

Development of an electronic CAPS-5 scale for clinical trials

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BACKGROUND

- Posttraumatic stress disorder (PTSD) has a global prevalence rate of nearly 4% (Koenen et al., 2017)
- The Clinician-Administered PTSD Scale (CAPS-5), a structured diagnostic interview, is commonly used to assess PTSD
- As the focus on developing pharmaceutical interventions for PTSD increases, there is a corresponding need to develop technological tools to facilitate standardized CAPS-5 assessment in clinical trials
- Our objective was to develop a “smart scale” based on the original paper version to enable reliable administration and scoring by global raters with diverse clinical backgrounds

METHODS

- We utilized the public domain version of the CAPS-5 provided by the National Center for PTSD, consulted PTSD subject matter experts, identified known challenges in administration and scoring of the CAPS-5 scale, and developed a digital CAPS-5 version with smart built-in algorithms



RESULTS

Our CAPS-5 digital version displays the following features:

- Easily accessible scale instructions and administration prompts

A screenshot of the CAPS-5 digital interface for Item 1 (B1). The left panel contains the item description: 'Item 1 (B1): Recurrent, involuntary, and intrusive distressing memories of the traumatic event(s). Note: In children older than 6 years, repetitive play may occur in which themes or aspects of the traumatic event(s) are expressed. In the past month, have you had any unwanted memories of (EVENT) while you were awake, so not counting dreams? (Rate 0=Absent if only during dreams)'. Below this, it says 'If you select No, further questions will not be asked. The symptom will be considered Absent and no Severity score will be assigned for this symptom.' and 'How does it happen that you start remembering (EVENT)?'. The right panel shows radio button options for 'No' and 'Yes' (selected), and a 'Free text' input field below.

- Built-in logic to help guide scale administration and scoring

A screenshot of the CAPS-5 digital interface for severity rating. The left panel shows instructions: 'Choose the Overall Severity Rating for this item: Key rating dimensions = frequency / intensity of distress'. It defines 'Moderate' as 'at least 2 X month / distress clearly present, some difficulty dismissing memories' and 'Severe' as 'at least 2 X week / pronounced distress, considerable difficulty dismissing memories'. It also includes a red warning: 'There is a possible discrepancy between the information provided for the item above and the overall severity score. Please check the responses and notes above for this item and review the rating on the item for consistency. (For discrepancy between intensity/frequency score and the overall severity score, please refer to the Scoring Grid Guidance Table). If you wish to keep your score, please provide a brief rationale for the overall severity rating'. The right panel shows radio button options for 'Absent', 'Mild / subthreshold' (selected), 'Moderate / threshold', 'Severe / markedly elevated', and 'Extreme / incapacitating', with a 'Free text' input field below.

- Integrated audio recording of CAPS-5 assessment to allow review for quality assurance



- Automated scoring to generate domain scores and total score, and to help determine whether patient meets PTSD diagnostic criteria

CONCLUSIONS

- Our electronic CAPS-5 scale strictly adheres to the paper version but leverages technology to provide built-in logic and scoring guidance for raters
- It ensures standardization in administration and scoring of the measure globally
- It is suitable for raters with diverse experience, a critical component of clinical trials
- Future directions include examining in-study performance of raters who utilize the CAPS-5 electronic scale

REFERENCES

Koenen, K. C., Ratanatharathorn, A., Ng, L., McLaughlin, K. A., Bromet, E. J., Stein, D. J., & Karam, E. G. (2017). *Posttraumatic stress disorder in the world mental health surveys*. *Psychological Medicine* , 47 (13), 2260-2274.