



Effects of internet-delivered cognitive behavioral therapy on use of child sexual abuse material: A randomized placebo-controlled trial on the Darknet

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ABSTRACT

Introduction: The use of child sexual abuse material (CSAM) is an international public health and child protection challenge.

Objective: To investigate whether Prevent It, a therapist-supported, internet-delivered, eight-week, cognitive behavioral therapy, reduces CSAM viewing among users.

Methods: We conducted a global online single-blind (participants), parallel-group, superiority, randomized, psychological placebo-controlled trial with a one-month follow-up, 2019–2021 (ISRCTN76841676). We recruited anonymous participants, mainly from Darknet forums. Inclusion criteria: age 18+ years, past week CSAM use, and sufficient English language skills; exclusion criteria: severe psychiatric illness or non-serious intent to participate. The main outcome was change in self-reported, weekly viewing time from pre- to post-treatment, according to the Sexual Child Molestation Risk Assessment+.

Results: A total of 160 participants (157 male, 2 non-binary, and 1 not reporting gender) from all world regions (age intervals [%]: 18–29 [49]; 30–39 [30]; 40–49 [15]; 50–59 [6]) were randomized (1:1) to Prevent It (N = 80) or Placebo (N = 80). Between-group, intention-to-treat analyses suggested a significantly larger decrease in viewing time in Prevent It participants vs. controls pre- to post-treatment (Prevent It: N = 76, Placebo: N = 78, estimate –0.25, 95 % CI, –0.46 to –0.04, $p = .017$, Cohen's d 0.18). Negative side effects from treatment were fewer in Prevent It compared to control participants and neither group reported severe adverse events.

Conclusion: We provide initial support for the feasibility, efficacy, and safety of Prevent It to reduce CSAM viewing among motivated users. Further research is needed to validate these findings.

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1. Introduction

Online sexual offending against children, including the production, consumption and distribution of CSAM,¹ is a substantial human rights violation and a rapidly growing international public health problem. In 2021, the US National Center for Missing and Exploited Children amassed 29 million CSAM reports including almost 85 million videos and images sent to various cyber-tiplines worldwide (NCMEC, 2022). The United Nations Global Sustainable Development Goals for 2030 highlight elimination of all exploitation and violence against children (UN, n.d.). However, several systematic reviews indicate uncertain empirical support for preventive interventions for individuals who have offended or are at risk of offending sexually against children (Långström et al., 2013; Grønnerød et al., 2014; Walton and Chou, 2015) or victims of any age (Schmucker and Lösel, 2017; Gannon et al., 2019). In particular, very few RCTs² have been published, partly due to substantial ethical, legal, and logistic complications. For CSAM users specifically, research on treatment needs and effectiveness has just begun (Ly et al., 2018).

The Darknet is an online overlay network requiring specific browsers (such as the Tor browser). This level of secrecy can be used to circumvent surveillance and detection by law enforcement. Several forums on Darknet allow people with a sexual interest in children to anonymously gather and discuss or share CSAM (Kloess and Bruggen, 2021). A recent Darknet survey indicated that many users report seeking direct online contact with children for sexual purposes after viewing CSAM (Insoll et al., 2022). Also, 49 % reported thoughts of self-harm or attempting suicide, and 52 % difficulties in handling emotions and stress (Insoll et al., 2021). Since the vast majority of sexual offending remains undetected by law enforcement (Scurich, 2020), selective strategies to prevent child sexual abuse could complement the work of law enforcement authorities (Di Gioia et al., 2022).

However, various barriers make undetected offenders or individuals at risk of offending hard-to-reach for preventive efforts (Jahnke, 2018) – including shame, stigma, fear of conviction, and limited availability of treatment. We anticipated that barriers might be overcome by safe and anonymous iCBT.³ iCBT has been found to be efficacious for a variety of health issues (Andersson et al., 2019), and described as a promising treatment option to reduce symptoms of hypersexuality among men in a feasibility pilot study (Hallberg et al., 2020). However, iCBT has not been evaluated specifically for sexually abusive behavior.

The aim of this study was to evaluate the effectiveness of iCBT (i.e., Prevent It) among anonymous, help-seeking CSAM users recruited globally from specialized Darknet forums. Our primary hypothesis was that iCBT would reduce CSAM viewing time more effectively than psychological placebo.

2. Material and methods

2.1. Study design

This study is a single-blind (participants), parallel-group, superiority, psychological placebo-controlled, randomized clinical trial. It was conducted over the internet from Karolinska Institutet, Stockholm, Sweden. The trial was conducted in accordance with the Helsinki Declaration. Permission was granted on March 18, 2019 by the Swedish Ethics Review Appeals Board (no. Ö2019-1). The trial was pre-registered at the ISRCTN Registry (ISRCTN76841676, see study protocol in Supplement). The Karolinska Trial Alliance, an external independent regulatory unit, which had full data access and regularly monitored study documentation, reporting of adverse events, and adherence to the protocol, made

no major critical remarks. The study monitor also randomized the participants. The initial planning of the trial included a waitlist comparison. However, since the monitor inadvertently excluded the waitlist arm from randomization it was discarded before online study registration and enrolment.

2.2. Patient and public involvement

The idea to this study arose from qualitative interview responses provided by participants in a previous clinical trial of pharmacological treatment of pedophilic disorder (Landgren et al., 2020). Several participants suggested that active recruitment on the internet and online delivered therapy should be considered to motivate patients to seek help earlier [unpublished data]. A person with lived experience of pedophilia was involved in the planning and preparation of this project, together with therapists from the ANOVA sexual medicine clinic and the Swedish Prison and Probation Service, as well as experts on CSAM from two Swedish child rights-based non-governmental organizations. In a series of workshops and meetings, the PPI⁴ methodology was taught and project research questions, outcome measures, and treatment manual contents discussed.

2.3. Participants

The inclusion criteria were 18+ years of age, CSAM viewing during the past week, sufficient English language skills, and provision of informed consent. Exclusion criteria were severe psychiatric illness and lack of serious intent to participate. Recruitment started on April 16, 2019, and ended on Sept 20, 2021, when the required sample size had been obtained.

We posted adverts and a link to the trial website (www.preventit.se) in chat forums and topic links on the Darknet regarding pedophilia or the use of CSAM. The trial was also advertised elsewhere on the internet (recruitment of included individuals: Darknet N = 114; elsewhere; N = 39 [including 14 reported as recruited via Virtuous Pedophiles, also present on Darknet]; no data available N = 7). To increase participant safety and anonymity, we obtained an *Onion certificate* in January 2020, enabling encrypted participation via an onion link (<https://6wvybf7ub3xk5ow66wt7os3aovbzoo2eei6vjrvhvvkmqg4alnezzid.onion/sites/preventit/register>), and reprogrammed the trial website so that neither JavaScript nor an email address was required.

Participants were assessed for eligibility in a semi-structured interview. Communication occurred mostly via an online chat, although audio calls were also offered. Participant identities remained unknown to the research team at all stages of the trial. We provided written trial information and obtained informed consent mostly via chat, and in a few cases by phone, before inclusion. Upon inclusion, participants were asked to start treatment within a week. We provided no monetary or similar incentives to participants.

2.4. Randomization and masking

Included participants were allocated to Prevent It or Psychological placebo by block randomization (1:1 ratio, block size 8). The allocation sequence was generated by a digital random number generator at Karolinska Trial Alliance. Following inclusion, a research team member opened the sealed envelope with allocation information, and the psychotherapist started the intervention. Participants were blinded, since we designed both interventions to be perceived as psychological treatment; however, it was not possible to blind psychotherapists and other research team members. Since one participant was mistakenly randomized twice, we deleted the first allocation, resulting in a total of 161 randomizations of 160 individuals.

¹ Child sexual abuse material, i.e. “child pornography”.

² Randomized clinical trials.

³ Internet-delivered cognitive behavioral therapy.

⁴ Patient and public involvement.

2.5. Procedure

We collected data through online psychometric tests and self-ratings. Interview information was obtained during eligibility assessments conducted by trained research team members. The semi-structured interviews were guided by a template with recurring questions and responses, based on the Mini International Neuropsychiatric Interview (M.I.N.I.), screen for common psychiatric disorders (Sheehan, 1998). Most interviews lasted approximately 1–2 h. Diagnostic decisions were made under the supervision of a senior consultant psychiatrist.

All primary and secondary outcomes, except for *quality of life*, were assessed at all time points: at inclusion (pre-treatment) and at 1, 2, 3, 4, 5, 6, 7, 8 (post-treatment), and 12 (follow-up) weeks, respectively. Quality of life was measured pre-, post-treatment, and at follow-up. Participants automatically gained access to the digital measurement interface regardless of individual treatment progression. To investigate data quality, we also asked participants to rate how truthfully they had completed questionnaires (0–10, with 0: not truthful at all; 10: 100 % truthful) pre-, post-treatment, and at follow-up.

Some possible unclarity in the data were observed. Occasionally, weekly measurements were completed less than seven days apart, possibly causing double registration due to a few overlapping days. Some participants who completed all modules either filled in post-treatment ratings before starting the last module (Placebo: N = 2) or before receiving final therapist feedback (Prevent It: N = 2; Placebo N = 3). A few unclear entries in self-reported time data were resolved by consensus between researchers at the data quality check.

At all data collection time points, participants received a link to a network of hotlines for anonymous reporting of web pages including CSAM for further investigation (<http://inhope.org>). At pre-treatment, post-treatment, and follow-up, we also asked participants to report any knowledge of identified children at risk of being harmed, and informed about the Swedish legislation regarding professionals' obligation to report such information to the social services.

2.6. Interventions

The interventions were provided online in English. Both treatments consisted of eight modules targeting themes related to CSAM viewing, and used written text, video presentations (2–10 min long), mandatory homework assignments, and weekly individualized written psychotherapist feedback based on a response bank via a message function in the platform. To decrease the risk that therapist-related factors would unduly affect the interpretation in favor of either intervention, the same therapists provided both treatments. Each patient was assigned a primary psychotherapist: a registered psychologist (~75 participants), a registered psychotherapist (~15), or a psychologist with an American MSc Psych degree, in training for Swedish registration (~70). The team had weekly case consultations. The maximum intervention duration was eight weeks and participants could partly affect their rate of progression. The therapists extended the treatment period (by 1–2 weeks) for three Prevent It and two Placebo group participants, mainly due to therapist-related administration issues. At the end of each module, participants reported the time spent working with that module (hh:mm).

We developed the novel Prevent It iCBT intervention to reduce CSAM use and other child-related sexually abusive and exploitative behaviors in help-seeking individuals. It was built on an existing iCBT protocol used in a feasibility study targeting hypersexual or compulsive sexual behavior (Hallberg et al., 2020), that was in turn based on a face-to-face CBT protocol found to reduce participants' hypersexual symptoms (Hallberg et al., 2019). To effect behavioral change, Prevent It uses CBT methods like psychoeducation and targets thoughts and emotions, such as sexual preoccupation, related to the problem behavior and high-risk situations. Therapist feedback aimed to be constructive, validating, and actively exploratory. Feedback was further customized according to

Table 1

Module completion, main content, and engagement of Prevent It and Psychological placebo interventions.

Module (last completed module Prevent It: n [%]; Placebo: n [%])	Prevent It (iCBT) (time spent on module, h, M [SD])	Psychological placebo (time spent on module, h, M [SD])
1	Welcome – analyze your behavior Introduction to CBT. Functional analyses and treatment goals. (1.0 [1.3]; 9 [11])	Welcome – being a study participant Introduction to the study and modules. Reflections on being a research participant. (0.6 [0.5])
2	Your balance in life Exploring life balance based on the excessive and deficient behaviors model. (7 [9]; 4 [5])	Increase your empathy with the child Information about children, sexuality and sexual consent. Writing a letter to a child seen in CSAM. (1.4 [1.1])
3	Controlling your sexuality Psychoeducation about uncontrolled sexuality. The function of sexual behaviors and maintenance factors (0.8 [0.5])	Your expectations of treatment Information about change. Expectations about the outcome of treatment. (0.6 [0.5])
4	Thoughts and feelings about changing your behavior Exploring ambivalence about changing sexual behavior(s), in order to increase motivation. (0.6 [0.3])	Learn why behaviors are maintained Problematic sexual behaviors; potential functions and exploration of impact on different areas of life. (0.9 [0.7])
5	Manage your impulses and risk cards Mindfulness and skills training. Risk situations; increased awareness and alternative behaviors. (7 [9]; 5 [6])	Manage your sexual behavior Background factors to the development of problematic sexual behaviors. Reflections about one's first contact with CSAM. (0.9 [1.4])
6	What is truly important in your life? Identifying core values and related goals. Improving goal setting and stress management skills to work towards goals. (0.9 [0.9])	What is truly important in your life? Identifying core values. Reflection on satisfaction with different areas of life and potential associations with CSAM use. (0.9 [0.8])
7	Behavioral experiment Behavioral experiments to start striving towards identified goals and identify specific factors related to increased risk. Psychoeducation about children's inability to consent to sex. (1.1 [1.0])	Manage your stress Information about stress and stress management skills to deal with daily challenges. (0.9 [0.7])
8	Maintain your change Summary. Creating a maintenance program to continue managing risk situations and working towards goals based on core values. (0.8 [0.6])	Maintain your change Summary. Creating a maintenance program without connection to values and goals. (1.1 [0.7])

Data are no. of participants (%) that ended their participation on completion of treatment module 1–8 (completion defined as receiving therapist feedback; however, some participants completed worksheets for an additional module beyond deadline), names and content of modules, and mean time in hours [SD] spent working with each module (all individuals providing data included). The most common scenario for treatment dropout was that the participant stopped working with modules and replying to messages from therapists. A total of 23

Prevent It individuals (29 %) and 4 Placebo arm individuals (5 %) did not complete any module.

individual responsiveness to treatment, such as psychiatric comorbidity and social situation, observed at the intake interview.

The psychological placebo was designed based on previous reports (Hegerl et al., 2010; Serfaty et al., 2009); it was structured similarly to Prevent It and had module names and content intended to be perceived as therapy. However, text and videos, home exercises, and therapist feedback lacked active CBT elements (e.g., focused on reflecting on the behavior as such rather than behavioral change). Neither did the placebo intervention include components of psychodynamic psychological therapy such as discussing the patient-therapist relationship, the role of childhood, previous trauma, or existential conflicts. Instead, peripheral but related topics were addressed, such as general mental health, legal aspects of sexual offending, and being a trial participant. Note though that placebo control also included potentially active components. For further description see Table 1, and Study protocol and Treatment modules in interventions in the Supplement.

2.7. Outcomes

2.7.1. Primary outcome

To target actual child sexual interest-related offending behavior, we chose as primary trial outcome *self-reported time spent using CSAM during the past week*, assessed with a computerized timeline follow-back questionnaire. This variable is part of the generic *Sexual Child Molestation Risk Assessment* SChIMRA+ measure (item B1). We developed and used the purpose-built SChIMRA in a previous drug trial and adapted it for online use (SChIMRA+ see Supplement for full description) (Landgren et al., 2020). The pre-planned primary analysis included data from all time points (pre-treatment, weeks 1–7, post-treatment) except for follow-up (due to an unknown but possibly high attrition rate). In secondary analyses, however, *follow-up data* were also included.

2.7.2. Secondary outcomes

As indicated above, SChIMRA+ part B covers past week behaviors (continuous variable), including time spent socializing (B2) or physically interacting with children for sexual arousal (B3). Further, it asks about time spent on other behaviors related to sexual interest in children (B4) (e.g., searching for and organizing CSAM, or fantasizing about or chatting with other people about children), and estimated age of the youngest child viewed/approached according to items B1–B3.

The four secondary outcomes were SChIMRA+ B2 and B3 together, B4, the severity of consumed CSAM assessed with a self-report version of the *Combating Paedophile Information Networks in Europe* (COPINE) scale (Quayle, 2008) (range 1 to 10 [1: indicative, 2: nudist, 3: erotica, 4: posing, 5: erotic posing, 6: explicit erotic posing, 7: explicit sexual activity, 8: assault, 9: gross assault, 10: sadistic/bestiality]), and quality of life measured with the *European Quality of Life Visual Analogue Scale* (EQ-VAS, range 0–100, with higher scores indicating better quality of life) (EuroQol Group, 1990). The primary and all secondary outcomes were pre-registered. However, note that the first secondary outcome according to the protocol is rather a secondary analysis of the primary outcome.

At post-treatment, participants reported adverse effects and events using the *Negative Effects Questionnaire* 20-item version (NEQ-20) (Rozenal et al., 2019). NEQ-20 taps the occurrence (binary) and severity (on a 5-point Likert scale, 0–4) of 20 statements regarding negative effects of psychological treatment and ends with one free-text question. Post-treatment, participants also reported positive and negative treatment experiences of trial participation in free-text answers and rated experienced empathy and interest from therapists (0: “I experienced no empathy” to 10: “I experienced the highest level of empathy and interest imaginable”). Free text answers were analyzed using descriptive content analysis (Sandelowski, 2000).

2.8. Statistical analysis

We found no published intervention studies using similar study populations and interventions to guide power calculation; hence, assumptions were based on research on pornography use. We specified a clinically meaningful mean difference of 30 min/week for the primary outcome and assumed a 1.75 h/week decreased viewing time for the Placebo group. The sample size was computed assuming independent groups and a two-sided, two-sample means test with 80 % power, alpha 0.05, and a common SD of 1 h/week. We expected 80 % to complete study participation, and therefore included 80 participants in each study arm. The power calculation was made before the start of data collection.

The intent-to-treat principle was applied in analyses of primary and secondary outcomes. We followed the pre-specified statistical analysis plan (see protocol in Supplement) using multivariate models with a participant-specific random intercept for all outcomes with time (treated as categorical) and group as independent variables. Further, we analyzed all outcomes in separate models with time treated as a continuous variable. For all applicable analyses, we provide 95 % confidence intervals (CI) and *p*-values of the Wald type. Although Cohen's *f* is the preferred effect size metric for the current model, we provide Cohen's *d* estimates (interpreted as 0.2: small, 0.5: medium, 0.8: large) to increase comparability (Cohen's *d* = Cohen's *f* × 2). See Supplement for a more detailed description of planned and post-hoc analyses.

To elucidate whether outcome variable data were missing at random, we created a dummy variable for missing data. We performed Chi-square tests of associations between dummy variables and other explanatory variables for the primary outcome. Only one variable, already included in all models (time from pre-treatment to follow-up), was significantly associated with missing values. Hence, we concluded that data were missing at random (MAR) and no further imputations were conducted. We used R version 4.1.1 (Core Team 2021) software for all analyses (R Core Team, 2021).

3. Results

3.1. Participants

A total of 5504 visits were registered (i.e., generated a study ID or provided an email address) on the trial website (see Fig. 1). We assessed eligibility for 185 individuals, and the pre-specified sample of 160 participants were included from April 16, 2019, to Sept 20, 2021. Data collection ended with the last follow-up measurement on Dec 17, 2021. Following exclusion of individuals lacking primary outcome data (Prevent It *N* = 4; Placebo *N* = 1) or without serious intent to participate (team assessment based on work in the therapy, Placebo *N* = 1), the primary outcome analysis included 76 Prevent It and 78 Placebo individuals. Participants completed 0 to 8 modules (see Table 1). The proportions of participants providing primary outcome data were 46 % (Prevent It) and 63 % (Placebo) post-treatment, and 20 % (Prevent It) and 30 % (Placebo) at follow-up, respectively.

Table 2 describes participants' baseline characteristics. Individuals from all geographical world regions were included, and all but three reported male gender.

3.2. Primary outcome

Analysis of the primary outcome, treating time as a continuous variable, suggested a small-sized but significantly larger decrease in weekly viewing time in Prevent It compared to Placebo participants; both from pre-treatment to post-treatment (estimate −0.25, 95 % CI, −0.46 to −0.04, *p* = .017, Cohen's *d* 0.18) and from pre-treatment to follow-up (estimate −0.27, 95 % CI, −0.46 to −0.08, *p* = .005, Cohen's *d* 0.20) (see Fig. 2A). When treating time as a categorical variable,

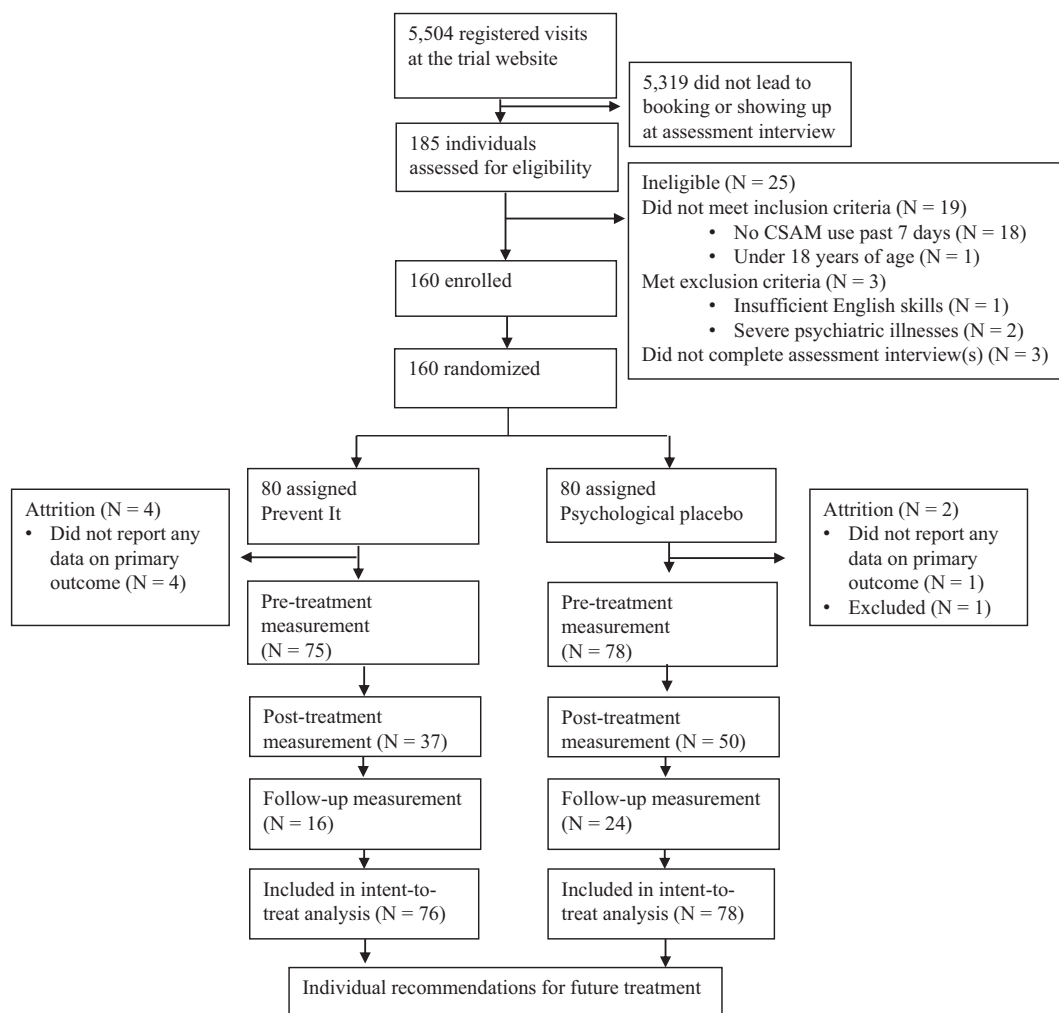


Fig. 1. CONSORT diagram.

Included individuals participated in 0–8 modules (among individuals providing post-treatment data, 33 completed all modules [Prevent It, N = 12; Placebo, N = 21]).

significant changes at 2/9 individual time points (week 1–7, post-treatment, and follow-up were analyzed) favored Prevent It (see Supplementary Fig. 1). No significant changes favored Placebo.

3.3. Secondary outcomes

We detected a significantly larger decrease from pre-treatment to follow-up in 1/4 secondary outcomes using time as a continuous variable: time spent on behaviors related to sexual interest in children other than viewing CSAM (SChiMRA+, B4) for Prevent It (Prevent It: N = 74, Placebo, N = 78, estimate -0.25 , 95 % CI, -0.43 to -0.07 , $p = .007$, Cohen’s d 0.20; see Fig. 2B) (see Fig. 2C and Supplementary Figs. 3b and 5b for non-significant results).

When using time as a categorical variable, significant between-group differences favoring Prevent It over Placebo were suggested at 10/29 time points (see Supplementary Figs. 2, 3a, 4, 5a) among the four secondary outcomes. No significant changes favored Placebo.

3.4. Post-hoc analyses

Post-hoc analyses included two between-group comparisons; we found no significant difference in the proportion of full responders (reporting zero minutes of CSAM viewing time following study participation), but a significantly larger increase in age of the youngest child in CSAM used during past week for Prevent It participants (see Fig. 2D). We

also performed within-group analyses of primary and secondary outcomes. See Supplement for more information.

3.5. Negative side effects and treatment experiences

At post-treatment, negative side effects were more commonly reported, and described as more severe, by Placebo participants (see Negative side effects in Supplement). A total of 86 participants also provided free-text answers regarding positive and negative treatment effects and experiences (see Supplementary Tables 4–5). Common categories (reported by more than 10 % in one/both arms) across groups included increased awareness of thoughts and behaviors, and support from therapist. Prevent It participants also reported positive treatment effects from having acquired useful tools, feelings of hope, and reduced use of CSAM.

3.6. Measures of trial quality

We observed adequate results on all trial quality measures. No indication of severely compromised blinding from participants’ allocation guessing was observed (Prevent It [N = 36]: active psychotherapy 16 [44 %], do not know 17 [47 %], Placebo 3 [8 %]; Placebo [N = 50]: active psychotherapy 17 [34 %], do not know 20 [40 %]; Placebo 13 [26 %], Fisher’s Exact Test $p = .12$). No difference was detected in

Table 2
Self-reported baseline characteristics of the intention-to-treat population.

Characteristic ^a	Prevent It (N = 80)	Placebo (N = 80)
Gender		
Male	78 (99)	79 (99)
Female	0	0
Non-binary	1 (1)	1 (1)
Age category, years		
18–29	36 (46)	42 (53)
30–39	31 (39)	16 (20)
40–49	8 (10)	15 (19)
50–59	4 (5)	6 (8)
Region		
Africa	1 (1)	0
Asia	7 (9)	8 (10)
Europe	38 (50)	37 (46)
North America	27 (36)	25 (31)
Oceania	1 (1)	5 (6)
South America	2 (3)	4 (5)
Highest level of education		
Primary school, 6–9 years	1 (1)	1 (1)
Post-secondary vocational or secondary education, 10–12 years	26 (35)	27 (35)
Post-secondary education	48 (64)	49 (64)
Social situation		
Ever lived with a partner 2+ years	21 (27)	24 (31)
Parent/guardian	7 (9)	15 (19)
Single-person household	31 (41)	29 (37)
Current employment	56 (74)	54 (70)
Prior criminal convictions		
Convicted of contact sexual offence	3 (4)	1 (1)
Convicted of non-contact sexual offence	4 (5)	3 (4)
Convicted of non-sexual offence	3 (4)	3 (4)
Psychiatric morbidity		
Current substance misuse ^b	22 (28)	24 (30)
Current depression ^c	26 (33)	27 (34)
Current psychiatric disorder, any ^d	52 (65)	55 (69)
Sexual behavior and interest		
Past week CSAM viewing time, h	6.7 (11.9)	4.8 (5.0)
Hypersexual or compulsive sexual behavior ^e	62 (19)	65 (16)
Pedophilic interest ^f	60 (83)	69 (87)
Probable pedophilic disorder ^g	44 (61)	47 (59)
Treatment experience		
Prior professional help with any psychiatric condition	46 (58)	45 (56)
Prior professional help with sexuality problem	20 (26)	18 (23)
Prior or current prescribed psychotropic medication ^h	16 (20)	22 (28)
Quality of life ⁱ	73 (19)	72 (17)

Data are n (%) or M (SD).

^a For missing data see Missing baseline data in Supplement.

^b Positive screening results on the Alcohol Use Disorder Identification Test (AUDIT) (8+ out of 40 points) (Bergman and Källmén, 2002) or the Drug Use Disorder Identification Test (DUDIT) (3+ out of 44 points) (Hildebrand, 2015).

^c According to DSM-IV/5 diagnostic criteria in the Mini International Neuropsychiatric Interview (M.I.N.I.) 6.0.0 (Sheehan et al., 1998).

^d According to DSM-IV/5 diagnostic criteria in M.I.N.I. 6.0.0, or positive screening results on the Adult ADHD (attention-deficit/hyperactivity disorder) Self-Report Scale screener (ASRS screener) (14+ out of 24 points indicating ADHD) (Kessler et al., 2005), or the Ritvo Autism and Asperger Diagnostic Scale Screen 14 (RAADS-14) (24+ out of 42 points indicating a higher likelihood of autism) (Eriksson et al., 2013).

^e Total score on the Hypersexual Behavior Inventory (53+ points out of 19–95 indicates hypersexuality) (Reid et al., 2011).

^f Responded *I somewhat or completely agree* to statement “I have had sexually arousing fantasies about, or urges to, have sex with someone who is prepubescent and at least 5 years younger than myself” presented in a self-report questionnaire addressing different paraphilic sexual interests based on DSM-IV/5 diagnostic criteria.

^g Judged to meet DSM-IV/5 diagnostic criteria based on self-report questionnaire and pre-treatment data: i) fulfilling inclusion criteria 18+ years of age and past week CSAM use, and ii) meeting criterion for pedophilic interest described above^f or responded *I somewhat or completely agree* to the statement “I

have had sex with someone who is prepubescent (and at least 5 years younger than myself)”, and iii) responded *I somewhat or completely agree* to the statement “At some point this lasted for a period of six months or more”.

^h Antidepressants, neuroleptics, and stimulants were the most common prescribed medication classes.

ⁱ Assessed with the European Quality of Life Visual Analogue Scale (EQ-VAS) (range 0–100, with higher scores indicating higher quality of life) (EuroQol Group, 1990).

experienced empathy and interest from therapists reported post-treatment (Prevent It: N = 36, M 8.4, SD 1.6; Placebo: N = 51, M 8.1, SD 1.9, $t(82.4) = 0.66, p = .51, d = 0.17$). Neither did we find any overall between-group difference in self-rated truthful responding across three timepoints (estimate $-0.02, 95\% \text{ CI}, -0.07 \text{ to } 0.03, p = .46$ based on pre-treatment measurements [Prevent It: N = 73, M 9.5, SD 1.2; Placebo: N = 78, M 9.3, SD 0.97], post-treatment [Prevent It: N = 35, M 9.6, SD 0.55; Placebo: N = 51, M 9.5, SD 0.86], and follow-up [Prevent It: N = 16, M 8.8, SD 1.5; Placebo: N = 23, M 9.3, SD 0.83]). Moreover, we found no between-group difference in overall time working with modules, based on reported time spent per module (see Table 1) (estimate 0.19, 95% CI, $-0.05 \text{ to } 0.42, p = .12$). Finally, for the primary outcome, we detected no overall significant between-group difference in attrition (all time points included, Fisher’s Exact Test $p = .12$).

4. Discussion

In this single-blinded RCT, the first conducted with online iCBT aimed at reducing child sexually abusive behaviors, our novel intervention reduced self-reported CSAM viewing and related behaviors among anonymous CSAM users more than psychological placebo. The effects were small but statistically significant. Furthermore, iCBT had fewer negative side effects. In both groups, the content severity of used CSAM decreased, and about half of the participants with post-treatment or follow-up ratings reported not having used CSAM during the preceding week, although no between-group differences were found.

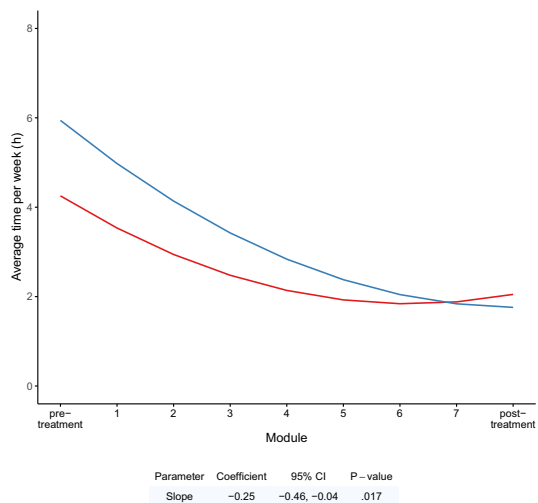
Baseline characteristics suggested success in recruiting individuals from the intended population of active CSAM users worldwide, with high rates of important risk factors for sexual (re)offending, such as pedophilic disorder (Ly et al., 2018). Despite high self-reported rates of psychiatric disorders and hypersexuality, relatively few participants reported prior or current mental health treatment, possibly indicating unaddressed psychiatric needs. Notably, none of the participants reported being female.

Prior evidence of psychological intervention effects on the risk of sexual offending has remained inconclusive, primarily due to a lack of high-quality studies (Långström et al., 2013; Grønnerød et al., 2014; Walton and Chou, 2015; Schmucker and Lösel, 2017; Gannon et al., 2019). The present results suggest initial support for the use of tailored iCBT to reduce child sexual offending behavior as represented by CSAM use. We propose that the CBT methods and intervention content (i.e., focusing on high-risk situations and targeting thoughts, emotions, and behaviors related to CSAM use, psychoeducative homework exercises, and individualized therapist feedback) might be possible contributing factors to the suggested superiority of Prevent It over psychological placebo.

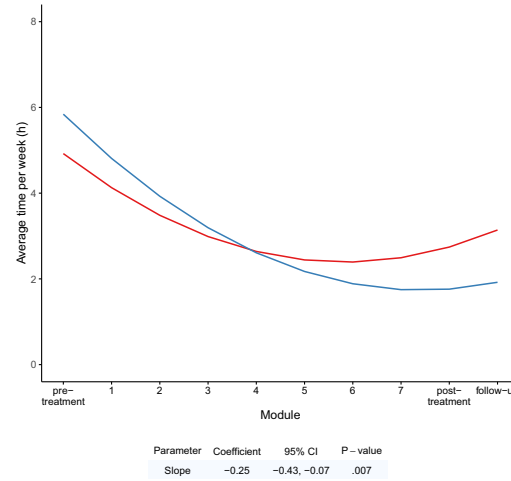
4.1. Strengths

Strengths of the current study include the recruitment of a large sample of difficult-to-reach individuals to a successfully participant-blinded psychotherapy RCT with an active psychological placebo condition and adequate results on methodological quality indices. Although our findings need replication for firmer conclusions about treatment efficacy, the interpretation of significant but small effects sizes might benefit from a recent systematic review (Faltinsen et al., 2022). The review suggested that placebo controls in psychiatric RCTs often lead to

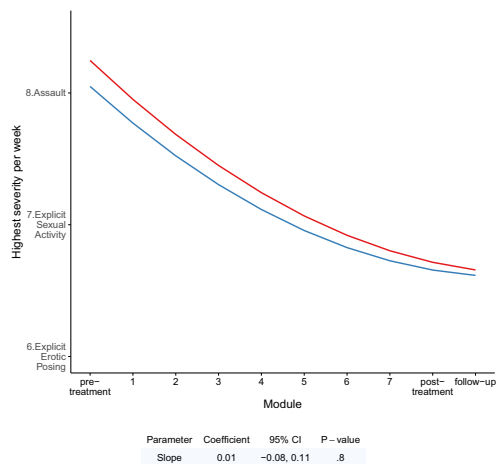
A) CSAM viewing time per week



B) Child sexual interest-related behavior (other than viewing CSAM) per week



C) Highest CSAM severity per week (COPINE rating)



D) Youngest child viewed in CSAM per week

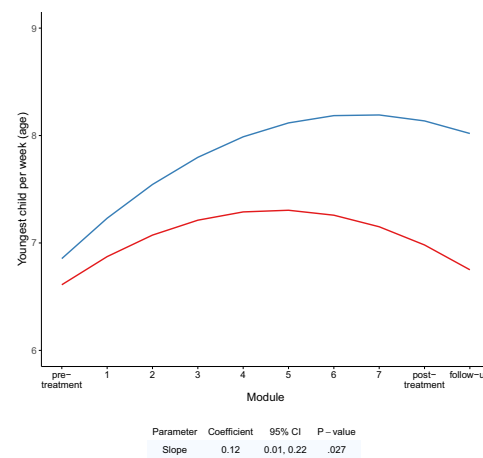


Fig. 2. Treatment effects on child sexual abuse-related behaviors.

All graphs represent mixed-effects regression models with time as a second-order polynomial. Blue = Prevent It, iCBT; red = Psychological placebo. Panels: A) Self-reported time (h) using CSAM per week, primary outcome. B) Time (h) spent weekly on behaviors related to sexual interest in children other than viewing CSAM, secondary outcome. C) Highest severity (COPINE scale 1–10) of consumed CSAM per week, secondary outcome. D) Age of youngest child (years) viewed in CSAM past week, post-hoc analysis.

lower estimated effects of an experimental intervention than do waitlist or no treatment controls. In addition, the more accentuated negative side effects found for placebo suggest caution in offering interventions to similar populations based solely on support and reflection.

4.2. Limitations

One limitation with the current trial was the attrition rate. Although treatment experiences reported by Prevent It participants post-treatment were mainly positive, substantial drop-out from the initial intent-to-treat sample following inclusion indicates that acceptability might be limited to a subgroup of participants. However, we tested potential attrition bias due to uneven drop-out rates between study arms but found no such significant difference in attrition regarding the primary outcome.

Another limitation was the unintended removal of the originally planned waitlist arm from the randomization sequence. This makes it more difficult to evaluate possible *regression to the mean*, and to distinguish between *specific* and *non-specific* treatment effects, as both conditions are expected to produce non-specific effects from “common factors” (Enck and Zipfel, 2019). Also, a longer follow-up period would have been beneficial to conclude if the behavioral changes were maintained.

Other potential biases include response and recall biases due to the overly sensitive, incriminating outcomes. However, importantly, participants reported high truthfulness and biases should have affected both arms similarly, thereby not substantially affecting observed between-group differences.

4.3. Interpretation and implications

Successful prevention of child sexual abuse requires several complementary intervention approaches (Di Gioia et al., 2022). By reaching a population of mainly undetected CSAM users, anonymous iCBT could possibly complement other initiatives by health care services, social media and tech companies, and law enforcement authorities. The generalizability of the present findings to similar populations should be good, given international coverage, feasibility, and acceptance of the intervention among participants with post-treatment data. However, the generalizability to CSAM-using individuals that are not currently help-seeking remains unknown.

Future studies may consider manual revisions to increase completion rate. For example, by altering the initial Prevent It modules more towards Placebo arm content, focusing on introduction and study engagement rather than immediate behavioral change, or using shorter online interventions such as motivational interviewing. Additional adaptations may be needed to improve geographical and socio-cultural outreach. Methodologically, a longer-term follow-up would help elucidate the need for iCBT booster sessions, and a waitlist control could assist in disentangling specific and non-specific effects of study participation.

5. Conclusions

To conclude, we found evidence for the feasibility of a Darknet recruitment strategy and initial support for efficacy and safety of a novel iCBT intervention to reduce CSAM viewing and related behaviors. The findings need replication for firmer conclusions about treatment efficacy.

Data statement

Due to their extremely sensitive nature, participant data will not be shared.

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CRediT authorship contribution statement

Johanna Lätth: Formal analysis, Data curation, Writing – original draft, Writing – review & editing, Visualization, Project administration. **Valdemar Landgren:** Formal analysis, Data curation, Writing – review & editing, Visualization. **Allison McMahan:** Investigation, Writing – review & editing. **Charlotte Sparre:** Methodology, Investigation, Writing – review & editing, Project administration. **Julia Eriksson:** Formal analysis, Data curation, Writing – review & editing, Visualization. **Kinda Malki:** Formal analysis, Writing – review & editing, Visualization. **Elin Söderquist:** Investigation, Writing – review & editing. **Katarina Görts Öberg:** Methodology, Investigation, Writing – review & editing. **Alexander Rozental:** Formal analysis, Writing – review & editing, Visualization. **Gerhard Andersson:** Methodology, Software, Resources, Writing – review & editing. **Viktor Kaldo:** Methodology, Writing – review & editing, Visualization. **Niklas Långström:** Formal analysis, Writing – review & editing, Visualization, Supervision. **Christoffer Rahm:** Conceptualization, Methodology, Investigation, Data curation, Writing – original draft, Writing – review & editing, Supervision, Project administration, Funding acquisition.

Declaration of competing interest

We declare no competing interests.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.invent.2022.100590>.

References

- Andersson, G., Titov, N., Dear, B.F., et al., 2019. Internet-delivered psychological treatments: from innovation to implementation. *World Psychiatry* 18 (1), 20–28.
- Bergman, H., Källmén, H., 2002. Alcohol use among swedes and a psychometric evaluation of the alcohol use disorders identification test. *Alcohol Alcohol.* 37 (3), 245–251.
- Di Gioia, R., Beslay, L., Cassar, A., 2022. Classification Criteria for Child Sexual Abuse and Exploitation Prevention Programmes, EUR 30973 EN. Publications Office of the European Union, Luxembourg.
- Enck, P., Zipfel, S., 2019. Placebo effects in psychotherapy: a framework. *Front Psychiatry* 10, 456.
- Eriksson, J.M., Andersen, L.M.J., Bejerot, S., 2013. RAADS-14 screen: validity of a screening tool for autism spectrum disorder in an adult psychiatric population. *Mol. Autism.* 4 (1), 49.
- EuroQol Group, 1990. EuroQol – a new facility for the measurement of health-related quality of life. *Health Policy* 16 (3), 199–208.
- Faltinsen, E., Todorovac, A., Staxen Bruun, L., et al., 2022. Control interventions in randomised trials among people with mental health disorders. *Cochrane Database Syst. Rev.* 4 (4), CDMr000050.
- Gannon, T., Olver, M., Mallion, J., et al., 2019. Does specialized psychological treatment for offending reduce recidivism? A meta-analysis examining staff and program variables as predictors of treatment effectiveness. *Clin. Psychol. Rev.* 73, 101752.

- Grønnerød, C., Grønnerød, J., Grøndahl, P., 2014. Psychological treatment of sexual offenders against children: a meta-analytic review of treatment outcome studies. *Trauma Violence Abuse* 16, 280–290.
- Hallberg, J., Kaldø, V., Arver, S., et al., 2019. A randomized controlled study of group-administered cognitive behavioral therapy for hypersexual disorder in men. *J. Sex. Med.* 16 (5), 733–745.
- Hallberg, J., Kaldø, V., Arver, S., et al., 2020. Internet-administered cognitive behavioral therapy for hypersexual disorder, with or without paraphilia(s) or paraphilic Disorder(s) in men: a pilot study. *J. Sex. Med.* 17 (10), 2039–2054.
- Hegerl, U., Hautzinger, M., Mergl, R., et al., 2010. Effects of pharmacotherapy and psychotherapy in depressed primary-care patients: a randomized, controlled trial including a patients' choice arm. *Int. J. Neuropsychopharmacol.* 13 (1), 31–44.
- Hildebrand, M., 2015. The psychometric properties of the drug use disorders identification test (DUDIT): a review of recent research. *J. Subst. Abuse Treat.* 53, 52–59.
- Insoll, T., Ovaska, A., Nurmi, J., et al., 2022. Risk factors for child sexual abuse material users contacting children online: results of an anonymous multilingual survey on the dark web. *J. Online Trust Saf.* 1 (2).
- Insoll, T., Ovaska, A., Vaaranen-Valkonen, N., 2021. CSAM Users in the Dark Web: Protecting Children Through Prevention. Suojellan Lapsia ry (Protect Children). Redirection Survey Report.
- Jahnke, S., 2018. The stigma of pedophilia: clinical and forensic implications. *Eur. Psychol.* 23 (2), 144–153.
- Kessler, R.C., Adler, L., Ames, M., et al., 2005. The World Health Organization adult ADHD self-report scale (ASRS): a short screening scale for use in the general population. *Psychol. Med.* 35 (2), 245–256.
- Kloess, J., Bruggen, M., 2021. Trust and relationship development among users in dark web child sexual exploitation and abuse networks: a literature review from a psychological and criminological perspective. *Trauma Violence Abuse* 1–18, 152483802110572.
- Landgren, V., Malki, K., Bottai, M., et al., 2020. Effect of gonadotropin-releasing hormone antagonist on risk of committing child sexual abuse in men with pedophilic disorder: a randomized clinical trial. *JAMA Psychiatry* 77 (9), 897–905.
- Ly, T., Dwyer, R.G., Fedoroff, J.P., 2018. Characteristics and treatment of internet child pornography offenders. *Behav. Sci. Law* 36 (2), 216–234.
- Långström, N., Enebrink, P., Laurén, E.-M., et al., 2013. Preventing sexual abusers of children from reoffending: systematic review of medical and psychological interventions. *BMJ* 347, f4630.
- National Centre of Missing or Exploited Children (NCMEC), 2022. European Union cyber-tipline data snapshot. NCMEC [cited 25 April 2022]. <https://www.missingkids.org/content/dam/missingkids/pdfs/pdf-thumbs/EU-2020v2021CyberTiplineData.pdf>.
- Quayle, E., 2008. The COPINE project. *Irish Prob. J.* 5 (9), 65–83.
- R Core Team, 2021. R: A Language and Environment for Statistical Computing. R Foundation for Statistical Computing, Vienna, Austria.
- Reid, R., Garos, S., Carpenter, B., 2011. Reliability, validity, and psychometric development of the hypersexual behavior inventory in an outpatient sample of men. *Sex. Addict. Compuls.* 18, 30–51.
- Rozental, A., Kottorp, A., Forsström, D., et al., 2019. The negative effects questionnaire: psychometric properties of an instrument for assessing negative effects in psychological treatments. *Behav. Cogn. Psychother.* 47 (5), 559–572.
- Sandelowski, M., 2000. Whatever happened to qualitative description? *Res. Nurs. Health* 3, 334–340.
- Schmucker, M., Lösel, F., 2017. Sexual offender treatment for reducing recidivism among convicted sex offenders: a systematic review and meta-analysis. *Campbell Syst. Rev.* 13 (1), 1–75.
- Scurich, N., 2020. Introduction to this special issue: underreporting of sexual abuse. *Behav. Sci. Law* 38 (6), 537–542.
- Serfaty, M.A., Haworth, D., Blanchard, M., et al., 2009. Clinical effectiveness of individual cognitive behavioral therapy for depressed older people in primary care: a randomized controlled trial. *Arch. Gen. Psychiatry* 66 (12), 1332–1340.
- Sheehan, D.V., Lecrubier, Y., Sheehan, K.H., et al., 1998. The mini-international neuropsychiatric interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *J. Clin. Psychiatry* 59 (Suppl. 20), 22–33 quiz 4–57.
- United Nations (UN). The sustainable development agenda. <https://www.un.org/sustainabledevelopment/development-agenda/> [cited 18 June 2022].
- Walton, J.S., Chou, S., 2015. The effectiveness of psychological treatment for reducing recidivism in child molesters: a systematic review of randomized and nonrandomized studies. *Trauma Violence Abuse* 16 (4), 401–417.