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PTSD Trials Standardized Data Repository (PTSD-Repository): How we did it, what the data tell us, and how you can use it

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National Center for
PTSD

POSTTRAUMATIC STRESS DISORDER



Agency for Healthcare Research and Quality
Advancing Excellence in Health Care



Pacific Northwest Evidence-based
Practice Center

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Project Overview

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PROJECT OVERVIEW

Phase 1:

Create a comprehensive database containing detailed information on RCTs of PTSD interventions

(completed)



Phase 2:

Make the database publicly accessible via an online data repository maintained by NCPTSD

(in progress)



NCPTSD BENEFITS

- PTSD Consultation Program
 - “How many patients complete trauma-focused psychotherapy?”
 - “Are there any RCTs on Reiki for PTSD?”
- VA Central Office Requests/Policymakers
 - “What is the evidence for Stellate Ganglion Block for PTSD”
- Media Requests
 - “What percentage of patients benefit from Hyperbaric Oxygen Therapy?”



POLL QUESTION # 1

What is your primary role?

1. Primarily clinical
2. Primarily policy/administration
3. Primarily research
4. Mixed



STAKEHOLDER BENEFITS

Clinicians, researchers, and administrators can access the data to:

- Enhance patient education
- Identify key gaps in the literature
- Conduct systematic reviews
- Inform PTSD policy



EXISTING REVIEWS

- Numerous small reviews
- Large Reviews
 - [AHRQ Comparative Effectiveness Review](#)
 - [VA/DoD Clinical Practice Guideline](#)



LIMITATIONS OF PRIOR REVIEWS

Limitations of prior reviews

No rapid updates

Narrow in scope

Limited Variables

Reliance on systematic reviews

Inaccessible/not user friendly

PTSD-Repository

Annual updates

Broad inclusion

> 74 data elements

Abstracted study level data

Publicly available/user friendly

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How we did it

Maya O'Neil, PhD

Neuropsychologist, RR&D CDA-II, Portland VA
Associate Professor, Oregon Health & Science University



GUIDING QUESTIONS



- What **pharmacologic** interventions have been studied for the treatment of PTSD since 1980?



- What **nonpharmacologic** interventions have been studied for the treatment of PTSD since 1980?



METHODS AND DATA (SLIDE 1 OF 6)

- Input from:
 - Partners
 - AHRQ, NCPTSD, Pacific Northwest EPC
 - Multidisciplinary Expert Panel
 - 9 PTSD experts with broad clinical and research expertise
 - Reviewed draft protocol and advised on:
 - A priori inclusion criteria
 - Variable selection
 - Key studies to include



METHODS AND DATA (SLIDE 2 OF 6)

Category	Inclusion Criteria	Exclusion Criteria
Population	Adults (less than or 18 years old) with a PTSD diagnosis diagnosed by a clinician or through the administration of a validated clinician-administered or patient-reported assessment tool	Children (less than 18 years old) Diagnosis of acute stress disorder Studies that do not specify criteria used to diagnose PTSD Sample population less than 80% of participants diagnosed with PTSD
Interventions	Pharmacologic treatments Nonpharmacologic treatments	Interventions designed to simultaneously treat PTSD and comorbid conditions if they cannot be standalone PTSD interventions Interventions designed to prevent PTSD
Comparators	No limitations applied	None
Outcomes	Any overall PTSD outcome	Studies reporting only individual symptoms or symptom clusters without overall PTSD outcome
Timing	Any study duration and length of follow-up	None
Study Design	Randomized controlled trials	Studies that do not have a randomized controlled trial design



We searched for RCTs in databases and reference lists

- PTSDpubs (formerly PILOTS)
- Ovid[®] MEDLINE[®]
- Cochrane CENTRAL
- PsycINFO[®]
- Embase[®]
- CINAHL[®]
- Scopus[®]
- Reference lists in systematic reviews and clinical practice guidelines



METHODS AND DATA (SLIDE 4 OF 6)

- Duplicate studies were removed
- Abstracts and full-text articles were reviewed for inclusion
- When studies met inclusion criteria, data were abstracted:
 - Two evidence tables were constructed according to the Guiding Questions (pharmacologic and nonpharmacologic treatments)
 - NCPTSD, AHRQ, and EPC reviewed updates and changes to tables during weekly meetings



METHODS AND DATA (SLIDE 5 OF 6)

- Abstracted data (337 variables)
 - Study and population characteristics
 - PTSD assessment
 - Intervention descriptives for each study arm
 - PTSD outcomes
 - Assessments for each intervention (i.e., baseline, end of treatment, less than 6 months, 6 to 11 months, 12 months or longer)
 - Secondary outcomes (i.e., depression, anxiety, substance use, sleep, anger, quality of life, functioning, harms)

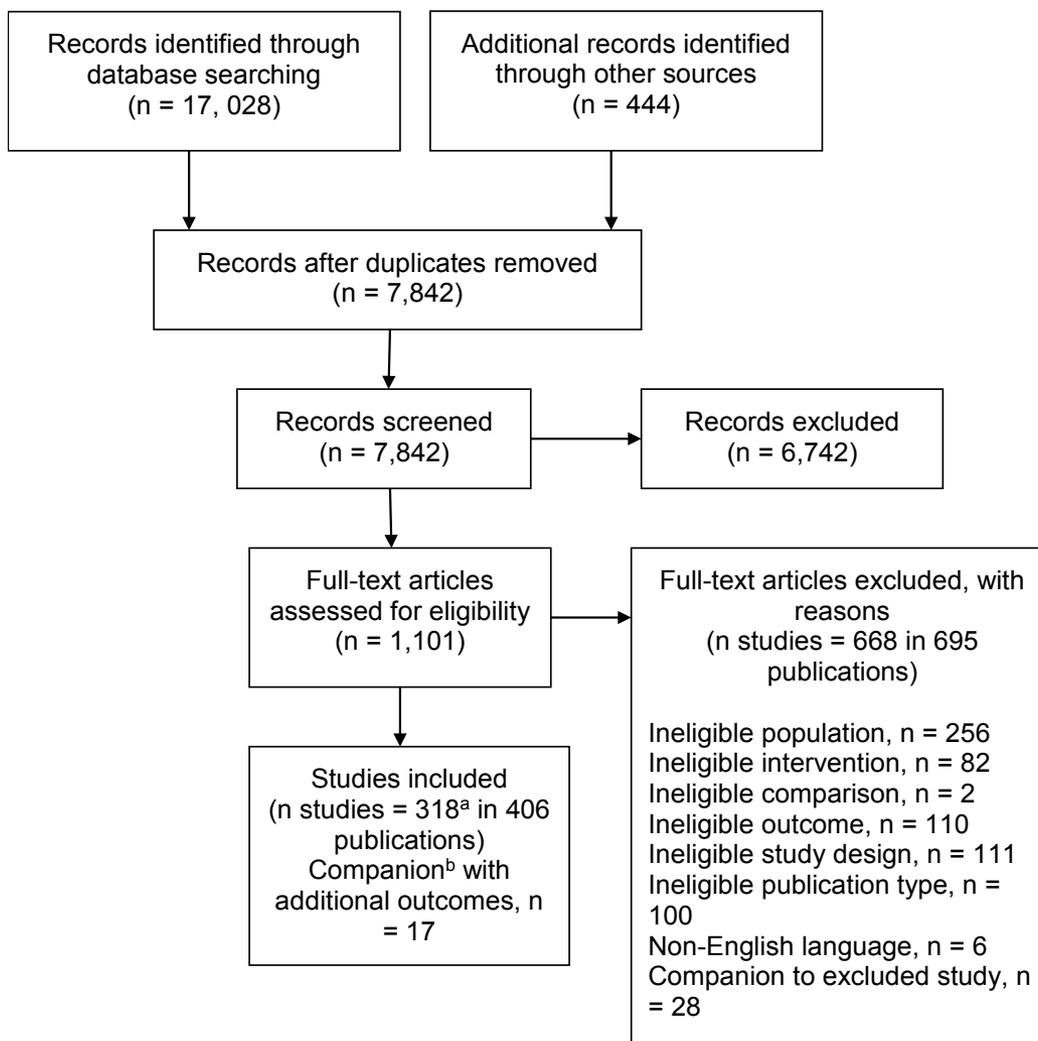


METHODS AND DATA (SLIDE 6 OF 6)

- Dual review by a senior team member for accuracy and completeness
- A record of excluded studies and reasons for exclusion was maintained
- Risk of bias, or quality assessment, was not conducted



LITERATURE FLOW DIAGRAM

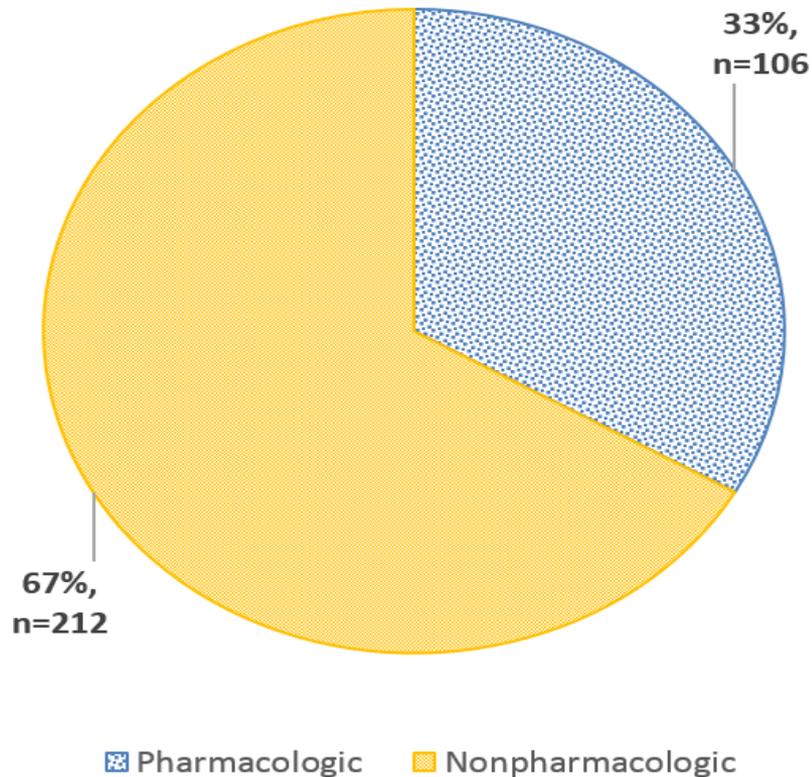


^aBadura-Brack, 2015 is a single publication that includes 2 studies



TREATMENT CLASSIFICATION

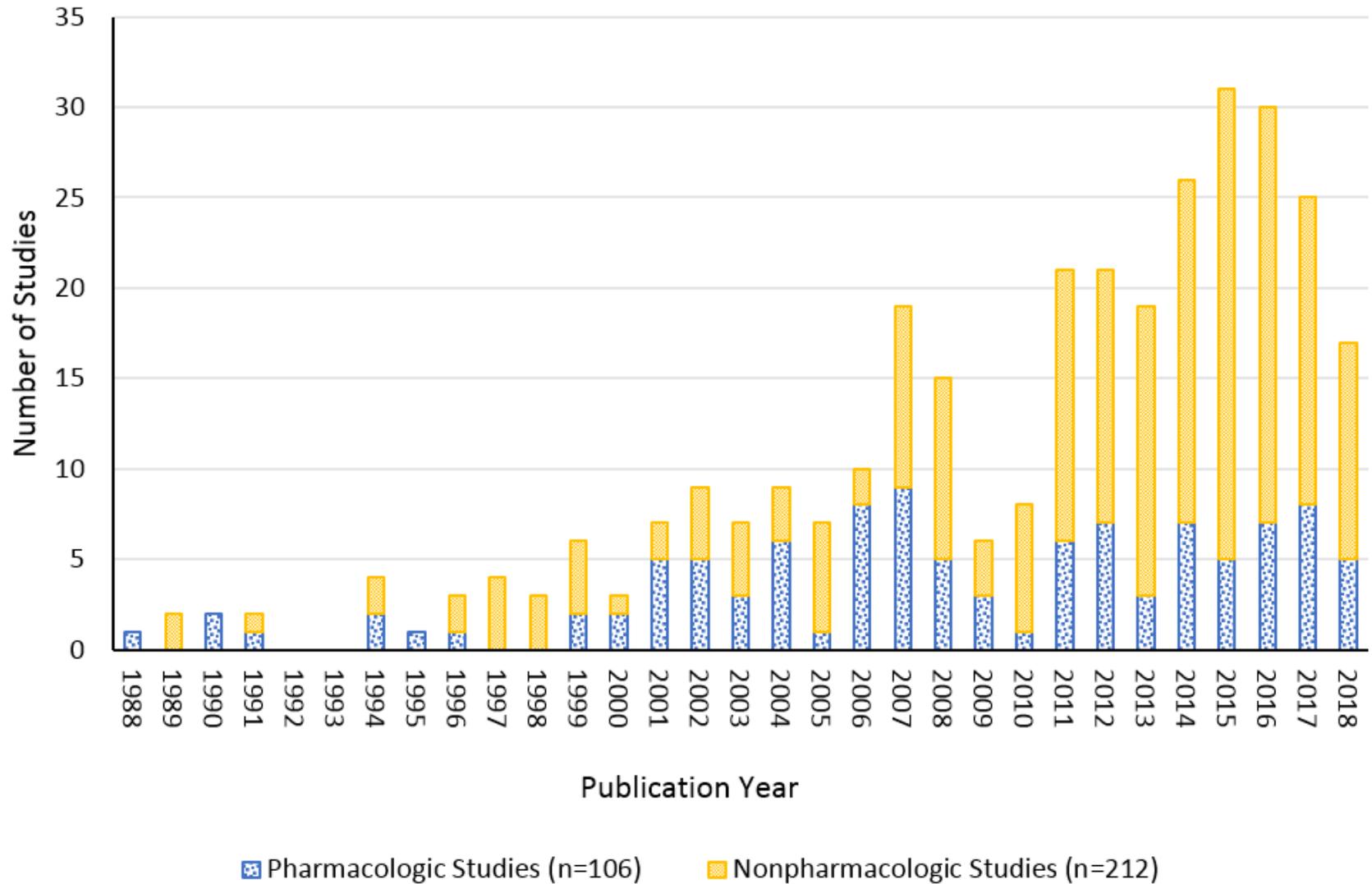
Percentage of Pharm and Nonpharm Interventions between 1988 and 2018



The 318 included RCTs were published from 1988 through 2018.

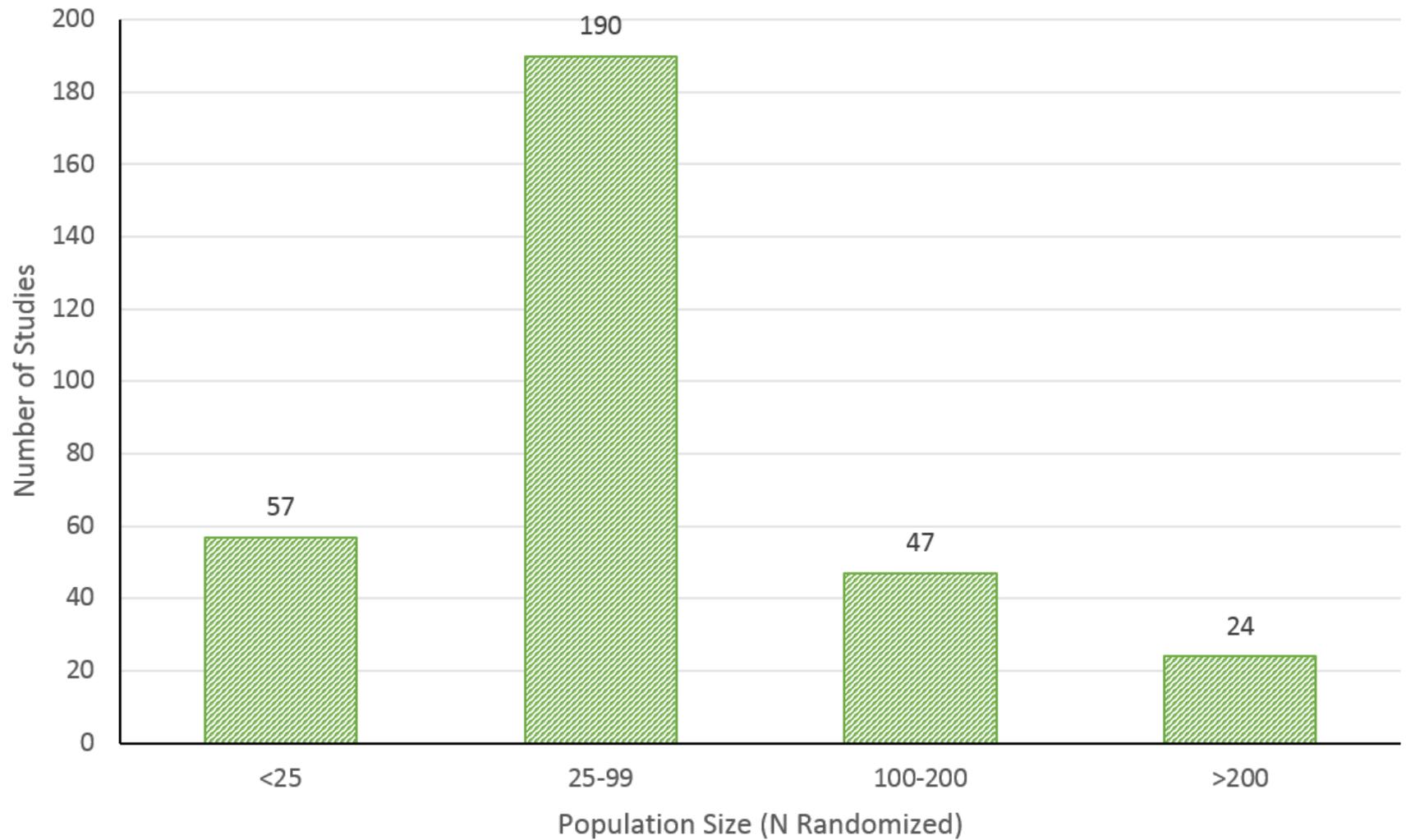


PUBLICATION YEAR



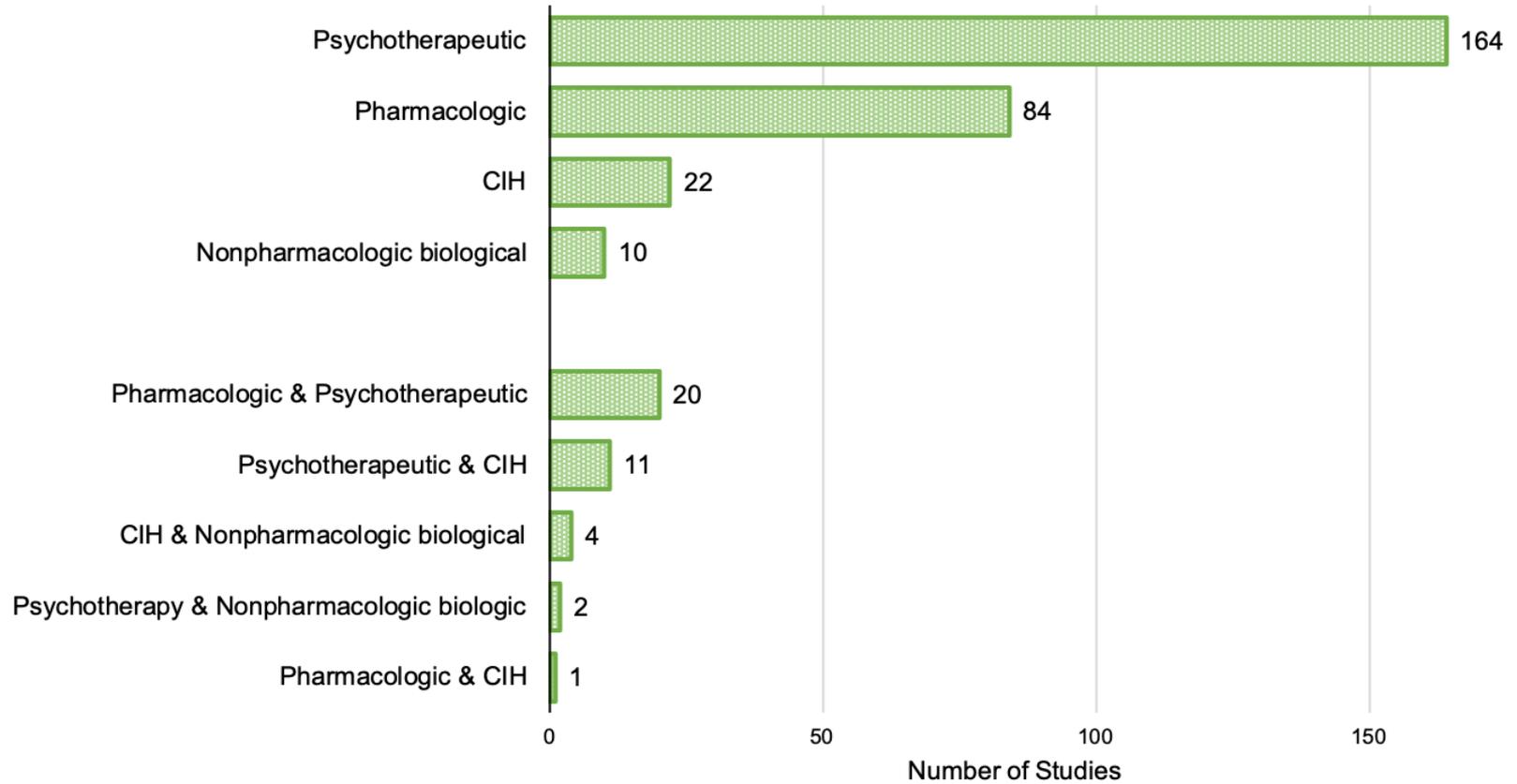


SAMPLE SIZE



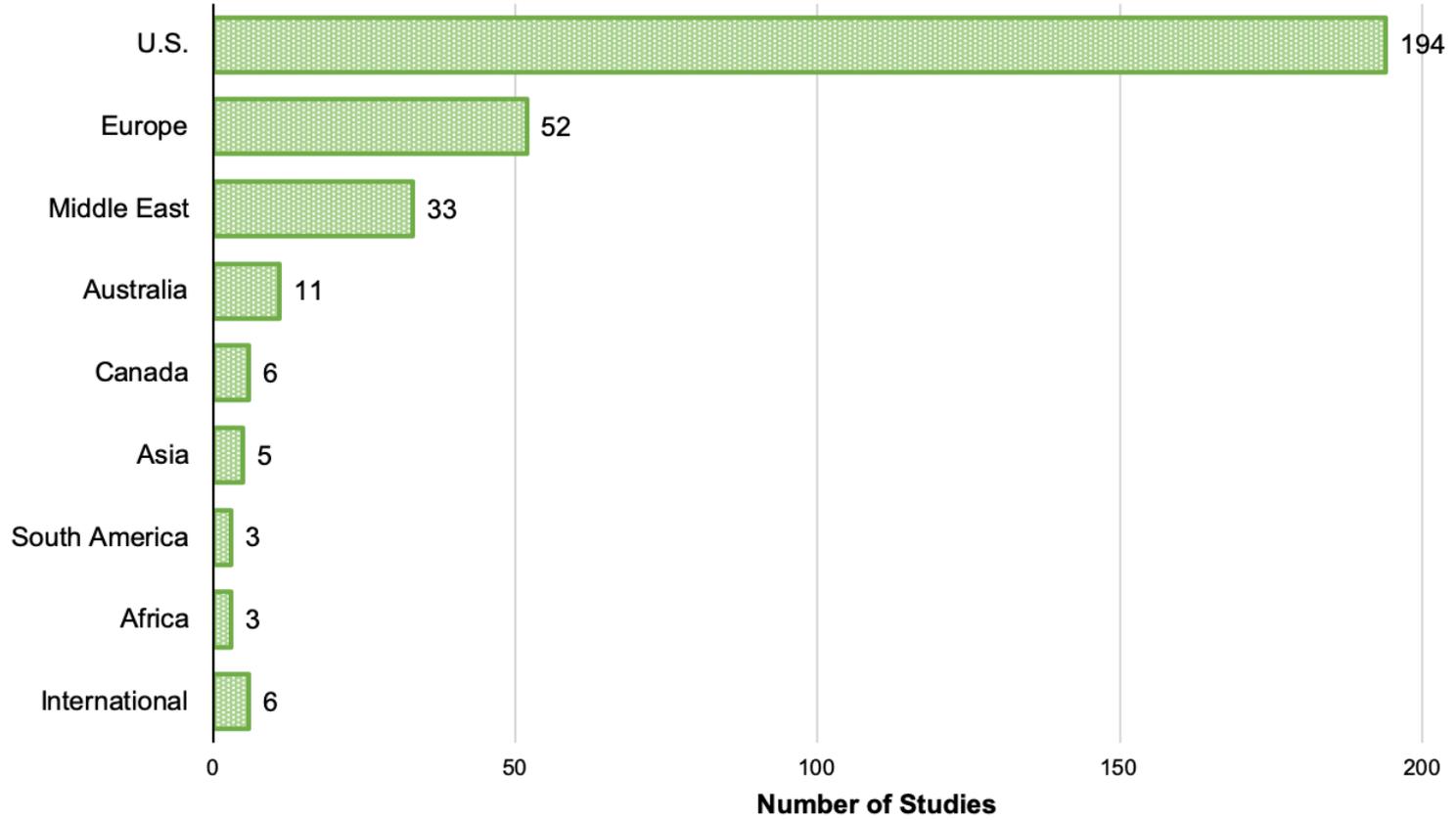


INTERVENTION CLASS – NUMBER OF STUDIES



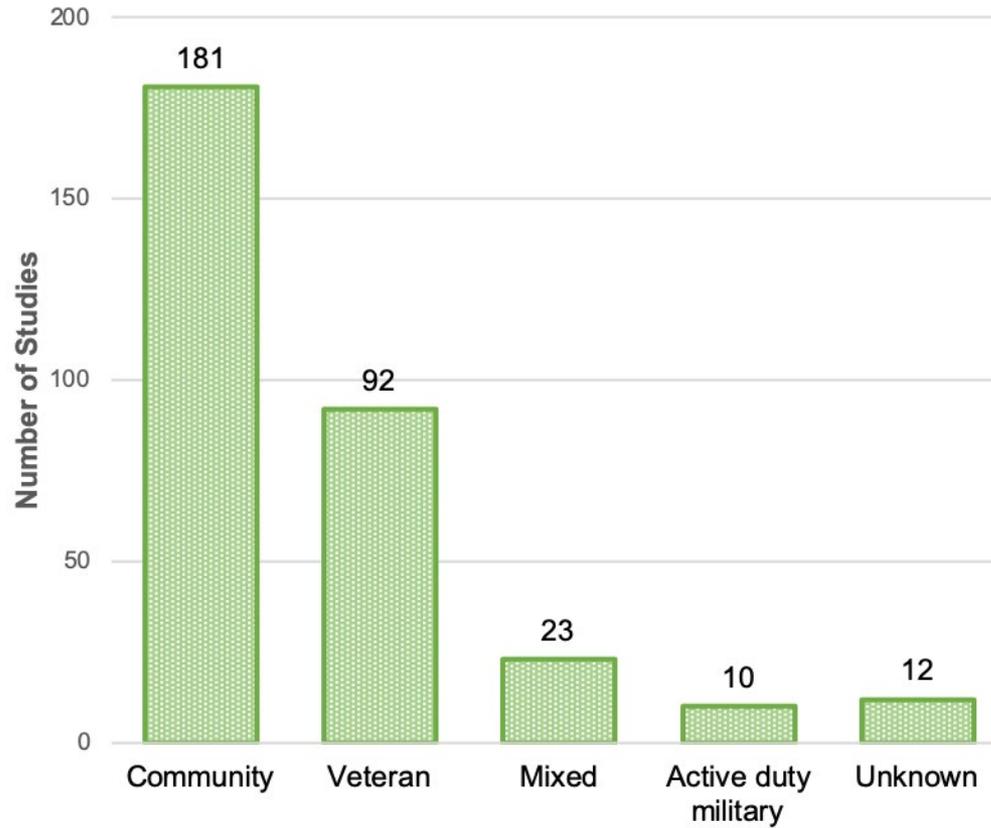


GEOGRAPHIC LOCATION – # STUDIES



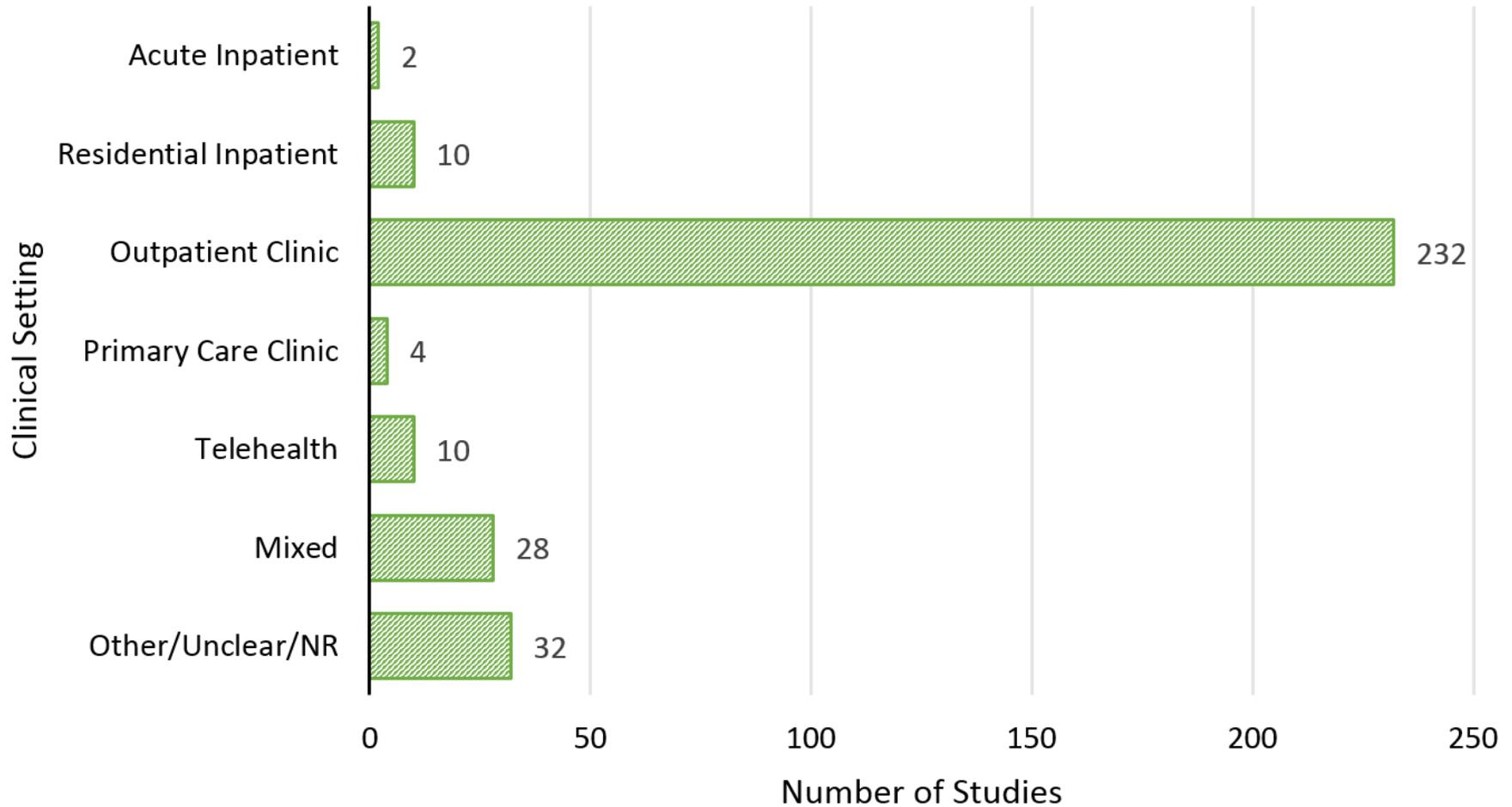


POPULATION TYPE – NUMBER OF STUDIES



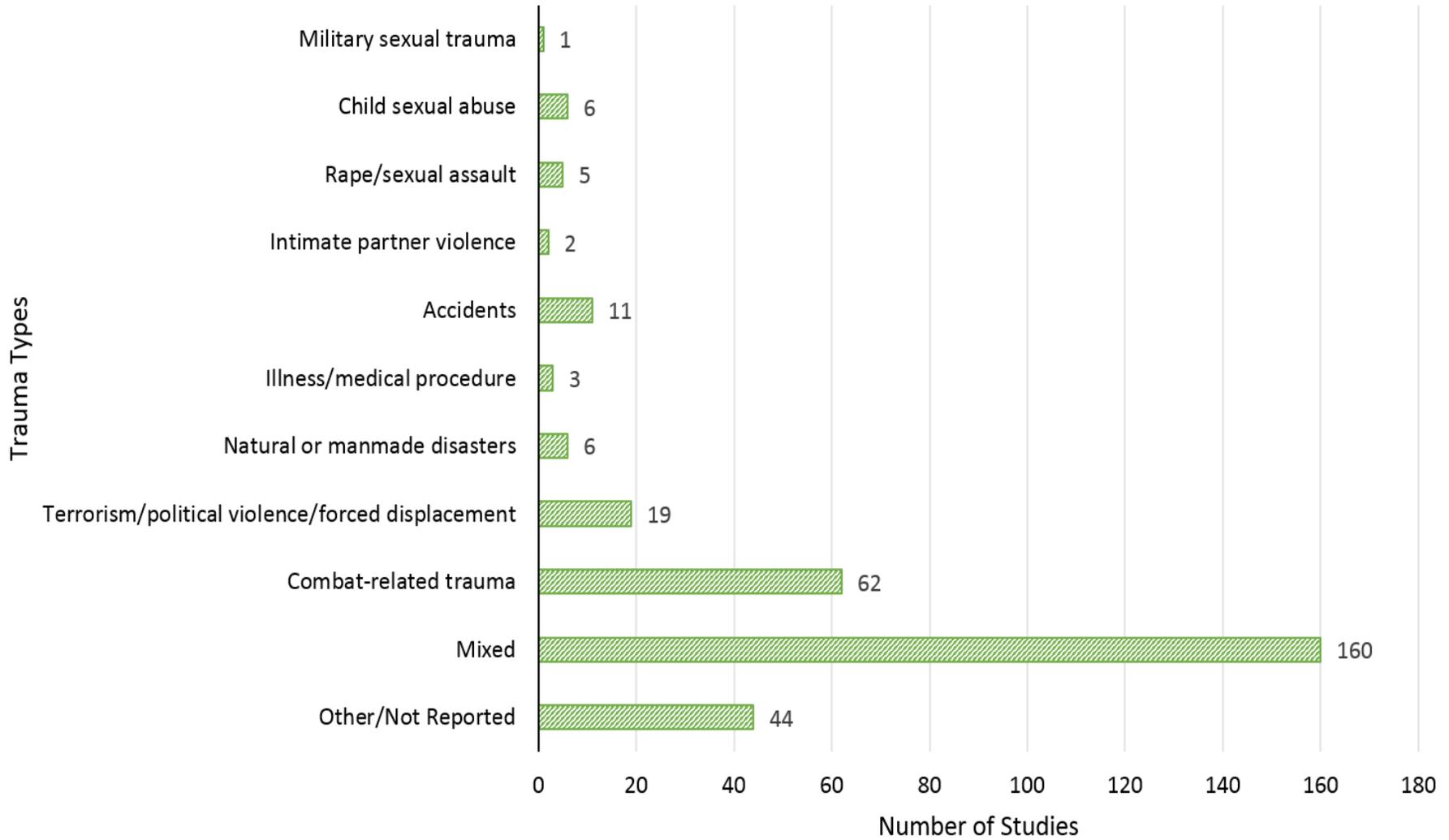


CLINICAL SETTING – NUMBER OF STUDIES



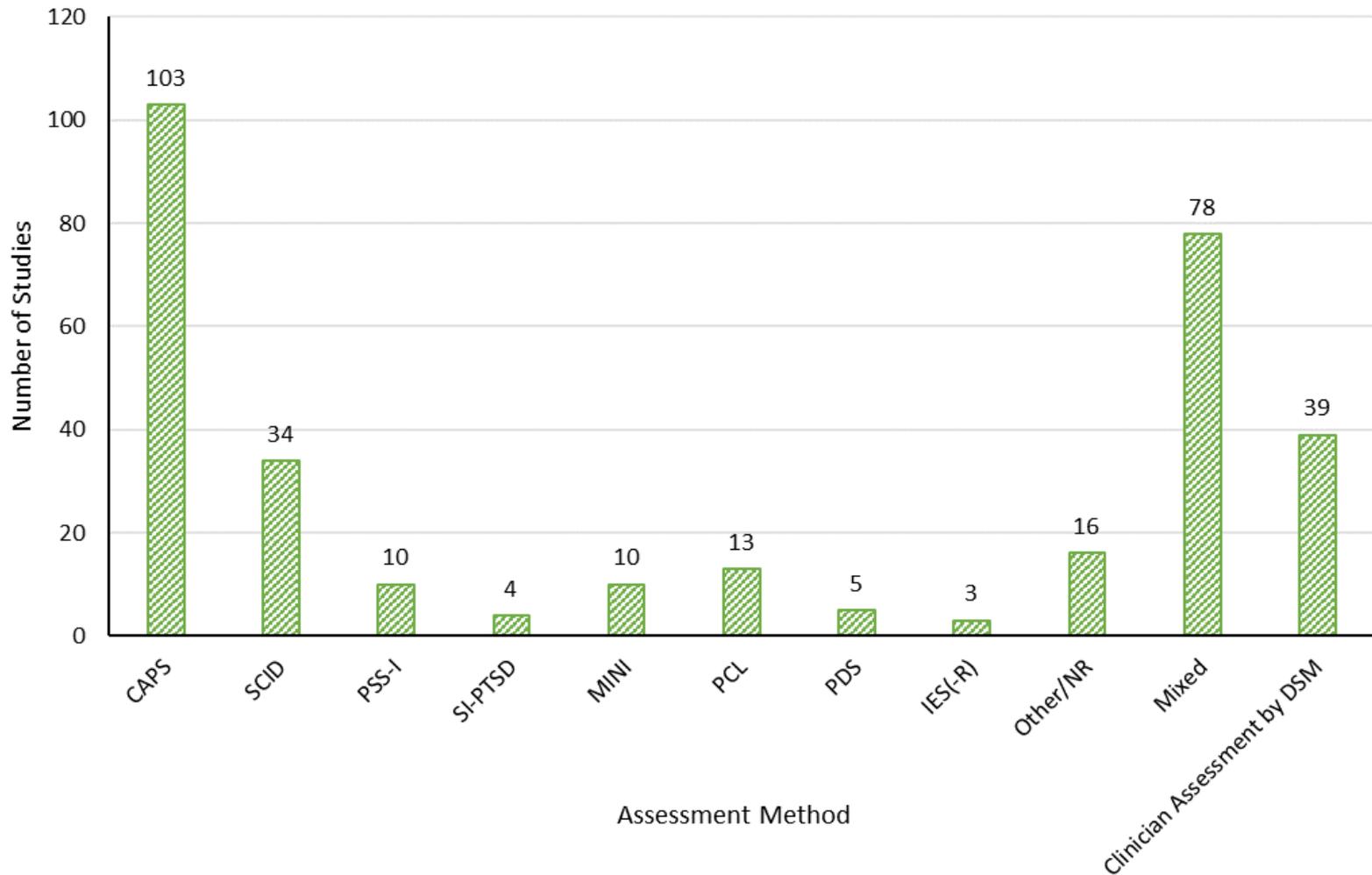


DISTRIBUTION BY TRAUMA TYPE





DISTRIBUTION BY ASSESSMENT METHOD





POLL QUESTION #2

What are you most interested in having added to the PTSD-Repository?

1. RCTs on SUD comorbidity
2. RCTs treating PTSD in children
3. Details about suicide-related variables
4. Details about TBI
5. Other

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What the data can tell us:

What can we answer?

What are the gaps?

Sonya B Norman, PhD

Director PTSD Consultation Program, National Center for PTSD
Professor, University of California School of Medicine

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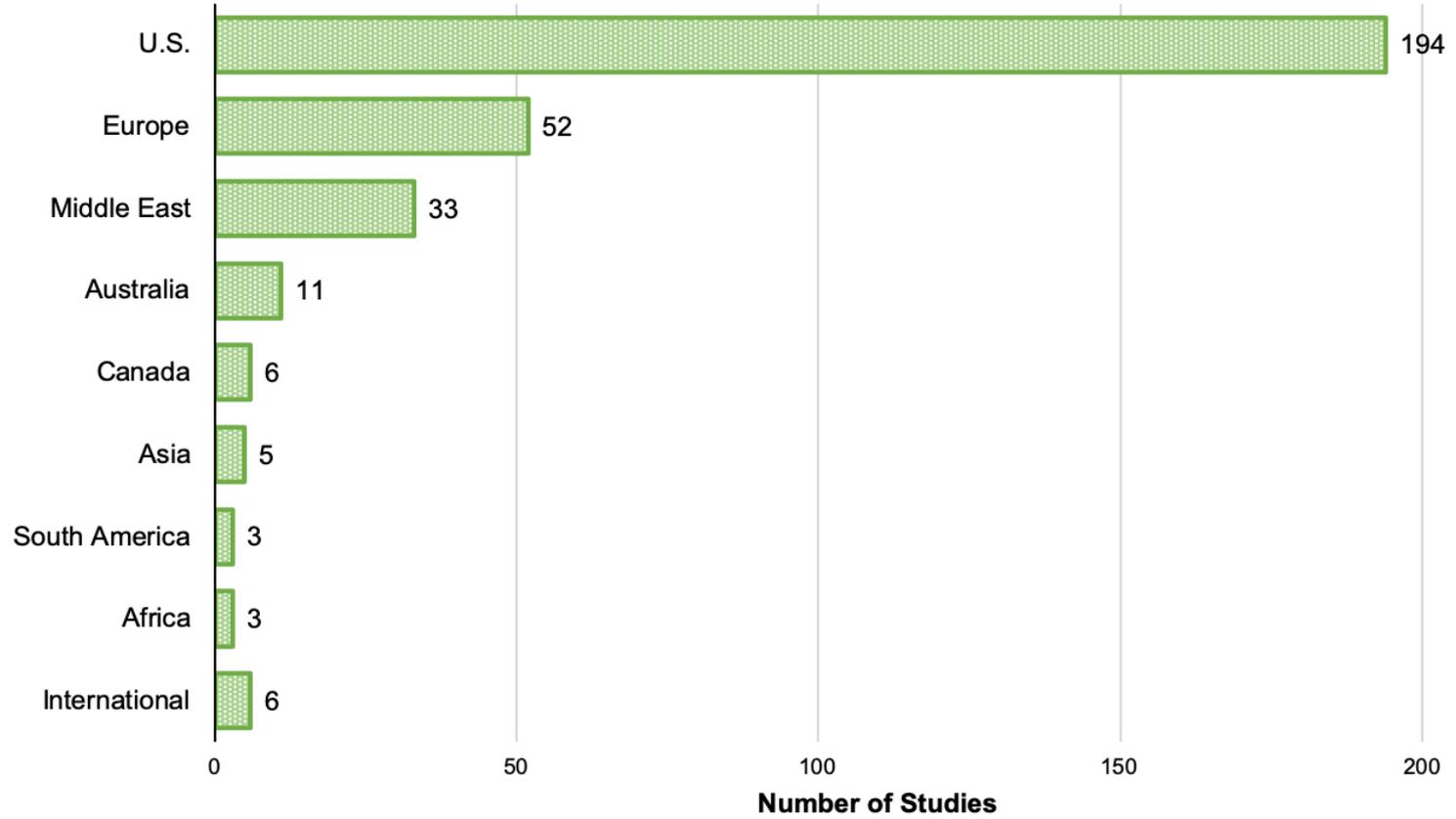
What the data can tell us:

Who are we studying?

(N up to 24,700)

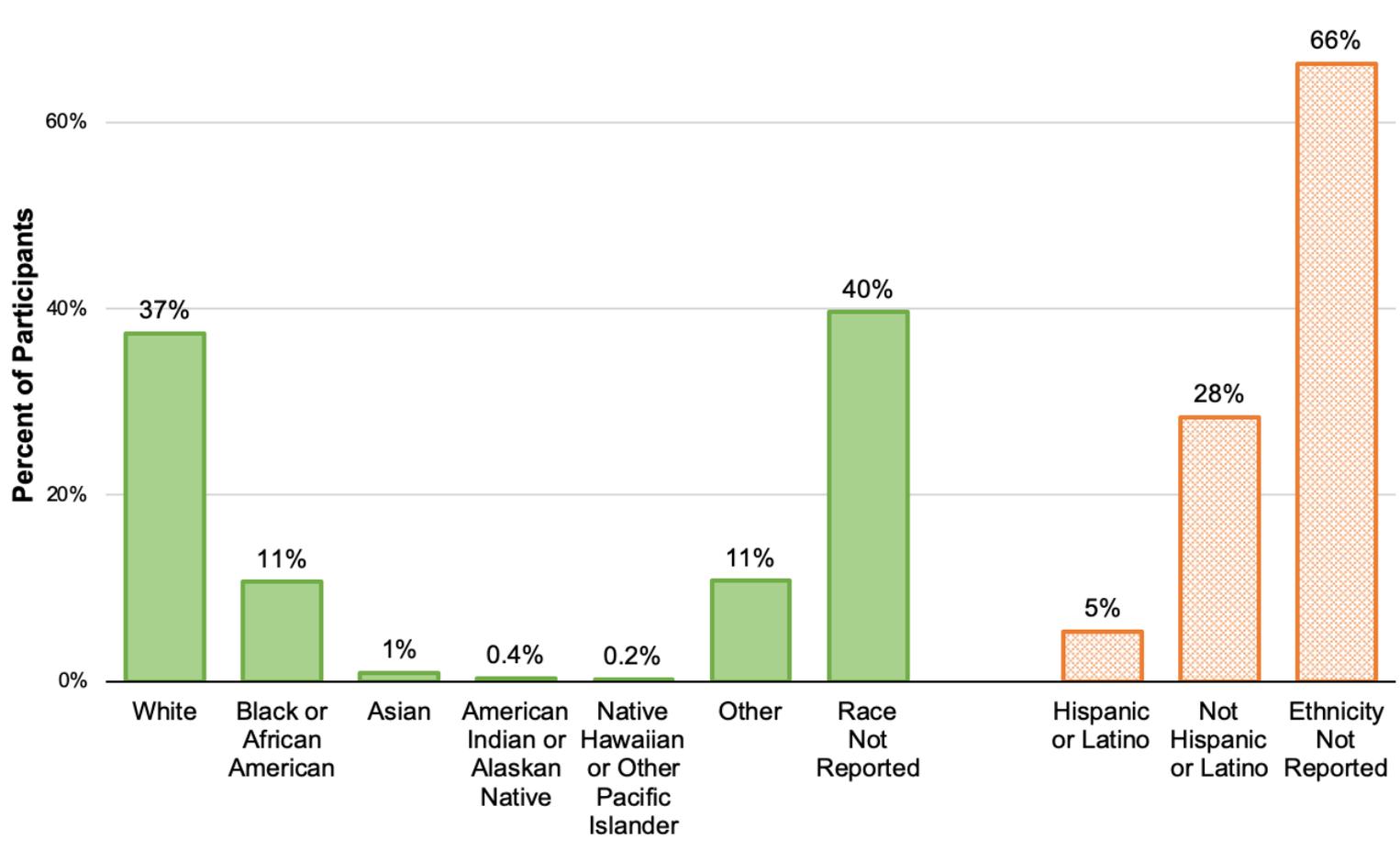


GEOGRAPHIC LOCATION



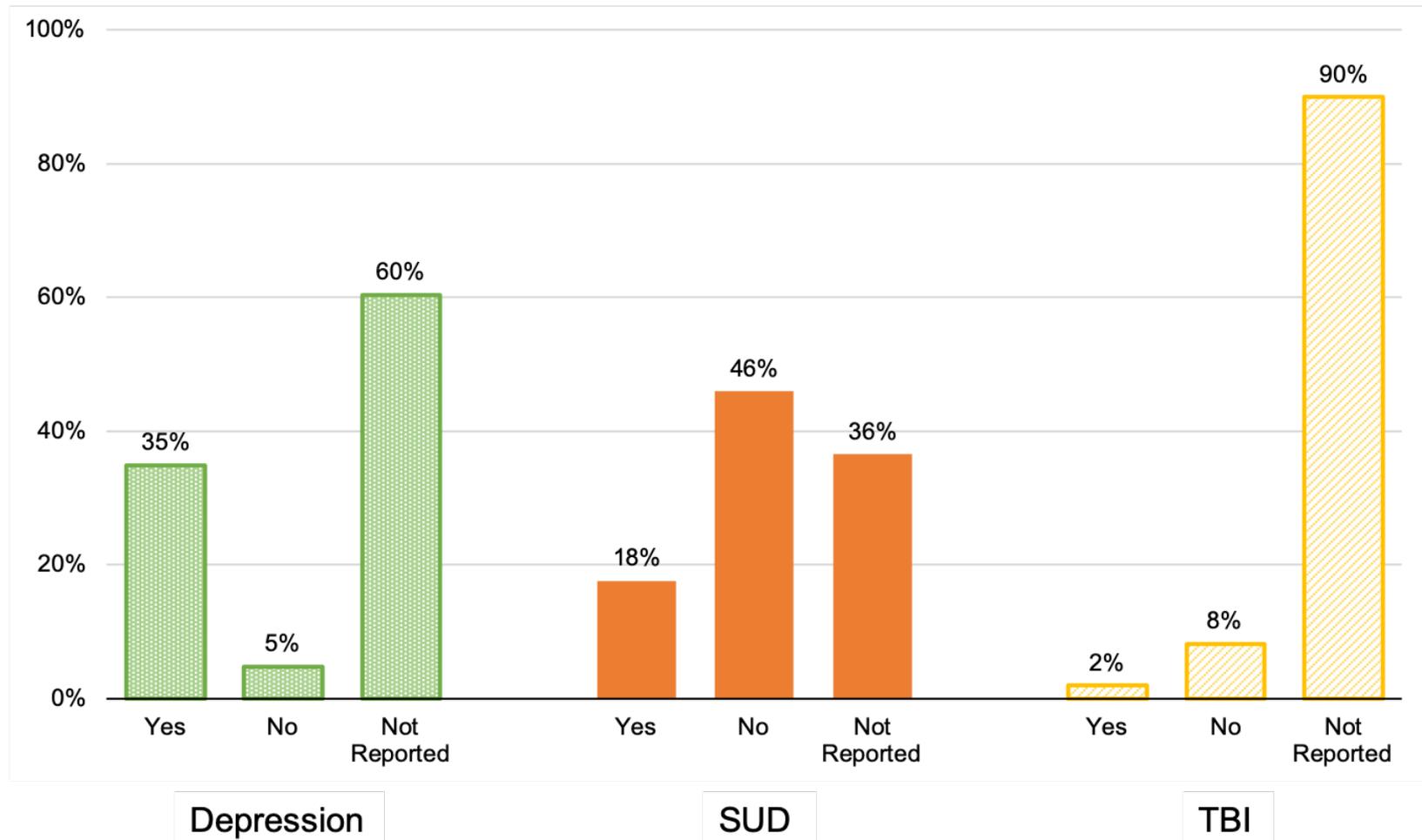


RACE AND ETHNICITY



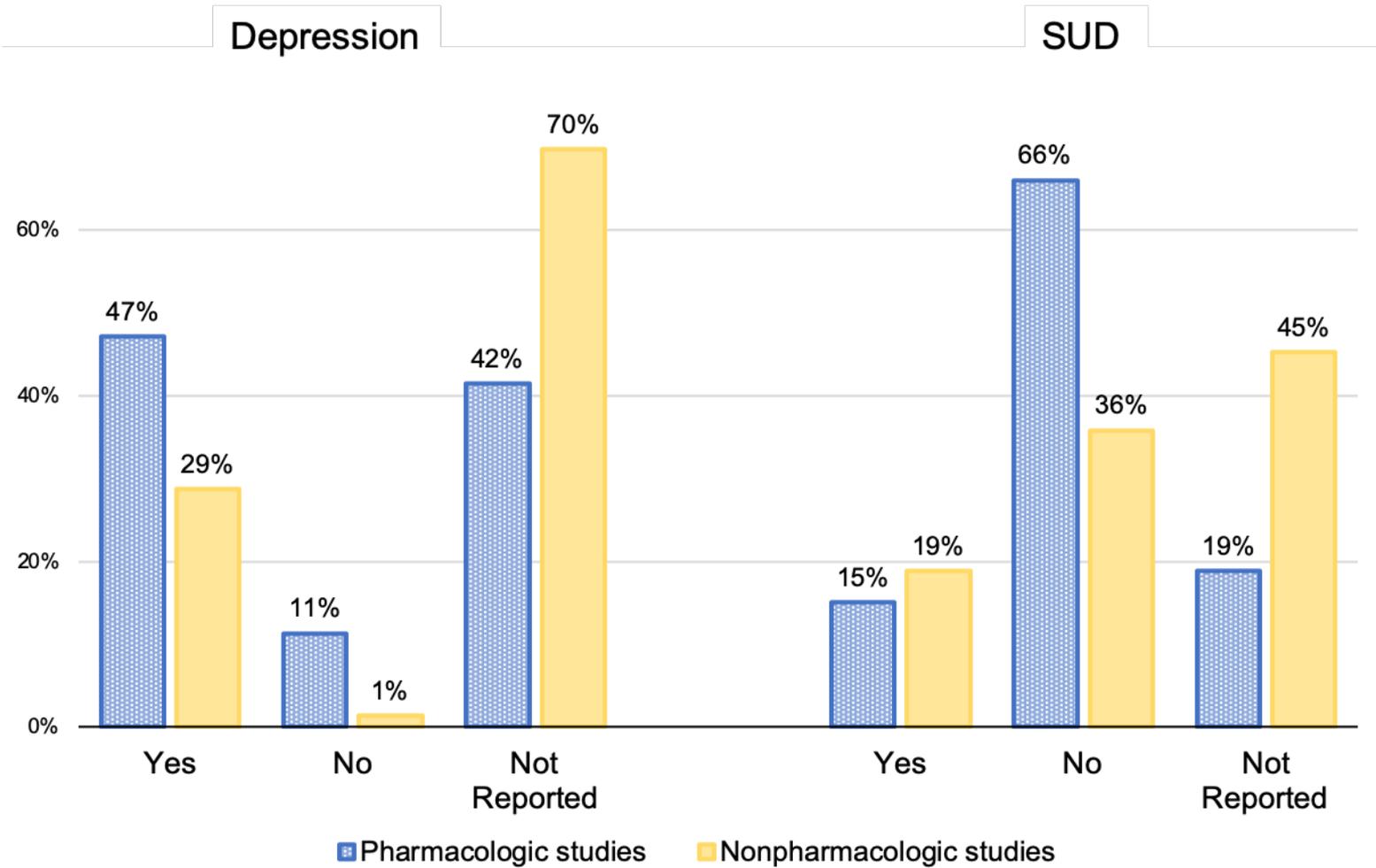


COMORBIDITIES





COMORBIDITIES IN PHARMACOLOGIC VS NONPHARMICOLOGIC STUDIES



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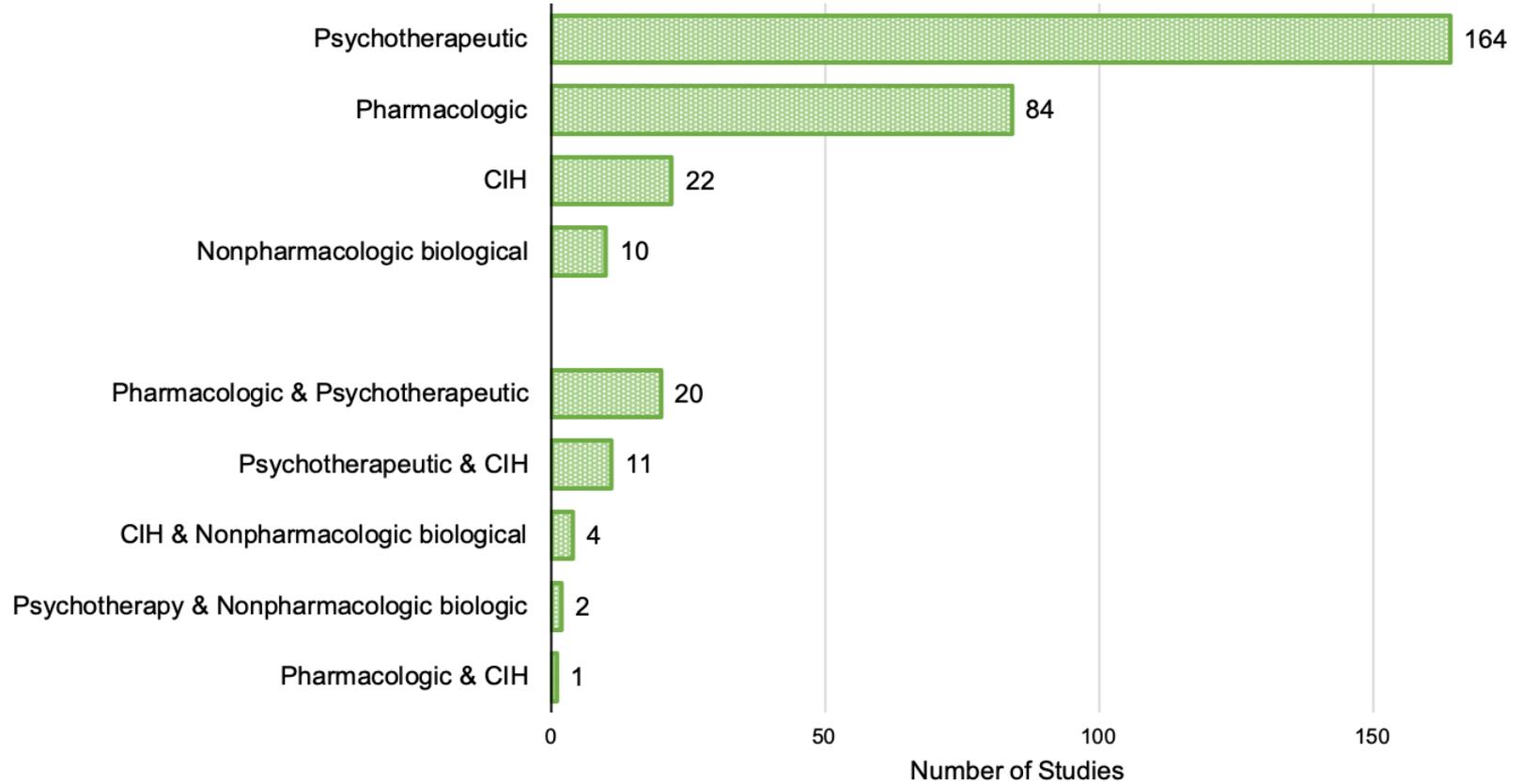
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What the data can tell us:

What are we studying and how?

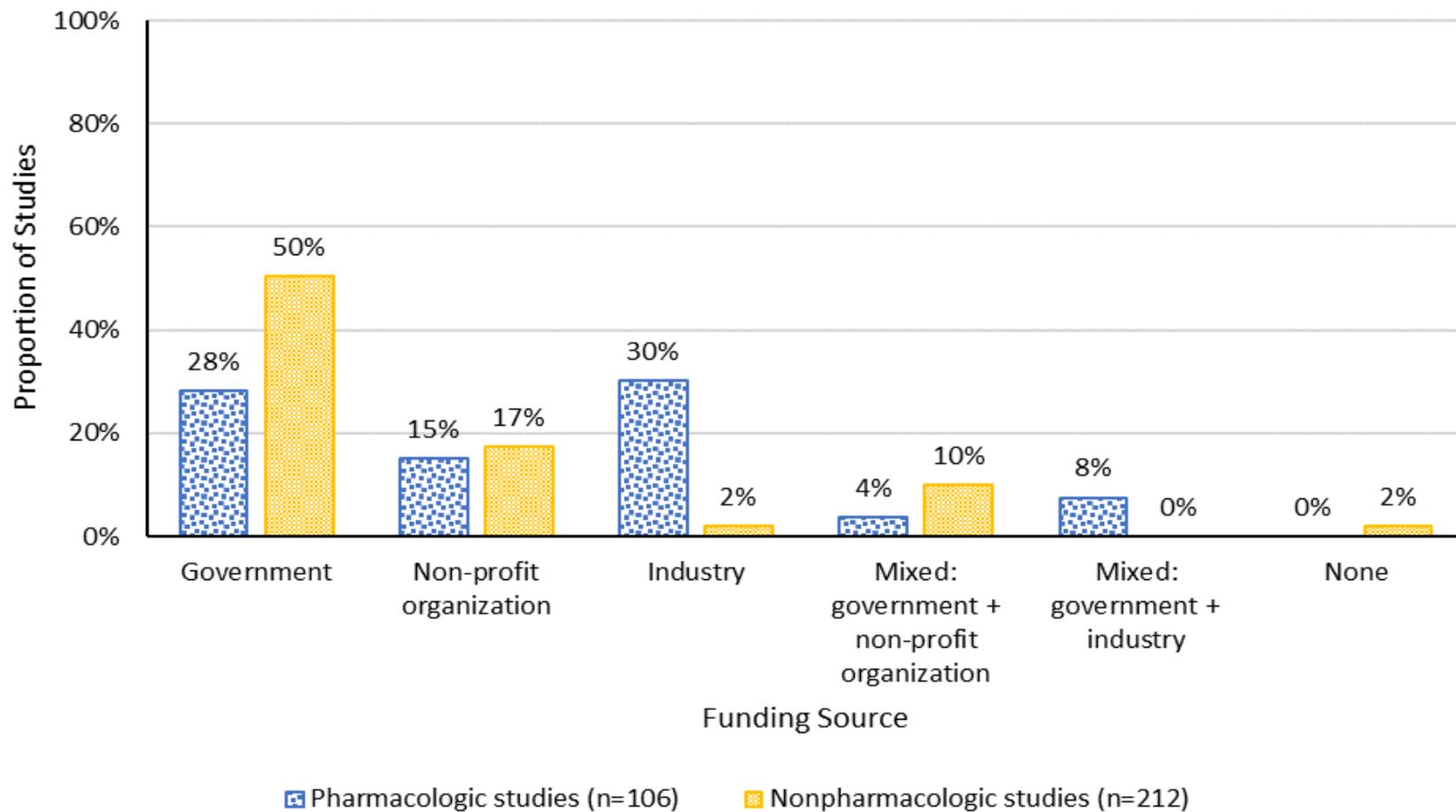


INTERVENTION CLASS – NUMBER OF STUDIES





FUNDING SOURCE



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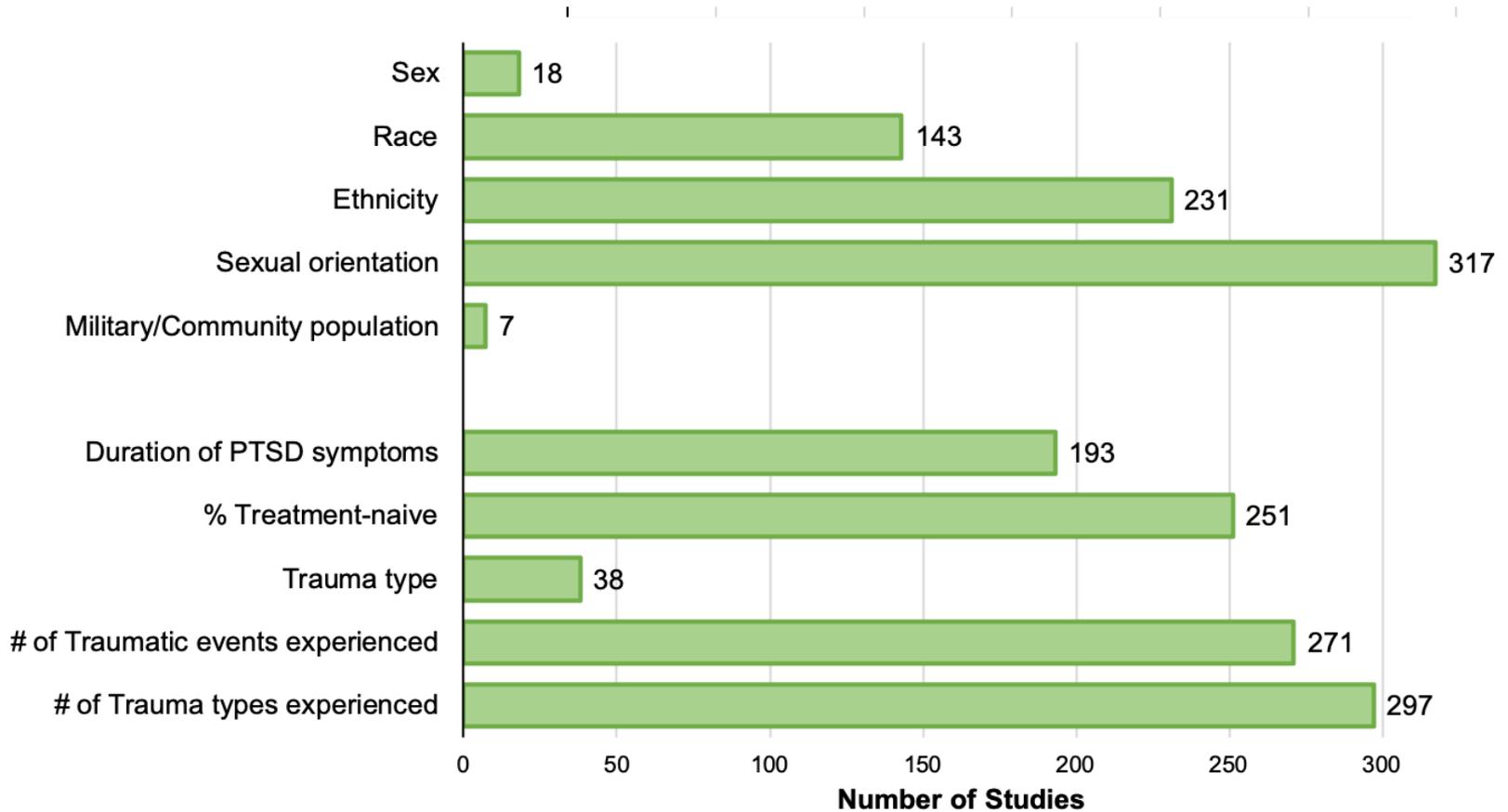
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What the data can tell us:

What are the gaps?

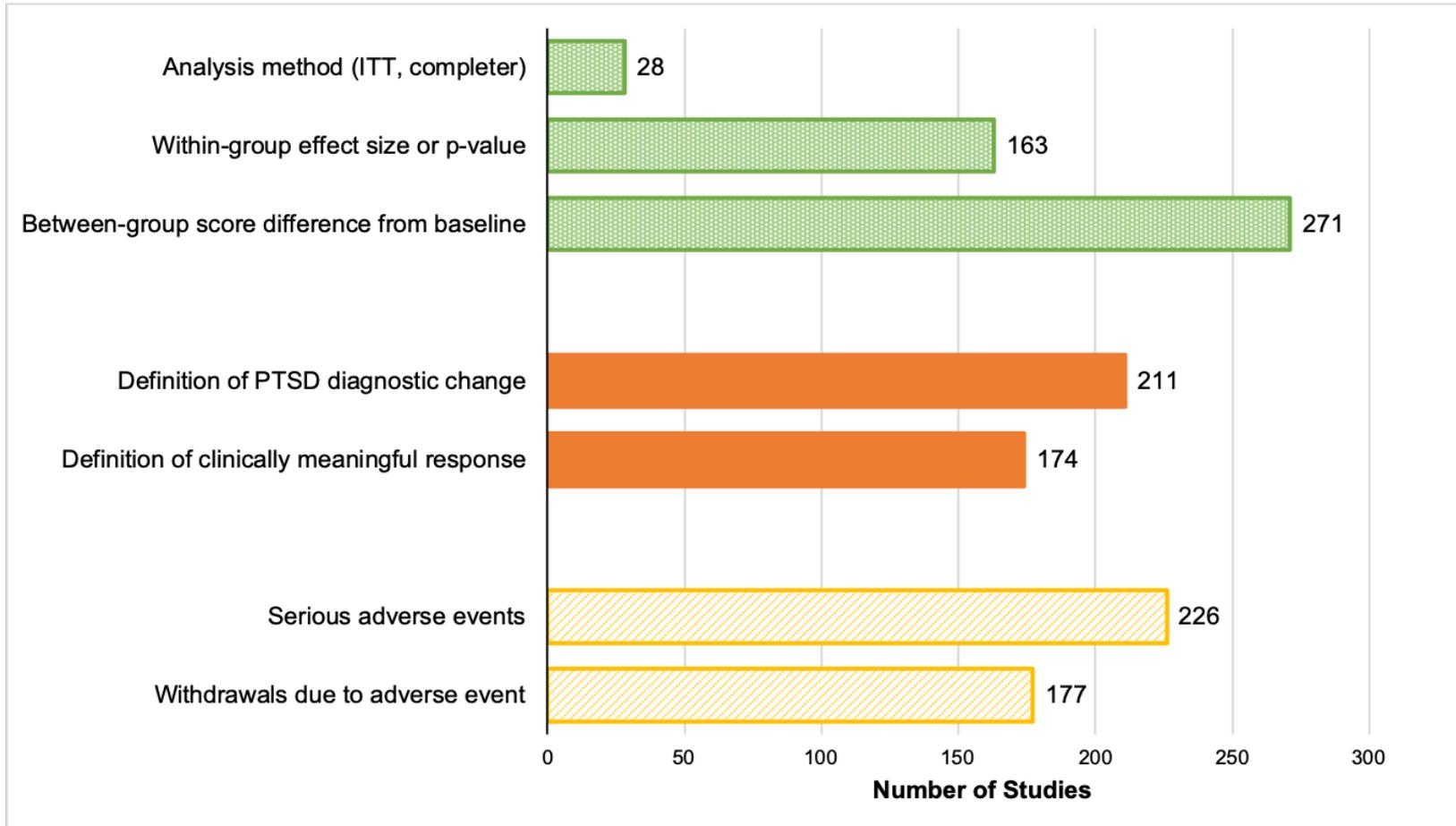


PARTICIPANT CHARACTERISTICS: WHAT ARE STUDIES NOT REPORTING



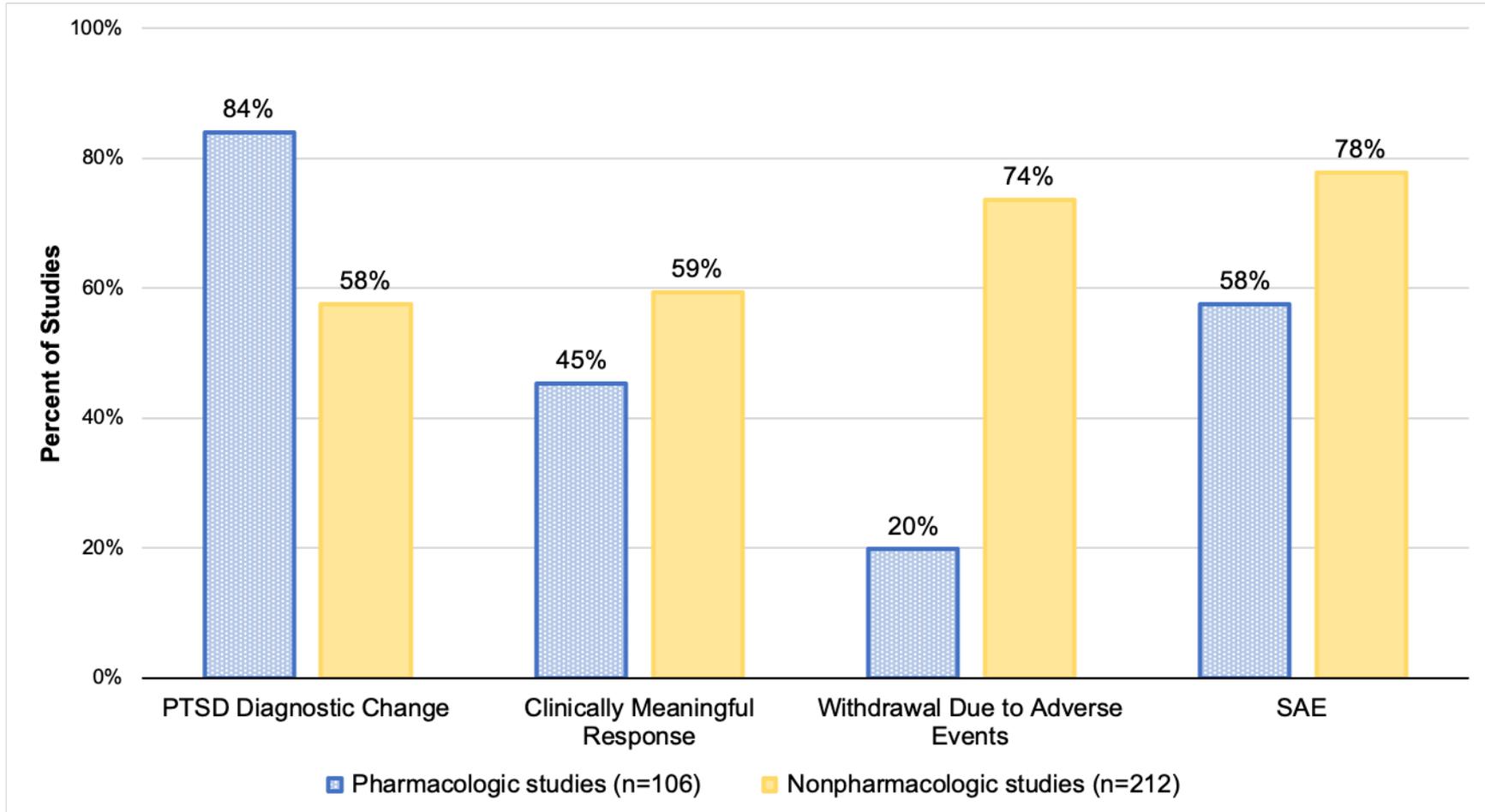


OUTCOMES: WHAT ARE WE NOT REPORTING?





OUTCOMES: WHAT ARE WE NOT REPORTING?





GAPS

- Less than half of the studies reported on loss of PTSD diagnosis, clinically meaningful response, or remission of symptoms.
- Reporting was incomplete for many data elements.



SUMMARY – WHO, WHAT, HOW

This birds eye view of the repository gives a sense of the state of the field, e.g.,

- Much of what we know is about treating predominantly white patients in the U.S.
 - We need more information about trauma among different countries, cultures, races, and ethnic groups
 - We need more information about comorbidities
- **We know some treatments are effective**
 - We have few direct treatment comparisons, especially across treatment classes
 - More consistency in analyses and outcome reporting would allow for more nuanced comparisons across treatments

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How you can use it



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PTSD Trials Standardized Data Repository (PTSD-Repository)

Users will be able to:

- Download the data (xls, csv, RDF, RSS, TSV)
- Manipulate the data: Search, sort, filter, reorder, etc.
- View and export pre-made graphical displays
- Link to each trial's record in [PTSDpubs](#)
- Access supporting documents (user guide, methods, glossary of key terms, etc.)
- Share “data stories”



STAKEHOLDER BENEFITS

Clinician

“I work with older Veterans. What PTSD treatments have been tested in this population?”

Patient

“My friend recommended acupuncture for PTSD. Have any studies looked at this?”

Researcher

“What is the average effect size of Transcranial Magnetic Stimulation for PTSD?”



ADDITIONAL STAKEHOLDER BENEFITS

- Assist funding agencies with identifying gaps and determining priorities
- Serve as a data source for students, trainees
- Augment existing educational tools, such as PTSDpubs and mobile apps
- Inform best practices for PTSD trial reporting



DATA UPDATES

- NCPTSD will commission an annual update
- **2019 update:**
 - Newly published RCTs
 - Risk of bias ratings for included studies
 - New variables:
 - RCTs of concurrent PTSD/SUD treatment
- **Future Updates**
 - Add newly published studies
 - Expand inclusion criteria
 - Abstract additional variables



POLL QUESTION #3

How might you use the PTSD-Repository?

1. Look at a graphic or written data summary
2. Pull data from the PTSD-Repository to answer a question for yourself or a patient
3. Manipulate data from the PTSD-Repository to conduct research (e.g., for a systematic review)
4. I'm not sure that I would ever use it



QUESTIONS

- Can I use these data to publish a paper?
 - Yes! And we'd love to hear how you used the data (NCPTSD@va.gov)
- Can I share the database with providers/students/researchers/patients?
 - Yes!
- Where can I download the data and fine out more about the methods?
 - <https://www.ptsd.va.gov/ptsdrepository/index.asp>
- How can I cite the data?
 - O'Neil M, McDonagh M, Hsu F, Cheney T, Carlson K, Holmes R, Ramirez S, Hart E, Murphy K, Graham E, Chou R. Pharmacologic and Nonpharmacologic Treatments for Posttraumatic Stress Disorder: Groundwork for a Publicly Available Repository of Randomized Controlled Trial Data. Technical Brief No. 32. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2015-00009-I.) AHRQ Publication No. 19-EHC018-EF. Rockville, MD: Agency for Healthcare Research and Quality; May 2019. Posted final reports are located on the Effective Health Care Program [search page](#). DOI: <https://doi.org/10.23970/AHRQEPCTB32>.



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