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ADDENDUM



BEST FOR CAN – bringing empirically supported treatments to children and adolescents after child abuse and neglect: update to the study protocol

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ABSTRACT

Background: The implementation trial BESTFORCAN aims to evaluate the dissemination of Trauma-Focused Behavioural Therapy (TF-CBT) for children and adolescents in Germany with posttraumatic stress symptoms (PTSS) after child abuse and neglect (CAN) with a focus on supervision.

Objective: This update to the study protocol outlines changes made due to practical reasons in the course of the ongoing trial while maintaining methodological quality.

Method: The amendments to the original study protocol comprise (1) a more refined operationalisation of the primary outcome sufficiently adherent TF-CBT therapy (SATT), (2) changes in the study sites and (3) additional inclusion of one post-gradual psychotherapy training institute.

Discussion: The adaptations to the original study protocol ensured high methodological quality through the transparent presentation of protocol modification: ensuring the recruitment of participating psychotherapists in training by including a further post-gradual training institute as well as an adaptation of the measurement of SATT with high external validity. The objectives, diagnostic set, and secondary outcomes remained unimpaired by the amendment. Therefore, we expect the trial to provide evidence for the effect of model-specific trauma-focused supervision on the implementation outcomes of TF-CBT as compared to supervision as usual.

Trial registration: German Clinical Trials Register identifier: DRKS00020516.

BEST FOR CAN – entregar tratamientos respaldados empíricamente a niños y adolescentes después de abuso y negligencia: actualización del protocolo de estudio

Antecedentes: La implementación del ensayo BESTFORCAN tiene como objetivo evaluar la diseminación de la Terapia Cognitivo Conductual Centrada en el Trauma (TF-CBT en su sigla en inglés) para niños y adolescentes de Alemania con síntomas de estrés postraumático (SEPT) luego de abuso y negligencia infantil (CAN en su sigla en inglés), con un foco en la supervisión.

Objetivo: Esta actualización del protocolo de estudio describe cambios hechos por razones prácticas a lo largo del ensayo en curso además de mantener la calidad metodológica.

Método: Las correcciones al protocolo original del estudio incluyen (1) una operacionalización más refinada del resultado primario terapia TF-CBT suficientemente adherente (SATT en su sigla en inglés), (2) cambios en los sitios de estudio e (3) inclusión adicional de un instituto de formación en psicoterapia de post-grad.

Discusión: Las adaptaciones al protocolo original de estudio reforzó la alta calidad metodológica mediante la presentación transparente de la modificación al protocolo: asegurar el reclutamiento de psicoterapeutas participantes en formación al incluir un instituto de formación de post-grad adicional además de adaptar la medición del SATT con alta validez externa. Los objetivos, el conjunto de diagnósticos y los resultados secundarios se mantuvieron inalterados por la corrección. Por lo tanto, esperamos que el ensayo entregue evidencia para el efecto de la supervisión específica al modelo y enfocada en el trauma en los resultados de implementación de la TF-CBT comparada con la supervisión usual.

KEYWORDS

Implementation; children; adolescents; supervision; abuse; neglect; trauma-focused cognitive behavioural therapy

PALABRAS CLAVE

Implementación; niños; adolescentes; supervisión; abuso; negligencia; enfocado en el trauma; terapia cognitivo-conductual

HIGHLIGHTS

- Update to the study protocol of the trial BESTFORCAN that investigates the implementation of trauma-focused behavioural therapy for children and adolescents with posttraumatic stress symptoms following abuse with a focus on the role of supervision.
- Adaptions have been made regarding the specification of the definition of sufficiently adherent intervention, relocation of the data-handling centre and the recruitment of one additional psychotherapy institute.
- The adaptations have no impact on the objectives, diagnostic set, secondary outcomes, or processes of data handling.

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1. Background

This addendum presents an update to the study protocol of the Hybrid Type III implementation study BESTFORCAN aiming to implement and disseminate Trauma-Focused Cognitive Behavioural Therapy (TF-CBT) in the German routine care with a focus on model-specific trauma-focused supervision (TFS) versus supervision as usual (SAU) as published in the *European Journal of Psychotraumatology* (Rosner et al., 2020). Practical experiences in combination with the COVID-19 pandemic and organisational reasons have led to three changes during the ongoing trial as compared to the originally published study protocol.

2. Changes to the study protocol

2.1. Specification of the primary outcome

The primary outcome is defined as whether the patients received a sufficiently adherent TF-CBT therapy (SATT), and which will be rated by two raters blind to the supervision condition based on a standardised TF-CBT Brief Practice Checklist-Revised (Deblinger et al., 2008; German translation by Thielemann et al., 2019) filled out by therapists after each session. TF-CBT is designed to involve a trusted caregiver in the treatment sessions, up to fifty percent. The original version of SATT was based on the assumption that the majority of therapies would be conducted with a large proportion of caregiver sessions (see section 2.7 Outcomes in the original version: ‘In order to qualify as a SATT, the therapist must complete at least eight double (or 16 single) sessions implementing TF-CBT modules (1–5); begin the trauma narrative in double sessions 7–11 (or 14–22 single), and complete the therapy within 18 double (36 single) sessions.’). However, temporary restrictions for psychotherapy in Germany during the COVID-19 pandemic impeded the inclusion of caregivers and practical experiences made it notable that not all of the patients could be accompanied by a trusted caregiver every week. Additionally, for patients between 18 and 21 years it was not always therapeutically useful and possible to include caregivers every week. Caregiver involvement is a key element within the TF-CBT manual and a large proportion of caregiver sessions is highly recommended. However, it is not obligatory (Cohen et al., 2009) and TF-CBT has been proven to be effective without caregiver involvement (e.g., Deblinger et al., 1999). The specification of SATT is now primarily based on patient sessions. Furthermore, it is now possible to conduct the stabilisation phase in preparation for the trauma narrative swiftly and SATT does not specify the number of sessions necessary for stabilisation anymore. Therefore, SATT is now operationalised as comprising at least eight sessions of TF-CBT, the completion of modules 1–5 (‘PRAC’ – psychoeducation, relaxation, affective

modulation, and cognitive coping) before the trauma narrative, at least one session dedicated to the trauma narrative with commencement no later than patient session 22.

These changes were complied with an independent statistician (Rainer Muche, University Ulm). They have no impact on the measures, hypotheses, and the statistical analysis of the trial. Also, the implementation of the intervention is not affected and there are no disadvantages for patients or therapists.

2.2. Recruitment of one additional post gradual psychotherapy training institute

A third change has been made regarding the study setting (see section 2.2 in the original version of the study protocol): One of the participating training institutes (University of Bielefeld) withdrew from the project due to personnel reasons. Therefore, for the recruitment of a sufficient number of psychotherapists in training (PITs), an additional post-gradual psychotherapy training institute (SAPPTI, state-accredited post gradual psychotherapy training institute) in Lueneburg has been invited and included in our TF-CBT training programme.

3. Discussion

The study protocol of the trial BESTFORCAN has been adapted in three aspects: (1) the specification of the primary outcome SATT, and (2) the recruitment of one additional post-gradual psychotherapy training institute. Given that TF-CBT is a phase-based and flexible intervention for traumatised children and adolescents and BESTFORCAN aims to disseminate and implement TF-CBT broadly within the German healthcare system, the described specification of SATT represents a definition of adherence to the manual while accounting for a high external validity. The changes to SATT have been made by the study team which is still blinded to the collected data.

Apart from the listed changes, the adaptations have no further impact on the existing processes in the project, neither regarding the implementation and conduction of the intervention, nor the evaluation of the data. All participants have been informed about these changes in written form and the participation documents have been updated.

Ethics approval and consent to participate

The Institutional Review Boards of all participating universities approved the research protocol: Friedrich Alexander University Erlangen (approval 18/12/2019; #266_19 B), Goethe University Frankfurt (approval 06/01/2020; #19-510), Philipps University Marburg (approval 14/01/2020; #2020-2), Catholic University Eichstaett-Ingolstadt (approval 15/01/2020; #010-20).

The Institutional Review Board of the Friedrich Alexander University Erlangen approved the amendment to the research protocol (approval 28/08/2023, #266_19 B). The Institutional Review Boards of all other coordination centres have been informed about the amendment and the approval by the Friedrich Alexander University Erlangen. The consent to participate is available in German and was reviewed by the IRBs.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Data availability statement

Upon request from the authors.

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