest from the therapist. The participant may also find it meaningful to engage in a study regarding CSAM, and every week do a structured rating of past week consumption of CSAM. These effects would be of the same kind as those of the placebo arm in a drug trial. The difference between "Prevent It" and psychological placebo are the CBT interventions.

All observations collected at all time-points will be included regardless of drop-out. The longitudinal data will be analyzed with linear random effect regression models to allow for potential intra-individual correlation. Due to the many repeat observations, the model can explore trends among individuals, detecting possible heterogeneity of treatment effect across participants. Because patients were randomized to either treatment group, no other covariates will be included. The investigators will evaluate the trajectories of the mean of the primary and all the secondary outcome variables in the two treatment groups over time. The participants will be measured at weeks 0 (baseline), 1, 2, 3, 4, 5, 6, 7, 8 weeks (end of treatment), and 12 weeks (1-month follow-up). The mean of each outcome variable will be estimated separately. For each outcome the investigators will use a linear mixed-effects regression model. All the models will include a binary treatment group indicator, binary indicator variables for each of the time occasions, and the interaction terms between the treatment indicator and the time occasions indicators. The models will also include a subject-specific random intercept, which will be assumed to follow a normal distribution. The random intercept will take into account the potential dependence in the repeated observations on each subject. The investigators will test for differences in the time trajectories between the treatment groups by testing the composite hypothesis that the interaction terms will be jointly equal to zero. All the tests will be Wald-type. To possibly improve the efficiency of the inference, the investigators will model the time trend during the 8-week treatment period with a second order polynomial. Because the polynomial model will be nested in the one that uses time indicator variables, they will use a Wald test to check which model fits the data better. The best fitting model will be used in the inferences.

Intervention Type
Behavioural

Primary outcome measure
Self-reported time spent viewing child sexual abuse material (CSAM) in the past week at baseline (the week before the start of the intervention) and week 8

Secondary outcome measures
1. Time spent consuming CSAM pre-treatment, weekly during treatment, post-treatment (8 weeks) and at follow-up (12 weeks)
2. Severity of CSAM consumed measured using the COPINE scale pre-treatment, weekly during treatment, post-treatment (8 weeks) and at follow-up (12 weeks)
3. Time spent socializing or interacting with children for sexual arousal pre-treatment, weekly during treatment, post-treatment (8 weeks) and at follow-up (12 weeks)
4. Time spent on behavior related to sexual interest in children pre-treatment, weekly during treatment, post-treatment (8 weeks) and at follow-up (12 weeks)
5. Quality of life assessed using the European quality of life visual analogue scale, which ranges from 0 to 100 pre-treatment, post-treatment and at 12-week follow-up

Overall study start date
01/04/2018

Overall study end date
31/12/2021

Eligibility

Participant inclusion criteria
1. Adult men and women located anywhere in the world
2. Aged 18 years or above
3. English speaking
4. Wishing to cease using CSAM online

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160 recruited in total, with 80 in the CBT arm, 80 in the psychological placebo arm

Total final enrolment
160

Participant exclusion criteria
1. Severe psychiatric illness (suicidal ideation, psychosis, intellectual disability, severe substance misuse)
2. No serious intention to participate, e.g. internet trolls

Recruitment start date
16/04/2019

Recruitment end date
20/09/2021

Locations

Countries of recruitment
Sweden

Study participating centre
ANOVA, a sexual medicine clinic
Karolinska University Hospital
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Sponsor information

Organisation
Karolinska University Hospital

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Sponsor type
Hospital/treatment centre

Website
www.karolinska.se

Funder(s)

Funder type
Charity

Funder Name
World Childhood Foundation

Alternative Name(s)
World Childhood Foundation Inc, Childhood USA

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
The results will be published in peer-reviewed scientific journals, and presented at scientific conferences.

Intention to publish date
01/06/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the sensitive nature of the content.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/11/2022	28/12/2022	Yes	No