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## Feasibility of a trauma-focused internet- and mobile-based intervention for youth with posttraumatic stress symptoms

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### ABSTRACT

**Background:** Many youth with posttraumatic stress symptoms (PTSS) do not receive evidence-based care. Internet- and Mobile-Based Interventions (IMIs) comprising evidence-based trauma-focused components can address this gap, but research is scarce. Thus, we investigated the feasibility of a trauma-focused IMI for youth with PTSS.

**Methods:** In a one-arm non-randomized prospective proof-of-concept study, 32 youths aged 15–21 years with clinically relevant PTSS (CATS  $\geq 21$ ) received access to a trauma-focused IMI with therapist guidance, comprising nine sessions on an eHealth platform accessible via web-browser. We used a feasibility framework assessing recruitment capability, sample characteristics, data collection, satisfaction, acceptability, study management abilities, safety aspects, and efficacy of the IMI in PTSS severity and related outcomes. Self-rated assessments took place pre-, mid-, post-intervention and at 3-month follow-up and clinician-rated assessments at baseline and post-intervention.

**Results:** The sample mainly consisted of young adult females with interpersonal trauma and high PTSS levels (CATS,  $M = 31.63$ ,  $SD = 7.64$ ). The IMI sessions were found useful and comprehensible, whereas feasibility of trauma processing was perceived as difficult. Around one-third of participants (31%) completed the IMI's eight core sessions. The study completion analysis showed a significant reduction with large effects in self-rated PTSS at post-treatment [ $t(21) = 4.27$ ;  $p < .001$ ;  $d = 0.88$ ] and follow-up [ $t(18) = 3.83$ ;  $p = .001$ ;  $d = 0.84$ ], and clinician-rated PTSD severity at post-treatment [ $t(21) = 4.52$ ;  $p < .001$ ;  $d = 0.93$ ]. The intention-to-treat analysis indicated significant reductions for PTSS at post-treatment and follow-up with large effect sizes ( $d = -0.97$ – $-1.02$ ). All participants experienced at least one negative effect, with the most common being the resurfacing of unpleasant memories ( $n = 17/22$ , 77%).

**Conclusion:** The study reached highly burdened young adults. The IMI was accepted in terms of usefulness and comprehensibility but many youths did not complete all sessions. Exploration of strategies to improve adherence in trauma-focused IMIs for youth is warranted, alongside the evaluation of the IMI's efficacy in a subsequent randomized controlled trial.

### Factibilidad de una intervención en línea y por dispositivo móvil centrada en el trauma para jóvenes con síntomas de estrés postraumático

**Antecedentes:** Muchos jóvenes con síntomas de estrés postraumáticos (PTSS en su sigla en inglés) no reciben atención basada en la evidencia. Las intervenciones en línea y por medio de dispositivos móviles (IMIs en su sigla en inglés) que incluyen componentes centrado en el trauma basados en la evidencia pueden abordar esta brecha, pero la investigación es escasa. Así, investigamos la factibilidad de una IMI centrada en el trauma para jóvenes con PTSS.

**Métodos:** En un estudio de prueba del concepto futuro no aleatorizado de un brazo, 32 jóvenes de 15 a 21 años con PTSS clínicamente relevante (CATS  $\geq 21$ ) recibieron acceso a la IMI centrada en el trauma con la guía de un terapeuta, incluyendo nueve sesiones en una plataforma eHealth de acceso por medio de página web. Usamos un marco de factibilidad para evaluar la capacidad de reclutamiento, las características de la muestra, la recolección de datos, satisfacción, aceptabilidad, habilidades de la gestión del estudio, aspectos de seguridad, y la eficacia de la IMI en la severidad de los PTSS y los resultados relacionados. Se realizaron las evaluaciones de autoinforme antes, en la mitad, y luego de la intervención y a los tres meses de seguimiento y las evaluaciones calificadas por los clínicos a nivel basal y después de la intervención.

**Resultados:** La muestra consistió principalmente de mujeres adultas jóvenes con trauma interpersonal y altos niveles de PTSS (CATS,  $M = 31.63$ ,  $DE = 7.64$ ). Las sesiones de la IMI se consideraron útiles y comprensivas, mientras que la factibilidad del procesamiento del

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Trauma; posttraumatic stress disorder; adolescents and young adults; internet- and mobile-based intervention; trauma-focused cognitive behaviour therapy; imaginal exposure; written-based exposure

### PALABRAS CLAVE

Trauma; trastorno de estrés postraumático; adolescentes y adultos jóvenes; intervención en línea y por dispositivo móvil; terapia cognitiva conductual centrada en el trauma; exposición por imágenes; exposición basada en la escritura

### HIGHLIGHTS

- Youth often lack access to evidence-based care after trauma. This study assessed the feasibility of a trauma-focused internet- and mobile-based intervention with therapist guidance.
- The intervention was accepted by youths, and the preliminary evaluation of participant responses suggests its efficacy.
- Future studies should examine strategies to improve adherence and the IMI's efficacy in a RCT.

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trauma fue percibida como difícil. Alrededor de uno de cada tres participantes (31%) completaron las ocho sesiones centrales de la IMI. El análisis de quienes completaron el estudio, mostró una reducción significativa con efectos grandes en los PTSS autoinformados después del tratamiento [ $t(21) = 4.27$ ;  $p < .001$ ;  $d = 0.88$ ] y seguimiento [ $t(18) = 3.83$ ;  $p = .001$ ;  $d = 0.84$ ], y la severidad del TEPT calificado por el clínico luego del tratamiento [ $t(21) = 4.52$ ;  $p < .001$ ;  $d = 0.93$ ]. El análisis de intención de tratar indicó reducciones significativas para los PTSS después del tratamiento y seguimiento con efectos de tamaño grande ( $d = -0.97$ – $-1.02$ ). Todos los participantes experimentaron por lo menos un efecto negativo, siendo el más común el resurgimiento de recuerdos desagradables ( $n = 17/22$ , 77%).

**Conclusión:** El estudio alcanzó a adultos jóvenes con alta carga. Las IMI fueron aceptadas en términos de la utilidad y compresibilidad pero muchos jóvenes no completaron todas las sesiones. Se garantiza la exploración de las estrategias para mejorar la adherencia en las IMIs centrada en el trauma para jóvenes, al mismo tiempo que la evaluación de la eficacia de las IMI en un ensayo controlado aleatorio subsecuente.

## List of Abbreviations

(S)AEs	Potential (Serious) Adverse Events
APOI	Attitudes towards Psychological Online Interventions Questionnaire
AUDIT	Alcohol use disorders identification test
CAPS-CA-5	Clinician-Administered PTSD Scale for DSM-5
CATS	Child and Adolescent Trauma Screen
CPTCI-SF	Child posttraumatic cognitions inventory short version
CSQ	Client satisfaction questionnaire
CSQ-I	Client Satisfaction Questionnaire, version adapted for Internet interventions
CUDIT-R	Cannabis use disorder identification test-revised
GAD-7	Generalized anxiety disorder assessment
IMIs	Internet – and Mobile-Based Interventions
i-tf-CBT	Internet-based trauma-focused cognitive behavioural therapy
KIDSCREEN	Health-Related Quality of Life Questionnaire for Children and Young People
Kinder-DIPS	Diagnostic Interview for Mental Disorders for Children
M	Mean
MMRM	Multivariate mixed effect models for repeated measures
NEQ	Negative Effects Questionnaire
PHQ-9	Patient health questionnaire
PTSD	Posttraumatic stress disorder
PTSS	Posttraumatic stress symptoms
SD	Standard Deviation
RCI	Reliable change index
RCT	Randomized controlled trial
SITBI	Self-Injurious Thoughts and Behaviours Interview
tf-CBT	Trauma-focused cognitive behavioural therapy

## 1. Theoretical background

Posttraumatic Stress Disorder (PTSD) in adolescents and young adults can be effectively treated with trauma-focused psychotherapy, as recommended in national and international treatment guidelines (ISTSS Guidelines Committee, 2019; Lethbridge & Australia, 2020; Rosner, Gutermann, et al., 2020). Trauma focus implies that cognitive, behavioural, or emotion-focused treatment components are used to facilitate the processing of the traumatic event(s) (Schnurr, 2017). Common components of evidence-

based trauma-focused treatments for PTSD include psychoeducation, emotion regulation and coping skills, exposure, cognitive processing, restructuring, and/or meaning-making (Kooij et al., 2022; Schnyder et al., 2015). In youth, trauma-focused cognitive behavioural therapy (tf-CBT) as one form of trauma-focused therapy, has proven effective in reducing post-traumatic stress symptoms (PTSS) with high effect sizes compared to waitlist ( $d = 1.17$ ; Mavranezouli et al., 2020) and medium effect sizes compared to treatments as usual ( $d = 0.52$ ; Thielemann et al., 2022).

Despite available evidence-based approaches, youth with PTSS often remain untreated or receive non-evidence-based interventions (Chen et al., 2010; Vogel et al., 2021). Youth report barriers hindering face-to-face treatment, such as difficulties trusting others, discomfort with self-disclosure, and the sense of having no influence on the therapy process (Ellinghaus et al., 2021; Truss et al., 2022). Further, youth seem to prefer self-help, struggle with navigating the health-care system, and face long waiting times due to a lack of available therapists, especially in terms of trauma-focused therapy (Bundes Psychotherapeuten Kammer, 2018; Ellinghaus et al., 2021; Gulliver et al., 2010; Müller et al., 2019).

Internet- and Mobile-based Interventions (IMIs) provide a promising opportunity to overcome structural and attitudinal barriers and expand treatment options. They are easily accessible, and provide greater anonymity, self-direction, and self-control than traditional treatment approaches (Boulos et al., 2014). Meta-analytic evidence supports the efficacy of IMIs for common mental health disorders in youth, e.g. depression and anxiety disorders (Ebert et al., 2015; Grist et al., 2019; Wu et al., 2023). In adults, trauma-focused internet-based CBTs (i-tf-CBTs) have been shown to be effective and non-inferior to face-to-face tf-CBT in meta-analyses (Bisson et al., 2022; Simon et al., 2021). Furthermore, i-tf-CBTs were found to be superior to non-trauma-focused internet-based cognitive behavioural stress management therapy in adults with PTSD in one study (Ehlers et al., 2023). They are

meanwhile included in the treatment guidelines from the International Society for Traumatic Stress Studies (ISTSS Guidelines Committee, 2019). However, such treatment recommendations are lacking for youth. Meanwhile, a systematic review on IMIs for youth experiencing trauma identified only six studies of those four were Randomized Controlled Trials (RCTs) and none evaluated a trauma-focused IMI for youth with clinically relevant PTSS (Schulte, Harrer, et al., 2024). The meta-analytic results furthermore did not provide conclusive support for the overall efficacy of IMIs in addressing youth PTSS, as only small within-group effects but no between-group effects were found (Schulte, Harrer, et al., 2024). Given the limited evidence on efficacy and uncertainty about how an IMI for youth should be designed, it is crucial to first test the feasibility of a trauma-focused IMI in a proof-of-concept study, before moving on to a RCT.

### 1.1. Objectives

This one-arm proof-of-concept study investigated the feasibility of a trauma-focused IMI with therapist guidance for youth aged 15–21 years with clinically relevant PTSS (score  $\geq 21$  on the Child and Adolescent Trauma Screen; CATS; Sachser et al., 2022). It aimed to evaluate different feasibility dimensions based on a formal feasibility framework to inform the decision on whether to conduct a subsequent large-scale RCT (Orsmond & Cohn, 2015).

## 2. Methods

### 2.1. Trial design

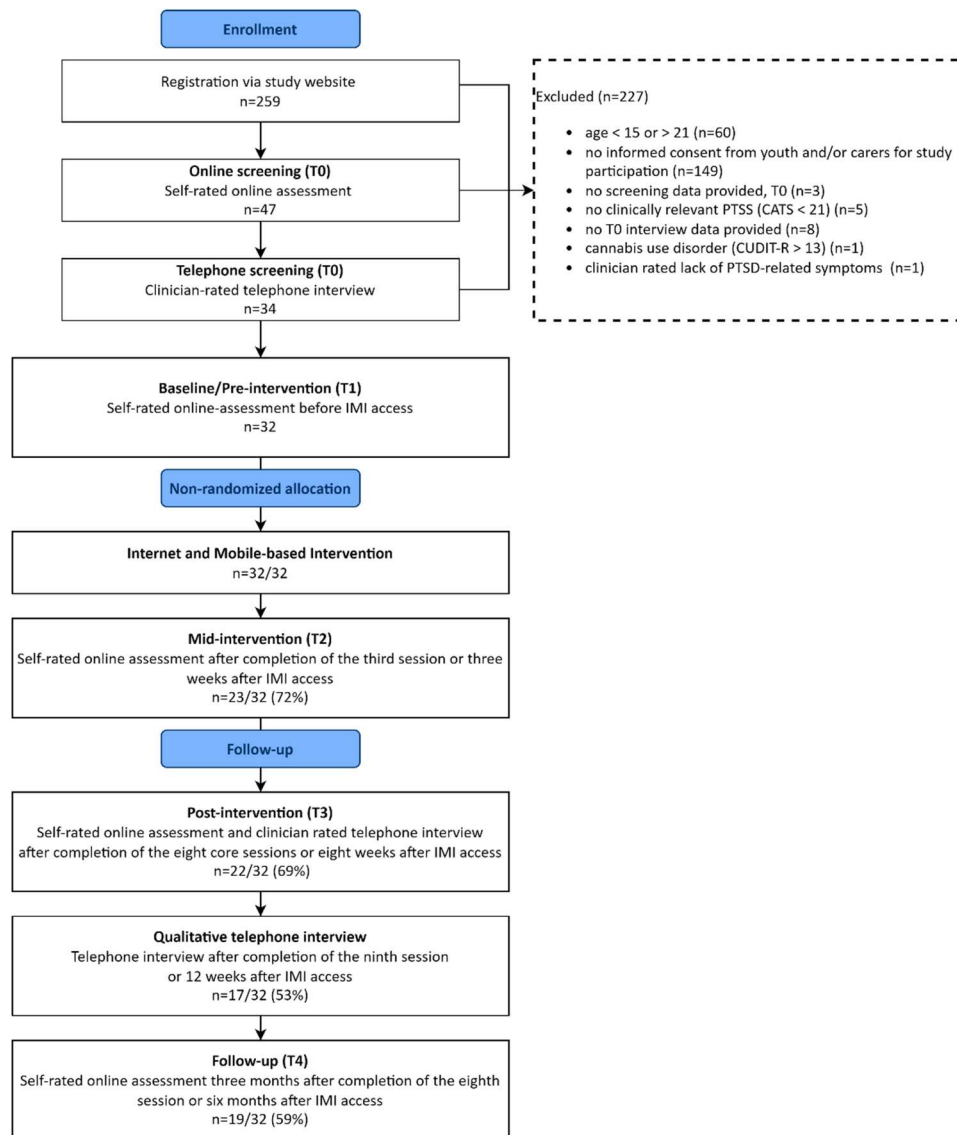
The study was conducted with a total sample of 32 participants. Self-rated online assessments took place at screening (T0), baseline/pre-intervention (T1), mid-intervention (T2), post-intervention (T3), and follow-up (T4) via the survey tool Limesurvey (Limesurvey GmbH., 2020). Clinician-rated telephone assessments were conducted at T0 and T3 (Figure 1). The study reporting follows the CONSORT guidelines for randomized pilot and feasibility trials and the complementary recommendations for reporting non-randomized pilot and feasibility studies (Eldridge et al., 2016; Lancaster & Thabane, 2019). This study was preregistered (GCTR, DRKS00023341), ethically approved (Ethics Committee of the German Psychological Society, EbertDavidDaniel2020-09-16-VA), and the study protocol was published (Schulte et al., 2022). This work is part of the collaborative BestForCan project, which aims at disseminating the TF-CBT developed by Cohen and colleagues (Cohen et al., 2009) for children, adolescents, and young adults after child abuse and neglect (Rosner, Barke, et al.,

2020) funded by the Federal Ministry of Education and Research (BMBF) under Grant (number 01KR1804).

### 2.2. Participants and procedure

We included youth aged 15–21 years with clinically relevant PTSS (CATS-score  $\geq 21$ ; Sachser et al., 2022). We chose this age range to include youth in the transitional phase aligning with German health-care practices, where youth up to the age of 21 can receive treatment from child therapists. The diagnosis of a clinical PTSD was assessed with all participants using the Clinician-Administered PTSD Scale for DSM-5 – Child and Adolescent Version (CAPS-CA-5; Pynoos et al., 2015); however, a PTSD diagnosis was not a requirement for inclusion. Participants had to reside in secure living conditions and provide written informed consent (minors required consent from both caregivers or the legal guardian). The study also required access to a laptop/computer with internet connectivity and sufficient German reading and writing skills. We excluded individuals with a history of psychotic disorder or acute psychosis (measured by adapted items from the Diagnostic Interview for Mental Disorders for Children; Kinder-DIPS; Schneider et al., 2017), acute suicidality (measured with items adapted from the Self-Injurious Thoughts and Behaviours Interview; SITBI; Nock et al., 2007), alcohol use disorder (score  $> 8$  on the Alcohol Use Disorders Identification Test; AUDIT; Saunders et al., 1993) or cannabis use disorder (score  $> 13$  on the Cannabis Use Disorder Identification Test-Revised; CUDIT-R  $> 13$ ; Adamson et al., 2010). Further, we excluded youth who recently started or planned to change medication within the next 10 weeks, and those currently receiving psychotherapy or being on a waiting list starting psychotherapy within the next 10 weeks. Individuals with comorbidities beyond these criteria were not excluded.

Interested individuals filled out a contact form on the study webpage (<http://hellobetter.de/star-studie/>) and subsequently received study information via e-mail. After providing written informed consent via e-mail, study applicants completed an initial online screening and participated in a semi-structured clinical telephone interview conducted by a licensed psychotherapist to assess study eligibility. To be included, applicants had to create a stepped crisis and emergency plan during the telephone interview, including coping skills, the involvement of significant others, and emergency contacts in case of suicidal or non-suicidal self-injurious thoughts or behaviours. Additionally, participants consented to a suicide prevention contract for the study period, agreeing to



**Figure 1.** Study flow.

Note. CATS = Child and Adolescent Trauma Screen, Sachser et al., 2022, CUDIT-R = Cannabis Use Disorder Identification Test-Revised, Adamson et al., 2010, IMI = Internet-and mobile-based intervention. PTSD = Posttraumatic Stress Disorder, PTSS = Posttraumatic Stress Symptoms.

adhere to the crisis and emergency plan, and refrain from engaging in any suicidal behaviours. After completing the baseline assessment (T1), participants were included in the study and received access to the IMI via an individual link (Figure 1).

### 2.3. Trauma-focused internet- and mobile-based intervention

The IMI is based on face-to-face tf-CBT and involves key components of different evidence-based manualized treatments for PTSD, namely psychoeducation, emotion/affect regulation and coping skills, imaginal exposure, cognitive processing and restructuring, and meaning/making (Dorsey et al., 2011; Schnyder et al., 2015). The IMI comprises three thematic units spread across nine sessions: (1) safety and coping skills, (2) trauma processing, and (3) consolidation/

integration. These sessions consist of eight core sessions and one booster session scheduled four weeks after the completion of the core sessions. Trauma processing was conducted by writing a trauma narrative (see Table 1 for an overview of content of each session). Each session is expected to last between 30 and 60 minutes. Participants are encouraged to complete one session per week, spanning a total of 12 weeks. The sessions consisted of written content accessible via a web browser on an eHealth platform. All sessions included pictures, videos, audio, and three fictional case descriptions together with drop-down sections providing options to read more about specific topics. Additionally, there was a diary function accessible via mobile phone, where participants could reflect on the implementation and usefulness of conducted exercises and plan activities in terms of behavioural activation. The IMI was designed as a self-help

**Table 1.** Overview of the session content of the IMI.

Thematic unit	Session content
Safety and coping skills (sessions 1–3)	Clarification of treatment motives and goals, Psychoeducation on trauma, PTSD, and trauma-focused interventions. Psychoeducation on arousal, developing an individual arousal scale, getting to know and practicing of relaxation skills encompassing self-soothing techniques and distress tolerance skills. Psychoeducation on the function of emotions, getting to know and practicing of affective regulation skills (i.e. acceptance-based emotion regulation).
Processing of the traumatic event (sessions 4–6)	Imaginal exposure of the traumatic event by drafting a first version of a trauma narrative from the perspective of a neutral observer. Imaginal exposure of the traumatic event by writing a trauma narrative from a first-person perspective. Imaginal exposure of the traumatic event by writing a further trauma narrative from a first person perspective focusing on feelings and thoughts.
Consolidation and integration (sessions 7–9)	Psychoeducation on maladaptive trauma-related thoughts, getting to know and practicing cognitive techniques for restructuring maladaptive thoughts and developing new helpful thoughts. Relapse prevention, Evaluation of predefined goals, psychoeducation on posttraumatic growth. Refreshment of skills, redefining individual goals.

intervention. Still, participants were guided through the IMI by an eCoach, a psychologist with a master's degree in training to become a psychological psychotherapist. The eCoach sent semi-standardized feedback on completed sessions and adherence reminders. Furthermore, youth had the opportunity to schedule a telephone contact with licensed therapists if needed. The IMI is described in detail in the study protocol (Schulte et al., 2022).

#### 2.4. Assessments

Feasibility was assessed based on a formal feasibility framework (Orsmond & Cohn, 2015) comprising five different dimensions: (1) recruitment capability and characteristics of the resulting sample; (2) procedures for data collection and outcome measurement; (3) satisfaction and acceptability of the IMI and study procedures; (4) resources and ability to manage and implement the study and the IMI; and (5) participants' preliminary responses to the IMI, i.e. in terms of symptom severity.

(1) **Recruitment capability and sample characteristics.** We collected data on recruitment (e.g. number of individuals applying for study participation; source of recruitment) and

sociodemographics (e.g. age, gender, residence, education) at T1.

- (2) **Data collection procedures and outcome measurement.** We asked participants to evaluate the data collection procedures using self-developed items related to item comprehensibility, assessment-associated stress, and time required for data collection at T3.
- (3) **Satisfaction and acceptability.** The Client Satisfaction Questionnaire (CSQ; Boß et al., 2016) in its version adapted for Internet interventions (CSQ-I; eight items, score range: 8–32;  $\alpha = .95$ ) was applied to measure treatment satisfaction at T3; scores exceeding 23 indicate high satisfaction (Attkisson & Zwick, 1982). The Attitudes towards Psychological Online Interventions Questionnaire (APOI; 16 items; score range: 16–80; Schröder et al., 2015) was used to assess intervention acceptability at T1 and T3. Intervention adherence was assessed by the number of completed sessions, and objective user data (e.g. number of logins) from the secure web-based e-health platform. Additionally, self-reported engagement and acceptance were assessed with self-developed items at T3. The acceptability of individual sessions was evaluated with four self-report items after each online session considering its usefulness, feasibility, comprehensibility, and aesthetics. To measure study adherence, we considered the number of completed online assessments ( $k = 5$ ) and telephone assessments ( $k = 3$ ). Data on help-seeking was assessed with self-developed items.
- (4) **Resources and study management abilities.** eCoaches documented the time dedicated to eCoaching, e.g. time spent learning the manual or providing feedback. We tracked data on the time spent for clinical interviews and additional support through psychotherapists, e.g. in telephone consultations. We also tracked time and counted the e-mails sent for study administration.
- (5) **Symptom severity.** The CATS-2 DSM-5 scale (20 items; score range: 0–60,  $\alpha = .81$ ; Sachser et al., 2022) was used to assess PTSS at each time point (T1–T4). The 15-item screen for exposure to potentially traumatic events of the CATS was applied to check for traumatic events at T0. Diagnosis of PTSD was assessed with the CAPS-CA-5 by licensed psychotherapists (20-item DSM-5 scale; score range: 0–80;  $\alpha = .76$ ; Pynoos et al., 2015). With the Patient Health Questionnaire (PHQ-9; item 09 was removed resulting in 8 items used; score range: 0–24;  $\alpha = .73$ ; Kroenke et al., 2001), depressive symptoms were assessed at each time point (T1–T4). The Generalized Anxiety Disorder Assessment (GAD-7; 7 items; score range: 0–21;  $\alpha = .89$ ; Spitzer et al., 2006)

was used to assess anxiety symptoms at T1-T4. The KIDSCREEN-10-Index (10 items; score range: 0–40;  $\alpha = .67$ ; Ravens-Sieberer et al., 2010) was utilized to measure health-related quality of life at T1-T4. The Child Posttraumatic Cognitions Inventory Short Form (CPTCI-SF; ten items; score range: 10–40;  $\alpha = .67$ ; McKinnon et al., 2016) was employed to assess posttraumatic cognitions at T1 and T3.

- (6) **Potential risks and negative effects.** The Negative Effects Questionnaire (NEQ, Rozental et al.,

2016) was used to assess the frequency (score range: 0–20), impact (score range: 0–80;  $\alpha = .68$ ), and attribution (to treatment or other circumstances) of negative effects during the treatment period (T3 and T4). Suicide item 9 of the Beck Depression Inventory-II was used to assess suicidality at T2 and T4 (single item; range: 0–3; BDI II item 09; Hautzinger et al., 2006). We systematically assessed other potential negative events and their relationship with intervention participation using a list of self-developed items about (serious) adverse events at each T1-T4.

**Table 2.** Sociodemographic data at baseline.

Characteristics	Total sample ( <i>N</i> = 32)
PTSS (CATS), <i>M</i> ( <i>SD</i> )	31.63 (7.64)
PTSD diagnosis (CAPS-CA-5, clinician-rated), <i>n</i> (%)	21 (66)
CAPS-CA-5, total score ( <i>SD</i> )	31.5 (7.89)
Dissociative symptoms, <i>n</i> (%)	8 (25)
Potentially traumatic events (most distressing) <i>M</i> ( <i>SD</i> )	2 (2.56)
Gender <i>n</i> (%)	
Female	28 (87)
Male	3 (9)
Diverse	1 (3)
Age <i>M</i> ( <i>SD</i> )	19 (1.7)
Minor <i>n</i> (%)	4 (13)
Self-reported mental disorder <i>n</i> (%)	
Lifetime diagnosis of any mental disorder	18 (56)
Depression	11 (34)
PTSD	7 (22)
Borderline personality disorder	3 (9)
Anxiety disorder	2 (6)
Attention deficit hyperactivity disorder	1 (3)
Bulimia nervosa	1 (3)
Personality disorder (not defined)	1 (3)
Alcohol consumption disorder	1 (3)
Previous treatment (for any mental disorder) <i>n</i> (%)	16 (50)
Physical disease <i>n</i> (%)	6 (19)
Current medical treatment <i>n</i> (%)	9 (28)
Reasons for participating in IMI study <i>n</i> (%)	
Preference for self-help	20 (62)
IMI seems appealing	14 (44)
Prolonged waiting times for face-to-face therapy	13 (41)
No psychotherapy facility located	9 (28)
Worries about not being taken seriously	6 (19)
Concerns about disclosing personal matters to strangers	5 (16)
Lack of knowledge of services available	5 (16)
Timing or travel constraints	4 (13)
No other treatment identified	4 (13)
Financial concerns	3 (9)
Problems not deemed severe enough for psychotherapy	3 (9)
Unavailable psychotherapy services in the residential region	2 (6)
No psychotherapy due to fear of stigmatization	2 (6)
Confidence in self-help	2 (6)
Other reasons	1 (3)
Recruitment source <i>n</i> (%)	
Relatives	9 (28)
Instagram	8 (25)
Friends	6 (19)
Counselling centre	6 (19)
Insurance company	4 (13)

Notes. *M* = mean. PTSD = Posttraumatic Stress Disorder. PTSS = Posttraumatic Stress Symptoms measured with CATS (Child and Adolescent Trauma Screen, Sachser et al., 2022). CAPS-CA-5 = Clinician Administered PTSD Scale for DSM 5 – Child and Adolescent Version (Pynoos et al., 2015). *SD* = standard deviation. T1 = Baseline, self-rated online assessment before IMI access.

\*15-item screen for exposure to potentially traumatic events defined as distressing and disturbing events in the Child and Adolescent Trauma Screen.

## 2.5. Management of negative events

To oversee negative events, predefined potential (Serious) Adverse Events ((S)AEs) were actively monitored throughout the study. A systematic, step-by-step manual outlining procedures for managing (S)AEs was developed and adhered to. Regular reports on all (S)AEs were provided to an independent Data Safety Monitoring Board, which could propose recommendations for their management (details on safety management in Schulte et al., 2024; 2022).

## 2.6. Data analysis

All analyses adhered to the guidelines for reporting non-randomized pilot and feasibility studies (Lancaster & Thabane, 2019). We report descriptive statistics for all outcomes of the feasibility dimensions at each time point. The evaluation of objective user data and satisfaction with the single sessions of the IMI was based on the intervention completer sample. The primary analyses regarding the preliminary evaluation of participant's responses to the intervention in terms of i.e. PTSS, depressive and anxiety symptoms, and health-related quality of life were based on per protocol principle, including study completer data. We reported within-group differences between time points (i.e. T1 and T2, T1 and T3, T1 and T4, T3 and T4) using a two-sided *t*-test for dependent groups. We reported Cohen's *d* within-group-effect sizes using the sample standard deviation of the mean difference adjusted by a correction factor as the denominator and their 95% CIs (Hedges & Olkin, 1985). To test for reliable improvement and deterioration of PTSS on a single-person level, we calculated the reliable change index (RCI) (Jacobson & Truax, 2004) based on study completer data. Besides, we reported the percentage of participants with PTSS scores below the cut-off for probable PTSD at T3 and T4 ( $\leq 21$ , CATS, Sachser et al., 2022), and the percentage of participants who lost PTSD diagnosis from T1 to T3. Additionally to the primary analysis, we used multivariate mixed effect models for repeated measures

(MMRM) to consider dropout (intention-to-treat analysis) and to assess the longitudinal relationship between each preliminary outcome and time (i.e. T1-T4) (Mallinckrodt et al., 2008), while using the 'Kenward-Roger' method to construct confidence intervals (Kenward & Roger, 1997). We estimate effect sizes for MMRM results using the standard deviation of the sample at T1 as the denominator. Analyses were performed using IBM SPSS Statistics (Version 27), and R statistics software (version 4.3.1) (R Core Team, 2022). The significance level for all analyses was set to 0.05 and reported *p*-values are two-sided.

### 3. Results

#### 3.1. Recruitment capability and sample characteristics

Participants were recruited via online (e.g., social media posts on Facebook, Instagram, and TikTok) and offline (e.g., flyers in schools, clinics, counselling centres, and youth welfare offices) strategies (see Figure 1). Between 14 July 2021, and 13 January 2023, a total of 259 individuals applied for study participation. Of the 199 individuals meeting the age criterion and receiving study information (77%,  $n = 199/259$ ), 41% were minors (41%,  $n = 82/199$ ) and the remaining were aged between 18 and 21 years (59%,  $n = 117/199$ ). Overall, only a quarter (25%,  $n = 50/199$ ) provided informed consent with the majority of them being aged 18–21 (88%,  $n = 44/50$ ). After a positive screening, 32 individuals with three of them being minor (9%,  $n = 3/32$ ) received access to the IMI (see reasons for exclusion in Figure 1). The recruitment process lasted 18 months yielding an average rate of 1.78 included cases per month. Most participants stated becoming aware of the study through their relatives (28%,  $n = 9/32$ ) or Instagram (25%,  $n = 8/32$ ). The most common reason for participation in an IMI study was a preference for self-help (63%,  $n = 20/32$ ), followed by perceived attractiveness of an IMI (44%,  $n = 14/32$ ), or overly long waiting times for on-site psychotherapy (41%,  $n = 13/32$ ) (Table 2).

Most participants were female (87%,  $n = 28/32$ ) with a mean age of 19.1 years ( $SD = 1.7$ , range: 15–21). PTSS severity in the sample was high (CATS:  $M = 32.63$ ,  $SD = 5.94$ , range: 22–44) and the majority fulfilled a PTSD diagnosis (CAPS CA 5: 66%,  $n = 21/32$ ). Half of the participants never had any prior mental health treatment (50%,  $n = 16/32$ ) (Table 2). The participants experienced, on average, two traumatic events ( $SD = 1.15$ , range: 1–5), with the most common events being exposure to sexualized violence (63%,  $n = 20/32$ ), bullying (28%,  $n = 9/32$ ), family violence (25%,  $n = 8/25$ ), other stressful events

(25%,  $n = 8/32$ ), sudden death of a loved person (19%,  $n = 6/32$ ), or a medical event (13%,  $n = 4/32$ ). The frequency of single potentially traumatic events (CATS) and additional sociodemographic variables are attached in the Appendix.

#### 3.2. Data collection procedures and outcome measurement

Youth providing data at T4 stated that the questions in the online assessments were understandable (84%,  $n = 16/19$ ) or partly understandable (16%,  $n = 3/19$ ). Most of them indicated that they had enough time to participate in the assessments (84%,  $n = 16/19$ ). The self-estimated time commitment for participating in the online assessments was deemed appropriate by most participants (84%,  $n = 16/19$ ). The dropout rate from the study's online- and telephone assessments increased over time with 28% at T2, 31% at T3, up to 47% for T4 (Figure 1). At the designated self-rated online assessments, a minority of individuals had finished the core sessions of the IMI (T3:  $n = 5/22$ , 23%; T4:  $n = 9/19$ , 47%, see Appendix).

#### 3.3. Satisfaction and acceptability

Satisfaction data was provided by 69% ( $n = 22/32$ ) of the sample. From those, ninety-one percent of participants ( $n = 20/22$ ) expressed satisfaction with the intervention, with 86% ( $n = 19/22$ ) willing to recommend the IMI to a friend in need and 77% ( $n = 17/22$ ) indicating that the intervention met their needs, resulting in an overall high satisfaction score ( $M = 26$ ,  $SD = 5.83$ , range: 8–32). The IMI was rated as compatible (45%,  $n = 10/22$ ) or partly compatible (55%,  $n = 12/22$ ) with daily life and the majority rated the time available for session completion as enough (45%,  $n = 10/22$ ) or, partly enough (36%,  $n = 8/22$ ). Only four participants indicated not having had enough time (18%,  $n = 4/22$ ). The ratings of the individual sessions indicated that youths mostly found them to be useful ( $M = 95\%$ ), understandable ( $M = 94\%$ ), and aesthetically pleasing ( $M = 94\%$ ). The sessions on the trauma narrative were predominantly rated as challenging ( $M = 80\%$ ), whereas the other sessions were considered easily manageable ( $M = 82\%$ ). The participants' positive attitudes towards IMIs in general were high at T1 (APOI total scale:  $M = 59.56$ ,  $SD = 5.56$ ,  $n = 32$ ) and still high at T3 (APOI total scale:  $M = 52.91$ ,  $SD = 9.42$ ,  $n = 22$ ), but significantly less positive compared to T1 [ $t(21) = 3.98$ ;  $p < .001$ ,  $d = 0.83$ ; 95%-CI = .35–1.33] (see Appendix for descriptive statistics of the APOI subscales).

All individuals (100%,  $n = 32/32$ ) logged into the IMI at least once. However, four of them (13%,  $n = 4/32$ ) did not proceed to actively engage with the IMI, and one participant (3%,  $n = 1/32$ ) solely utilized the diary

function but never started completing the sessions. Reasons for not starting intervention completion included finding the intervention unhelpful (20%,  $n = 1/5$ ), lack of motivation and time constraints (20%,  $n = 1/5$ ), and a broken laptop (20%,  $n = 1/5$ ). The first stabilization phase of the IMI (1–3) was completed by 75% of participants ( $n = 24/32$ ). Among the four who discontinued the IMI during the stabilization phase, two reported initiating on-site psychotherapy instead (50%,  $n = 2/4$ ). Forty-one percent of participants also completed the second phase (4–6), where trauma processing was conducted (41%,  $n = 13/32$ ). Reasons for discontinuation in the second phase included experiencing symptom remission (10%,  $n = 1/10$ ), finding the intervention unhelpful or too stressful (20%,  $n = 2/10$ ), preferring personal contact (10%,  $n = 1/10$ ), starting on-site psychotherapy (10%,  $n = 1/10$ ), or external stressors (10%,  $n = 1/10$ ). The last and third phase (7–8), with consolidation and integration of the traumatic event, was completed by 31% of participants ( $n = 10/32$ ), whereas reasons for discontinuation were available in two cases describing symptom remission (67%,  $n = 2/3$ ). All sessions including the ninth booster session were completed by 25% ( $n = 8/32$ ) (Figure 2).

On average, participants logged into the IMI 37.35 times ( $SD = 29.31$ , range:4–115,  $n = 32$ ) and used the intervention for 121 days ( $SD = 119$ , range:13–554,  $n = 32$ ). The diary feature was employed by 21 participants (66%,  $n = 21/32$ ,  $M = 27.1$ ,  $SD = 24.66$ , range: 1–72,  $n = 21$ ). Participants received on average 10.25 messages from their eCoach ( $SD = 5.69$ , range: 1–22,  $n = 32$ ), while 22 participants (69%,  $n = 22/32$ ) actively used the chat function to contact the eCoach ( $M = 5.82$ ,  $SD = 5.13$ , range: 1–21,  $n = 22$ ). Overall, participants required 43 minutes for session completion ( $SD = 16$ ).

All participants (100%,  $n = 32/32$ ) had sought help before study participation, mostly from friends or close relatives (75%,  $n = 24/32$ ), or parents and family members (56%,  $n = 18/32$ ). More than half of the sample also sought professional help before study start by psychological counselling centres (59%,  $n = 19/32$ ) or a therapist (53%,  $n = 17/32$ ). After participating in the study and the IMI, 73% ( $n = 16/22$ ) of participants expressed an increased likelihood of seeking general help and 73% ( $n = 16/22$ ) stated more likely considering on-site psychotherapists in the future.

### 3.4. Resources and study management abilities

Interviewers spent an average of 2.49 hours at T0 ( $k = 37$ , range: 1.5–3.25) and 1.99 hours at T3 ( $k = 23$ , range: 1–2.75) conducting interviews. eCoaches took an average of 1.5 hours (range: 1–4) to learn the manual. Each session feedback took approximately 18

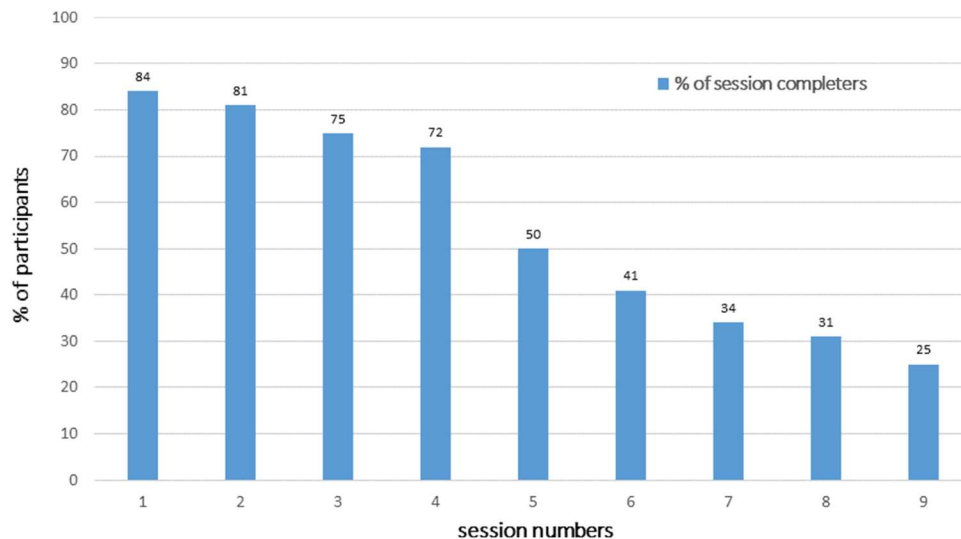
minutes (range: 10–25). eCoaches who were already acquainted with eCoaching in general rated the overall effort for guidance as low. Twelve participants (38%,  $n = 12/32$ ) opted for telephone consultations, totalling 14 clinical consultation sessions lasting 1.7 hours on average (range: 1.25–3), focusing mainly on resource activation and emotion regulation. In total, 7.9 hours of therapeutic resources were acquired per participant, including 4.48 hours for clinical assessments, and 3.44 hours for therapist guidance through the intervention and the study. The study team sent 1569 e-mails to participants, 298 to interviewers, and 170 to eCoaches for study administration and negative effect management, which dedicated approximately 1.5 hours per day (range: 20 minutes to 3 hours).

### 3.5. Symptom severity

The evaluation of the symptom scores in the study completer sample showed a decrease of PTSS and PTSD severity over all time points (T2–T4, Table 3). Furthermore, depressive symptoms, symptoms of anxiety, and posttraumatic cognitions were lower at post-assessment time points (T3, T4) compared to baseline (T1). Health-related quality of life improved over all time points (Table 3).

In the per-protocol analyses with the study completer sample, significant small to medium effects were observed in PTSS via CATS from T1 to T2 [ $t(22) = 2.27$ ,  $p = .033$ ,  $d = 0.46$ ], large effects from T1 to T3 [ $t(21) = 4.27$ ,  $p < .001$ ,  $d = 0.88$ ] and T1 to T4 [ $t(18) = 3.83$ ;  $p = .001$ ;  $d = 0.84$ ]. Clinician-rated PTSD severity significantly decreased from T1 to T3 [ $t(21) = 4.52$ ;  $p < .001$ ;  $d = 0.93$ ]. There were no significant differences in depressive symptoms from T1 to T2 [ $t(22) = -0.01$ ,  $p = .913$ ]. At T3 [ $t(21) = 3.48$ ;  $p = .002$ ;  $d = 0.71$ ] and T4 [ $t(18) = 2.34$ ;  $p = .031$ ;  $d = 0.51$ ], depressive symptoms were significantly lower compared to T1. Symptoms of anxiety did not change significantly from T1 to T2 [ $t(22) = -1.53$ ;  $p = .139$ ] and T1 to T3 [ $t(21) = 1.61$ ;  $p = .123$ ]. At T4, anxiety symptoms were significantly lower compared to T1 [ $t(18) = 2.44$ ,  $p = .025$ ,  $d = 0.54$ ]. Health-related quality of life did not change significantly from T1 to T2 [ $t(22) = -0.80$ ;  $p = .434$ ], but was significantly higher at T3 [ $t(21) = -2.26$ ;  $p = .034$ ;  $d = -0.47$ ] and T4 [ $t(18) = -2.85$ ;  $p = .011$ ;  $d = -0.63$ ] compared to T1. There were no significant differences in any outcome from T3 to T4. Posttraumatic cognitions did not change on a significant level from T1 to T3 [ $t(df) = 2.07(21)$ ;  $p = .052$ ] (Table 4).

Intention-to-treat analysis via MMRM models indicated a significant reduction in PTSS via CATS from T1 to T2 [ $\beta = -3.43$ ;  $SE = 1.33$ ;  $t(df) = 2.59$  (24.33);  $p = .016$ ], T1 to T3 [ $\beta = -7.44$ ;  $SE = 1.81$ ;  $t(df) = 4.12(23.56)$ ;  $p < .005$ ], and T1 to T4 [ $\beta = -7.78$ ;  $SE = 1.96$ ;  $t(df) = 3.96(23.96)$ ;  $p < .005$ ], with



**Figure 2.** Completion rates of IMI sessions in % ( $n = 32$ ).

Note. Session numbers 1–3 deal with safety and coping skills. Sessions 4–6 deal with trauma processing. Session 7–9 deal with consolidation/integration of the traumatic event(s), with session 9 being a booster-session.

small to large effect sizes ( $d = -0.45$  to  $-1.02$ ). PTSD severity via CAPS-CA-5 was significantly reduced at T3 compared to T1 [ $\beta = -10.08$ ;  $SE = 2.13$ ;  $t(df) = 4.74(21.24)$ ;  $p < .001$ ] with large effect size ( $d = -1.31$ ). Concerning depressive symptoms, MMRM analysis demonstrated a significant reduction from T1 to T3 [ $\beta = -3.01$ ;  $SE = 0.91$ ;  $t(df) = 3.29(23.85)$ ;  $p = .003$ ] and T1 to T4 [ $\beta = -2.29$ ;  $SE = 0.96$ ;  $t(df) = 2.39(23.45)$ ;  $p = .025$ ] with small effect sizes ( $d = -0.58$  to  $-0.76$ ). The same pattern was found for health-related quality of life from T1 to T3 [ $\beta = 3.81$ ;  $SE = 1.39$ ;  $t(df) = 2.74(23.8)$ ;  $p = .011$ ] and T1 to T4 [ $\beta = 4.71$ ;  $SE = 1.31$ ;  $t(df) = 3.59(22.5)$ ;  $p = .001$ ] with medium effect sizes ( $d = 0.77$ – $0.95$ ). For symptoms of anxiety, a significant reduction was observed from T1 to T4 [ $\beta = -2.48$ ;  $SE = 0.84$ ;  $t(df) = 2.95(23.57)$ ;  $p = .007$ ] with medium effect size ( $d = -0.6$ ) (Table 5).

The RCI indicated reliable improvement in PTSS for 32% of cases from T1 to T3 ( $n = 7/22$ , 32%), and 37% from T1 to T4 ( $n = 7/19$ , 37%). None of the participants showed reliable deterioration of PTSS from T1 to T3 or T1 to T4 according to RCI scores. PTSS scores were below the cut-off ( $< 21$  for probable PTSD) in 41% of cases at T3 ( $n = 9/22$ , 41%) and in 63% at T4 ( $n = 12/22$ , 63%) (see Appendix eFigure 1, 2, 3 for individual trajectories of PTSS). Regarding PTSD diagnosis, 45% of participants ( $n = 10/22$ ) no longer met the criteria for PTSD diagnosis at T3.

### 3.6. Potential risks and negative effects

All participants at T3 (100%,  $n = 22/22$ ) reported experiencing negative effects during the study, with the most common being the resurfacing of unpleasant memories (77%,  $n = 17/22$ ), more unpleasant feelings

(68%,  $n = 15/22$ ), increased stress (68%,  $n = 15/22$ ), and heightened worries (59%,  $n = 13/22$ ) (see Appendix). Overall, there were 120 instances of negative effects at T3 experienced by participants ( $M = 6.4$ ,  $SD = 4.2$ , range: 1–20 per participant), of which 82 (59%) instances ( $M = 3.7$ ,  $SD = 3.99$ , range: 0–18 per participant) were attributed to the IMI. The impact of the negative effects was generally rated as low ( $M = 13.8$ ;  $SD = 9.86$ ; range: 1–39,  $n = 22$ ). In total, six participants reported the presence of suicidal thoughts or behaviours at some time point (19%,  $n = 6/32$ ). Of those six, three cases at T2 (13%,  $n = 3/23$ ) and four cases at T4 (21%,  $n = 4/19$ ) reported thoughts of killing themselves without intent, while one participant (5%,  $n = 1/19$ ) expressed a desire to do so at T4. Throughout the study, there were 17 incidents of adverse events, including suicidality, in 12 participants (38%,  $n = 12/32$ ). Four of these 17 incidents were related to the intervention due to elevated symptom burden. There were five incidents of serious adverse events in five participants (15%,  $n = 5/32$ ), all of them not being related to the intervention. All negative effects were closely monitored according to the safety management concept and forwarded to the Data Safety Monitoring Board.

## 4. Discussion

This study evaluated the feasibility of a trauma-focused IMI with therapist guidance for youth with clinically relevant PTSS. Recruitment proved successful but time-consuming with over half of the applicants not providing informed consent, and only one in twelve being eligible. The sample, predominantly young women, had an underrepresentation of minors. The majority of participants had experienced

**Table 3.** Means and Standard Deviations for participant responses to the IMI for all time points in the study completer sample

Variable/time point	Pre (T1) (n = 32)	Mid (T2) (n = 23)	Post (T3) (n = 22)	Follow-Up (T4) (n = 19)
Posttraumatic stress symptoms (CATS), <i>M, SD</i>	31.63 (7.64)	27.17 (8.59)	22.59 (10.59)	21.63 (11.21)
PTSD severity (CAPS-CA-5), total score, <i>SD</i>	31.47 (7.89)	–	21.14 (11.82)	–
Depressive symptoms (PHQ-9*), <i>M, SD</i>	12.66 (4.11)	11.91 (4.79)	8.73 (5.21)	8.68 (4.55)
Anxiety symptoms (GAD-7), <i>M, SD</i>	10.78 (4.41)	10.78 (3.91)	8.27 (4.93)	7.37 (4.23)
Health-related quality of life (KIDSCREEN), <i>M, SD</i>	28.50 (4.93)	29.83 (6.11)	32.64 (6.58)	33.84 (6.44)
Posttraumatic cognitions (CPTCI-SF), <i>M, SD</i>	25.97 (5.6)	–	23.82 (7.51)	–

Note. CAPS-CA-5 = Clinician Administered PTSD Scale for DSM 5 – Child and Adolescent Version (Pynoos et al., 2015).

CATS = Child and Adolescent Trauma Screen (Sachser et al., 2022). CPTCI-SF = Posttraumatic Cognitions Inventory Short Form (McKinnon et al., 2016).

GAD-7 = Generalized Anxiety Disorder Assessment (Spitzer et al., 2006). KIDSCREEN = Health-Related Quality of Life Questionnaire for Children and Young People (Ravens-Sieberer et al., 2010). *M* = Mean. PHQ-9 = Patient Health Questionnaire (Kroenke et al., 2001). *SD* = Standard Deviation. T1 = Baseline before IMI access. T2 = after completion of the third session or 3 weeks after IMI access. T3 = after completion of the eight core sessions, or 8 weeks after IMI access. T4 = 6 months after IMI access.

interpersonal traumatic events, with elevated PTSS levels and almost two-thirds received a PTSD diagnosis. Data collection procedures were deemed appropriate and half the sample completed all assessments. Each participant required around seven hours of therapeutic resources including eCoaching, mostly for clinical study assessment. Satisfaction with the IMI was high, with online sessions well-accepted. However, the trauma processing sessions were perceived as difficult. A quarter of the participants discontinued treatment at this stage, with reasons including finding the intervention too stressful, starting on-site psychotherapy and symptom remission. Self-rated PTSS significantly decreased from T1 to T3 ( $d = 0.88$ ) and from T1 to T4 ( $d = 0.88$ ). Reliable improvement was evident for 37% of cases from T1 to T3 ( $n = 7/22$ ) and 37% of cases from T1 to T4 ( $n = 7/19$ ). Clinician-rated PTSD severity significantly decreased from

T1 to T3 ( $d = 0.93$ ) among study completers. Significant improvements with small to large effects were observed post-treatment and at follow-up for all outcomes in the intention-to-treat analysis. Despite experiencing treatment content, some individuals did not benefit from the IMI. Negative effects were observed, the majority of which were primarily linked to the IMI and characterized by resurfacing unpleasant memories and unpleasant feelings. All (S)AEs were promptly addressed, and no clinically significant deterioration in PTSS occurred.

Recruiting via social media enabled the use of precise targeting, potentially contributing to reaching a wider pool of participants, including those who had never received treatment before, as a large proportion of young people use the internet and social media to search for health information (Rideout & Fox, 2018). However, limitations of social media recruiting like

**Table 4.** Participant responses from Pre (T1) to Post-Treatment (T3), Pre-Treatment (T1) to Follow-Up (T4), and Post-Treatment (T3) to Follow-Up (T4) in a per-protocol analysis with study completer data.

Variable	<i>M (SD)*</i> Pre (T1)	<i>M (SD)*</i> Mid (T2)	<i>n</i>	<i>t(df)</i>	<i>p</i>	<i>d</i>	95%CI
Posttraumatic stress symptoms (CATS)	30.39 (7.38)	27.17 (8.59)	23	2.27 (22)	0.033	0.46	0.04–0.87
Depressive symptoms (PHQ-9*)	11.83 (3.94)	11.91 (4.79)	23	–0.01 (22)	0.913	–0.02	–0.42–0.37
Anxiety symptoms (GAD-7)	9.70 (4.18)	10.65 (3.92)	23	–1.53 (22)	0.139	–0.31	–0.71–0.10
Health-related quality of life (KIDSCREEN)	29.04 (4.93)	29.83 (6.10)	23	–0.80 (22)	0.434	–0.16	–0.56–0.24
	<i>Pre (T1)</i>	<i>Post (T3)</i>					
Posttraumatic stress symptoms (CATS)	31.05 (8.45)	22.59 (10.59)	22	4.27 (21)	<.001	0.88	0.39–1.35
PTSD severity (CAPS-CA-5)	31.14 (7.69)	21.14 (11.82)	22	4.52 (21)	<.001	0.93	0.43–1.41
Depressive symptoms (PHQ-9*)	12.23 (4.67)	8.73 (5.21)	22	3.48 (21)	0.002	0.71	.25–1.16
Anxiety symptoms (GAD-7)	10 (4.71)	8.27 (4.94)	22	1.61 (21)	0.123	0.33	–.09–.74
Health-related quality of life (KIDSCREEN)	29.18 (5.07)	32.64 (6.58)	22	–2.26 (21)	0.034	–0.47	–.89– –.03
Posttraumatic cognitions (CPTCI-SF)	25.95 (6.29)	23.82 (7.51)	22	2.07 (21)	0.052	0.42	0–.84
	<i>Pre (T1)</i>	<i>Follow-Up (T4)</i>					
Posttraumatic stress symptoms (CATS)	30.53 (7.98)	21.63 (11.21)	19	3.83 (18)	0.001	0.84	0.32–1.34
Depressive symptoms (PHQ-9*)	11.37 (3.89)	8.68 (4.55)	19	2.34 (18)	0.031	0.51	.05–.97
Anxiety symptoms (GAD-7)	9.84 (4.68)	7.37 (4.23)	19	2.44 (18)	0.025	0.54	.06–0.99
Health-related quality of life (KIDSCREEN)	29.63 (4.90)	33.84 (6.44)	19	–2.85 (18)	0.011	–0.63	–1.09– –.15
	<i>Post (T3)</i>	<i>Follow-Up (T4)</i>					
Posttraumatic stress symptoms (CATS)	20.18 (9.29)	19.47 (9.7)	17	.52 (16)	0.612	0.12	–.34–.57
Depressive symptoms (PHQ-9*)	6.94 (3.29)	8.06 (4.38)	17	–1.42 (16)	0.174	–0.33	–.79–.14
Anxiety symptoms (GAD-7)	6.67 (3.99)	6.67 (4.01)	17	0 (16)	1	0	–.45–.45
Health-related quality of life (KIDSCREEN)	33.82 (6.43)	34.35 (6.52)	17	–.35 (16)	0.734	–0.08	–.53–.37

Note. \*Means and standard deviations represent pairwise data. CAPS-CA-5 = Clinician Administered PTSD Scale for DSM 5 – Child and Adolescent Version (Pynoos et al., 2015). CATS = Child and Adolescent Trauma Screen (Sachser et al., 2022). CPTCI-SF = Posttraumatic Cognitions Inventory Short Form (McKinnon et al., 2016). CSQ-I = Client Satisfaction Questionnaire, adapted for internet-based interventions (Boß et al., 2016). GAD-7 = Generalized Anxiety Disorder Assessment (Spitzer et al., 2006). KIDSCREEN = Health-Related Quality of Life Questionnaire for Children and Young People (Ravens-Sieberer et al., 2010). PHQ-9 = Patient Health Questionnaire (Kroenke et al., 2001). T1 = Baseline before IMI access. T2 = after completion of the third session or 3 weeks after IMI access. T3 = after completion of the eight core sessions, or 8 weeks after IMI access. T4 = 6 months after IMI access.

**Table 5.** Longitudinal relationship between outcomes and time (T1 to T2, T1 to T3, T1 to T4) in a multivariate model repeated measures (MMRM) analysis.

Variable/Outcome	Regression Coefficient		MMRM Model			Effect size	
	$\beta_{\text{change}}$	SE	T	df	p	d	95%CI
Posttraumatic stress symptoms (CATS)							
Mid-Intervention (T2)	-3.43	1.33	2.59	24.33	.016	-0.45	-0.8- -0.1
Post-Assessment (T3)	-7.44	1.81	4.12	23.56	<.005	-0.97	-1.46- -0.49
Follow-Up (T4)	-7.78	1.96	3.96	23.96	<.005	-1.02	-1.54- -0.5
PTSD severity (CAPS-CA-5)							
Post-Assessment (T3)	-10.08	2.13	4.74	21.24	<.001	-1.31	-1.87- -0.75
Depressive symptoms (PHQ-9*)							
Mid-Intervention (T2)	0.07	0.72	0.09	25.07	.927	0.02	-0.35- -0.39
Post-Assessment (T3)	-3.01	0.91	3.29	23.85	.003	-0.76	-1.23- -0.29
Follow-Up (T4)	-2.29	0.96	2.39	23.45	.025	-0.58	-1.07- -0.08
Anxiety symptoms (GAD-7)							
Mid-Intervention (T2)	0.62	0.59	1.06	23.34	.302	0.15	-0.13-0.44
Post-Assessment (T3)	-1.82	0.95	1.92	25.91	.066	-0.44	-0.9-0.02
Follow-Up (T4)	-2.48	0.84	2.95	23.57	.007	-0.6	-1.02- -0.18
Health-related quality of life (KIDSCREEN)							
Mid-Intervention (T2)	0.58	0.95	0.62	22.48	.544	0.11	-0.27-0.51
Post-Assessment (T3)	3.81	1.39	2.74	23.8	.011	0.77	0.19-1.35
Follow-Up (T4)	4.71	1.31	3.59	22.5	.001	0.95	0.41-1.5
Posttraumatic Cognitions (CPTCI)							
Post-Assessment (T3)	-2.14	0.99	2.14	21.13	.044	-0.34	-0.6- -0.02

Note. CAPS-CA-5 = Clinician Administered PTSD Scale for DSM 5 – Child and Adolescent Version (Pynoos et al., 2015). CATS = Child and Adolescent Trauma Screen (Sachser et al., 2022). CPTCI-SF = Posttraumatic Cognitions Inventory Short Form (McKinnon et al., 2016). GAD-7 = Generalized Anxiety Disorder Assessment (Spitzer et al., 2006). KIDSCREEN = Health-Related Quality of Life Questionnaire for Children and Young People (Ravens-Sieberer et al., 2010). PHQ-9 = Patient Health Questionnaire (Kroenke et al., 2001). T1 = Baseline before IMI access. T2 = after completion of the third session or 3 weeks after IMI access. T3 = after completion of the eight core sessions, or 8 weeks after IMI access. T4 = 6 months after IMI access.

selection bias and self-selection when solely using social media recruitment should be noted. Therefore, we supplemented our approach with offline recruitment strategies, reaching out to counselling centres, youth clinics, and schools via flyers. Despite high initial study interest, there were few youth who provided informed consent, indicating barriers to youth treatment initiation in this study. Trust issues, fear of negative responses, and questioning the validity of trauma response could be factors that may have impeded personal data disclosure and led to waning interest after reviewing inclusion criteria in the consent form (Truss et al., 2022). For minors, reasons such as parental separation or institutional placement leading to difficulties in providing informed consent from both, caretakers or legal guardians, could have posed significant barriers. Furthermore, the sample exhibited elevated symptom strain compared to national and international samples of traumatized children and adolescents, with CATS scores ranging between 25.66 and 30.75, and 54% fulfilling PTSD diagnosis in CAPS-CA DSM 5 (Sachser et al., 2022). Yet, the symptom profile resembled those in IMI studies for adults with PTSD, where trauma-focused IMIs have effectively treated individuals with interpersonal and multiple traumas and severe, or even chronic, PTSD (Ehlers et al., 2023; Spence et al., 2014). Compared to face-to-face tf-CBT for youth, with completion rates ranging from 60% to 90% (Cohen & Mannarino, 1998; Peters et al., 2021), and therapist-assisted i-tf-CBTs for adults, which showed a mean completion rate of 77% (Simon et al., 2021),

the completion rate in this study was lower. Over half of the dropouts occurred during the trauma processing phase. This contrasts with findings in i-tf-CBTs for adults, where neither increased dropout rates during trauma processing nor differences between study groups receiving trauma-focused versus non-trauma-focused IMIs were reported (Ehlers et al., 2023; Spence et al., 2014). Weekly phone calls with a trained tf-CBT therapist in these studies may have strengthened the therapeutic alliance and session engagement commitment. Therapeutic resources for the IMI were considerably lower compared to the recommended resources for face-to-face first-line therapies (NICE, 2005), typically involving 8–12 sessions lasting 50–90 minutes each. Required resources in this study were similar to those in i-tf-CBTs for adults, ranging from 2.5 hours (Lewis et al., 2017; Spence et al., 2014) to half of the ‘usual therapist time’ (Ehlers et al., 2023). The effect sizes for the PTSS reduction in the intention-to-treat analysis ( $d = -1.31$ ,  $n = 32$ ) are lower compared to those found in a recent study on a i-tf-CBTs for adults with PTSD ( $d = 2.22$ ,  $n = 100$ ; Ehlers et al., 2023). However, they are comparable to the within-group effects found in a face-to-face tf-CBT feasibility study on youth with interpersonal trauma ( $d = -0.83$ ,  $n = 20$ ; Peters et al., 2021). This suggests that i-tf-CBT might be effective for young adults, but more research is needed to understand mechanisms of action in the online setting to achieve similar efficacy findings as seen in adults. No comparable studies were found to compare the effect sizes found in the study completer analysis. Some individuals

showed a worsening in PTSS symptoms, however, not clinically significant, which was not observed in the findings of IMI studies on adults or, if present, was limited to one up to three cases (Ehlers et al., 2023; Lewis et al., 2017; Spence et al., 2014). Direct comparison to other studies and interpreting negative effects is limited due to scarce research in youth and adults. A single identified study on youth with various mental disorders reported similar findings, indicating that all participants experienced at least one negative effect, with 67% attributing at least one negative effect to psychotherapy (Watson et al., 2023). Consistent with our results, the most prevalent negative effects associated with the intervention were unpleasant memories and increased stress (Watson et al., 2023), suggesting that these effects might be common effects of psychotherapy rather than specifically relatable to i-tf-CBTs.

#### 4.1. Limitations

Several limitations should be considered when interpreting the study findings. First, selection bias might have occurred due to the requirement for minors to obtain informed consent from both legal guardians, possibly resulting in an underrepresentation of underage participants and potentially affecting the generalizability of the results to younger samples. Moreover, the chosen recruitment strategy might have led to a predominantly young adult, female sample with interpersonal traumatic experiences, which further limits the generalizability of the findings. Second, as a feasibility study without a control group and randomization, the results of participant responses are preliminary, and no conclusions can be drawn on the efficacy of the IMI. Furthermore, the drop-out rates for study assessments must be considered when interpreting the findings. Satisfaction scores were obtained from study completers and were not imputed, potentially introducing attrition bias. Third, we utilized one single item to assess suicidality, which is not recommended for safety management procedures (Schulte & Sextl-Plötz, et al., 2024) and our safety management did not include symptom deterioration, although representing a possible negative effect of an intervention (Rozenal et al., 2014). Fourth, the assessors conducting the interviews at post-assessment were not masked to treatment allocation due to the nature of the study. Further, in some cases, the assessors were involved in the intervention progress as they conducted therapeutic telephone consultations during intervention participation. Fifthly, our study lacks a clear definition of feasibility thresholds in the form of progression criteria to proceed with an RCT. While there is development of traffic light systems to guide feasibility studies, clear evidence-based thresholds for feasibility criteria have yet to be established (Herbert et al., 2019).

#### 4.2. Future research

Future research should enhance accessibility to study participation, particularly for minors. Introducing more youth-friendly communication options, such as secure data-based chat programmes, could facilitate addressing concerns related to data security, trauma exposure, or consent issues from legal guardians. Besides, exploring participation possibilities for minors without requiring consent from legal guardians, while considering data security and ethical considerations, seems to be crucial. In some cases, an offending parent might still retain the right of custody, so the likelihood of potential participants having the offending caregiver sign the consent form will be close to zero. Tailoring recruitment strategies, to better engage youth with accidental or single trauma, could involve targeting settings like hospitals or law enforcement departments. In adults, trauma-focused treatment is recommended as the preferred choice in digital interventions, as it proves superior to non-trauma-focused approaches (Ehlers et al., 2023). Exploring whether and how the specific effects of trauma-focused interventions can be achieved in youth should be the focus of future research. In the first step, the key components contributing to symptom improvement should be identified. Therefore, future research should rigorously measure PTSS to inform a more targeted intervention approach. Further, strategies to enhance adherence, such as facilitating access to the IMI via a smartphone app, shortening the length of the sessions, rearranging the session sequence and starting with exposure early on, as well as expanding therapeutic guidance through scheduled calls or video sessions to promote commitment in engagement, should be investigated. Young individuals facing challenges in completing the IMI sessions may benefit from a stepped-care approach, beginning with a low-threshold IMI as the initial step and progressing to more intensive interventions as needed, such as referral to face-to-face therapy. Blended approaches might be particularly promising for youth uncomfortable working on trauma independently. For efficacy evaluation, conducting an RCT is pivotal. Regarding negative effects, future research should focus on distinguishing between those due to treatment and those inherent in the treatment process (Watson et al., 2023). Negative experiences may result in premature discontinuation and render therapy unhelpful for some individuals. Conversely, one study provides initial evidence that others may perceive these experiences as integral to the therapeutic process and recovery (Watson et al., 2023). Subsequent studies should explore whether negative effects truly bear negative implications, enabling researchers to inform participants comprehensively about the short- and long-term consequences of

such experiences. Furthermore, the safety management concept should be expanded on procedures for dealing with symptom deterioration or absence of change. Finally, future pilot studies should define formal progression criteria, for instance, akin to a traffic light system (Avery et al., 2017). This predefined system enables to identify feasibility dimensions to be adapted before moving on to a subsequent trial (orange) as well as dimensions clearly rejecting trial progression (red) more quickly and objectively (Avery et al., 2017; Herbert et al., 2019).

### 4.3. Conclusion

This study is the first to investigate the feasibility of a trauma-focused IMI with therapist guidance for youth with PTSD, making a significant contribution to the literature on empirically tested IMIs for youth with PTSD. The study found feasibility in recruitment, data collection, and safety. The IMIs online session were deemed useful, aesthetically pleasing, and comprehensible by those who completed them. However, a notable number of youths discontinued the intervention. Further investigation into strategies aimed at improving adherence, including expanding therapeutic guidance or rearranging the sequence of online session, is warranted. The results also suggest potential efficacy in PTSS symptom change, underscoring the need for a randomized controlled trial to rigorously evaluate the efficacy of i-tf-CBTs.

### Disclosure statement

Christina Schulte (CS), Cedric Sachser (CeS), and Rita Rosner (RR) have nothing to disclose. David Daniel Ebert (DE) reports receiving fees from Get.On Institute, personal fees from Sanofi, personal fees from Novartis, personal fees from Minddistrict, personal fees from Lantern, personal fees from Schoen Kliniken, personal fees from Ideamed, grants from EU H2020, grants from BMBF, outside the submitted work; and Dr. Ebert has served as a consultant to/on the scientific advisory boards of Sanofi, Novartis, Minddistrict, Lantern, Schoen Kliniken, Ideamed and German health insurance companies (BARMER, Techniker Krankenkasse) and several federal chambers for psychotherapy. He is also a stakeholder in the Institute for Health Training Online (formerly GET.ON, now HelloBetter), which aims to implement scientific findings related to digital health interventions into routine care. HelloBetter distributes the Internet platform for the digital intervention under study. Anna-Carlotta Zarski (AZ) reports to have received fees for lectures or workshops and for expert videos for an internet-based intervention for sexual dysfunctions.

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### Authors' contributions

CeS drafted the study's original design for the grant application and advised CS and AZ on the design of the intervention. AZ and CS developed and implemented the intervention, conducted the study, and drafted the manuscript. DE is the principal investigator of the study.

### Ethics approval and consent to participate

The DGPs approved the research protocol (DGPs, the Society, EbertDavidDaniel2020-09-16-VA). The consent to participate is available in German and was reviewed by the Institutional Review Board. The study is registered in the German Clinical Trial Registry (GCTR, DRKS00023341), Registered on 20 July 2021, [https://www.drks.de/drks\\_web/navigate.do?navigationId=trial.HTML&TRIAL\\_ID=DRKS00023341](https://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00023341).

### Data availability statement

The data that support the findings of this study are available from the corresponding author, [ChS], upon request.

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