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PTSD treatment after intensive care

ORIGINAL RESEARCH Multicentre, observer blind, randomised controlled trial

Effects of a general practitioner-led brief narrative exposure intervention on symptoms of post-traumatic stress disorder after intensive care (PICTURE)

Gensichen J, Schmidt K, Sanftenberg L, et al

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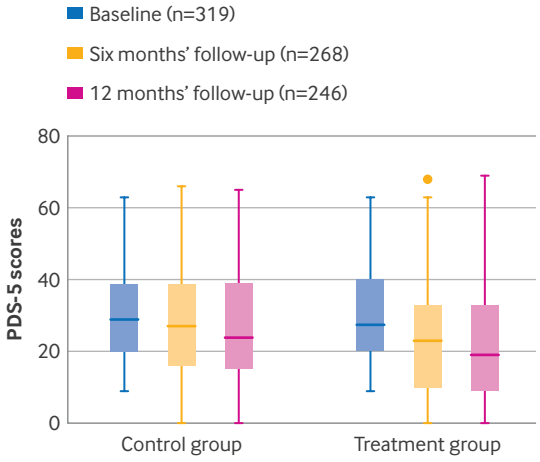
Study question Can a brief general practitioner (GP)-led narrative exposure intervention effectively reduce symptoms of post-traumatic stress disorder (PTSD) in patients discharged from an intensive care unit (ICU)?

Methods 319 adults who survived critical illness with symptoms of PTSD after discharge from an ICU were randomly assigned to receive the intervention (n=160) or improved usual care (n=159) from a general practitioner (GP). Participants in the intervention group had three narrative exposure consultations with a GP (a trauma focused intervention using storytelling to reconsolidate autobiographical memory) and eight scheduled contacts with a nurse. The control group received improved care in the form of three consultations focused on PTSD symptoms with a duration of 45 minutes each.The primary clinical outcome was self-reported PTSD symptoms using the post-traumatic diagnostic scale (PDS-5, range 0-80, higher scores indicating more severe symptoms) at six months of follow-up. The minimal clinically important difference was 6 points. Secondary outcomes included changes in depression, anxiety, health related quality of life, and disability at six and 12 months of follow-up.

Study answer and limitations Mean patient age was 57.7 years (standard deviation (SD) 12.7) and 61% of participants were male. Mean baseline PDS-5 score



Boxplots for change in PDS-5 by treatment group at baseline, six months, and 12 months. Boxes indicate median and interquartile range, whiskers indicate range, y axis shows PDS-5 sum scores. PDS-5=post-traumatic diagnostic scale 5 for PTSD

was 30.6 (SD 13.3) in both groups. Adults in the intervention group showed a reduction in PTSD symptoms that did not reach the minimal clinically important difference. Mean between group difference in PDS-5 score was 4.7 points ((95% confidence interval 1.6 to 7.8); P=0.003, Cohen's d=0.37) at six months and 5.4 points ((9.0 to 1.8); P=0.003, Cohen's d=0.41) at 12 months. Among secondary outcomes, patients in the intervention group had greater improvements in depression, health related quality of life, and disability. The exclusion criteria limit the generalisability of the findings to individuals with more severe PTSD.

What this study adds A novel intervention of brief narrative exposure therapy in general practice reduced PTSD symptoms in patients after ICU care but was less than the predefined minimal clinically important difference. The effect was maintained at six and 12 months of follow-up. The intervention was feasible in small general practice teams.

Funding, competing interests, and data sharing
This study was funded by the German Research Foundation. No competing interests declared. The analytical dataset can be accessed at https://data.ub.uni-muenchen.de/557/.

Study registration ClinicalTrials.gov NCT03315390; German Clinical Trials Register DRKS00012589.

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Advances in intensive care medicine have improved survival rates, yet post-traumatic stress disorder (PTSD) remains a prevalent and often underdiagnosed consequence among patients who are discharged from intensive care units (ICUs).[1] Approximately 20% of these individuals develop PTSD symptoms, which can lead to lasting impairments in quality of life, occupational functioning, and overall physical health.[2 3] Contributing factors include exposure to life threatening conditions, invasive procedures, prolonged isolation, and a profound loss of control.[4 5] Early identification and targeted support of PTSD symptoms after ICU care are essential because systematic screening and tailored intervention can significantly reduce long term psychiatric impairment.[6]

Despite increasing awareness of PTSD after ICU care, access to effective treatments remains limited. Cognitive behavioural therapy and eye movement desensitisation and reprocessing are well established treatments for PTSD, yet their accessibility is limited due to long wait times and workforce shortages.[7] Given these barriers, and considering that many of these affected patients initially reconnect with the healthcare system through general practitioners (GPs), primary care settings might have a role for feasible, scalable interventions. GPs frequently serve as first line providers following ICU discharge and are well positioned to identify early signs of mental health impairment and to deliver early stage mental health support. However, structured interventions in primary care contexts for PTSD have been largely absent.

The study by Gensichen and colleagues addresses this gap. The authors conducted a multicentre, observer blind, randomised controlled trial evaluating a novel, brief, GP-led narrative exposure therapy tailored for people discharged from the ICU.[8]

The study, involving 319 general practices in Germany, tested an intervention consisting of three structured GP consultations and eight follow-up nurse interactions, targeting post-traumatic stress symptoms. The primary outcome was the severity of post-traumatic stress symptoms at six months, measured using the post-traumatic diagnostic scale for DSM-5 (PDS-5), a validated 20 item patient reported outcome measure (range 0-80).

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Narrative processing and biographical integration may alleviate certain cognitive affective dimensions of PTSD

The predefined minimal clinically important difference was 6 points.

The findings suggest that the intervention was feasible, with more than 90% of participating GPs adhering to the structured protocol, despite known time constraints. Nearly a third of patients in the intervention group met a more than 50% reduction in PTSD symptoms compared with 12.6% in the control group. These results represent a clinically meaningful outcome considering the brief and low intensity nature of the intervention. Additionally, improvements in secondary outcomes such as depression, disability, and quality of life, indicated potential broader psychosocial benefits beyond reduction of post-traumatic stress symptoms.

What the findings mean

However, the intervention did not meet the predefined minimal clinically important difference for the primary outcome. At six months, symptom reduction averaged 1.5 points in the control group and 6.2 points in the intervention group, resulting in a group difference of 4.7 points. At 12 months, symptom reduction was 2.5 points in the control group and 7.9 points in the intervention group, corresponding to a group difference of 5.4 points. In both cases, the differences did not reach the predefined threshold of 6 points. Moreover, the intervention did not impact core symptom clusters such as avoidance and hyperarousal. These findings suggest that narrative processing and biographical integration may alleviate certain cognitive affective dimensions of PTSD (eg, intrusions, mood, and distress), yet additional emotionally activating or exposure based components might be required to address the full spectrum of symptoms. Combining exposure based methods with cognitive restructuring could target these resistant symptom clusters more effectively.[2]

Another limitation concerns the inclusion criteria, which excluded patients with severe PTSD (PDS-5 score of >70) and people already receiving psychiatric care. While this approach enhances generalisability to typical primary care populations, it also limits the applicability of the findings for people with the highest clinical need. Moreover, the intervention was delivered by GPs after brief training, without ongoing supervision or structured case discussion, which may have constrained the therapeutic depth and adaptability of the intervention.

Although the observed treatment effects were moderate, their importance lies in the intervention's potential for scalability and broad accessibility, especially in healthcare systems facing limited specialist resources. This represents an important step towards designing and evaluating trauma informed primary care interventions.

Widespread clinical implications

Integration of structured PTSD interventions and trauma informed principles into GP training, including brief screening tools and stepped care models, could help to address the growing mental health burden, particularly in underserved areas. Moreover, embedding trauma insights into routine care, as emphasised by McBain and Cordova,[5] such as anticipatory guidance, validation of trauma related symptoms, and pacing of medical communication, may further enhance recovery and resilience.

That said, addressing PTSD in people who were in ICUs requires a broad approach, including strengthening interfaces between ICU and primary care, embedding trauma informed diagnostics earlier in the treatment pathway, and establishing preventive measures during ICU stays.

Gensichen and colleagues' trial represents an important advance in trauma informed primary care interventions, bridging acute care and long term psychotherapeutic support. While not a replacement for specialised psychiatric treatment, such models offer a pragmatic strategy to reduce the psychological burden of critical illness. The ability to deliver structured, low risk psychotherapeutical support within a familiar, trusted setting is invaluable; yet feasibility alone should not define the limits of evidence based care. Feasibility is a starting point, not the endpoint, for the development of high quality GP-led interventions for post-traumatic stress symptoms after ICU care. As research continues, the challenge will be to refine these early interventions without diluting their therapeutic effectiveness. Future research should focus on refining content of therapy, optimising delivery of care, and ensuring broad integration across healthcare systems.

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Improving the reporting of randomised trials

RESEARCH METHODS AND REPORTING CONSORT 2025 statement

Updated guideline for reporting randomised trials

Hopewell S, Chan A-W, Collins GS, et al

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"Readers should not have to infer what was probably done; they should be told explicitly." is the famous quote in 1996 by the late Doug Altman, and is still very pertinent today. Well designed and properly executed randomised trials are considered the most reliable evidence on the benefits of healthcare interventions. However, there is overwhelming evidence that the quality of reporting is not optimal. The CONSORT (Consolidated Standards of Reporting Trials) statement first published in 1996, then updated in 2001 and 2010, is designed to improve the quality of reporting and provide a minimum set of items to be included in a report of a randomised trial. Here, we present the updated CONSORT 2025 statement, which aims to account for recent methodological advancements and feedback from end users.

We conducted a scoping review of the literature and developed a project specific database of empirical and theoretical evidence related to CONSORT, to generate a list of potential changes to the checklist. The list was enriched with recommendations provided by the lead authors of existing CONSORT extensions (Harms, Outcomes, Non-pharmacological Treatment), other related reporting guidelines (TIDieR), and recommendations from other sources (eg, personal communications). The list of potential changes to the checklist was assessed in an international, online, three round Delphi survey including 317 participants and discussed at an online expert consensus meeting of 30 invited international experts over two days.

We have made substantive changes to the CONSORT checklist (box). We added seven new checklist items, revised three items, deleted one item, and integrated several items from key CONSORT extensions. The CONSORT checklist has also been restructured, with a new section on open science. The CONSORT 2025 statement consists of a checklist of 30 essential items that should be included when reporting the results of a randomised trial and a diagram for documenting the flow of participants through the trial. To facilitate implementation of CONSORT 2025, we have also developed an expanded version of the CONSORT 2025 checklist, with bullet points eliciting critical elements of each item.

Published alongside the CONSORT 2025 statement is the updated CONSORT 2025 explanation and elaboration document (doi:10.1136/bmj-2024-081124), which provides the meaning and rationale for each checklist item, examples of good reporting, and relevant empirical evidence where possible.

Summary of main changes in CONSORT 2025

Addition of new checklist items

- Item 4: added item on data sharing, including where and how individual de-identified participant data, statistical code, and any other materials can be accessed.
- Item 5b: added item on financial and other conflicts of interest of manuscript authors.
- Item 8: added item on how patients and/or the public were involved in the design, conduct, and/or reporting of the trial.
- Item 12b: added item on eligibility criteria for sites and for individuals delivering the interventions, where applicable.
- Item 15: added item on how harms and other unintended effects were assessed.
- Item 21: added items to define who is included in each analysis (eg, all randomised participants) and in which group (item 21b), and how missing data were handled in the analysis (item 21c).
- Item 24: added item on intervention delivery, including how the intervention and comparator were actually administered (item 24a) and details of concomitant care received during the trial (item 24b).

Completely revised checklist items

- Item 3: revised item to include where the statistical analysis plan can be accessed in addition to the trial protocol.
- Item 10: revised item to include reporting of important changes to the trial after it commenced, including any outcomes or analyses that were not prespecified.
- Item 26: revised item to specify for each primary and secondary outcome—the number of participants included in the analysis and the number of participants with available data at each time point for each treatment group.

Deletion of checklist item

- Deleted item on generalisability of trial findings, which is now incorporated under trial limitations (item 30).

Integration of checklist items from key CONSORT extensions

- Addition of items related to reporting of how harms were assessed and analysed (items 7, 15, 21a, 23a, 27), how outcomes were measured and analysed (items 14, 26), and how the intervention and comparator were actually administered and by whom (item 24).

Structure and organisation of checklist items

- Restructuring of checklist, with a new section on open science, which includes items that are conceptually linked such as trial registration (item 2), where the trial protocol and statistical analysis plan can be accessed (item 3), sharing of de-identified participant level data (item 4), and funding and conflicts of interest (item 5).
- Aligned wording of some CONSORT checklist items with that of SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) checklist items and vice versa.
- Clarified and simplified wording of some items.

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Updated guideline for protocols of randomised trials

Chan A-W, Boutron I, Hopewell S, et al

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The protocol of a randomised trial is the foundation for study planning, conduct, reporting, and external review. Despite their importance, trial protocols vary in their completeness and often do not address key elements of design and conduct. The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement was first published in 2013 as guidance to improve the completeness of trial protocols. Periodic updates incorporating the latest evidence and best practices are needed to ensure that the guidance remains relevant to users.

We systematically updated the SPIRIT recommendations for key items to address in the protocol of a randomised trial. We completed a scoping review, developed an evidence database, and conducted a three-round Delphi survey (317 respondents) followed by a consensus meeting (30 participants). The process led to the addition of two new protocol items, revision to five items, deletion or merger of five items, and integration of key items from other relevant reporting guidelines. Notable changes include a new open science section, additional emphasis on the assessment of harms and description of interventions and comparators, and a new item on how patients and the public will be involved in trial design, conduct, and reporting.

The updated SPIRIT 2025 statement consists of an evidence based checklist of 34 minimum items to address in a trial protocol (table), along with a diagram illustrating the schedule of enrolment, interventions, and assessments for trial participants. An accompanying explanation and elaboration document provides model examples and outlines the key considerations for each item (doi:10.1136/bmj-2024-081660). To facilitate implementation, we also developed an expanded version of the SPIRIT 2025 checklist with bullet points of key issues to consider for each item.

SPIRIT 2025 serves as a resource for developing a trial protocol and reporting its core elements. Widespread endorsement and adherence to the updated SPIRIT 2025 statement have the potential to enhance the transparency and completeness of trial protocols—promoting better conduct, external review, and understanding of the trial.

Overview of protocol items recommended by SPIRIT 2025. Full checklist is available on bmj.com

Section	Item
Administrative information	Title and structured summary
	Protocol version
	Roles and responsibilities
Open science	Trial registration
	Protocol and statistical analysis plan
	Data sharing
	Funding and conflicts of interest
	Dissemination policy
Introduction	Background and rationale
	Objectives
Methods	Patient and public involvement
	Trial design
	Trial setting
	Eligibility criteria
	Intervention and comparator
	Outcomes
	Harms
	Participant timeline
	Sample size
	Recruitment
	Randomisation: Sequence generation
	Randomisation: Allocation concealment mechanism
	Randomisation: Implementation
	Blinding
	Data collection methods
	Data management
	Statistical methods
	Data monitoring committee
	Trial monitoring
Ethics	Research ethics approval
	Protocol amendments
	Consent or assent
	Confidentiality
	Ancillary and post-trial care

First published in 1996, CONSORT emphasised the importance of accurate and complete reporting of randomised clinical trials.[1] Journal articles were the only public records of many such trials, and the CONSORT reporting guidelines described the minimum information those articles should include. Most recommendations focused on methods and results. At the time, articles were published on paper and supplements were limited. Infrastructure to register clinical trials and to share other artefacts (eg, data, code) had not been invented. The first CONSORT update in 2001 described trial registration as desirable but not essential.[2] When an update in 2010 added trial registration as a checklist item,[3] opportunities for sharing data and code were still relatively new.[4] SPIRIT 2013, the first reporting guidelines for trial protocols, introduced recommendations about data and code sharing.[5]

CONSORT 2025 and SPIRIT 2025 update and replace previous versions of these essential reporting guidelines.[6 7] These updates are the first since guidance for statistical analysis plans was published in 2017[8] and the first since data and code sharing became relatively commonplace. Updating both guidelines in tandem has led to helpful clarifications and harmonisation. The updated guidelines also include some new items. An especially welcome section on "Open science" recommends reporting whether other research artefacts are publicly available. This new section highlights an important shift from focusing on journal articles towards a contemporary understanding of "reporting" as sharing a collection of research artefacts associated with a study.

The CONSORT 1996 checklist fit on half a page. The developers predicted the checklist would grow as researchers identified more information considered important for all randomised clinical trials and for specific types of these trials.[1] Indeed, the detailed SPIRIT 2025 and CONSORT 2025 checklists are 24 and 12 pages long, respectively.[9 10] Consequently, it might be difficult to follow the CONSORT 2025 guidance that every checklist item be reported "somewhere in the article, with sufficient detail and clarity."

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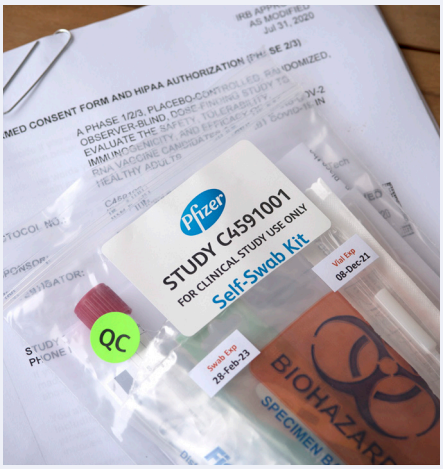

CONSORT 2025 and SPIRIT 2025 update and replace previous versions of these essential reporting guidelines

Usability issues

The current system is more comprehensive than CONSORT 1996, but it is not always easy to use. Notably, it is no longer clear where and how all the recommended items should be reported so that every reader can find the information that matters to them. While CONSORT 1996 focused on the main text of journal articles—even recommending the organisation of information under five suggested subheadings—CONSORT 2025 stops short of stating which items are essential for the main text and which might be included in supplementary materials. Consequently, it might be difficult for authors, peer reviewers, and editors to implement its recommendations. Clearer guidance is needed about what information is essential for the main text of every journal article and where the other recommended information belongs.

There is limited evidence that reporting guideline endorsement is associated with more complete reporting,[30] and the developers of SPIRIT 2025 and CONSORT 2025 rightly argue that reporting quality remains suboptimal.[31] Standards for assessing adherence to SPIRIT 2025 and CONSORT 2025 could help bridge the gap between recommendations and practice. For some items, the presence or absence of information might be easy to assess (eg, allocation ratio). For other items, it is unclear what constitutes complete reporting (eg, background and rationale, trial settings). The developers say that SPIRIT 2025 and CONSORT 2025 are not tools for assessing trial quality (eg, risk of bias), but many studies have and will use reporting guidelines to assess reporting quality, including important studies by the developers.[32-37]

Where do we go from here?

It might not be feasible for a few thousand words in a journal article to constitute a complete report of a randomised clinical trial. However, infrastructure and technology better support research transparency today than in 1996. Expanding the scope of reporting guidelines to include recommendations for sharing and organising multiple research artefacts would promote greater transparency and openness. Future updates to SPIRIT and CONSORT could articulate how those practices should be implemented to make randomised clinical trials verifiable and useful for multiple interest holders. Future updates might state that journal articles should include links to intervention protocols. Within ethical and legal limits, individual data should be available to support reanalysis, new research, and evidence synthesis. A truly complete report of a randomised clinical trial would include all these in addition to a journal article summarising the methods and results.

The new "Open science" section underscores that reporting a randomised clinical trial is not synonymous with publishing a journal article. SPIRIT, CONSORT, and other reporting guidelines should continue to develop recommendations about the collection of artefacts that are essential for different study types. SPIRIT and CONSORT are guidelines for randomised clinical trials, so updates and extensions should describe the minimum information to be included in the main text of articles summarising randomised clinical trials, other artefacts that should be available for every randomised clinical trial, and what information those artefacts should contain to meet the needs of various interest holders. To improve implementation and research, objective standards for assessing adherence to each item in these reporting guidelines should be developed.

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