Ineligibility for and Refusal to Participate in Randomized Controlled Trials That Have Studied Impact on Suicide-Related Outcomes in the United States: A Meta-Analysis

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ABSTRACT

Objective: Ineligibility for and refusal to participate in randomized controlled trials (RCTs) can potentially lead to unrepresentative study samples and limited generalizability of findings. We examined the rates of exclusion and refusal in RCTs that have studied impact on suicide-related outcomes in the US.

Data Sources: PubMed, the Cochrane Library, the Campbell Collaboration Library of Systematic Reviews, CINAHL, PsycINFO, and Education Resources Information Center were searched from January 1990 to May 2020 using the terms (*suicide prevention*) AND (*clinical trial*).

Study Selection: Of 8,403 studies retrieved, 36 RCTs assessing effectiveness on suicide-related outcomes in youth (≤ 25 years old) conducted in the US were included.

Data Extraction: Study-level data were extracted by 2 independent investigators for a random-effects meta-analysis and meta-regression.

Results: The study participants (N = 13,264) had a mean (SD) age of 14.87 (1.58) years and were 50% male, 23% African American, and 24% Hispanic. The exclusion rate was 36.4%, while the refusal rate was 25.5%. The exclusion rate was significantly higher in the studies excluding individuals not exceeding specified cutoff points of suicide screening tools (51.2%; adjusted linear coefficient [β] = 1.30, standard error [SE] = 0.15; $P = .041$) and individuals not meeting the age or school grade criterion (45.9%; β = 1.37, SE = 0.13; $P = .005$).

Conclusions: The rates of exclusion and refusal in youth prevention interventions studying impact on suicide-related outcomes were not as high compared to the rates found in other mental and behavioral interventions. While there was strong racial/ethnic group representation in RCTs examining youth suicide–related outcomes, suicide severity and age limited eligibility.

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Suicide among youth is a growing public health problem in the US. The suicide rate among individuals aged 10–24 years increased 57.4% from 6.8 to 10.7 per 100,000 between 2007 and 2018.[1] The 2019 National Youth Risk Behavior Survey of high school students found that 7.4% of high school students reported making a suicide attempt in the prior year.[2] To address the increase in suicide among youth, a growing number of randomized controlled trials (RCTs) have been conducted.[3–5] According to the recent systematic review study by Robinson et al,[5] RCTs demonstrated that psychoeducational interventions with screening in school settings, brief contact interventions in clinical settings, and multifaceted place-based interventions in community settings have shown promising effectiveness in reducing suicide ideation and attempts among youth.

While RCTs are the gold standard in establishing effectiveness of interventions and treatments, a growing literature has indicated that a standard set of exclusion criteria used in the RCTs of various mental and behavioral interventions tend to exclude a large proportion of potential study participants, which may potentially lead to unrepresentative samples and limited generalizability of findings.[6] A growing number of studies document the high rates of exclusion in the RCTs of clinical interventions for depression, anxiety, bipolar, and alcohol and substance use disorders.[7–15] Most recently, Blanco et al.[13] applied a standard set of exclusion criteria used in the RCTs for major depressive disorder (MDD) in youth to all adolescents in the National Comorbidity Survey–Adolescent Supplement with diagnosis of MDD and estimated the proportion of adolescents who would have been excluded by the standard set of exclusion criteria. This study demonstrated that 62% of adolescents with MDD would have been excluded from

Clinical Points

- Ineligibility for and refusal to participate in randomized controlled trials (RCTs) can lead to unrepresentative sample selection and limited generalizability of findings. Until now, little has been known about the extent to which study participants are ineligible for or unwilling to participate in RCTs examining youth suicide–related outcomes.
- Clinicians and other interventionists use the published RCT evidence base to guide public health efforts and clinical decision making. Therefore, it is important that this evidence base be representative of and generalizable to a broad range of individuals at risk for suicide.
- While there was strong racial/ethnic group representation in RCTs examining youth suicide–related outcomes in the US, suicide severity and age limited eligibility.

a typical pharmacologic RCT while 42% would have been excluded from a psychotherapy RCT. In addition to the high exclusion rate, prior research has suggested that a non-negligible proportion of potential RCT participants in mental and behavioral research refuse to participate due to study burden and concerns about the stigma of mental illness, which may further negatively impact the representativeness of RCT samples.[16,17]

To the best of our knowledge, a systematic evaluation has yet to examine the extent to which study participants are ineligible for or unwilling to participate in RCTs examining youth suicide–related outcomes. Human subject research on suicide prevention among youth is associated with a number of ethical and practical concerns including adverse events, liability, and patient safety, which may result in a more restrictive set of exclusion criteria.[18–20] Furthermore, while an increasing number of studies have demonstrated that asking questions about suicide does not have iatrogenic effects on youth,[21] parents and youth may refuse participation in RCTs of suicide prevention interventions due to the perception that they may induce psychological distress.[22]

In this study, we conducted a meta-analysis to estimate the rates of exclusion and refusal in youth suicide prevention RCTs and other RCTs that have studied impact on suicide outcomes in the US. We also conducted a meta-regression analysis to examine the associations of the rates of exclusion and refusal with various study-level characteristics. In addition, we compared characteristics of RCT samples with the corresponding target population samples to assess sample representativeness of RCTs. All analyses took into account 3 levels of intervention: universal, selective, and indicated.

METHODS

Data Sources and Search Strategy

We searched PubMed, the Cochrane Library, Campbell Collaboration Library of Systematic Reviews, CINAHL, PsycINFO, and ERIC for English language articles published from January 1990 to May 31, 2020. The search strategy is detailed in Wilcox et al.[23]

Study Selection

Two investigators independently reviewed titles and abstracts and then full-text articles using prespecified eligibility criteria. The proportion of disagreements about article eligibility was under 10%. The disagreements that could not be resolved by two reviewers were resolved by the domain experts on the team. We included RCT studies on humans 25 years old or younger that included at least one suicide-related outcome (ie, suicide, suicide attempt, and suicidal ideation). Studies targeting only non-suicidal self-injury were excluded. Any interventions consisting of behavioral, community, or clinical interventions, or any combination thereof, were eligible for inclusion in the current study. Meeting abstracts, articles without original data, and studies conducted outside of the US were excluded. Studies published prior to 1990 were not included because abstractable data were significantly limited before 1990. If there were multiple articles published from the same trial, we included only the main outcome article per trial. Studies were excluded from the meta-analysis if they did not explicitly report the number of individuals who were initially approached to participate in the study and those who refused to participate in the study.

Data Extraction and Quality Assessment

Two investigators independently abstracted data on the following study-level characteristics: year of publication, study setting, name of prevention strategies, level of interventions (ie, universal, selective, and indicated), type of intervention, the number of individuals who were approached to participate, the number of non-eligible individuals, the number of individuals who refused to participate, the number of randomized individuals, and characteristics of participants including sex, age, race/ethnicity, household income, and living with a single parent. To obtain all information regarding eligibility criteria, the supplementary materials linked to the original articles were also extracted. Those who refused to participate include those who initially consented, but withdrew their consent and were not randomized. The list of eligibility criteria is provided in Supplementary Table 2.

No standard tool exists for assessing quality of reporting on the issues of exclusion and refusal. Therefore, we used the following criteria to assess quality of reporting in the included studies: (1) if a CONSORT diagram was available in any of the published reports of the study, (2) if the number of individuals excluded was reported per exclusion criterion, and (3) if the investigators compared characteristics of those who were randomized with those who were not. Because the first CONSORT statement was published in 1996,[24] we did not use the first quality criterion for those studies published between 1990 and 1996.

Statistical Analysis

Median and range for the rates of exclusion and refusal were provided by the level of intervention (ie, universal, selective, and indicated). The median and range

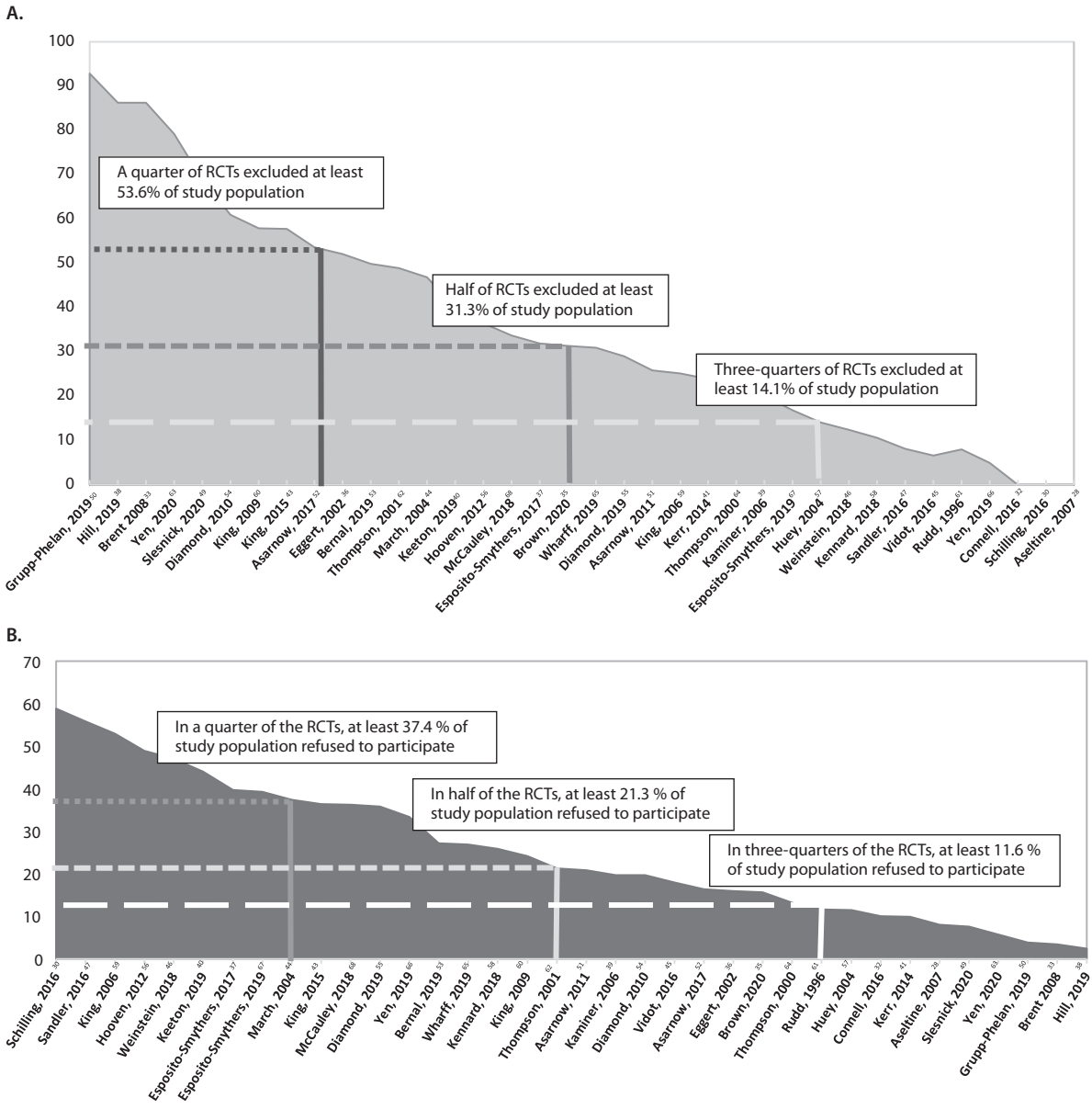
Table 1. Characteristics of Included Studies by the Level of Intervention

First Author, Year	Age of Target Group, y	Years of Study	Prevention Strategies	Type of Intervention	Setting
Universal Level					
Aseltine, 2007[28]	14–18	2001–2003	SOS	BT	School
Schilling, 2014[29]	10–13	2009–2010	SOS	BT	School
Schilling, 2016[30]	14–18	2007–2009	SOS	BT	School
Wilcox, 2008[31]	6–8	1985–1987	GBG	BT	School
Connell, 2016[32]	13–18	1996–1998	FCU	BT	School
Selective Level					
Brent 2008[33]	12–18	2000–2006	SSRI + CBT	MED and BT	Hospital
Brown, 2001[34]	14–17	1995–2000	Project Chrysalis	BT	School
Brown, 2019[35]	13–18	2006–2012	PET	BT	Hospital
Eggert, 2002[36]	14–19	1995–1998	C-CARE and CAST	BT	School
Esposito-Smythers, 2017[37]	13–17	2010–2014	ASH-P	BT	Hospital
Hill, 2019[38]	13–19	2015	LEAP	BT	Community
Kaminer, 2006[39]	14–18	2001–2006	In-person and telephone aftercare	BT	Hospital
Keeton, 2019[40]	10–26	2002–2007	Sertraline + CBT	MED and BT	Hospital
Kerr, 2014[41]	13–17	1997–2006	MTFC	BT	Juvenile justice
King, 2012[42]	13–17	2009–2010	IPF	Follow-up	ED
King, 2015[43]	14–19	NA	TOC	BT	ED
March 2004[44]	12–17	2000–2003	TADS	MED and BT	Hospital
Vidot, 2016[45]	NA	2010–2014	Familias Unidas	BT	School
Weinstein, 2018[46]	7–13	2010–2014	CFF-CBT	BT	Hospital
Sandler, 2016[47]	8–16	1994–2000	FBT	BT	Community
Spirito, 2015[48]	11–17	2009–2012	PA-CBT	BT	Hospital
Slesnick, 2020[49]	18–24	2015–2019	CTSP + TAU	BT	Drop-in center
Grupp-Phelan, 2019[50]	12–17	2013–2015	STAT-ED	BT	ED
Indicated Level					
Asarnow, 2011[51]	10–18	2003–2005	F-CBT	BT	ED
Asarnow, 2017[52]	11–18	2011–2015	SAFETY Program	BT	ED
Bernal, 2019[53]	13–17.5	2005–2007	TEPSI + CBT	BT	Hospital
Diamond, 2010[54]	12–17	2005–2007	ABFT	BT	Hospital
Diamond, 2019[55]	12–18	2012–2015	ABFT	BT	Hospital
Hooven, 2012[56]	14–19	1999–2005	Promoting CARE	BT	Home
Huey, 2004[57]	10–17	NA	MST	BT	Hospital
Kennard, 2018[58]	12–18	2014–2017	ASAP supported by BRITE	BT	Hospital
King, 2006[59]	12–17	1998–2000	YST-1	BT	Hospital
King, 2009[60]	13–17	2002–2005	YST-2	BT	Hospital
Rudd, 1996[61]	NA	1990–1995	Problem solving and psychoeducation	BT	Hospital
Thompson, 2001[62]	14–18	1995–2000	C-CARE and CAST	BT	School
Yen, 2020[63]	12–18	2015–2016	STEP	BT	Hospital
Thompson, 2000[64]	14–18	1990–1993	PGC Program	BT	School
Wharff, 2019[65]	13–18	2012–2014	FBCI	BT	ED
Yen, 2019[66]	12–18	2011–2012	CLASP	BT	Hospital
Esposito-Smythers, 2019[67]	12–18	2012–2017	F-CBT	BT	Hospital
McCauley, 2018[68]	10–24	2012–2014	DBT	BT	Hospital

Abbreviations: ABFT = attachment-based family therapy; ASAP = As Safe as Possible supported by a smartphone app (BRITE); ASH-P = adjunctive cognitive-behavioral family-based alcohol, deliberate self-harm, and HIV prevention program; BT = behavioral therapy; CAST = Coping and Support Training; CBT = cognitive-behavioral therapy; C-CARE = Counselors CARE; CFF-CBT = child- and family-focused cognitive-behavioral therapy; CLASP = Coping Long Term with Active Suicide Program; CTSP = cognitive therapy for suicide prevention; DBT = dialectical behavior therapy; ED = emergency department; FBCI = family-based crisis intervention; FBP = Family Bereavement Program; F-CBT = family-focused outpatient cognitive-behavioral treatment; FCU = Family Check-Up; GBG: Good Behavior Game; IPF = in-person follow-up; LEAP = Lean, Explore, Assess, and Plan intervention; MED = medication; MST = multisystemic therapy; MTFC = Multidimensional Treatment Foster Care; NA = not available; PA-CBT = Parent-Adolescent Cognitive-Behavioral Therapy; PET = prolonged exposure therapy; PGC = personal growth class; SAFETY = Safe Alternatives for Teens and Youths; SOS = Signs of Suicide; SSRI = selective serotonin reuptake inhibitor; STAT-ED = Suicidal Teens Accessing Treatment After an Emergency Department Visit; STEP = Skills to Enhance Positivity; TADS = Treatment for Adolescents with Depression Study; TAU = treatment as usual; TEPSI = Talleres de Educacion Psicologica (a parent psychoeducational intervention as a part of CBT); TOC = Teen Options for Change; YNS-1 = Youth-Nominated Support Team–Version 1, YNS-2 = Youth-Nominated Support Team–Version 2.

were reported for each individual criterion if available (Supplementary Table 3). We used the *metaprop* command of Stata version 16 (2019; StataCorp) and performed a random-effects model to assess heterogeneity across studies. We provided forest plots to visualize overall rates of exclusion and refusal and cumulative plots to present the distributions of the rates of exclusion and refusal. A meta-regression analysis was conducted to assess the associations between study-level characteristics and the rates of exclusion and refusal. Study-level characteristics included the level of prevention intervention, year of publication, study settings, the number of eligibility criteria, lower age bound of the eligible individuals, and statistical significance ($P < .05$) of the effectiveness of the intervention on at least one suicide-related outcome. We used a median split to categorize all continuous variables except for the year of publication.

Figure 1. Randomized Controlled Trials (RCTs) Ranked in Descending Order of (A) Exclusion Rate and (B) Refusal Rate[a]

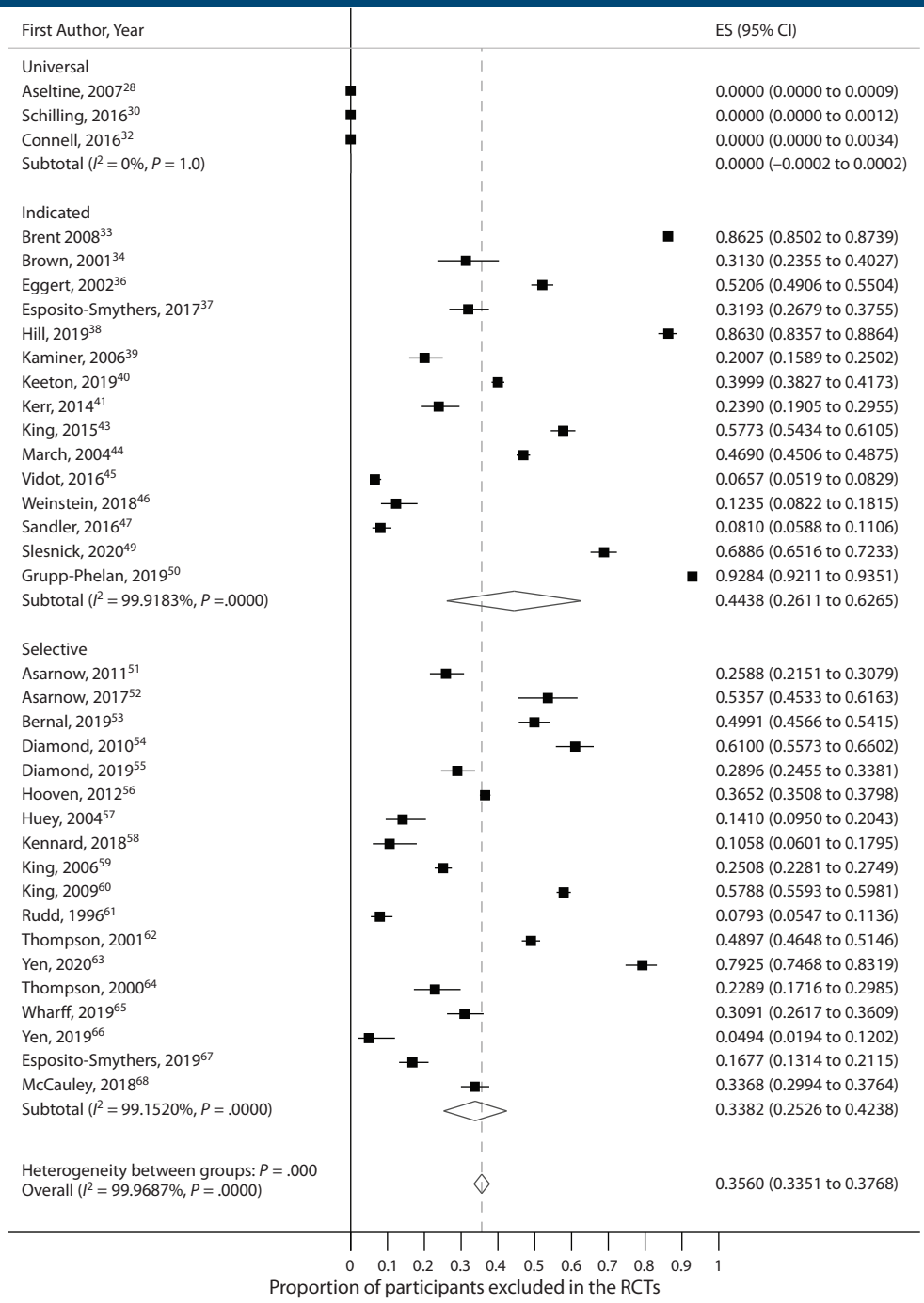


[a]Only first authors are listed for individual studies.

We created a binary variable for the year of publication in which a value of 1 indicates that a study was published in or after 2010, the year when the current version of CONSORT was published.[25] Meta-regression analysis for the rate of exclusion also included the number of exclusion criteria and 8 categories of exclusion criteria including not being at risk of suicide determined by the cutoff points of suicide screening tools, not being at risk of suicide determined by self-report or clinical impression, age/grade, medical/health conditions, mental/behavioral/cognitive conditions, service/treatment utilization, logistical challenges, and pregnancy/reproductive health conditions.

To assess representativeness of the RCT samples, we drew 3 separate target populations for universal, selective, and indicated interventions. For universal interventions, the target population of individuals between 0 and 24 years old was drawn from the 2019 US Census.[26] For selective and indicated interventions, the target populations were drawn from the 2018 National Survey on Drug Use and Health.[27] For selective interventions, the target population was defined as individuals aged between 12 and 25 years who had a major depressive episode and/or received specialty mental health services in the past 12 months. For indicated interventions, the target population was defined as individuals aged between 12 and 25 years old who seriously thought about killing themselves, made plans to kill themselves, tried to kill themselves, and/or received specialty mental health services due to suicide attempts in the past 12 months. We calculated the means and 95% CIs for the sociodemographic characteristics in the RCT samples and the corresponding

Figure 2A. Exclusion Rate by Level of Intervention



Abbreviation: ES = effect size.

target populations to assess the representativeness of the RCT samples.

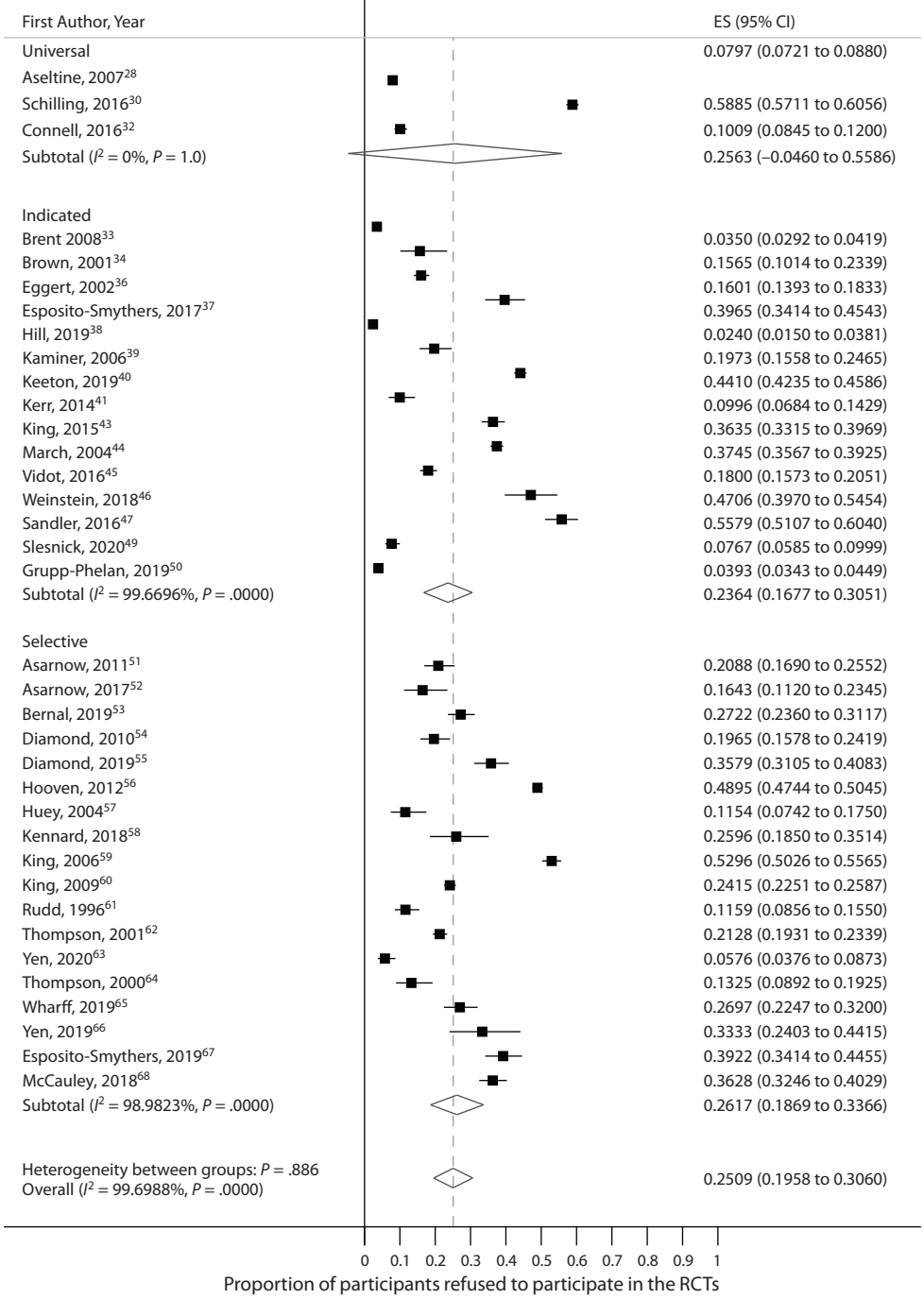
RESULTS

We retrieved 8,403 records from electronic databases as well as additional sources including scanning reference lists of included studies. The data for all 41 studies[28–68] were extracted; however, only 36 studies were eligible for meta-analysis (Supplementary Figure 1).

Description of the Included Studies

Table 1 presents the characteristics of the included studies by the level of intervention. Of the total 41 studies, 5 studies involved a universal intervention, 18 studies involved a selective intervention, and the remaining 18 studies involved an indicated intervention. Most (90.2%) of the studies involved behavioral interventions. Over 60% of the studies took place in hospitals or emergency departments, while 24.4% of the studies took place in schools. The number of individuals who were approached, the number of individuals

Figure 2B. Refusal Rate by Level of Intervention



Abbreviation: ES = effect size.

who were excluded, and the number of individuals who refused to participate were reported explicitly in 36 studies. The total number of approached individuals was 42,547, of whom 18,170 were not eligible and 11,098 refused to participate. The number of randomized individuals ranged from 24 to 4,133 per each RCT. The mean (SD) age of the participants was 14.87 (1.58) years, 50% were male, 23% were African American, 24% were Hispanic, 53% had less than $50,000 overall household income, and 43% lived in a single parent household. The rates of exclusion, refusal, and detailed extracted data for each RCT are available in Supplementary Table 1 and Supplementary Table 2.

Rates of Exclusion and Refusal and Meta-Regression Analysis

The most commonly used exclusion criteria were age/school grade criterion (25 studies); not being at risk of suicide determined by self-report or clinical impression (25 studies); presence of mental, cognitive, and behavioral conditions (eg, active psychosis, substance abuse) (25 studies); parent

Table 2. Meta-Regression Analyses of Associations of Exclusion and Refusal Rates With Study-Level Characteristics[a]

	Exclusion			Refusal		
Characteristic	No. of Studies	Mean (95% CI)	Coefficient (SE)	No. of Studies	Mean (95% CI)	Coefficient (SE)
Level of prevention						
Universal	NA	NA	NA	3	25.6 (0.0 to 55.9)	Ref.
Selective	18	33.8 (25.3 to 42.4)	Ref.	18	26.2 (18.7 to 33.7)	1.07 (0.15)
Indicated	15	44.4 (26.1 to 62.6)	1.04 (0.14)	15	23.6 (16.8 to 30.5)	1.03 (0.15)
Study setting						
School	4	32.6 (5.6 to 59.6)	Ref.	7	20.8 (6.2 to 35.3)	Ref.
Hospital	24	38.4 (25.3 to 51.4)	1.18 (0.26)	24	26.4 (20.0 to 32.8)	1.02 (0.10)
Other	5	44.7 (17.5 to 72.0)	1.36 (0.26)	5	24.9 (1.9 to 48.0)	0.95 (0.12)
Type of intervention						
Behavioral	30	36.7 (23.3 to 50.1)	Ref.	33	24.8 (18.9 to 30.7)	Ref.
Medication and behavioral	3	57.7 (26.3 to 89.1)	1.24 (0.23)	3	28.3 (0.0 to 57.5)	1.11 (0.13)
Significant efficacy on suicide outcome						
Yes	13	36.6 (27.4 to 45.8)	Ref.	16	27.6 (17.6 to 37.6)	1.14 (0.08)†
No	20	40.0 (23.4 to 56.5)	1.02 (0.11)	20	22.9 (17.6 to 28.2)	Ref.
Lower bound age, y						
< 12	7	26.7 (14.1 to 39.2)	Ref.	7	33.2 (21.9 to 44.4)	Ref.
≥ 12	26	41.8 (28.7 to 54.9)	1.11 (0.13)	29	23.2 (17.3 to 29.0)	0.95 (0.07)
Year of study publication						
≤ 2010	11	40.3 (23.6 to 57.0)	Ref.	12	19.9 (12.3 to 27.6)	Ref.
> 2010	22	37.8 (21.3 to 54.3)	0.95 (0.13)	24	27.7 (19.1 to 36.3)	1.17 (0.09)†
No. of eligibility criteria						
< 7	12	36.7 (22.4 to 51.0)	Ref.		…	…
≥ 7	21	39.7 (25.2 to 54.2)	1.29 (0.19)†		…	…
Exclusion for not being at risk of suicide determined by the cutoff points of the suicide screening tools						
Yes	12	51.2 (36.8 to 65.6)	1.30 (0.15)*		…	…
No	21	31.4 (13.4 to 49.5)	Ref.		…	…
Exclusion for not meeting age/grade criterion						
Yes	11	45.9 (31.9 to 59.9)	1.37 (0.13)*		…	…
No	22	24.1 (14.6 to 33.5)	Ref.		…	…
Exclusion for not being at risk of suicide determined by self-report or clinical impression						
Yes	25	39.5 (26.0 to 53.0)	0.89 (0.14)		…	…
No	8	35.8 (8.8 to 62.8)	Ref.		…	…
Exclusion for mental/behavioral/cognitive conditions						
Yes	24	36.4 (24.9 to 47.9)	0.79 (0.12)		…	…
No	9	44.6 (17.6 to 71.6)	Ref.		…	…
Exclusion for medical/health-related conditions						
Yes	12	48.4 (33.2 to 63.6)	1.23 (0.16)		…	…
No	21	33.1 (22.3 to 43.8)	Ref.		…	…
Exclusion for service/treatment utilization						
Yes	21	40.9 (27.0 to 54.7)	0.99 (0.11)		…	…
No	12	34.7 (22.7 to 46.8)	Ref.		…	…
Exclusion for logistical challenges						
Yes	17	39.7 (20.3 to 59.0)	1.01 (0.09)		…	…
No	16	37.5 (23.9 to 51.1)	Ref.		…	…
Exclusion for pregnancy/reproductive health						
Yes	6	46.5 (24.6 to 68.5)	0.70 (0.13)†		…	…
No	27	36.9 (22.5 to 51.2)	Ref.		…	…

[a]Only RCTs with selective and indicated interventions were included in meta-regression analysis for exclusion rate.
*$P < .05$.
†$P < .10$.
Abbreviations: NA = not applicable, RCT = randomized controlled trial, Ref = reference group.

or child does not speak English (16 studies); and not living with parents (14 studies). A detailed description of exclusion criteria along with the median percentage of exclusion due to each criterion is presented in Supplementary Table 3. The overall rate of exclusion was 36.4%, while the rate of refusal was 25.5%. In Figures 1A and 1B, RCTs are ranked in descending order according to the exclusion and refusal rates. In one-quarter of the trials, at least 53.6% of approached individuals were excluded and 37.4% of eligible individuals refused to participate. The pooled rates of exclusion and refusal, respectively, are presented by level of intervention in Figures 2A and 2B. By nature of the definition of universal intervention, the rate of exclusion was 0.0%; the rate of exclusion was 44.4% for selective interventions and 33.8% for indicated interventions. The rate of refusal was 25.6% for universal interventions, 23.6% for selective interventions, and 26.2% for indicated interventions.

The results of a meta-regression analysis investigating the source of heterogeneity in the rates of exclusion and refusal are presented in Table 2. The rates of exclusion were

Table 3. Comparison of Sociodemographic Characteristics Between Randomized Controlled Trial (RCT) Samples and the Target Population Samples[a]

Characteristic	Trial Sample, % (95% CI)	Population Sample, % (95% CI)
Universal[b]		
Male	50.84 (49.74 to 51.95)	50.87 (50.56 to 51.17)
African American	27.12 (26.15 to 28.11)*	14.98 (14.76 to 15.20)
Hispanic	27.45 (26.39 to 28.53)*	24.81 (24.54 to 25.07)
Selective[c]		
Male	46.77 (44.91 to 48.64)	36.16 (34.98 to 37.34)
African American	17.71 (16.22 to 19.28)*	9.31 (8.61 to 10.04)
Hispanic	26.26 (24.52 to 28.05)*	19.73 (18.76 to 20.72)
Single parent	39.04 (36.63 to 41.49)	36.91 (35.26 to 38.57)
Annual household income < $50,000	67.36 (61.02 to 73.27)*	50.51 (49.28 to 51.74)
Indicated[d]		
Male	37.27 (35.66 to 38.90)	37.63 (35.60 to 39.70)
African American	15.01 (13.78 to 16.30)*	10.88 (9.61 to 12.26)
Hispanic	15.22 (13.94 to 16.57)	18.47 (16.87 to 20.16)
Single parent	54.55 (50.28 to 58.76)*	37.83 (34.09 to 41.67)
Annual household income < $50,000	46.79 (42.33 to 51.28)	57.89 (55.79 to 59.97)

[a]The studies that included only female participants (ie, Brown et al,[34] Brown et al,[35] and Kerr et al[41]) and a study by Vidot et al[49] that included only Hispanic participants were excluded from this analysis.
[b]The target population of those between 0 and 24 years old was drawn from the 2019 US Census.[26]
[c]The target population was drawn from the 2018 National Survey on Drug Use and Health (NSDUH)[27] and defined as those aged between 12 and 25 years who had a major depressive episode and/or received specialty mental health services in the past 12 months.
[d]The target population was drawn from the 2018 NSDUH[27] and defined as those aged between 12 and 25 years who seriously thought about killing themselves, made plans to kill themselves, tried to kill themselves, and/or received specialty mental health services due to suicide attempts in the past 12 months.
*Indicates that the 95% CI of the RCT sample did not overlap the 95% CI of the corresponding target population.

significantly higher in the studies excluding individuals not being at risk of suicide determined by the cutoff points of suicide screening tools (51.2%; adjusted linear coefficient [β] = 1.30, standard error [SE] = 0.15 ; $P = .041$) and individuals not meeting the age or school grade criterion (45.9%; β = 1.37, SE = 0.13; $P = .005$). The rates of exclusion were marginally higher in the RCTs with 7 or more exclusion criteria (39.7%; β = 1.29, SE = 0.19; $P = .092$) and individuals with pregnancy/reproductive health conditions (46.5%; β = 0.70, SE = 0.13; $P = .070$). The rates of refusal were marginally higher in the RCTs in which the intervention had a significant effect on the suicide outcome (27.6%; β = 1.14, SE = 0.08; $P = .082$) and in the RCTs published after 2010 (27.7%; β = 1.17, SE = 0.09; $P = .060$).

Assessment of Reporting Quality

Among 40 RCTs that were published after 1996 (exluding one trial by Rudd et al[61] published in 1996), 16 trials (40.0%) did not provide a CONSORT diagram to describe the numbers of approached, eligible, and randomized participants. Among the overall 41 trials, 11 RCTs (26.8%) reported the number of excluded individuals per each criterion; these trials had significantly higher rates of exclusion compared to the RCTs that did not report the numbers (57.7% vs 30.5%, $P = .009$). In only 4 trials, the investigators compared the characteristics of those who were randomized with those who were not randomized.

Representativeness of RCT Samples

Table 3 presents comparison of the sociodemographic characteristics between RCT samples and the target population samples. In all levels of interventions, the distribution of females and males in the RCT samples resembled that of their target populations. In universal interventions, the proportions of African American (27% vs 15%) and Hispanic subjects (27% vs 25%) were higher than in the target population. In selective interventions, the proportions of African American (18% vs 9%) and Hispanic subjects (26% vs 20%) and those living in a household with annual income less than $50,000 (67% vs 51%) were higher than in the target population. In indicated interventions, the proportions of African Americans (15% vs 11%) and those living with a single parent (55% vs 38%) were higher than in the target population.

DISCUSSION

This meta-analysis was the first to estimate the rates of exclusion and refusal in RCTs studying suicide-related outcomes in the US. In this meta-analysis of 36 studies, the rate of exclusion was 36.4%, while the rate of refusal was 25.5%. The most commonly used exclusion criteria were age/school grade criterion; not being at risk of suicide determined by self-report or clinical impression; presence of mental, cognitive, and behavioral conditions; parent or child does not speak English; and not living with parents. The rates of

exclusion were significantly higher in the studies excluding individuals not at risk of suicide determined by the cutoff points of suicide screening tools (51.2%) and individuals not meeting the age or school grade criterion (45.9%). While a CONSORT diagram was provided in the majority of the studies included in this study, the rate of exclusion per each exclusion criterion and comparison of characteristics between the RCT participants and non-participants were provided only in a relatively small proportion of the included studies. Finally, while the distribution of females and males in the RCT samples resembled that in the target populations, the proportions of African Americans were significantly higher in the RCT samples than in the corresponding target populations for universal, selective, and indicated intervention RCTs.

While previous studies suggested that a standard set of exclusion criteria commonly used in the RCTs of mental and behavioral health interventions would exclude a large proportion of potential study participants,[6–13] the rates of exclusion and refusal in RCTs examining suicide-related outcomes found in this current study were not as high compared to the rates found in other mental and behavioral health interventions (eg, anxiety disorders, depression, bipolar disorder, schizophrenia, alcohol and substance use disorders).[69] The rate of exclusion in RCTs examining suicide-related outcomes was rather similar to the rate reported in the RCTs targeting conditions such as posttraumatic stress disorder and bulimia.[69] The higher rate of exclusion in the studies determining the level of suicide risk with screening tools indicates that the studies do not represent a broader range of suicide risk.

In most of the studies, the numbers of individuals who were approached to participate, non-eligible individuals, and individuals who refused to participate were provided; however, many of these studies did not report the rate of exclusion per each exclusion criterion, which precluded direct examination of which specific criterion tended to exclude more potential participants. Additionally, very few studies reported comparison between those who were randomized and those who were not, and the discussion with regard to representativeness of the RCT samples and generalizability of the findings was limited. Moreover, no studies used statistical techniques to correct for potential sample selection bias.[70] Our study was the first to examine sample representativeness of RCTs examining suicide-related outcomes. We demonstrated that the distribution of females and males in the RCT samples resembled that in the target populations, and there was a sizeable representation of sociodemographic minority groups in RCTs examining suicide-related outcomes. Particularly, a sizeable representation of African American youth in the RCT samples is encouraging for future research given the rapidly increasing rate of suicide among African American youth in the US.[71]

The results of this study should be interpreted within the context of the limitations. First, the scope of the study was limited to the studies that took place in the US, and our findings may not be directly applicable to the studies of youth suicide prevention interventions conducted outside of the US. Second, the definition of individuals initially approached by study investigators was not exactly the same across different RCTs. The estimated rates of exclusion and refusal were dependent on recruiting methods in each RCT and possible pre-selection by potential participants or recruiters. Third, the information regarding specific reasons for participation refusal was not available consistently across RCTs included in this study. Future studies should investigate why some children or their parents are unwilling to participate in suicide prevention studies. Fourth, the target population samples we drew from the observational data did not include samples that matched the exact age/school grade ranges and levels of suicide risk of the RCT samples that were included in this study. Limited availability of the target population data is one of the major challenges in generalizability research fields.[72] However, even without access to ideal target population data, RCT investigators can easily report a comparison of the characteristics of RCT participants and non-participants to examine sample representativeness. As recommended in Melberg and Humphreys,[6] editorial policy could be strengthened to require investigators of RCTs to include such information in publications.

CONCLUSIONS

The results of this study suggest that the rates of exclusion and refusal in youth suicide prevention RCTs and other RCTs studying suicide outcomes in the US were moderate. While there was strong sociodemographic and racial/ethnic group representation in youth suicide prevention RCTs in the US, the specific exclusion criteria of many studies limited the range of suicide risk and comorbid conditions. The quality of future RCTs of youth suicide prevention interventions could be improved by better reporting and more awareness of sample representativeness and generalizability.

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Editor's Note: We encourage authors to submit papers for consideration as a part of our Focus on Suicide section. Please contact Philippe Courtet, MD, PhD, at pcourtet@psychiatrist.com.

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Supplementary Material

Article Title: Ineligibility and Refusal to Participate in Randomized Controlled Trials That Have Studied Impact on Suicide-Related Outcomes in the United States: A Meta-Analysis

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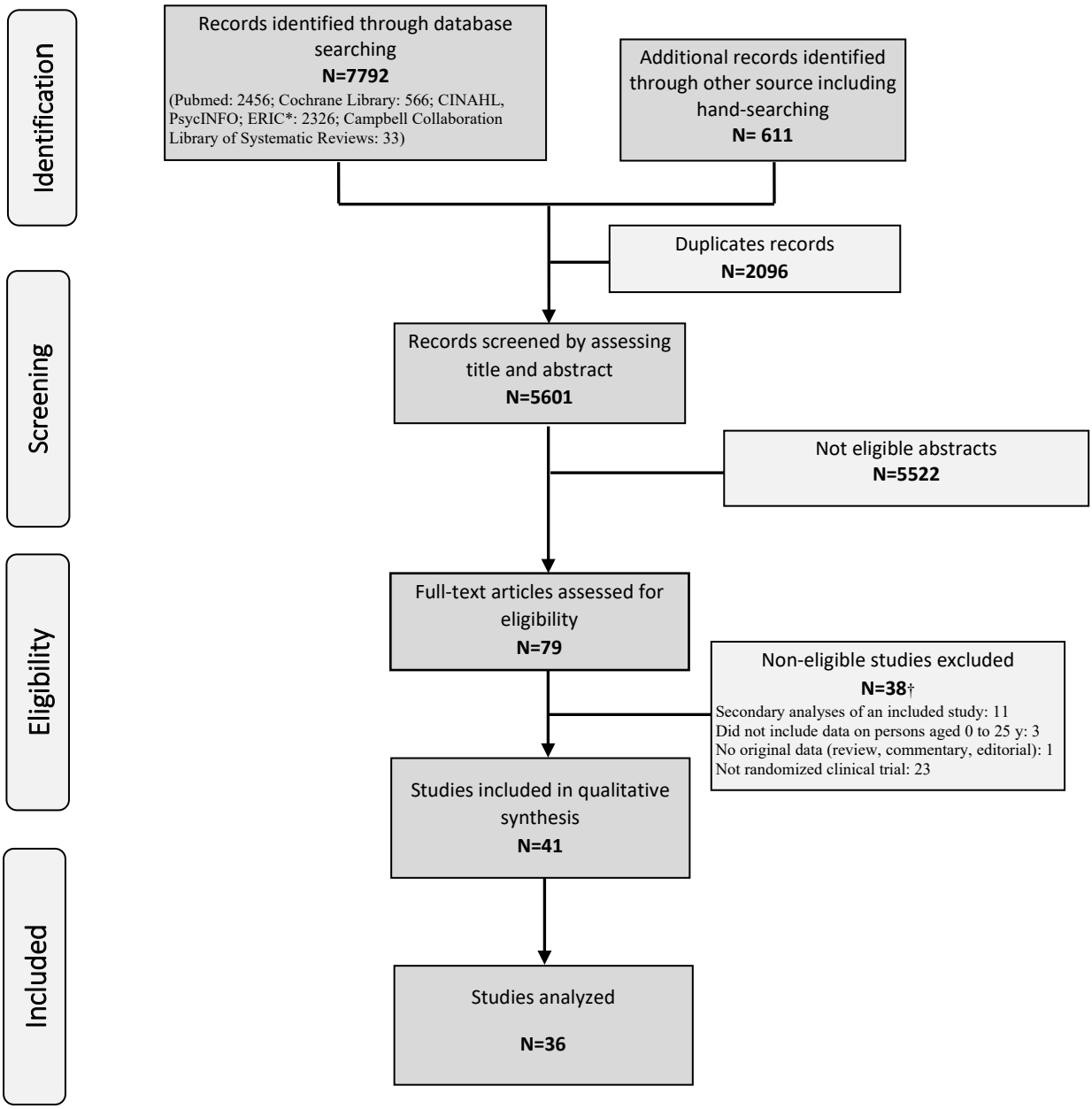
List of Supplementary Material for the article

1. **Figure 1** Flow-chart of identification, screening and selection of the studies
2. **Table 1** Rates of exclusion and refusal in included studies by the level of intervention
3. **Table 2** Extracted data in 36 studies included in the meta-analysis
4. **Table 3** Prevalence of exclusion criteria of RCTs (Selective & indicated level) by specific exclusion criterion

Disclaimer

This Supplementary Material has been provided by the author(s) as an enhancement to the published article. It has been approved by peer review; however, it has undergone neither editing nor formatting by in-house editorial staff. The material is presented in the manner supplied by the author.



Supplementary Figure 1. Flow-chart of identification, screening and selection of the studies

ERIC = Education Resources Information Center.

* Searched simultaneously through the EBSCO database.

† Sum of individual reasons exceeds total number of exclusions because reviewers were not required to agree on reason for exclusion.

Supplementary Table 1. Rates of exclusion and refusal in included studies by the level of intervention

First author (Year)	# Approached	# Randomized	Excluded		Refused	
			N	% (95% CI)	n%	(95% CI)
Universal						
Aseltine, 2007[28]	4491	4133	0	0	358	8.0 (7.2-8.8)
Schilling, 2014[29]	NA	386	NA	NA	NA	–
Schilling, 2016[30]	3120	1284	0	0	1836	58.8 (57.1-60.6)
Wilcox, 2008[31]	NA	1196	0	NA	NA	–
Connell, 2016[32]	1110	998	0	0	112	10.1 (8.5-12.0)
Selective						
Brent 2008[33]	3258	334	2810	86.2 (85.0–87.4)	114	3.5 (2.9-4.2)
Brown, 2001[34]	NA	1108	NA	–	NA	
Brown, 2019[35]	115	61	36	31.3 (23.5-40.3)	18	15.7 (10.1-23.4)
Eggert, 2002[36]	1068	341	556	52.1 (49.1-55.0)	171	16.0 (13.9-18.3)
Esposito-Smythers, 2017[37]	285	81	91	31.9 (26.8-37.6)	113	39.6 (34.1-45.4)
Hill, 2019[38]	708	80	611	86.3 (83.6-89.6)	17	2.4 (1.5-3.8)
Kaminer, 2006[39]	294	177	59	20.1 (15.9-25.0)	58	19.7 (15.6-24.7)
Keeton, 2019[40]	3066	488	1226	40.0 (38.3-41.7)	1352	44.1 (42.3-45.9)
Kerr, 2014[41]	251	166	60	23.9 (19.0-29.5)	25	10.0 (6.8-14.3)
King, 2012[42]	NA	245	NA	-	105	-
King, 2015[43]	828	49	478	57.7 (54.3-61.1)	301	36.4 (33.1-39.7)
March, 2004[44]	2804	439	1315	46.9 (45.1-48.7)	1050	37.4 (35.7-39.3)
Vidot, 2016[45]	989	746	65	6.6 (5.2-8.3)	178	18.0 (15.7-20.5)
Weinstein, 2018[46]	170	71	21	12.4 (8.1-18.1)	80	47.1 (39.7-54.5)
Sandler, 2016[47]	432	156	35	8.1 (5.9-11.1)	241	55.8 (51.1-60.4)
Spirito, 2015[48]	NA	24	NA	-	NA	-
Slesnick,2019[49]	639	150	440	68.9 (65.2-72.3)	49	7.7 (5.8-10.0)
Grupp-Phelan, 2019[50]	5195	168	4823	92.8 (92.1-93.5)	204	3.9 (3.4-4.5)
Indicated						
Asarnow, 2011[51]	340	181	88	25.9 (21.5-30.8)	71	20.9 (16.9-25.5)
Asarnow, 2017[52]	140	42	75	53.6 (45.3-61.6)	23	16.4 (11.2-23.4)
Bernal, 2019[53]	529	121	264	49.9 (45.7-54.2)	144	27.2 (23.6-31.2)
Diamond, 2010[54]	341	66	208	61.0 (55.7-66.0)	67	19.6 (15.8-24.2)
Diamond, 2019[55]	366	129	106	29.0 (24.6-33.8)	131	35.8 (31.1-40.8)
Hooven, 2012[56]	4231	615	1545	36.5 (35.1-38.0)	2071	48.9 (47.4-50.5)
Huey, 2004[57]	156	116	22	14.1 (9.5-20.4)	18	11.5 (7.4-17.5)
Kennard, 2018[58]	104	66	11	10.6 (6.0-18.0)	27	26.0 (18.5-35.1)
King, 2006[59]	1316	289	330	25.1 (22.8-27.5)	697	53.0 (50.3-55.6)
King, 2009[60]	2493	448	1443	57.9 (55.9-59.8)	602	24.1 (22.5-25.9)
Rudd, 1996[61]	328	264	26	7.9 (5.5-11.4)	38	11.6 (8.6-15.5)
Thompson, 2001[62]	1546	460	757	49.0 (46.5-51.5)	329	21.3 (19.3-23.4)
Yen, 2020[63]	347	52	275	79.3 (74.7-83.2)	20	5.8 (3.8-8.7)
Thompson, 2000[64]	166	106	38	22.9 (17.2-29.9)	22	13.3 (8.9-19.3)
Wharff, 2019[65]	330	139	102	30.9 (26.2-36.1)	89	27.0 (22.5-32.0)
Yen, 2019[66]	123	50	46	4.9 (1.9-12.0)	27	33.3 (24.0-44.1)
Esposito-Smythers, 2019[67]	334	147	56	16.8 (13.1-21.1)	131	39.2 (34.1-44.6)
McCauley, 2018[68]	576	173	194	33.7 (29.9-37.6)	209	36.3 (32.5-40.3)

NA: Not available

Supplementary Table 2. Extracted data in 36 studies included in the meta-analysis

Author, Year	Setting	Name of intervention	Age group	Year of study	Inclusion criteria	Exclusion criteria
Universal						
Aseltine, 2007[28]	School	Signs of Suicide (SOS)	14 to 18	2001-2003	1-Ninth-grade classes	None
Schilling, 2014[29]	School	Signs of Suicide (SOS)	10 to 13	2009-2010	1-Middle schools identified by the Department of Defense as high-impact	None
Schilling, 2016[30]	School	Signs of Suicide (SOS)	14 to 18	2007-2009	1-Ninth grade students in 16 technical high schools in the state of Connecticut	None
Wilcox, 2008[31]	School	Good Behavior Game (GBG)	6 to 8	1985-1987	1- All first grade in 41 classrooms in 19 elementary schools of the Baltimore City Public School System during two successive academic years: 1985–1986 for Cohort 1 first graders and 1986–1987 for Cohort 2 first graders.	None
Connell, 2016[32]	School	Family Check Up (FCU)	13 to 18	1996-1998	1- Sixth grade from three middle schools within a metropolitan community in the northwestern US	None
Selective						
Brent 2008[33]	Hospital	SSRI plus cognitive behavioral therapy	12 to 18	2000-2006	1- Aged 12 to 18 years 2-In active treatment for MDD, with a clinically significant depression (CDRS-R total score >= 40 and a Clinical Global Impressions- Severity subscale>= 4) despite being in treatment with an SSRI regimen for at least 8 weeks the last 4 of which were at a dosage of at least 40 mg per day of fluoxetine or its equivalent	1-Two or more adequate trials of an SSRI 2-Participants currently receiving CBT 3-Participants taking medications with psychoactive properties with the exception of those who were prescribed stable doses (≥12 weeks) of stimulants, hypnotics, or antianxiety agents 4-Diagnoses of bipolar spectrum disorder 5-Diagnosis of psychosis 6-Diagnosis of pervasive developmental disorder or autism 7-Diagnosis of eating disorders 8-Diagnosis of substance abuse or dependence 9-Diagnosis of hypertension 10-Pregnancy 11-Breastfeeding 12-Having unprotected sex.
Brown, 2001[34]	School	Project Chrysalis	14 to 17	1995-2000	1-Female students in grade 9, 10, or 11 in the Portland Public School District 2-Identified as a victim of sexual/physical/ emotional abuse 3-Identified as having a minimum of two risk factors	None

Brown, 2019[35]	Hospital	prolonged exposure therapy	13-18	2006-2012	1- A primary diagnosis of chronic/subthreshold PTSD 2-sexual abuse index trauma at least 3 months earlier	1-Untreated bipolar disorder 2-Untreated schizophrenia 3-Untreated conduct disorder 4- Untreated pervasive developmental disorder 5- Diagnosis of substance abuse or dependence 6-Current inpatient psychiatric treatment 7-Initiation of psychotropic medication within the previous 12 weeks
Eggert, 2002[36]	School	Counselors-CARE (C-CARE) and Coping and Support Training (CAST)	14 to 19	1995-1998	1-Seven high schools representing two Pacific Northwest urban school districts	1-not currently at risk for suicide (with the SRS) (n=556)
Esposito-Smythers, 2017[37]	Hospital	adjunctive cognitive-behavioral family-based alcohol, DSH, and HIV prevention program (ASH-P)	13 to 17	2010-2014	1- Aged 13 to 17 years 2-Receiving mental healthcare in the community at the time of recruitment 3-Living with a parent/guardian willing to participate 4-English speaking	1-Unable to provide assent or participate in groups due to cognitive limitations 2-Psychotic 3-Homicidal (n=1) 4-Alcohol/drug dependent (n=20) 5-Pregnant (N=3) 6-HIV+ 7-Not within the age range (n=10) 8-Not in MH treatment (n=18) 9-Not living with gaurdian (n=12) 10-Not English speaking (n=9) 11-Moving out of state (n=8) 12-Sibling participting (n=2) 13-Intelectual disability (n=1)
Hill, 2019[38]	Community	Lean, Explore, Assess, and Plan (LEAP) intervention	13-19	2015	1- Aged 13 to 19 years 2-Endorsing a perceived burdensomeness score >=17 on the Interpersonal Needs Questionnaire Perceived Burdensomeness subscale (n=593) 3-Having available Internet access for completion of the intervention modules	1-Current psychosocial treatment or use of psychoactive medications (n=15) 2-Severe suicide ideation (n=3) 3-parent did not speak English or Spanish (n = 2)
Kaminer, 2006[39]	Hospital	In-Person Aftercare and Telephone Aftercare	14 to 18	2001-2006	1-Current diagnosis of DSM-IV Alcohol Abuse or Alcohol Dependence Disorder 2-Current level of potentially harmful drinking 3-Willingness to accept treatment and random assignment to aftercare condition 4-Residence within 45 minutes drive from the two treatment sites 5-Expectation of stable residence 6-Ability to comprehend and read English	1-Met DSM-IV criteria for substance dependence other than nicotine or marijuana 2-Llifetime diagnosis of schizophrenia 3-Lifetime diagnosis of bipolar disorder 4-Lifetime diagnosis of other psychotic disorder 5-Report suicidal ideation with a plan, suicidal behavior, or self injurious behavior in the last 30 days 6-Have any current medical condition that could compromise the participant's ability to regularly attend, and constructively participate, in treatment or aftercare

Keeton, 2019[40]	Hospital	Sertraline with cognitive behavioral therapy	10 to 26	2002-2007	1-Aged 7 to 17 years 2-A primary diagnosis of separation or generalized anxiety disorder or social phobia 3-Substantial impairment 4- IQ >=80	1-Unstable medical condition 2-Refusing to attend school because of anxiety 3-Not had a response to two adequate trials of SSRIs 4-Not had a response to an adequate trial of cognitive behavioral therapy 5-Girls who were pregnant 6-Girls who were sexually active and were not using an effective method of birth control 7-Children who were receiving psychoactive medications other than stable doses of stimulants 8-Current major depressive 9-Current substance-use disorder 10- Unmedicated ADHD, combined type 11-Lifetime history of bipolar disorder 12-Lifetime psychotic disorder 13- Lifetime pervasive developmental disorders 14-Presented an acute risk to themselves or others
Kerr, 2014[41]	Juvenile justice	Multidimensional Treatment Foster Care (MTFC)	Mean age 15.3 (SD=1.2)	1997-2006	1-Aged 13 to 17 years 2-Had at least one criminal referral in the prior 12 months 3-Were placed in out- of-home care within 12 months following referral	1-pregnant at the time of recruitment
King, 2012[42]	ED	In-person follow-up (IPF)	13 to 17	2009-2010	1-Aged 13 to 17 years 2-Seeking emergency services	1-A life-threatening condition (Level 1 trauma, e.g., intubated and unconscious) 2-Severe cognitive impairment (as reported by medical staff)
King, 2015[43]	ED	Teen Options for Change (TOC)	14 to 19	NA	1-Aged 14 to 19 years 2-A positive suicide risk screen, defined as suicidal ideation, a recent suicide attempt or positive screens for both depression and alcohol or drug abuse (n=450) 3-Presenting with a non-psychiatric chief complaint	1- A psychiatric chief complaint (n = 15) 2--A level one trauma 3-Significant cognitive impairment 4-Disposition of psychiatric hospitalization (n=9) 5-unknown disposition (n = 3)

March, 2004[44]	Hospital	Treatment for Adolescents With Depression Study (TADS)	12 to 17	2000-2003	1-Aged 12 to 17 years 2-Ability to receive care as an outpatient 3-DSM-IV diagnosis of MDD at consent and again at baseline (n=408) 3- Children's Depression Rating Scale-Revised (CDRS-R) total score>=45 at baseline (n=55) 4- A full- scale IQ of 80 or higher (n=36) 5-Not taking antidepressant(s) prior to consent (n=82)	1-Current or past diagnosis of bipolar disorder 2-Current or past diagnosis of severe conduct disorder (n=37) 3-Current substance abuse or dependence 4-Pervasive developmental disorder(s) 5-Thought disorder 6-Concurrent treatment with psychotropic medication or psychotherapy outside the study (n=202) 7-Two failed selective serotonin reuptake inhibitor (SSRI) trials 8-A poor response to clinical treatment containing CBT for depression 9-Intolerance to fluoxetine 10-Confounding medical condition 11-Non- English speaking patient or parent 12-Pregnancy 13-Refusal to use birth control 14-Dangerousness to self or others (n=6) 15-Missed more than 25% of school days in previous 2 months (n=262) 16-Not Resided With a Primary Caretaker for ≥6 Months (n=65) 17-Hospitalized for a Psychiatric Indication in Past 3 Months (n=58) 18-Diagnosis of MDD Not Stable and Pervasive (n=275)
Vidot, 2016[45]	School	Familias Unidas	Mean 13.9 years old (SD = 0.67)	2010-2014	1-Be of Hispanic origin 2-Attend 8 grade at the time of the baseline assessment 3-Live with an adult primary caregiver who was willing to participate 4-Live within the catchment areas of the participating middle school 5-Plan to live in South Florida for the duration of the study	None
Weinstein, 2018[46]	Hospital	Child- and Family-Focused Cognitive Behavioral Therapy (CFF-CBT)	7 to 13	2010-2014	1-Youth stabilized on medication 2-Indicating no acute, severe symptoms requiring immediate, more intensive care	1- Youth IQ < 70 on the Kaufman Brief Intelligence 2- Active psychosis 3-Active substance abuse/dependence 4-Neurological or other medical problems 5-current severe suicidality with intent or plan requiring immediate hospitalization, n=0 6-Youth whose primary caretakers were experiencing current depressive or manic episodes (n=0)

Sandler, 2016[47]	Community	Family Bereavement Program (FBP)	8 to 16	1994-2000	1-Death of a biological parent or parent figure 2-Death occurrence no more recent than 4 months or more distant than 30 months prior to the start of the program 3-At least one child and one caregiver were willing to be randomly assigned to either the group or self-study program and participate in assessments 4-caregiver and child could complete the assessment battery in English	1-Caregiver or child was currently receiving other mental health or bereavement services 2-In a special class for the mentally handicapped 3-Planning to move out of the area in the next 6 months 4-Child or caregiver expressed suicidal intent 5-Caregiver had a current diagnosis of major depression 5-Conduct disorder, oppositional defiant disorder 6-Attenattention-deficit/hyperactive disorder 7-Parent and adolescent lived together
Spirito, 2015[48]	Hospital	Parent-Adolescent-CBT [PA-CBT]	11 to 17	2009-2012	1-Aged 11 to 17 years 2-Current MDE 3-CDRS t score >= 65 4- Experienced current or past suicidality 5-Parent-current or past MDE 6-Parent- a minimum BDI score of 15 for parents with a current MDE and a minimum BDI score of 10 for parents with a past MD	1- Bipolar disorder 2-Substance use disorder 3-Developmental/cognitive delays 4-Psychosis 5-Not Spoke English 6-who not lived together in the Northeast
Slesnick, 2019[49]	drop-in center	Cognitive Therapy for Suicide Prevention (CTSP) + Treatment as Usual (TAU)	18-24	2015-2019	1-Aged 18 to 24 years 2-Currently homeless 3-Were able to provide informed consent 4-Reported one or more episodes of severe suicidal ideation in the past 90 days 5-Complete the Social Network Interview 6-Score > 16 on the Scale for Suicide Ideation-Worst Point (n=43)	1- Under age 18 (n=2) 2-Over age 24 (n=4) 3-Not require hospitalization 4-Psychotic 5-Does not meet criteria for homelessness (n=21) 6-Reported no suicidal thoughts (n=368)
Grupp-Phelan, 2019[50]	ED	The Suicidal Teens Accessing Treatment After an Emergency Department Visit (STAT-ED) intervention	12 to 17	2013-2015	1-Aged 12 to 17 years 2-Positive screen result for suicide risk 3-Lived within 100 miles of the hospital 4-No contact with a mental health care practitioner in the 90 days preceding the index ED visit 5-Stable as determined by vital signs and triage criteria	1-Presented to the ED with a chief concern of suicidal behavior or a primary or secondary psychiatric concern or altered mental status attributable to illness or medication 2-lacked telephone access 3-Unable to understand the study process 4-Unable to speak or read English adequately
Indicated						
Asarnow, 2011[51]	ED	Family-based cognitive-behavior therapy	10 to 18	2003-2005	1-Aged 10 to 18 years 2-presenting to the ED for suicide attempts and/or ideation	1-Acute psychosis/symptoms that impede consent/assessment 2-No parent/guardian to consent 3-Youth not English-speaking 4-Parents/guardians not English or Spanish-speaking 5-Intoxicated

Asarnow, 2017[52]	ED	SAFETY Program	11 to 18	2011-2015	1-Aged 11 to 18 years (n=5) 2-A recent (past 3 months) SA 3-NSSI as primary problem, with the additional requirement of repetitive SH (n=29) 4-Living in a stable family situation 5-At least one parent willing to participate in treatment	1-psychosis (n=7) 2-Substance dependence (n=2)) 3-Inability to speak English (n=2) 4-Living in a stable family situation (no plans for residential placement) (n=13) 5-Medical condition (n=1) 6- Left emergency room/unit (n=11)
Bernal, 2019[53]	Hospital	A parent psychoeducation intervention (TEPSI) as part of cognitive-behavioral therapy (CBT)	13-17.5	2005-2007	1-Aged 13 to 17.5 years 2-Had a Children's Depression Inventory score ≥ 20 or a Children's Depression Rating Scale-Revised score ≥ 44 3-Met full DSM-IV criteria for MDD 4-Maintained clinically significant depressive symptoms for at least 6 weeks before randomization	1-Be on antidepressants 2-History of any bipolar disorder 3-Psychotherapy and pharmacological treatment for other conditions (e.g., anxiety, ADHD, or disruptive disorders) if it was considered to impact depression symptoms. 4-Current diagnosis of other Axis I disorder that was more primary than MDD 5-Current sexual or physical abuse 6-Subnormal intellectual capacity (IQ below 80) 7-Evidence of any medical or neurological condition that could preclude participation 8-Pregnancy of more than 3 months 9-Current chronic pain 10-Substance abuse or dependency within the past year 11-Current suicide risk sufficient to preclude outpatient treatment 12-Adolescent or caregiver serious legal problems 13-Unavailability to attend to the assessment 14-History of any psychotic disorder 15-History of organic brain syndrome
Diamond, 2010[54]	Hospital	Attachment-Based Family Therapy (ABFT)	12 to 17	2005-2007	1-Aged 12 to 17 years 2-Scores above 31 on the Suicidal Ideation Questionnaire and Score above 20 (i.e., moderate depression) on the Beck Depression Inventory (n=199)	1-Needed psychiatric hospitalization (n=6) 2-Recently discharged from a psychiatric hospital 3-Current psychosis (n=3) 4-Mental retardation or history of borderline intellectual functioning
Diamond, 2019[55]	Hospital	Attachment-based family therapy (ABFT)	12 to 18	2012-2015	1-At least clinically significant levels of suicidal ideation and moderate levels of depressive symptoms 2-At least 1 primary caregiver required to participate in assessments and treatments	1- Imminent risk of harm to self or others 2-Psychotic features 3-Severe cognitive impairment based on educational records, parent report and/or clinical impression 4-Non–English-speaking participating parent 5-Began psychiatric medication within 3 weeks of the initial pretreatment screening

Hooven, 2012[56]	Home	Promoting CARE	14 to 19	1999-2005	1-Suicide attempts and elevated suicide ideation or depression 2-Two criteria must be met and include moderate depression, moderate suicide ideation/threats, and/or alcohol and drug use in conjunction with suicide risk)	1-Not currently at risk for suicide (with the SRS)
Huey, 2004[57]	Hospital	Multisystemic Therapy (MST)	10 to 17	NA	1-Aged 10 to 17 years 2-Medicaid-funded or without health insurance 3-Residing in a noninstitutional environment	1-Diagnosis of autism 2-Family already received MST treatment
Kennard, 2018[58]	Hospital	As Safe as Possible (ASAP), supported by a smartphone app (BRITE)	12 to 18	2014-2017	1-Aged 12 to 18 years 2-Presented to psychiatric inpatient units at two academic medical centers with recent suicidal ideation with a plan or intent or a recent suicide attempt	1-Need for residential treatment 2-Active involvement of child protective services 3-Mania 4-Psychosis 5-Autism 6-Intellectual disability
King, 2006[59]	Hospital	Youth-Nominated Support Team—Version 1 (YST–1)	12 to 17	1998-2000	1-Aged 12 to 17 years 2-Suicide attempt or significant suicidal ideation/intent during the past month 3-A score of 20 or 30 on the Self-Harm subscale of the Child and Adolescent Functional Assessment Scale 4- At least one completed baseline measure	1-Severely or profoundly mentally retarded (special education certification) 2-Presented with incapacitating psychosis
King, 2009[60]	Hospital	Youth-Nominated Support Team – Version 2 (YST-2)	13 to 17	2002-2005	1-Aged 13 to 17 years 2-Significant suicidal ideation or suicide attempt within the past four weeks	1- Mental retardation & Acute psychosis (n=196) 2-Direct transfer to medical unit/ residential placement (n=2) 3-Lived > 1-hour drive (n=123) 4-No legal guardian available--ward of court or state (n = 36)
Rudd, 1996[61]	Hospital	Outpatient intervention	NA	1990-1995	1-Individuals who made an attempt precipitating referral 2-Those suffering a mood disorder with concurrent ideation 3-Those abusing alcohol episodically with concurrent ideation	1- substance dependence or chronic abuse requiring separate treatment 2-Psychotic component to the patient's presentation 3-A diagnosable thought disorder 4-A personality disorder diagnosis
Thompson, 2001[62]	School	Counselors-CARE (C-CARE) and Coping and Support Training (CAST)	14 to 18	1995-2000	1-Potential high school dropouts 2-At risk for suicide	1-not currently at risk for suicide (with the SRS)

Yen, 2020[63]	Hospital	Skills to Enhance Positivity (STEP)	12 to 18	2015-2016	1-Aged 12 to 18 years (n=11) 2-English speaking (n=4) 3-Have access to text messaging (n=1)	1-Diagnosed with a psychotic disorder (n=53) 2-Exhibited cognitive or intellectual disabilities (n=1) 3-A ward of the state (n=56) 4-Autism Spectrum Disorder (n=6) 5-Lives too far way (n=1) 6-Homicidal Ideation (n=8) 7-Moving out of area (n=4) 8-Wayward (n=1) 9-Completed STEP OPEN (n=4) 10-Too close to discharge (n=20) 11-Treating MD suggested passing (n=2)
Thompson, 2000[64]	School	Personal Growth Class (PGC) Program	14 to 18	1990-1993	1-Prior school dropout 2-Below-expected credits earned for current grade level 3-Top 25th percentile for days absent per semester 4-GPA<2.3 with a pattern of declining grades or a precipitous drop in GPA >0.7 5-Referral from school personnel as being in jeopardy of school failure or dropping out	1-Not currently at risk for suicide (with the SRS)
Wharff, 2019[65]	ED	Family-Based Crisis Intervention (FBCI)	13-18	2012-2014	1-Presenting to the ED with suicidality 2-Presence of a consenting parent or legal guardian	1- Either adolescent or parent/guardian lacked fluency in English 2-Adolescent was not medically stable, including intoxication 3-Demonstrated cognitive limitations prohibiting completion of research instruments 4-Presented with active psychosis. 5-Required physical or medication restraint in the ED.
Yen, 2019[66]	Hospital	Coping Long Term with Active Suicide Program (CLASP)	12 to 18	2011-2012	1-Aged 12 to 18 years 2-Admitted to the inpatient psychiatric unit on the basis of suicide risk (attempt or ideation)	1-Psychotic disorders that would preclude full understanding of the protocol, intervention, and assessment materials 2-Cognitive deficits that would preclude full understanding of the protocol, intervention, and assessment materials 3-Wards of the state
Esposito-Smythers, 2019[67]	Hospital	family-focused outpatient cognitive behavioral treatment (F-CBT)	12 to 18	2012-2017	1-English speaking 2-Met criteria for major depressive disorder, dysthymia, depression, or mood disorder not otherwise specified 3-Were hospitalized for a SA or SI 4-Had at least one of the following co-occurring risk factors: a SA prior to the index admission, NSSI, or a substance use disorder	1-Cognitive or developmental delays 2-A diagnosis of autism spectrum disorder 3-A primary diagnosis of a psychotic disorder 4-A primary diagnosis of Obsessive–compulsive disorder 5-A primary diagnosis of Eating disorder 6-Used “hard” illicit substances, such as opiates.

McCauley, 2018[68]	Hospital	dialectical behavior therapy (DBT)	10 to 24	2012-2014	1-Aged 12 to 18 years 2-At least 1 lifetime suicide attempt 3-Elevated past-month suicidal ideation 4-Self-injury repetition 5-Three or more borderline personality disorder criteria	1-IQ less than 70 on the Kauffman Brief Intelligence Test 2-Primary problem of psychosis 3-Primary problem of Mania 4-Primary problem of anorexia 5-Life-threatening condition 6-Youth without English fluency 7-Parent without English or Spanish fluency

Supplementary Table 3. Prevalence of exclusion criteria of RCTs (Selective & indicated level) by specific exclusion criterion

Criteria	Studies using the criteria	
	N	% Median percent (range)*
Sociodemographic criterion	**25**	
Specific age or grade included	25	3.3 (0.9-3.6)
Be Hispanic origin	1	Not available
Not being at risk of suicide determined by the cut-off points of the suicide screening tools	**13**	**36.4 (2.0-83.8)**
Not being at risk of suicide determined by self-report or clinical impression	**25**	**38.9 (0.4-83.8)**
Mental, behavioral and cognitive conditions	**25**	
Psychotic disorder/psychotic features (lifetime, current)	22	2.9 (0.9-15.3)
Substance abuse or dependence or used "hard" illicit substances	11	1.4 (0.9-7.0)
Subnormal intellectual capacity	11	0.8 (0.2-7.9)
Imminent risk of harm to self or others	10	0.4 (0.2-7.8)
Bipolar disorder (lifetime, current)	8	5.2
Significant cognitive impairment	7	0.3
Pervasive developmental disorders	7	1.7
Conduct disorder/oppositional defiant disorder (current, past)	4	1.3 (0.3-1.7)
Eating disorders	3	Not available
Homicidal Ideation	3	0.3 (0-2.3)
Attention-deficit/hyperactive disorder (ADHD)	2	Not available
A primary Axis I disorder (current)	2	1.8
Current major depressive	1	Not available
Obsessive–compulsive disorder	1	Not available
Personality disorder diagnosis	1	Not available
current sexual or physical abuse	1	Not available
Primary caretakers experiencing current depressive episodes	2	Not available
Primary caretakers experiencing manic episodes	1	Not available
Medical or health related conditions	**12**	
Current serious/unstable medical condition	10	0.4 (0.1-0.7)
HIV positive	1	Not available
Hypertension	1	Not available
Service/treatment utilization	**21**	
Receiving psychotropic medication & not stabilized on medication	9	2.1 (1.7-10.1)
Inpatient psychiatric treatment/recently discharged	7	1.6 (1.1-2.1)
Currently receiving CBT/ psychosocial treatment	4	Not available
History of failed antidepressant treatment	3	Not available
Not in mental health treatment	3	6.3
A poor response CBT for depression	2	Not available
Intolerance to fluoxetine	1	Not available
Logistical challenges	**17**	
Not living with a parent/guardian	14	3.3 (1.4-16.1)
Not English-speaking participants	11	1.3 (1.1-1.4)
Not English-speaking parent	5	3.2
Lives too far away	5	2.6 (0.3-4.9)
Unstable residence/planning to move out of the area	4	3.1 (1.2-9.3)

Not English or Spanish-speaking parents/guardians	3	0.3
No Internet/text messaging/phone access	3	0.3
Problem with attending school	2	11.1
Too close to discharge (n=20)	1	20 (5.8)
Pregnancy/reproductive health	**6**	
Pregnancy	6	1.1
Having unprotected sex/refused to use birth control methods	3	Not available
Breastfeeding	1	Not available
Miscellaneous	**3**	
Sibling participating	1	0.7
Not under Medicaid or health insurance	1	Not available
Adolescent or caregiver serious legal problems	1	Not available

CBT: Cognitive-Behavioral Therapy

*Where there is only one RCT, the number reported is the value for that RCT, otherwise median percent and range were reported.