

**VA**



U.S. Department  
of Veterans Affairs

# Suicide Prevention Trials Database (SPTD): RCTs in Suicide Prevention

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# HOW ARE CLINICAL TRIAL DATABASES USED?





# SPTD PROJECT OVERVIEW

## Phase 1: Development (2021-2022)

Develop initial database scope; search for & extract data from 100-150 RCT studies; stand up database online



## Phase 2: Expansion (2023)

Expand database scope; add data from ~100 non-RCT additional studies; assess risk of bias of included phase I and II studies



## Phase 3: Maintenance (2024-2025)

Disseminate key findings; develop long-term maintenance plan



# PHASE 1 GUIDING QUESTION



What are the characteristics,

Population

Interventions

Comparators

Otcomes

Timing

Settings

Study Design

of randomized controlled trials (RCTs) examining individual, relationship, system, community, and population-level suicide prevention interventions?

Photo #1: Photo by [René Ranisch](#) on [Unsplash](#)

Photo #2: Photo by [insung yoon](#) on [Unsplash](#)

Photo #3: Photo by [Katerina Jerabkova](#) on [Unsplash](#)



# PHASE 1 SCOPE

Category	Inclusion Criteria	Exclusion Criteria
<b>Population</b>	Adults ( $\geq 18$ years old)	Children and adolescents ( $< 18$ years old)
<b>Interventions</b>	Interventions from studies whose primary aim is preventing suicidal ideation, suicide, or suicidal self-directed violence	Interventions from studies whose primary aim is not preventing suicidal ideation, suicide or suicidal self-directed violence
<b>Comparators</b>	No limitations applied (e.g., another intervention; usual care; no intervention)	None
<b>Outcomes</b>	<p><u>Primary</u>: Studies must report on suicide or suicidal self-directed violence (e.g., fatal or non-fatal suicide attempts) to be included</p> <p><u>Secondary</u>: Suicide ideation and harms (e.g., any reported unintended consequences such as medication side effects) are additional outcomes of interest</p>	Studies that do not report the primary outcome will be excluded
<b>Timing</b>	Any study duration and length of follow-up	None
<b>Study Design</b>	Randomized controlled trials where the individual is the unit of randomization	Studies that do not have a randomized controlled trial design; cluster-randomized trials
<b>Publication language &amp; dates</b>	English language articles 1980 to present	Non-English language articles Unpublished data Publication date prior to 1980



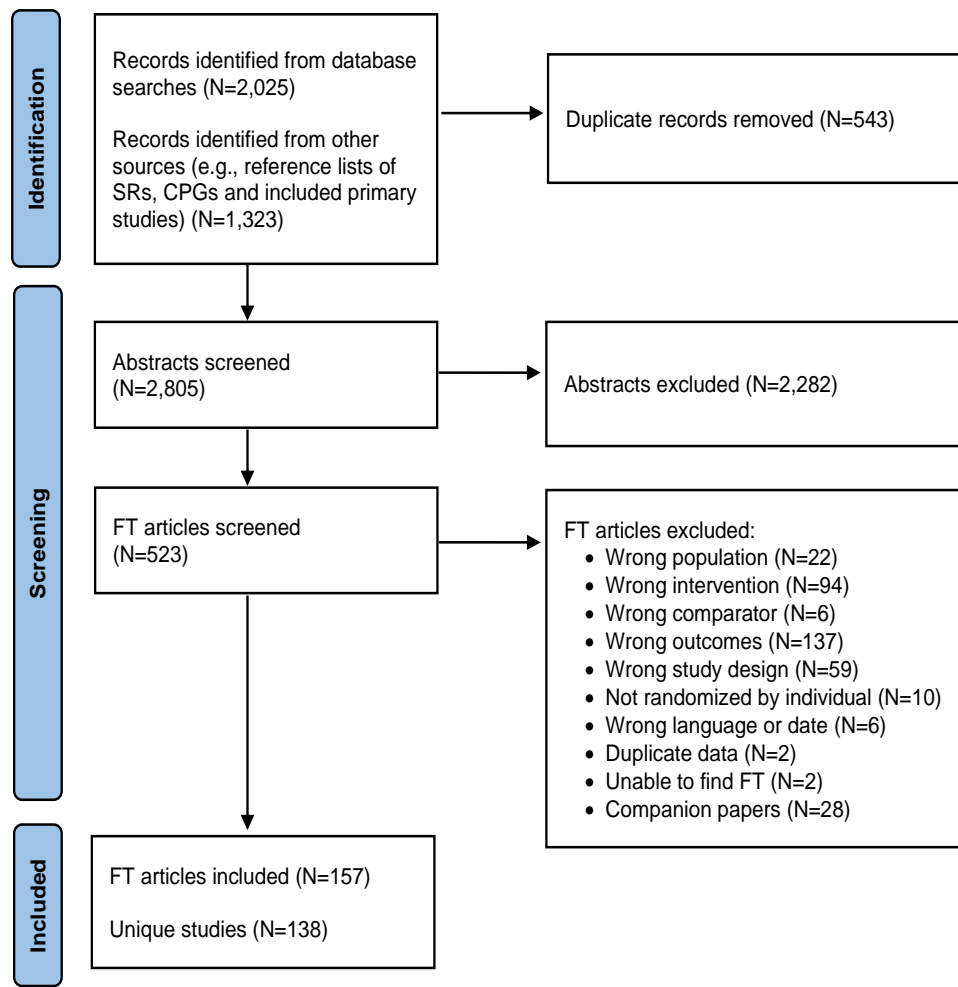
# INTERVENTION CATEGORIES

Category	Examples
<b>Behavioral</b>	CBT, DBT, Problem-solving therapies
<b>Pharmacological</b>	Ketamine, Lithium, Clozapine, SSRI
<b>Non-pharm biological</b>	ECT, Neuromodulation
<b>Care mgmt, follow-up or monitoring</b>	Periodic caring communication, Home visits, Safety planning
<b>Complementary &amp; integrative health</b>	Mindfulness, meditation, yoga
<b>Technology-based</b>	Mobile or web applications
<b>Risk assessment &amp; screening</b>	Predictive analytics, Suicide risk screening

Category	Examples
<b>Strengthening access to care</b>	Reducing provider shortages, Coverage of MH conditions
<b>Reducing access to lethal means</b>	Firearm safety, Bridge barriers
<b>Crisis hotlines</b>	Veterans Crisis Line
<b>Gatekeeper training</b>	Army ACE, SAVE
<b>Peer support programs</b>	Buddy intervention support group
<b>Media campaigns &amp; safe reporting</b>	Recommendations for reporting
<b>Addressing SDOH</b>	Strengthen household financial security, Housing stabilization
<b>Postvention</b>	StandBy Support After Suicide
<b>Other</b>	Social-emotional learning, Parenting skills



# PHASE 1 STUDY SELECTION





# Phase I Database

- 134 included studies
- Tabs 1-5 include study characteristics and intervention information
- Tabs 6-9 include outcome data including dichotomous, continuous, time to event, and count data
- Tabs 10 and 11 provide information on non-suicide outcomes and harms reported by studies
- <https://www.hsrd.research.va.gov/centers/core/sprint/sptd.cfm>





## Non-Outcome Tabs in Database

Category	Variables
Study Characteristics	<ul style="list-style-type: none"><li>• Recruitment year</li><li>• Country, clinical setting</li><li>• Study design, inclusion and exclusion criteria</li></ul>
Sample Characteristics	<ul style="list-style-type: none"><li>• Age, gender, race, ethnicity, sexual orientation</li><li>• Percent active duty/veteran/reintegrating veteran/community</li><li>• Suicide attempt history and prior inpatient hospitalization</li><li>• Percent with PTSD, depression, TBI, substance abuse, psychotic disorder, borderline personality disorder, bipolar disorder, or anxiety disorder</li></ul>
Study Interventions	<ul style="list-style-type: none"><li>• Intervention name and intervention category</li><li>• N randomized to each intervention</li><li>• Description and format of intervention</li><li>• Delivery method</li><li>• Dose and dose schedule</li></ul>



## Intervention Categories in the Database

Intervention	
Behavioral (CBT, DBT)	Gatekeeper training (SAVE, army ACE)
Pharmacological (ketamine, SSRI)	Peer and buddy support programs
Nonpharmacological biological (ECT, neuromodulation)	Media campaigns, public awareness, and safe reporting and messaging about suicide
Care management, follow up, or monitoring (CAMS, caring contacts)	Addressing social determinants of health (housing stabilization)
Complementary and Integrative Health (mediation, yoga)	Other (Social emotional learning programs)
Technology-based modalities (phone app)	Placebo/Sham
Risk assessment/screening	Treatment as usual
Strengthening access to care/increasing system capacity	Wait-list or other passive control (wait-list, educational handout)
Reducing access to lethal means (firearm safety)	Time and attention control (Educational group sessions)
Crisis hotlines and chatlines	



## Example of Non-Outcome Data

author_year	intervention_label	arm_n	arm_n_detail	intervention_name	intervention_category
Jobes, 2017	A	73		Collaborative Assessment a	Behavioral;Care management,
Jobes, 2017	B	75		Enhanced Care as Usual	Behavioral

- The above snapshot is abstracted data from the Study Interventions tab
- Each study arm was given a label A or B. There is one arm per row
- We provide the N in each arm, list the intervention name, and categorize the intervention
- The detail column is qualitative and can provide information such as how many participants received the intervention, and if participants were excluded from analysis



## Outcome Tabs in Database

Category	Abstraction
Suicide Outcomes (suicide deaths, suicide attempts, self-harm events, suicide ideation, and suicide risk)	<ul style="list-style-type: none"><li>• Suicide outcomes are broken up in tabs by data type (continuous, dichotomous, time to event, and count)</li><li>• Studies can have multiple rows per outcome (one row per timepoint, one row per analysis type (ITT vs per protocol), and one row per arm comparison)</li><li>• Abstracted variables include: analysis method, adjusted variables, method for handling missing data, with &amp; between group differences, and effect size</li></ul>
Other Outcomes	<ul style="list-style-type: none"><li>• Abstracted indicators (yes/no) for whether the study reported outcomes on depression, anxiety, traumatic disorders, substance use, sleep, anger, quality of life, functioning, loneliness, social isolation, and clinician assessed suicide-risk</li></ul>
Harms	<ul style="list-style-type: none"><li>• Studies can have multiple rows in the harms tab (one row per harms category, and one row for each arm comparison)</li><li>• Harms categories include Serious Adverse Events, withdrawal due to adverse events, non-suicide deaths, unspecified deaths, and other</li><li>• We did not abstract suicide-related outcomes that were reported as harms. Instead, those were extracted in the suicide outcomes tabs</li></ul>



## Example of Extracted Data

contin_outcome_category ▾	contin_analysis_type ▾	contin_missing_category ▾	contin_missing_detail ▾	contin_analysis_method ▾	contin_crude_category ▾
Suicide ideation	ITT	Likelihood		Hurdle Regression	Crude
Suicide ideation	ITT	Likelihood		Hurdle Regression	Crude
Suicide ideation	ITT	Likelihood		Hurdle Regression	Crude
Suicide ideation	ITT	Likelihood		Hurdle Regression	Crude

- The above snapshot is from the continuous outcome tab. All rows correspond to the same study
- From the abstraction, we know the study reported a crude ITT analysis of suicide ideation, used likelihood to handle missingness, and analyzed the data with hurdle regression
- There are multiple rows since the study reported information for multiple timepoints
- This information is reported in all suicide outcome tabs



# Protocol of Abstracting Suicide Outcomes

- We did not abstract self-harm events if the study explicitly stated it was NSSI
- If a study reported suicide attempts and self-harm events, we only abstracted suicide attempts
- We abstracted 0 suicide deaths if the study reported there were no serious adverse events
- We did not include outcomes if they did not report enough information to calculate or report an effect size
- We abstracted three rows per outcome for studies with three intervention arms (A vs B, A vs C, B vs C)



## Data Dictionary

- A data dictionary is available on the SPTD website
- Includes the definition for 335 variables
- It is available in Word and Excel
- <https://www.hsrd.research.va.gov/centers/core/sprint/sptd.cfm>

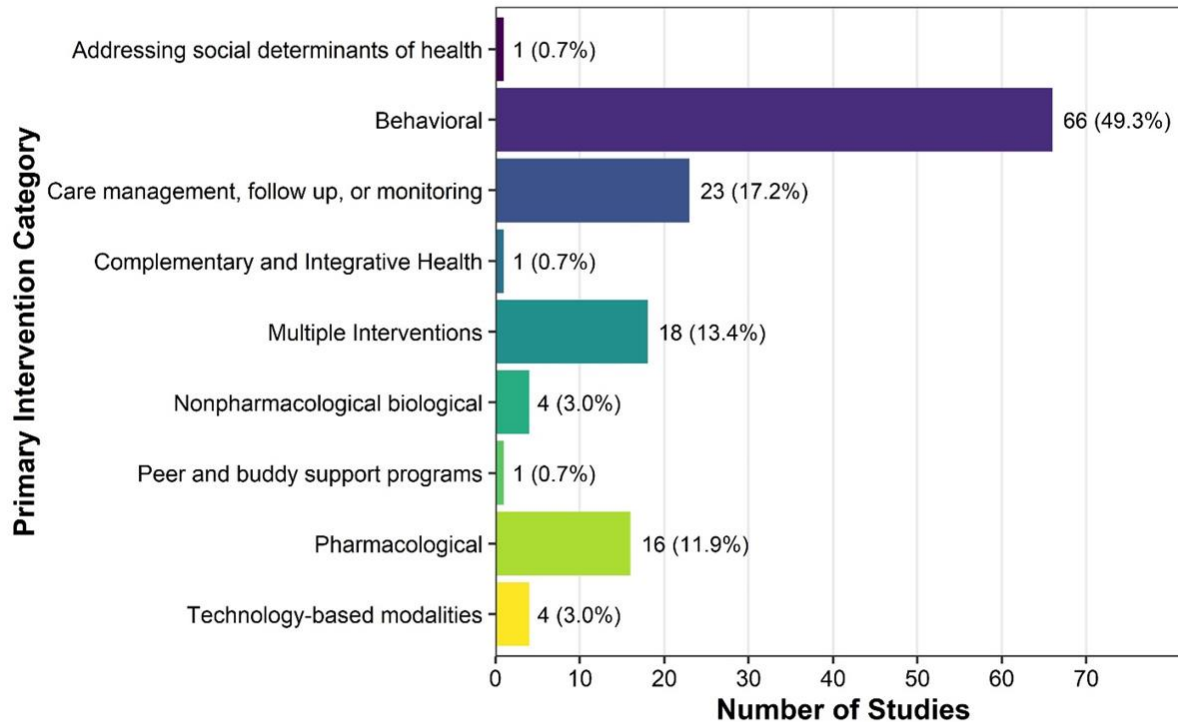
Data sheet	Data Element	Variable Name	Data definition*
Included in all data sheets	Row Label	data_row_label	Description of the row of data
Included in all data sheets	Study ID	study_id	Study Identifier
Included in all data sheets	Author Year	author_year	Author, Year of the primary publication
1- Study Identifiers	Citation	citation	JAMA-style citation
1- Study Identifiers	ClinicalTrials ID	nct_id	ClinicalTrials Identifier



# PHASE I DATA VISUALIZATIONS

## Number of Studies by Primary Intervention Category

SPTD Phase 1 Dataset; N = 134 Studies



The Multiple Interventions category includes studies that delivered interventions from more than one category, e.g., Behavioral and Care Management, Follow-up, or Monitoring.

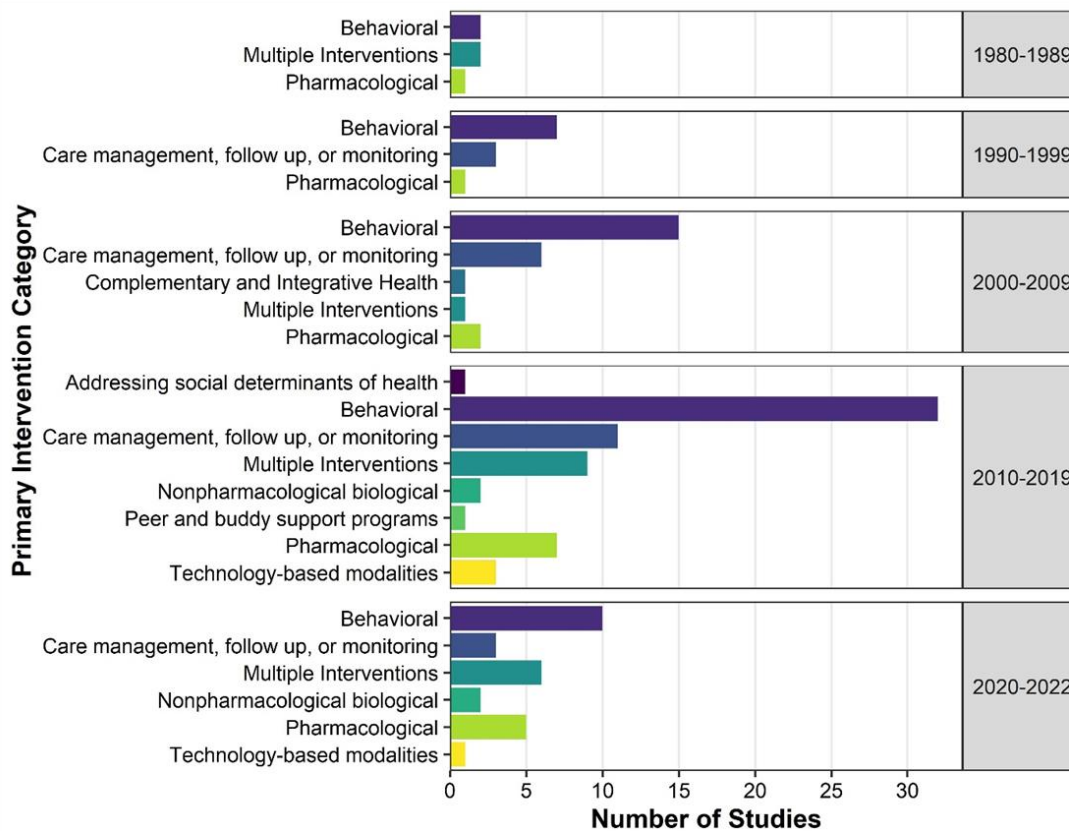




# PHASE I DATA VISUALIZATIONS

## Number of Studies by Decade and Primary Intervention Category

SPTD Phase 1 Dataset; N = 134 Studies



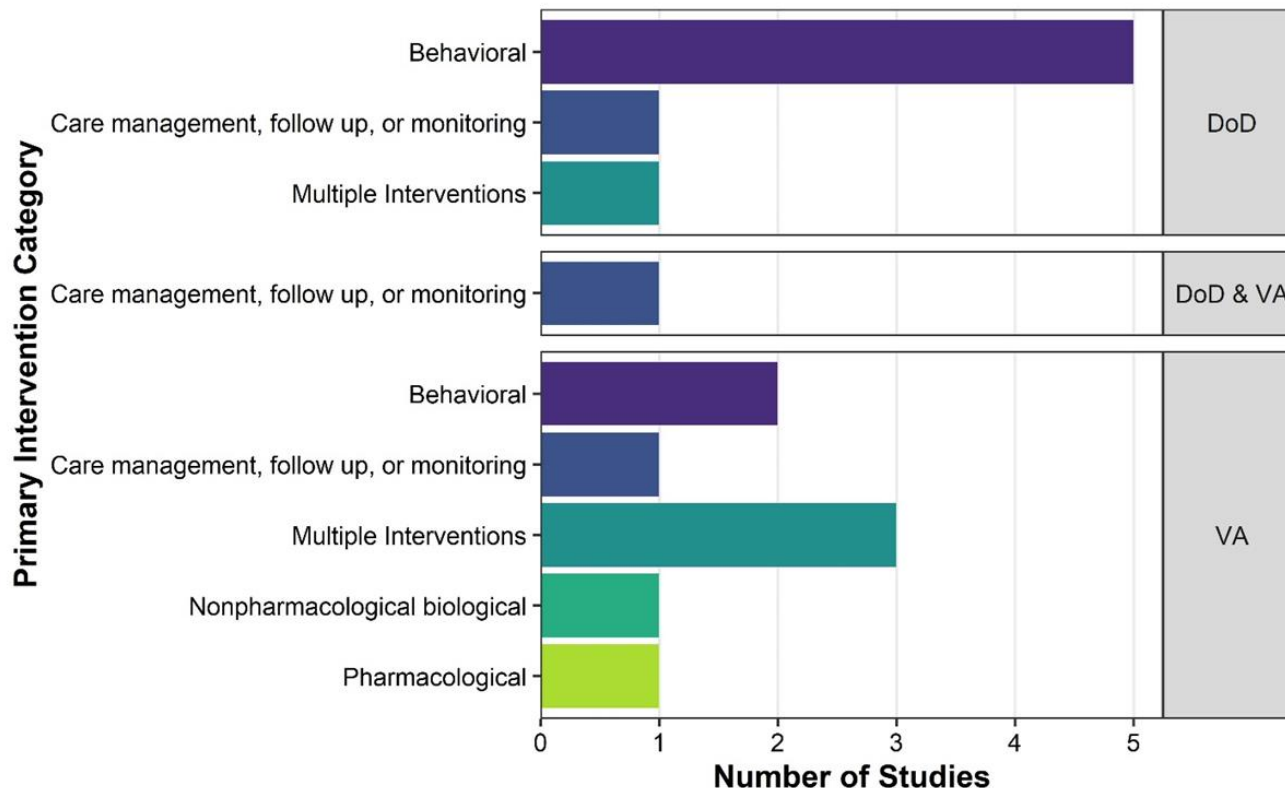
The Multiple Interventions category includes studies that delivered interventions from more than one category, e.g., Behavioral and Care Management, Follow-up, or Monitoring.



# PHASE I DATA VISUALIZATIONS

## Number of Studies by Primary Intervention Category and VA/DOD Setting Category

SPTD Phase 1 Dataset; N = 134 Studies

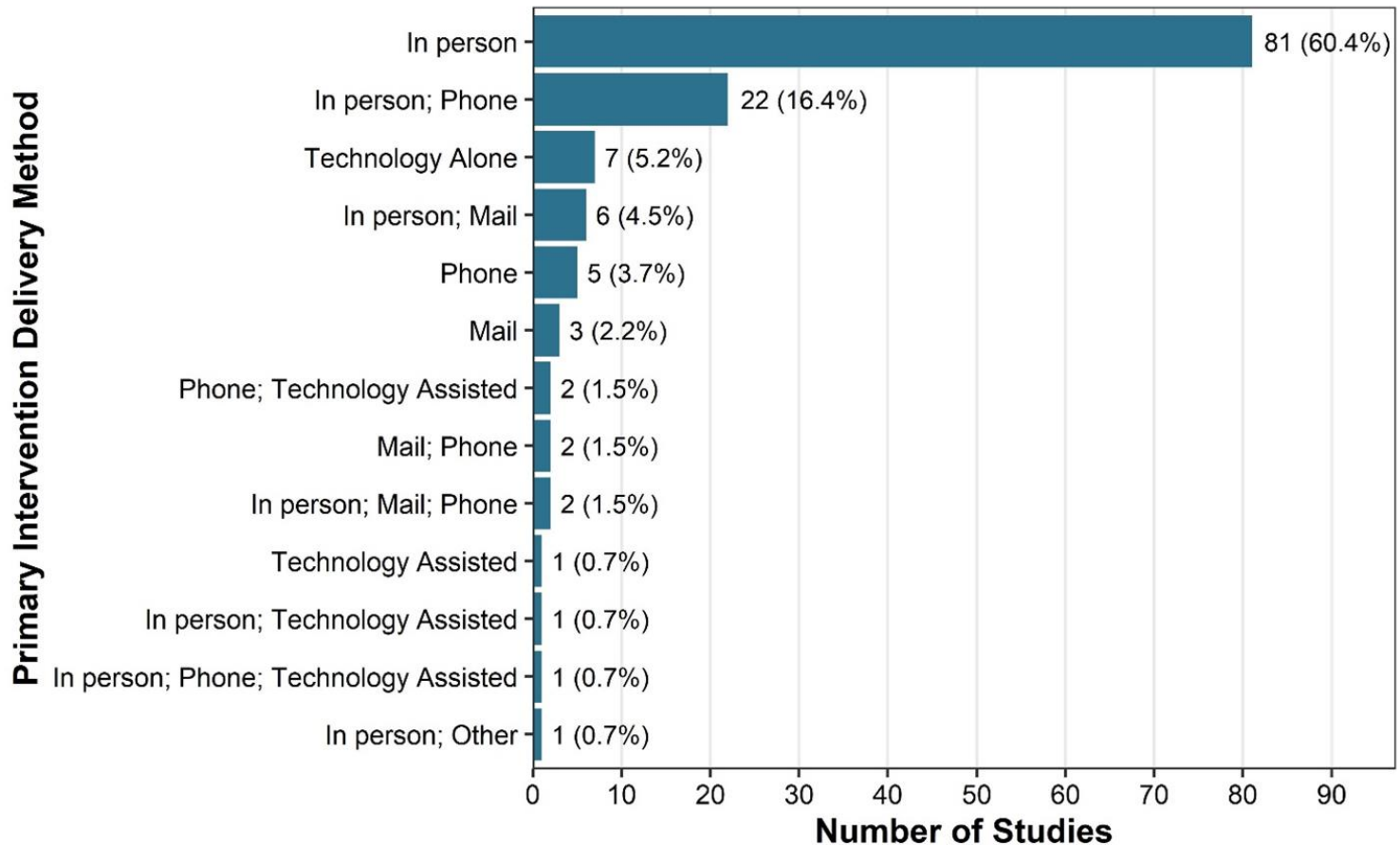


The Multiple Interventions category includes studies that delivered interventions from more than one category, e.g., Behavioral and Care Management, Follow-up, or Monitoring.



# PHASE I DATA VISUALIZATIONS

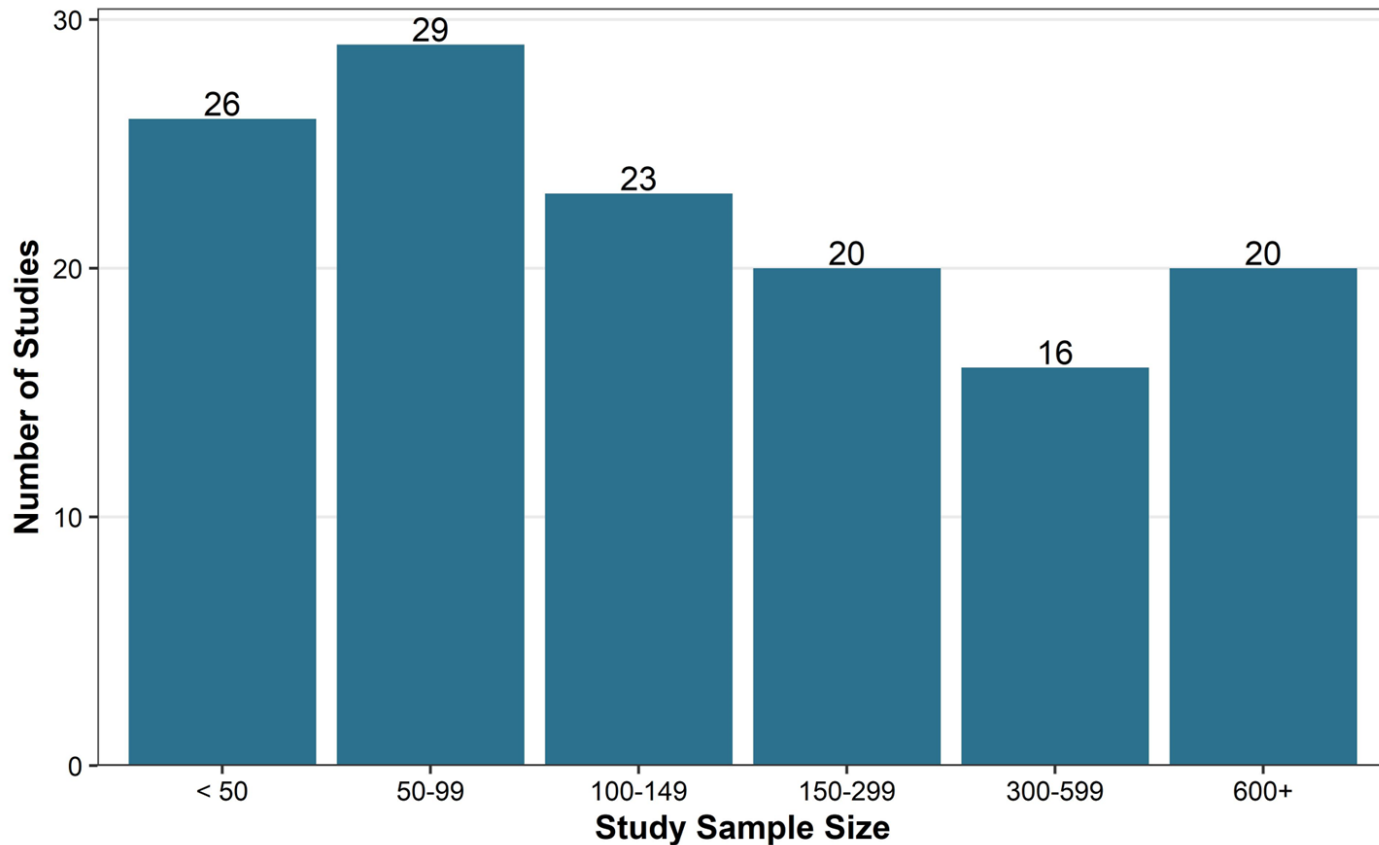
## Number of Studies by Primary Intervention Delivery Method





## Number of Studies by Study Sample Size

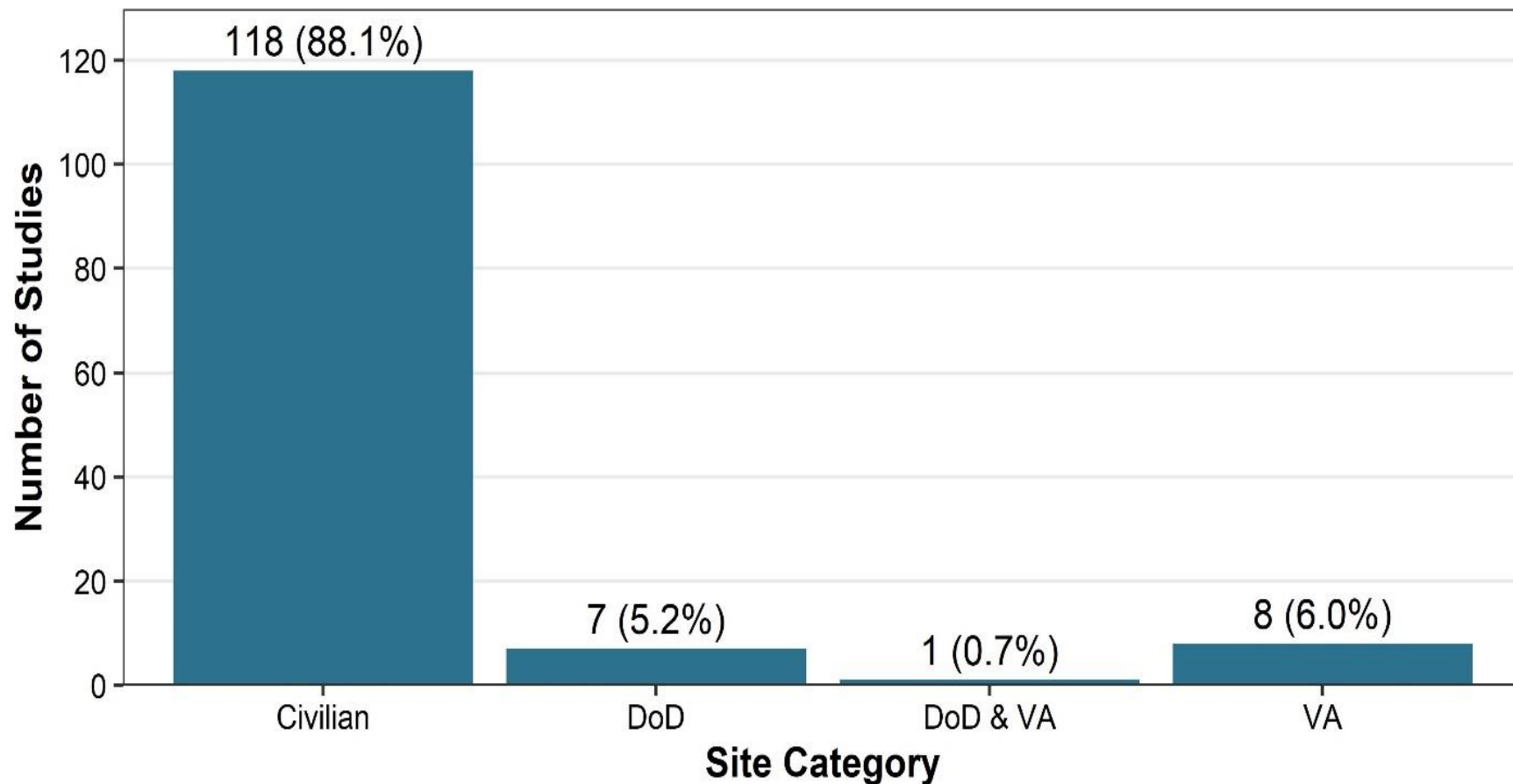
SPTD Phase 1 Dataset; N = 134 Studies





## Number of Studies by Site Category

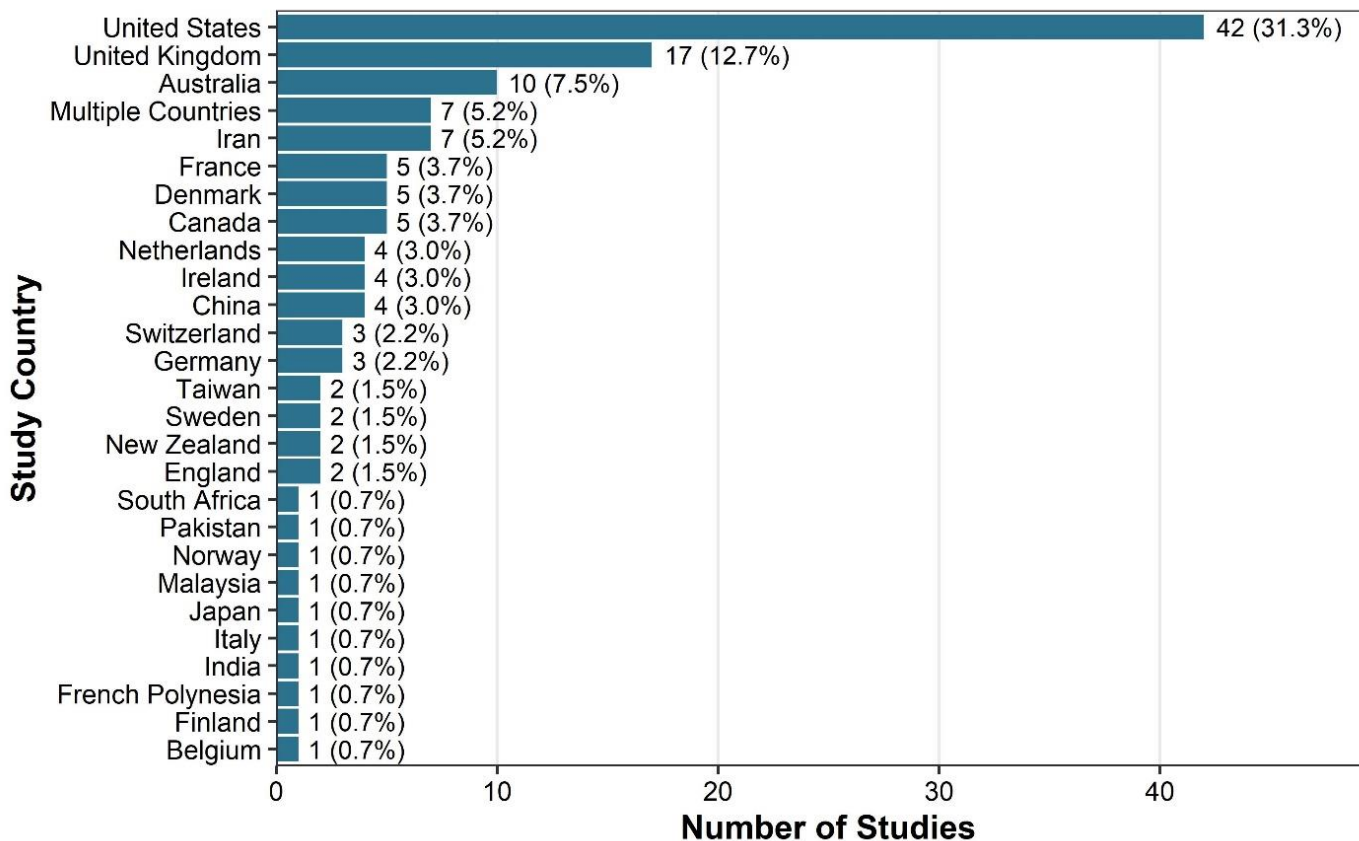
SPTD Phase 1 Dataset; N = 134 Studies





## Number of Studies by Country

SPTD Phase 1 Dataset; N = 134 Studies

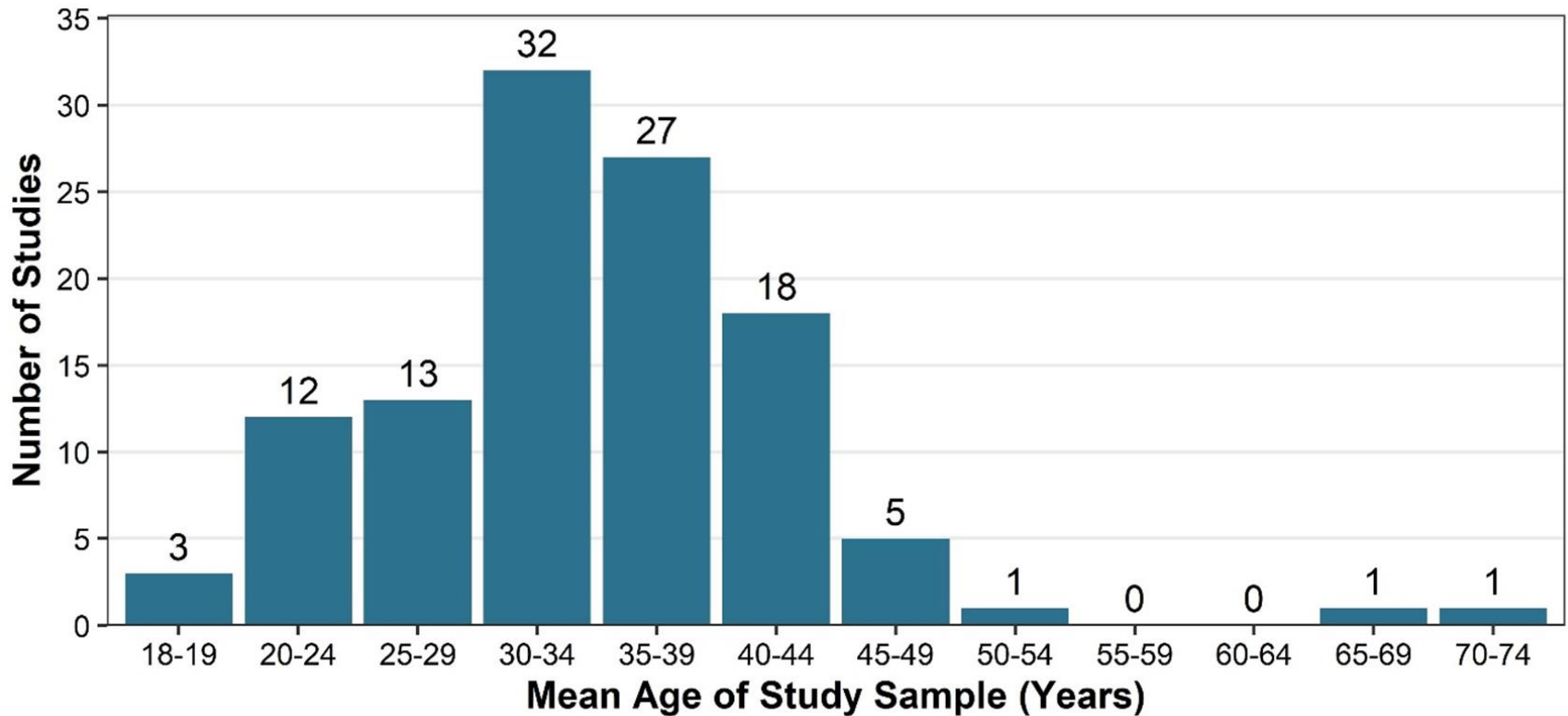


The Multiple Countries category includes studies that took place in more than one Country (e.g., Australia, Canada, and United States).



## Number of Studies by Mean Age of Study Sample

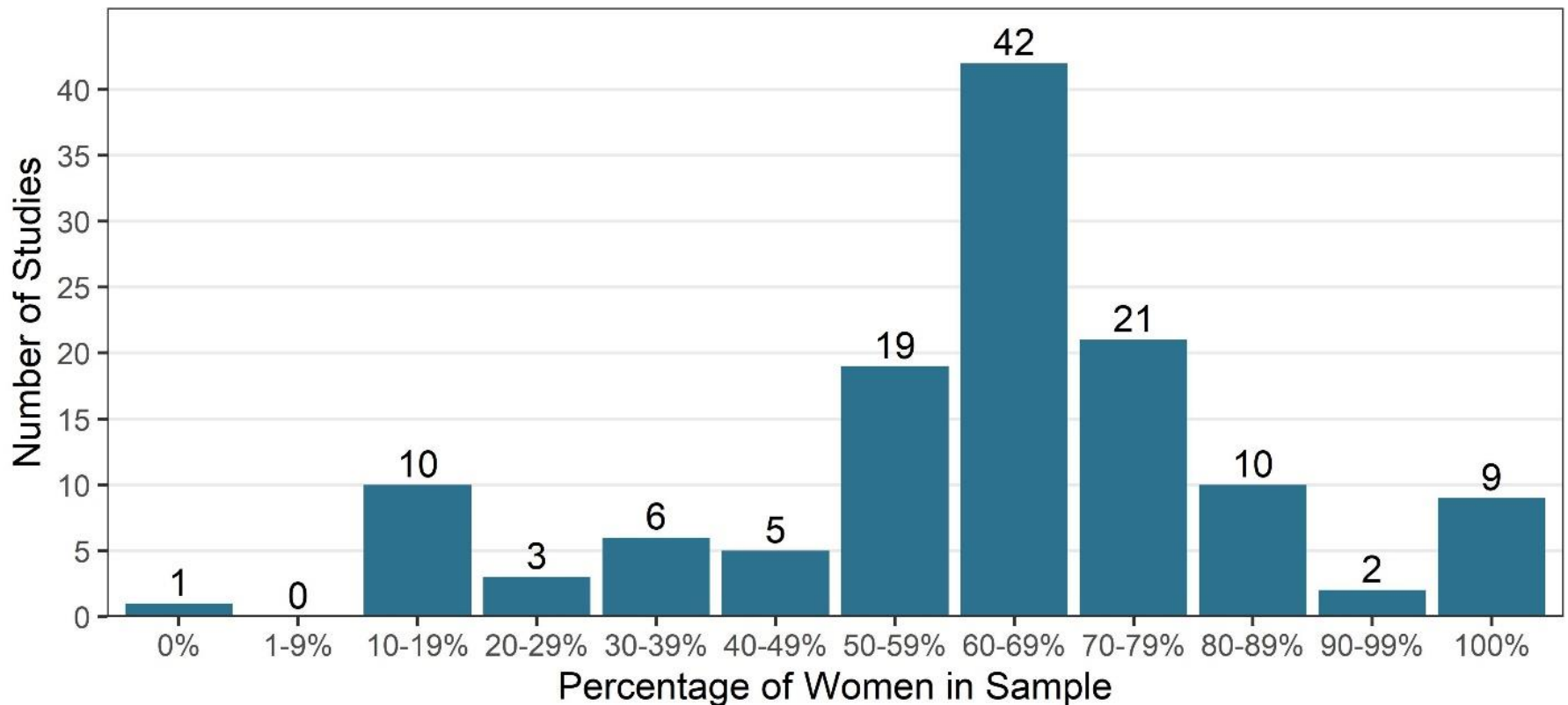
SPTD Phase 1 Dataset; N = 134 Studies





## Number of Studies by Percent of Women in Study Sample

SPTD Phase 1 Dataset; N = 134 Studies



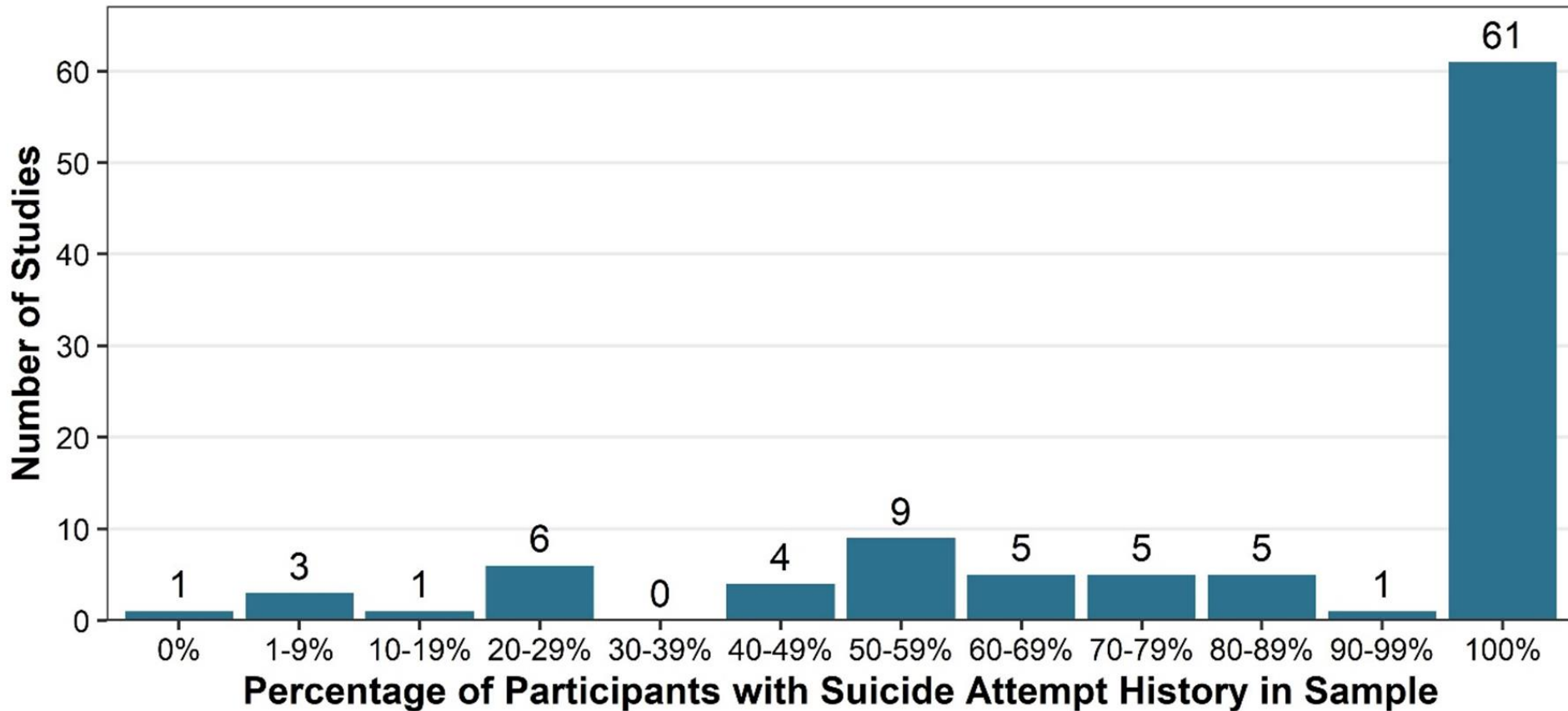




# PHASE I DATA VISUALIZATIONS

## Number of Studies by Percent of Sample with Suicide Attempt History

SPTD Phase 1 Dataset; N = 134 Studies

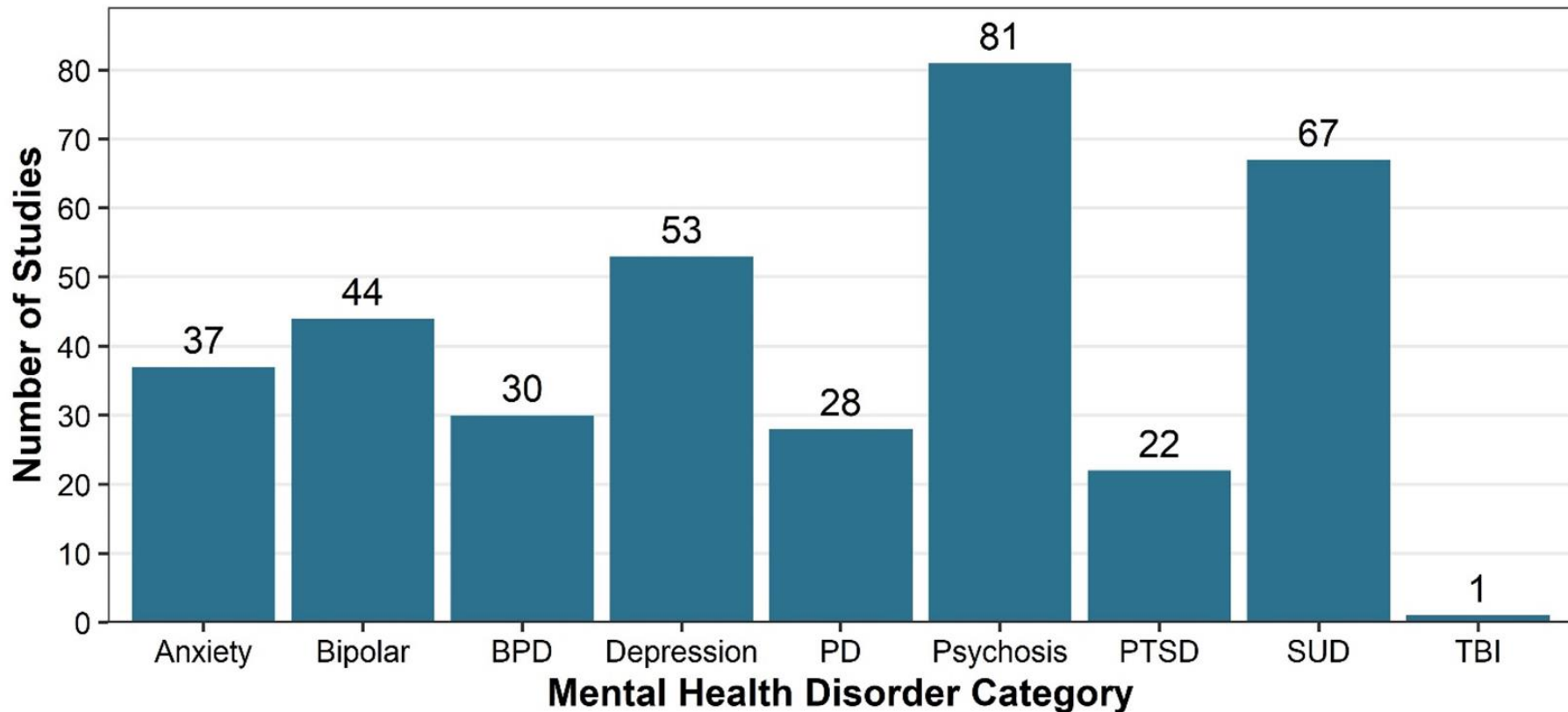




# PHASE I DATA VISUALIZATIONS

## Number of Studies Reporting Mental Health Disorders of Enrolled Participants

SPTD Phase 1 Dataset; N = 134 Studies



BPD = Borderline Personality Disorder, PD = Personality Disorder, PTSD = Posttraumatic Stress Disorder, SUD = Substance Use Disorder, TBI = Traumatic Brain Injury.



### Expansion to include non-RCTs, including studies of community- and population-level interventions

- Published 1980-present
- Population: Adults ( $\geq 18$  years old)
- Studies with primary aim to prevent suicide
- Large-scale rollout of tool or intervention, or community or population based intervention
- Studies must report on suicidal behavior as an outcome



# Data Extraction Variables, Phase 2

<b>Publication details</b>	Study ID, author & year, citation, PMID, Pubmed link, funding source
<b>Study characteristics</b>	Study publication year, study category, target population, countries, setting, study design
<b>Sample/population characteristics</b>	Number included, suicide attempt history, veteran/military targeted, homeless targeted, rural targeted, other subgroups targeted, detail description of sample/population
<b>Interventions and comparators</b>	Intervention category, intervention name, intervention description, number included in intervention, comparator name, comparator description, number included in comparator
<b>Outcomes</b>	Analysis method, suicide related outcomes, assessment point, suicide outcomes results, other outcomes
<b>Secondary studies</b>	Author & year, citation, PMID, Study ID



# THANK YOU

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# QUESTIONS?

