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Comparative efficacy and acceptability of psychosocial treatments for conduct disorder problems in children and adolescents: study protocol for a systematic review and network meta-analysis

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Comparative efficacy and acceptability of psychosocial treatments for conduct disorder problems in children and adolescents: study protocol for a systematic review and network meta-analysis

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ABSTRACT

Introduction Conduct disorder problems are common among children and adolescents, with negative impacts on the youths, their families, and society. Although multiple psychosocial treatments have been proven to be effective for conduct disorder problems, comprehensive evidence regarding the comparative efficacy and acceptability between these treatments is still lacking. Therefore, we propose a systematic review and network meta-analysis, integrating both direct and indirect comparisons to obtain a hierarchy of treatment efficacy and acceptability.

Methods and analysis The present protocol will be reported according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols. Ten databases, including Web of Science, PubMed, PsycINFO, MEDLINE, APA PsycArticles, Psychology and Behavioral Sciences Collection, OpenDissertations, The Cochrane Library, Embase, and CINAHL, will be searched from inception for randomized controlled trials of psychosocial treatments for children and adolescents with conduct disorder problems, regardless of language, publication year and publication status. The primary outcomes will be efficacy at post-treatment (severity of conduct disorder problems at post-treatment) and acceptability (dropout rate for any reason) of psychosocial treatments. The secondary outcomes will include efficacy at follow-up, severity of internalizing problems, and improvement of social functioning. Two authors will independently conduct the study selection and data extraction, assess the risk of bias using the revised Cochrane Collaboration's Risk of Bias tool, and evaluate the quality of the evidence using the Grading of Recommendations Assessment, Development and Evaluation framework to network meta-analysis. We will perform Bayesian network meta-analyses with random-effects model. Subgroup and sensitivity analyses will be performed to evaluate the robustness of the findings.

Ethics and dissemination The research does not require ethical approval. Results are planned to be published in journals or presented at conferences. The network meta-analysis will provide information on a hierarchy of treatment efficacy and

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4 acceptability and help make a clinical treatment choice.
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7 **PROSPERO registration number** CRD42020197448
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10 **Strengths and limitations of this study**
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13 Bayesian network meta-analysis can synthesize all direct and indirect evidence and
14 allows the comparison of multiple treatments simultaneously within a single analysis,
15 which is beneficial for clinical practitioners to make an optimal and evidence-based
16 decision on the treatment of conduct disorder problems.
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22 The present study focuses on psychosocial treatment types rather than delivery
23 conditions for treating conduct disorder problems, which contributes to filling the lack
24 of comprehensive comparisons between psychosocial treatment types.
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29 We will not exclude trials with participants suffering conduct disorder problems
30 comorbid with attention deficit and hyperactivity disorder. Although results will
31 reflect the real situation and contribute to more generalizable inferences, the risk of
32 bias for outcomes will be raised.
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38 **BACKGROUND**
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42 Conduct disorder problems (CDPs), which include conduct disorder (CD) and other
43 related behavior problems in the clinical range (e.g. oppositional defiant disorder),¹
44 are common mental and behavioral problems among children and adolescents (more
45 common in boys than in girls), affecting more than 50 million children and
46 adolescents worldwide according to the survey by Global Burden of Disease Study
47 2013 Collaborators.² As addressed in the Diagnostic and Statistical Manual of Mental
48 Disorders, fifth edition (DSM-5), CD is characterized by repetitive and persistent
49 patterns of antisocial, aggressive, or rule-breaking behavior.³ Patients with CD have a
50 high rate of comorbidity with other mental health problems such as attention deficit
51 hyperactivity disorder (ADHD).⁴ CD is costly, and can persist over time and bring
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4 about many serious consequences to the individual, school, family, and society,
5 including bad health conditions, poor school performance, social disadvantage, family
6 conflicts, and criminal behaviors.⁵ Besides, untreated CD not only can influence the
7 functioning and quality of life of children and adolescents during their childhood and
8 adolescence but also may develop into antisocial personality in their adulthood.⁶ On
9 the contrary, an effective treatment could save 128 disability-adjusted life years
10 (DALY) per 100,000 boys and 90 DALY per 100,000 girls in the United States.⁷
11 Given the adverse influence of CDPs and the benefits of effective treatment,
12 researchers and practitioners have devoted their efforts to providing professional
13 treatments effectively and timely to children and adolescents with CDPs.
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24 Several disciplines, such as developmental psychopathology, child psychiatry, and
25 social psychology, have contributed to understanding the course, causes, and
26 development of CDPs, and have yielded different perspectives for treating CDPs.
27 Among the evidence-based interventions, psychosocial treatment is an important
28 approach for treating CDPs, taking priority over the pharmacological treatment.
29 Although some medications (e.g. risperidone) may have beneficial effects for CDPs,
30 they have side effects and are not suggested for routine management.⁴ Evidence from
31 previous meta-analyses indicated that psychosocial treatment can significantly
32 improve CDPs,^{1 8 9} thence, this study focuses on psychosocial treatment for youth
33 with CDPs. To date, there are many types of psychosocial treatments available for
34 treating CDPs, such as behavior therapy (BT),¹⁰ cognitive-behavioral therapy
35 (CBT),¹¹ psychodynamic therapy (DYN),¹² and play therapy (PT).¹³ These
36 psychosocial treatments can be delivered with diverse conditions, including parent
37 training programs, foster carer/guardian training programs, child-focused programs,
38 multimodal interventions.⁴ Regarding the suitable delivery conditions for different age
39 groups, National Institute for Health and Care Excellence (NICE) has recommended
40 (1) parent and foster carer or guardian training programs or (2) child-focused
41 programs or (3) parent and child training programs, for children and adolescents with
42 CDPs aged 3-14. Meanwhile, for children and adolescents aged 11-17 NICE has
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4 recommended multimodal interventions. Previous research has not checked the
5 comparative effectiveness of all the psychosocial treatment types yet, therefore, the
6 current research will focus mainly on treatment types rather than delivery conditions
7 unless there are enough numbers of included trials to distinguish between them.
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9 Another concern for psychotherapists, psychological counselors, and social workers is
10 the acceptability of these psychosocial treatments. Some treatments are not easily
11 accepted by participants due to high demands, long durations, stigmatization, etc.,
12 even though they can be effective for children and adolescents with CDPs.¹⁴ Besides,
13 due to methodological restrictions of conventional meta-analyses, it is still unclear
14 which are the most efficacious and the most acceptable psychosocial treatments for
15 CDPs. Fully investigating the comparative effectiveness and acceptability of all
16 psychosocial treatments is beneficial for clinical practitioners to make an optimal and
17 evidence-based decision on the treatment of CDPs.
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30 Network meta-analysis (NMA), which can consider both direct (head-to-head
31 comparison) and indirect (comparison of treatments via a common comparator)
32 evidence, is an appropriate method to answer the questions above.¹⁵ The standard
33 pairwise meta-analysis cannot be used to assess relative effects across treatments if
34 the comparisons have not been evaluated in head-to-head trials. Instead, NMA allows
35 comparison of multiple treatments simultaneously within a single analysis as long as
36 every treatment is connected to at least one of the other treatments under evaluation
37 through direct comparisons.¹⁶ Some researchers have compared the efficacy of
38 psychotherapies or psychosocial therapies for the treatment of depression,¹⁷ acute
39 anxiety disorders,¹⁸ post-traumatic stress disorders (PTSD)¹⁹ in children and
40 adolescents. One NMA has investigated the comparative effects of psychosocial and
41 pharmacologic interventions for disruptive behavior in children and adolescents.²⁰
42 However, the previous NMA grouped the same delivery conditions of psychosocial
43 interventions (i.e. child component, parent component, and multi-component) into a
44 node. With an increasing body of research investigating the effectiveness of treatment
45 for CDPs, it is possible to group the same types of psychosocial treatments into a node
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4 and conduct NMA. Besides, the previous research has not explicitly made a
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6 distinction between prevention and treatment, though their backgrounds, places, and
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8 intervention methods are different.²¹ Therefore, the present protocol aims to address
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10 the above limitations and synthesize all direct and indirect evidence for identifying the
11
12 optimal psychosocial treatment for children and adolescents with CDPs.
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14 15 **OBJECTIVES**

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18 The purpose of this study is to evaluate and compare the effectiveness and
19
20 acceptability of psychosocial treatments for CDPs. Specifically, we aim to
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23 1. assess the relative psychosocial treatment effects at post-treatment for CDPs, in
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25 comparison to one another.
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28 2. determine the acceptability of these psychosocial treatments.
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31 3. assess the relative psychosocial treatment effects at follow-up for CDPs, in
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33 comparison to one another.
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36 4. compare the effectiveness of psychosocial treatments on the improvement of
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38 internalizing problem outcomes at post-treatment in children and adolescents with
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40 CDPs.
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43 5. compare the effectiveness of psychosocial treatments on the improvement of
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45 social functioning outcomes at post-treatment in children and adolescents with
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47 CDPs.
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50 51 **METHODS AND ANALYSIS**

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54 The systematic review and NMA is registered in the PROSPERO database
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56 (registration number: CRD42020197448) and has been developed according to the
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58 Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols
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60 (PRISMA-P) checklist, the extension statement for NMA (PRISMA-NMA), and

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4 proposed additional considerations for protocols of systematic reviews including
5 NMA²²⁻²⁴.
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8 **Eligibility criteria**

9 **Study design**

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15 All randomized controlled trials (RCTs), including cluster RCTs and first phase of
16 cross-over studies, will be included. Quasi-randomized trials (e.g. randomization by
17 the last number of the date of birth, or day of the week) will be excluded. Moreover,
18 trials will be excluded if the sample size is less than 10 per study. Because the
19 psychosocial treatments are difficult to be conducted in a double-blind design, we will
20 include single-blind RCTs (i.e. raters were blinded) or trails in which participants
21 were assessed by self-rating scales. Language, year of publication, publication status
22 will not be restricted.
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31 **Types of participants**

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35 Children and adolescents with CDPs, who were no more than 18 years old when they
36 initially enrolled in studies, will be included. We will follow broad criteria to identify
37 CDPs: (1) diagnosed as CD, oppositional defiant disorder (ODD) or disruptive
38 behavior disorder (DBD), in accordance with diagnostic interviews on the basis of the
39 Diagnostic and Statistical Manual (DSM) or the International Classification of
40 Diseases (ICD), or (2) clinically significant symptoms of CDPs, defined as scoring no
41 less than a clinical cut-off measured by a standardized rating scale on CDPs. The
42 common scales measuring CDPs and their clinical cut-off values are shown in Table 1.
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will be included.

Table 1 Hierarchy of CDPs severity scales and their clinical cut-off values

Hierarchy	Scales	Abbreviation	Clinical Range
1	Eyberg Child Behavior Inventory	ECBI	Norway version: > 90th percentile US version: > 15 for the Problem score scale or/and > 131 for the Intensity score scale (> 93th percentile)
2	Achenbach System of Empirically Based Assessment	ASEBA	> 98th percentile (T score > 70) for oppositional defiant problems or conduct problems in DSM-oriented scales, or for rule-breaking behavior or aggressive behavior syndrome scale scores, or for externalizing problems scores
3	Strengths and Difficulties Questionnaire	SDQ	conduct problems subscale score > 5
4	Behavior Assessment System for Children	BASC	T score > 70 for externalizing problems subscale
5	Revised Behavior Problem Checklist	RBPC	T score > 70 for conduct disorder subscale
6	Conners Rating Scales	CRS	T score \geq 65 for defiance/aggression scale and symptom count at or above DSM cut-off score

Types of treatments

According to NICE guidelines, psychosocial interventions for CDPs can be delivered through parent training programs, parent and child training programs for children with complex needs, foster carer/guardian training programs, child-focused programs, and multimodal interventions.⁴ Psychosocial interventions are categorized according to the delivery conditions but not treatment types. Table S1 shows descriptions and examples of common psychosocial treatment types and control conditions on the topic.

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4 The effects of many types of psychosocial treatments on CDPs have been explored in
5 several reviews, traditional meta-analyses, or RCTs. Because CBT is the most
6 common treatment type for CDPs, CBT with different delivery conditions may be
7 separated as independent nodes if data are available. For the other treatment types,
8 trials comparing the same treatment types will be grouped into the same node no
9 matter which delivery conditions they used. Control groups include no treatment,
10 waitlist, and treatment as usual.
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18 Types of outcome measures

19 *Primary outcomes*

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25 1. Efficacy at post-treatment, measured using the end-point score (at post-treatment)
26 from scales assessing the severity of CDPs.²⁵ Where multiple scales are reported,
27 we will extract data from the CSPs severity scales in a hierarchical fashion (table
28 1). Besides, when multiple raters report a CSPs severity scale, the most preferable
29 data for inclusion will be the self-rated outcome, followed by parent/guardian
30 rated outcome, or if not available, teacher, clinician, or researcher rated outcome.
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- 38 2. Acceptability of psychosocial treatment, defined as the dropout rate for any reason
39 during psychological treatments.
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43 *Secondary outcomes*

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47 1. Efficacy at follow up, measured by the score from CDPs severity scales at the
48 6-month follow up, or if not available, measured by the score nearest 6-month
49 follow-up.
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- 53 2. Internalizing problems, measured by the end-point score (at post-treatment) from
54 internalizing problem scales, such as Achenbach System of Empirically Based
55 Assessment (i.e. Child Behavior Checklist, Teacher's Report Form and Youth
56 Self-Report), Revised Behavior Problem Checklist, Child and Adolescent
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4 Functional Assessment Scale, Revised Children's Manifest Anxiety Scale, State
5 Trait Anxiety Inventory for Children, Beck Depression Inventory, Children's
6 Depression Rating Scale Revised, Hamilton Depression Rating Scale. If the above
7 scales are not available, other valid scales on internalizing problems will be used.
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13 3. Social functioning, measured by the end-point score (at post-treatment) from
14 social functioning scales, such as Children's Global Assessment Scale, Social
15 Competence Inventory, Matson Evaluation of Social Skills with Youngsters,
16 School Social Behavior Scales, Social Skills Improvement System Rating Scales.
17 If the above scales are not available, other valid scales on social functioning will
18 be used.
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25 **Search strategy**

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28 Ten electronic databases, including Web of Science, PubMed, PsycINFO, MEDLINE,
29 APA PsycArticles, Psychology and Behavioral Sciences Collection, Open
30 Dissertations, The Cochrane Library, Embase, and CINAHL will be searched without
31 restriction on language, publication status, or publication period. We take Web of
32 Science as an example, the following search terms are applied:
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40 TS=("conduct problem*" OR "conduct disorder*" OR "oppositional behavior*" OR
41 "oppositional behaviour*" OR "oppositional defiant disorder*" OR "externalizing
42 behavior*" OR "externalizing behaviour*" OR "externalizing disorder*" OR
43 "disruptive behavior disorder*" OR "disruptive behaviour disorder*" OR "disruptive
44 behavior*" OR "disruptive behaviour*")
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51 AND TS=(youth* OR child* OR adolescent* OR juvenile* OR boy* OR girl* OR
52 parent* OR teenage*)
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56 AND TS=(intervention OR therapy OR treatment OR evaluation OR "randomized
57 controlled trial" OR "controlled clinical trial" OR effectiveness OR efficacy OR
58 "controlled trial" OR randomized OR trial)
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4 NOT TS=(animal*)
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7 NOT TS=(pharmacolo*)
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10 In order not to omit any relevant research, we will search eligible studies of reviews
11 and meta-analyses on related topics, and further search reference lists of all eligible
12 studies manually. Moreover, we will contact the corresponding author to complement
13 incomplete data.
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18 19 **Selection of studies and data extraction** 20

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22 All results generated from systematic searches will be imported in Noteexpress and
23 duplicates will be excluded. Two independent authors will identify initially 10% of
24 studies from the titles and abstracts according to the predefined eligibility criteria for
25 ensuring consistency. If a high level of inconsistency occurs, the eligibility criteria of
26 the studies will be clarified through a discussion with a senior researcher. If there is a
27 high degree of consistency, all potentially eligible articles will be identified from titles
28 and abstracts by the two authors independently and disagreements will be resolved by
29 a senior researcher. Then, all full-text potentially eligible articles will be obtained and
30 screened by the two independent authors according to the same criteria and
31 disagreements will be resolved as aforementioned. Additional information will be
32 obtained from study authors if required. Reasons for exclusion for each trial will be
33 reported at the stage of full-text screening. Finally, the process of study selection will
34 be shown by using a PRISMA flow chart.
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48 49 **Data extraction** 50

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52 The following data will be extracted by two authors independently from all selected
53 trials and disagreements will be resolved by a senior researcher if required.
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56
57 Study characteristics include study title, study authors, publication year, publication
58 type, publication journal, country and source of funding, study design, randomization,
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4 and blinding.
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7 Participant characteristics include age, gender, race/ethnicity (if it was reported in the
8 study), socioeconomic status (if it was reported in the study), sample size, diagnostic
9 criteria for CDPs, comorbidities, and the total number of participants.
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12

13
14 Intervention characteristics include the type of psychosocial therapy, delivery
15 conditions (parent training program, parent and child training program for children
16 with complex needs, foster carer/guardian training program, child-focused program,
17 or multimodal interventions), delivery medium (Internet-based or face-to-face),
18 delivery format (group, individual or group plus individual), treatment setting,
19 duration of a session, number of sessions, frequency of treatment, length of treatment,
20 people who delivered the treatment, follow-up duration, and co-interventions.
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29 Outcome measures include scores of mean and standard deviation, number of
30 participants, and people who rated the outcome (i.e. children, parents, teachers,
31 clinicians, or researchers) for each predefined outcome.
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36 Adherence measures include the total number of subjects at pre- and post-treatment
37 and at follow-up measurements, and reasons for attrition to treatment.
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41 Data at the closest time point to six-month follow-up will be extracted if data for
42 multiple follow-up time points were provided in the studies. We will contact the
43 corresponding authors by sending emails if any information that we want to extract
44 was not provided in their studies.
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50 Risk of bias assessment 51 52

53 The risk of bias assessment will be assessed by two authors independently according
54 to the revised Cochrane Collaboration's risk of bias tool (RoB 2.0) for RCTs.²⁶ Any
55 disagreement will be resolved by a senior researcher if required. The overall risk of
56 bias will be rated as 'low risk' (i.e. low risk of bias in all domains), 'high risk' (i.e.
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4 high risk of bias in at least one domain, or having some concerns in multiple domains),
5 or 'some concerns' (i.e. having some concerns in at least one domain and no high risk
6 of bias in any domain). Specifically, we will answer the signaling questions following
7 available algorithms and judge the risk of bias as low, high, or some concerns for each
8 domain: (1) bias deriving from the randomization process (e.g. sequence generation
9 and allocation concealment), (2) bias arising from the blinding (e.g. blinding of
10 participants and blinding of outcome assessors), (3) bias caused by incomplete
11 outcome data, (4) bias due to the measurement of outcome and (5) bias due to the
12 selective reporting. The result of the assessment of the risk of bias will be presented in
13 a risk of bias summary graph.
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24 **Data analysis**

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27 Bayesian NMA with random-effects model will be performed by using WinBUGS
28 V.1.4.3 to synthesize all evidence for each outcome. Compared with frequentist
29 approach, Bayesian framework can benefit decision making, which can help create
30 stable estimates and their credible intervals, which is further advantageous for making
31 probabilistic statements and predictions on the treatment effects more
32 straightforward.²⁷ Besides the Bayesian NMA, conventional pairwise meta-analyses
33 with random-effects model will be employed for the comparison between active
34 treatments and control arms by using Stata V.16. as a reference for the results of
35 NMAs.
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46 For continuous outcomes, standardized mean difference (SMD) will be used as a
47 measurement of effect size. We will use published mean values and SDs, if not
48 available, we will estimate values by conversion from SEs, *p* values, CIs, or *t*-values.
49 We will contact the authors of the study to obtain information if none of the above
50 values is provided in the published paper. If we cannot obtain the information using
51 this approach, missing SDs will be derived from those of the other studies using a
52 validated imputation technique.²⁸ For the dichotomous outcome, the risk ratio (RR)
53 and its 95% CIs will be calculated as effect sizes. Missing data will be managed with
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4 respect to the intention to treat (ITT) principle. Participants who drop out after
5 randomization are regarded as non-responders.
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8
9 In order to assess the transitivity assumption of NMA, we will assess the distribution
10 of clinical and methodological variables.²⁹ Concerning clinical variables, we have
11 assured the transitivity by limiting our samples to participants with CDPs and
12 excluding participants with comorbid psychiatric disorders (autism spectrum disorder,
13 depressive disorder, anxiety disorder, etc.), or intellectual, or neurological, or physical
14 disability. Other clinical or methodological variables that may influence the efficacy
15 of psychosocial treatments include age, number of sessions, length of treatment.
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24 Heterogeneity will be assessed using the I^2 statistic and its 95% confidence interval
25 (CI). For visualization, the overlap of the CIs will be shown with forest plots. For the
26 NMA, we assume a common heterogeneity variance across the various treatment
27 comparisons and assess it with τ^2 . Possible reasons for heterogeneity will be examined
28 by subgroup analysis.
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34 Furthermore, we will assess the global inconsistency as well as local inconsistency.
35 Global consistency will be evaluated by calculating the design-by-treatment
36 interaction test. The local inconsistency will be evaluated by comparing the
37 disagreement between direct and indirect evidence in evidence loops. The results of
38 the inconsistency test will be interpreted with caution because the test is known to
39 have low power.³⁰
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48 Finally, the surface under the cumulative ranking curve (SUCRA) and mean ranks
49 will be used to summarize the probabilities of treatments and provide a hierarchy of
50 competing treatments.
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55 Subgroup analyses, meta-regression, and sensitivity analyses
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58 If there are sufficient data in each subgroup, we will conduct a subgroup analysis to
59 examine how treatment efficacy varies across different subgroups: (1) study setting
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4 (clinic, school or community) and (2) outcome rater (child, parent, teacher, clinician
5 or researcher). Besides, we will conduct network meta-regression meta-analyses of
6 data on the outcome of efficacy at post-treatment to evaluate the influence of the
7 following potential moderators: (1) age group, (2) number of sessions, and (3) length
8 of treatment. Moreover, we will explore the sensitivity analyses by excluding: (1)
9 studies in which missing data have been imputed, (2) studies in which high risk of
10 bias rating have been assessed, and (3) studies in which participants comorbidity with
11 ADHD have been included.
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20 Publication bias

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23 First, if ten or more studies are included in the NMA, funnel plots of pairwise NMAs
24 will be examined. Moreover, comparison-adjusted funnel plots will be used to
25 examine the association between study size and effect size. Furthermore, Egger's test
26 will be used to examine the significance of publication bias.
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32 Quality of the evidence

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35 Grading of Recommendations Assessment, Development, and Evaluation framework
36 specifically developed for NMA will be applied to evaluate the quality of evidence.³¹
37 Specifically, we will characterize the credibility of a body of evidence on the basis of
38 within-study bias, reporting bias, indirectness, imprecision, heterogeneity, and
39 incoherence by using the CINeMA software.³² The starting point for confidence in
40 each network estimate is high but will be downgraded according to the assessments of
41 the above six domains.
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50 Ethics and dissemination

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53 The NMA does not need ethical approval as no primary data are collected, and none
54 human nor animal participants will be involved directly. Findings of the present
55 research are planned to be published at national or international psychological
56 conferences, or in a reputable scientific journal.
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DISCUSSION AND SUMMARY

The systematic review and NMA will provide an overview and information on the comparative efficacy and acceptability of psychosocial treatments for children and adolescents with CDPs. The results will show a hierarchy of comparative efficacy with regard to symptoms of CDPs at post-treatment and follow-up, as well as in terms of acceptability, improvement of internalizing problems, and improvement of social functioning. To the best of our knowledge, this study will be the first NMA focusing on the treatment types rather than the delivery conditions in investigating the hierarchy of effectiveness and acceptability of psychosocial treatments for CDPs. The findings are expected to assist psychological counselors, psychotherapists, and social workers to make a better and evidence-based treatment choice.

It is worth noting that the findings need to be understood in light of study limitations. First, because of the fact that CDPs have high comorbidity with ADHD, we will not exclude trials with participants suffering CDPs comorbid with ADHD. Although results will reflect the real situation and contribute to more generalizable inferences, the risk of bias for outcomes will be raised. Second, when interpreting the results of NMA, we have to consider the heterogeneity of some variables (e.g. duration of the treatment), which are not always the same across psychosocial treatments.

Contributors LZ designed this study and drafted the protocol. ZR, XM, DR, GJ critically revised the protocol. LZ will screen search results for inclusion, conduct data extraction and data analysis and draft the final manuscript. XM, CZ will assist with data extraction and analysis and revise the final manuscript. ZZ and QL will screen search results for inclusion and conduct data extraction. All authors contributed to and have approved the final manuscript.

Competing interests The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as potential competing interests.

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Provenance and peer review Not commissioned; externally peer-reviewed.

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For peer review only

Table S1 Descriptions and examples of common psychosocial treatment types and control conditions

Treatments	Abbreviation	Description	Example (review or meta-analysis or trails)
Art Therapy	AT	AT uses art medium, including drawing, painting, clay to enable psychological change and personal growth of children and adolescents.	Moula ¹
Behavioral Therapy	BT	BT trains participants (children and adolescents, parents, teachers, etc.) using behavior management techniques such as differential reinforcement.	Axberg and Broberg ²
Cognitive Behavioral Therapy	CBT	CBT combines BT with CT. CBT techniques commonly involve social skill training, cognitive restructuring, problem-solving, anger management.	Chen et al. ³
Family Therapy	FT	FT works with youths and their families, in order to address family dysfunction by changing maladaptive patterns of interaction between family members, like parent-child interaction therapy.	van der Pol et al. ⁴
Mindfulness	MBT	MBT trains youths' attentional awareness, strengthens the capacity of emotional and behavioral regulation and generates a shift in one's view of self.	Simpson et al. ⁵
Multisystemic Therapy	MST	MST targets to address problems regarding environmental systems.	Tan and Fajardo ⁶
Narrative Therapy	NAT	NAT uses narrative techniques like storytelling to cope with children and adolescents' aggression and anger.	Hosseini et al. ⁷
Play Therapy	PT	PT copes with aggressive behavior, hostility, anger, etc. in recreational activities.	Bagherizadeh et al. ⁸
Psychodynamic Therapy	DYN	DYN emphasizes youths' unconscious feelings and the effect of unconscious feelings on their behavior and emotions.	Weitkamp et al. ⁹
Psychoeducation	PE	PE provides education or information to participants.	van der Put ¹⁰
Control Conditions			
Treatment as Usual	TAU	TAU represents an usual treatment. It may involve in some components of psychosocial treatment and have some treatment effects, but is not a structured or formal psychosocial treatment.	-

Table S1 Descriptions and examples of common psychosocial treatment types and control conditions

Treatments	Abbreviation	Description	Example (review or meta-analysis or trails)
Waitlist	WL	WL means that participants in this control group receive any psychosocial treatments during the study, but are told they will receive one when the study finishes.	-
No treatment	NT	NT stands for that neither during the study nor the study finishes, participants in this control group will not receive any psychosocial treatments.	-

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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on Page
Administrative information			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	1
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	3
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	1, 16
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	
Support:			

Sources	5a	Indicate sources of financial or other support for the review	16
Sponsor	5b	Provide name for the review funder and/or sponsor	16
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	16
Introduction			
Rationale	6	Describe the rationale for the review in the context of what is already known	3-6
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
Methods			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	6-10
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	10-11
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	10-11
Study records:			

Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	11-12
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	11-13
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	11-12
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	12-13
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	9-10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	12-13
	15a	Describe criteria under which study data will be quantitatively synthesised	13-16
Data synthesis	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I ² , Kendall's τ)	13-16
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	14-15

	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	13-16
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies or selective reporting within studies)	15
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	15

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

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Comparative efficacy and acceptability of psychosocial treatments for disruptive behaviour disorders in children and adolescents: study protocol for a systematic review and network meta-analysis

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Comparative efficacy and acceptability of psychosocial treatments for disruptive behaviour disorders in children and adolescents: study protocol for a systematic review and network meta-analysis

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1 ABSTRACT

2 **Introduction** Disruptive behaviour disorders are common among children and
3 adolescents, with negative impacts on the youths, their families, and society.
4 Although multiple psychosocial treatments are effective in decreasing the symptoms
5 of disruptive behaviour disorders, comprehensive evidence regarding the comparative
6 efficacy and acceptability between these treatments is still lacking. Therefore, we
7 propose a systematic review and network meta-analysis, integrating both direct and
8 indirect comparisons to obtain a hierarchy of treatment efficacy and acceptability.

9 **Methods and analysis** The present protocol will be reported according to Preferred
10 Reporting Items for Systematic Reviews and Meta-Analyses Protocols. Ten databases,
11 including Web of Science, PubMed, PsycINFO, MEDLINE, APA PsycArticles,
12 Psychology and Behavioral Sciences Collection, OpenDissertations, The Cochrane
13 Library, Embase, and CINAHL, will be searched from inception for randomized
14 controlled trials of psychosocial treatments for children and adolescents with
15 disruptive behaviour disorders, without restrictions on language, publication year and
16 status. The primary outcomes will be efficacy at post-treatment (severity of disruptive
17 behaviour disorders at post-treatment) and acceptability (dropout rate for any reason)
18 of psychosocial treatments. The secondary outcomes will involve efficacy at
19 follow-up, severity of internalizing problems, and improvement of social functioning.
20 Two authors will independently conduct the study selection and data extraction,
21 assess the risk of bias using the revised Cochrane Collaboration's Risk of Bias tool,
22 and evaluate the quality of the evidence using the Grading of Recommendations
23 Assessment, Development and Evaluation framework to network meta-analysis. We
24 will perform Bayesian network meta-analyses with random-effects model. Subgroup
25 and sensitivity analyses will be performed to evaluate the robustness of the findings.

26 **Ethics and dissemination** The research does not require ethical approval. Results are
27 planned to be published in journals or presented at conferences. The network
28 meta-analysis will provide information on a hierarchy of treatment efficacy and

29 acceptability and help make a clinical treatment choice.

30 **PROSPERO registration number** CRD42020197448

31 **Strengths and limitations of this study**

32 Bayesian network meta-analysis can synthesize all direct and indirect evidence and
33 allows the comparison of multiple treatments simultaneously within a single analysis.

34 We investigate psychosocial treatment types rather than delivery conditions for
35 treating disruptive behaviour disorders, which contributes to complement the
36 guidelines of National Institute for Health and Care Excellence.

37 Bayesian network meta-analysis will provide a hierarchy of effectiveness and
38 acceptability of all psychosocial types for treatments of disruptive behaviour disorders,
39 which can help clinical practitioners make optimal and evidence-based decisions.

40 We will not exclude trials with participants suffering disruptive behaviour disorders
41 comorbid with attention deficit and hyperactivity disorder, which may raise the risk of
42 bias for outcomes.

43 The generalizability may be impacted by the differences between treatments within
44 categories/nodes.

45 **BACKGROUND**

46 Disruptive behavior disorders (DBDs), which include conduct disorder (CD) and
47 oppositional defiant disorder (ODD),¹ are common mental and behavioral problems
48 among children and adolescents (more common in boys than in girls), affecting more
49 than 50 million children and adolescents worldwide according to the survey by Global
50 Burden of Disease Study 2013 Collaborators.² According to the Diagnostic and
51 Statistical Manual of Mental Disorders, fifth edition (DSM-5), CD is characterized by
52 repetitive and persistent patterns of antisocial, aggressive, or rule-breaking behavior.

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4 53 ODD is characterized by irritable mood, argumentative behaviour or vindictiveness.³
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6 54 Patients with DBDs have a high rate of comorbidity with other mental health
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8 55 problems such as attention deficit hyperactivity disorder (ADHD).⁴ DBDs is costly,
9
10 56 and can persist over time and bring about many serious consequences to the
11
12 57 individual, school, family, and society, including poor physical health, poor school
13
14 58 performance, social disadvantage, family conflicts, and criminal behaviors.⁵ Besides,
15
16 59 untreated CD not only can influence the functioning and quality of life of children and
17
18 60 adolescents during their childhood and adolescence but also may develop into
19
20 61 antisocial personality in their adulthood.⁶ On the contrary, an effective treatment
21
22 62 could increase adaptive behaviors, improve social functioning and further save 128
23
24 63 disability-adjusted life years (DALY) per 100,000 boys and 90 DALY per 100,000
25
26 64 girls in the United States.⁷ Given the adverse influence of DBDs and the benefits of
27
28 65 effective treatment, researchers and practitioners have devoted their efforts to
29
30 66 providing professional treatments effectively and timely to children and adolescents
31
32 67 with DBDs.

33
34 68 Several disciplines, such as developmental psychopathology, child psychiatry, and
35
36 69 social psychology, have contributed to understanding the course, causes, and
37
38 70 development of DBDs, and have yielded different perspectives for treating DBDs.
39
40 71 Among the evidence-based interventions, psychosocial treatment is an important
41
42 72 approach for treating DBDs, taking priority over the pharmacological treatment.
43
44 73 Although some medications (e.g. risperidone) may have beneficial effects for DBDs,
45
46 74 they have side effects and are not suggested for routine management.⁴ Evidence from
47
48 75 previous meta-analyses indicated that psychosocial treatment can significantly
49
50 76 improve DBDs,^{1 8 9} thence, this study focuses on psychosocial treatment for youth
51
52 77 with DBDs. To date, there are many types of psychosocial treatments available for
53
54 78 treating DBDs, such as behavior therapy (BT),¹⁰ cognitive-behavioral therapy
55
56 79 (CBT),¹¹ psychodynamic therapy (DYN),¹² and play therapy (PT).¹³ These
57
58 80 psychosocial treatments can be delivered with diverse conditions, including parent
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60 81 training programs, foster carer/guardian training programs, child-focused programs,

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4 82 multimodal interventions.⁴ Regarding the suitable delivery conditions for different age
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6 83 groups, National Institute for Health and Care Excellence (NICE) has recommended
7
8 84 (1) parent and foster carer or guardian training programs or (2) child-focused
9
10 85 programs or (3) parent and child training programs, for children and adolescents with
11
12 86 DBDs aged 3-14. Meanwhile, for children and adolescents aged 11-17 NICE has
13
14 87 recommended multimodal interventions. Previous research has not checked the
15
16 88 comparative effectiveness of all the psychosocial treatment types yet, therefore, the
17
18 89 current research will focus mainly on treatment types rather than delivery conditions
19
20 90 unless there are enough numbers of included trials to distinguish between them.
21
22 91 Another concern for psychotherapists, psychological counselors, and social workers is
23
24 92 the acceptability of these psychosocial treatments. Some treatments are not easily
25
26 93 accepted by participants due to high demands, long durations, stigmatization, etc.,
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28 94 even though they can significantly reduce symptoms of DBDs.¹⁴ Besides, due to
29
30 95 methodological restrictions of conventional meta-analyses, it is still unclear which are
31
32 96 the most efficacious and the most acceptable psychosocial treatments for DBDs. Fully
33
34 97 investigating the comparative effectiveness and acceptability of all psychosocial
35
36 98 treatments is beneficial for clinical practitioners to make an optimal and
37
38 99 evidence-based decision on the treatment of DBDs.

40 100 Network meta-analysis (NMA), which can consider both direct (head-to-head
41
42 101 comparison) and indirect (comparison of treatments via a common comparator)
43
44 102 evidence, is an appropriate method to answer the questions above.¹⁵ The standard
45
46 103 pairwise meta-analysis cannot be used to assess relative effects across treatments if
47
48 104 the comparisons have not been evaluated in head-to-head trials. Instead, NMA allows
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50 105 comparison of multiple treatments simultaneously within a single analysis as long as
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52 106 every treatment is connected to at least one of the other treatments under evaluation
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54 107 through direct comparisons.¹⁶ Some researchers have compared the efficacy of
55
56 108 psychotherapies or psychosocial therapies for the treatment of mental illnesses in
57
58 109 children and adolescents, including depression,¹⁷ acute anxiety disorders¹⁸ and
59
60 110 post-traumatic stress disorders (PTSD)¹⁹. One NMA has investigated the comparative

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4 111 effects of psychosocial and pharmacologic interventions for disruptive behavior in
5
6 112 children and adolescents.²⁰ However, the previous NMA grouped the same delivery
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8 113 conditions of psychosocial interventions (i.e. child component, parent component, and
9
10 114 multi-component) into a node. With an increasing body of research investigating the
11
12 115 effectiveness of treatment for DBDs, it is possible to group the same types of
13
14 116 psychosocial treatments into a node and conduct NMA. Besides, the previous research
15
16 117 has not explicitly made a distinction between prevention and treatment, though their
17
18 118 backgrounds, places, and intervention methods are different.²¹ Therefore, the present
19
20 119 protocol aims to address the above limitations and synthesize all direct and indirect
21
22 120 evidence for identifying the optimal psychosocial treatment for children and
23
24 121 adolescents with DBDs.

122 **OBJECTIVES**

123 The purpose of this study is to evaluate and compare the effectiveness and
124 acceptability of psychosocial treatments for DBDs. Specifically, we aim to

- 125 1. assess the relative psychosocial treatment effects at post-treatment for DBDs, in
126 comparison to one another.
- 127 2. determine the acceptability of these psychosocial treatments.
- 128 3. assess the relative psychosocial treatment effects at follow-up for DBDs, in
129 comparison to one another.
- 130 4. compare the effectiveness of psychosocial treatments on the improvement of
131 internalizing problem outcomes at post-treatment in children and adolescents with
132 DBDs.
- 133 5. compare the effectiveness of psychosocial treatments on the improvement of
134 social functioning outcomes at post-treatment in children and adolescents with
135 DBDs.

136 **METHODS AND ANALYSIS**

137 The systematic review and NMA is registered in the PROSPERO database
138 (registration number: CRD42020197448) and has been developed according to the
139 Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols
140 (PRISMA-P) checklist, the extension statement for NMA (PRISMA-NMA), and
141 proposed additional considerations for protocols of systematic reviews including
142 NMA²²⁻²⁴. The planned start and end dates are June 07, 2020 and August 31, 2021,
143 respectively.

144 **Eligibility criteria for study design, participants, treatments and outcomes**

145 Designs of studies

146 All randomized controlled trials (RCTs), including cluster RCTs and first phase of
147 cross-over studies, will be included. Quasi-randomized trials (e.g. randomization by
148 the last number of the date of birth, or day of the week) will be excluded. Moreover,
149 according to many previous NMA, if the sample size is less than ten per arm, the trials
150 will be excluded for ensuring the power. Because the psychosocial treatments are
151 difficult to be conducted in a double-blind design, we will include single-blind RCTs
152 (i.e. raters were blinded) or trials in which participants were assessed by self-rating
153 scales. Considering the validity of young children's reports, we will exclude trials in
154 which outcomes were only reported by children younger than 11 years old. Language,
155 year of publication, publication status will not be restricted.

156 Types of participants

157 Children and adolescents with DBDs, who were no more than 18 years old when they
158 enrolled in trials, will be included. We will identify DBDs by either a formal
159 diagnosis of DBDs on the basis of the Diagnostic and Statistical Manual (DSM) or the
160 International Classification of Diseases (ICD), or a standardized rating scale on DBDs.
161 The common scales measuring DBDs and their clinical cut-off values are shown in

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4 162 Table 1. Trials in which participants have a secondary diagnosis of comorbid
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6 163 psychiatric disorders (autism spectrum disorder, depressive disorder, anxiety disorder,
7
8 164 etc.), or intellectual, or neurological, or physical disability will be excluded. We will
9
10 165 also exclude trials in which participants are at risk of other mental disorders (learning
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12 166 disorder, substance-related disorders, etc). It is noteworthy that trials in which
13
14 167 participants have comorbidity with ADHD or emotional problems (i.e., do not meet
15
16 168 diagnostic criteria for mood disorders, anxiety disorder, etc.) will be included. All
17
18 169 treatment settings (i.e. outpatient, inpatient services, community clinics, and schools)
19
20 170 will be included.

21
22 **Table 1 Hierarchy of DBDs severity scales and their clinical cut-off values**

Hierarchy	Scales	Abbreviation	Clinical Range
1	Eyberg Child Behavior Inventory	ECBI	Norway version: > 90th percentile US version: > 15 for the Problem score scale or/and > 132 for the Intensity score scale (> 93th percentile), problem score > 15
2	Achenbach System of Empirically Based Assessment	ASEBA	> 98th percentile (T score > 70) for oppositional defiant problems or conduct problems in DSM-oriented scales
3	Strengths and Difficulties Questionnaire	SDQ	conduct problems subscale score > 5
4	Revised Behavior Problem Checklist	RBPC	T score > 70 for conduct disorder subscale

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49 172 Types of treatments

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53 173 According to NICE guidelines, psychosocial interventions for DBDs can be delivered
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55 174 through parent training programs, parent and child training programs for children with
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57 175 complex needs, foster carer/guardian training programs, child-focused programs, and
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59 176 multimodal interventions.⁴ Psychosocial interventions are categorized according to

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4 177 the delivery conditions but not treatment types. Table S1 shows descriptions and
5
6 178 examples of common psychosocial treatment types and control conditions on the topic.
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8 179 The effects of many types of psychosocial treatments on DBDs have been explored in
9
10 180 several reviews, traditional meta-analyses, or RCTs. Because CBT is the most
11
12 181 common treatment type for DBDs, CBT with different treatment focuses (social skills
13
14 182 training, anger coping/management training, or problem-solving skills-training)
15
16 183 different delivery conditions (child-focused, parent-focused, or both parent and child
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18 184 involved), delivery mediums (Internet-based or face-to-face) and delivery formats
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20 185 (group, individual or group plus individual) will be separated as independent nodes if
21
22 186 data are available. For the other treatment types, trials comparing the same treatment
23
24 187 types will be grouped into the same node no matter which delivery conditions,
25
26 188 delivery mediums, and delivery formats they used. Control groups include no
27
28 189 treatment, waitlist, and treatment as usual.

30 190 Types of outcome measures

33 191 *Primary outcomes*

- 36
37 192 1. Efficacy at post-treatment, measured using the change score between baseline and
38
39 193 end-point (at post-treatment) from scales assessing the severity of DBDs.²⁵ Where
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41 194 multiple scales are reported, we will extract data from the DBDs severity scales in
42
43 195 a hierarchical fashion (table 1). Besides, when multiple raters report a DBDs
44
45 196 severity scale, we will calculate the composite score according to
46
47 197 NICE-guidelines⁴.
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49
50 198 2. Acceptability of psychosocial treatment, defined as the dropout rate for any reason
51
52 199 during psychological treatments.

55 200 *Secondary outcomes*

58 201 Besides the primary outcomes, we will also assess relative psychosocial treatment
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60 202 effects at follow-up for DBDs because we want to know whether the short-term

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4 203 effects of the psychosocial types are different from the long-term effects. Moreover,
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6 204 we will also compare the effectiveness of psychosocial treatments on the
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8 205 improvement of internalizing problems and social functioning. We focus on these
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10 206 questions because DBDs are always complied with internalizing problems and
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12 207 impairment of social functioning. It would be valuable to examine whether treatments
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14 208 that are effective in decreasing DBDs symptoms are equally effective in improving
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16 209 internalizing problems and social functioning.

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19 210 1. Efficacy at follow up, measured by the change score of DBDs severity scales
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21 211 between baseline and 6-month follow up/ nearest 6-month follow-up.

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24 212 2. Internalizing problems, measured by the change score between baseline and
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26 213 end-point (at post-treatment) from internalizing problem scales, such as
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28 214 Achenbach System of Empirically Based Assessment (i.e. Child Behavior
29
30 215 Checklist, Teacher's Report Form and Youth Self-Report), Revised Behavior
31
32 216 Problem Checklist, Child and Adolescent Functional Assessment Scale, Revised
33
34 217 Children's Manifest Anxiety Scale, State Trait Anxiety Inventory for Children,
35
36 218 Beck Depression Inventory, Children's Depression Rating Scale Revised,
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38 219 Hamilton Depression Rating Scale. If the above scales are not available, other
39
40 220 valid scales on internalizing problems will be used.

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43 221 3. Social functioning, measured by the change score between baseline and end-point
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45 222 (at post-treatment) from social functioning scales, such as Children's Global
46
47 223 Assessment Scale, Social Competence Inventory, Matson Evaluation of Social
48
49 224 Skills with Youngsters, School Social Behavior Scales, Social Skills Improvement
50
51 225 System Rating Scales. If the above scales are not available, other valid scales on
52
53 226 social functioning will be used.

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56 227 **Search strategy**

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59 228 Ten electronic databases, including Web of Science, PubMed, PsycINFO, MEDLINE,
60

229 APA PsycArticles, Psychology and Behavioral Sciences Collection, Open
230 Dissertations, The Cochrane Library, Embase, and CINAHL will be searched without
231 restriction on language, publication status, or publication period. We take Web of
232 Science as an example, the following search terms are applied:

233 TS=("conduct problem*" OR "conduct disorder*" OR "oppositional behavior*" OR
234 "oppositional behaviour*" OR "oppositional defiant disorder*" OR "externalizing
235 behavior*" OR "externalizing behaviour*" OR "externalizing disorder*" OR
236 "disruptive behavior disorder*" OR "disruptive behaviour disorder*" OR "disruptive
237 behavior*" OR "disruptive behaviour*" OR agressi* OR antisocial* OR
238 callous-unemotion* OR delinquen* OR devian* OR hostile OR hostility OR bully*
239 OR bullie*)

240 AND TS=(youth* OR child* OR adolescent* OR juvenile* OR boy* OR girl* OR
241 parent* OR teenage*)

242 AND TS=(intervention OR therapy OR treatment OR evaluation OR "randomized
243 controlled trial" OR "controlled clinical trial" OR effectiveness OR efficacy OR
244 "controlled trial" OR randomized OR trial)

245 NOT TS=(animal*)

246 In order not to omit any relevant research, we will search eligible studies of reviews
247 and meta-analyses on related topics, and further search reference lists of all eligible
248 studies manually. Moreover, we will contact the corresponding author to complement
249 incomplete data.

250 **Selection of studies and data extraction**

251 All results generated from systematic searches will be imported in Noteexpress and
252 duplicates will be excluded. Two independent authors will identify initially 10% of
253 studies from the titles and abstracts according to the predefined eligibility criteria for

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4 254 ensuring consistency. If a high level of inconsistency occurs, the eligibility criteria of
5
6 255 the studies will be clarified through a discussion with a senior researcher. If there is a
7
8 256 high degree of consistency, all potentially eligible articles will be identified from titles
9
10 257 and abstracts by the two authors independently and disagreements will be resolved by
11
12 258 a senior researcher. Then, all full-text potentially eligible articles will be obtained and
13
14 259 screened by the two independent authors according to the same criteria and
15
16 260 disagreements will be resolved as aforementioned. Additional information will be
17
18 261 obtained from study authors if required. Reasons for exclusion for each trial will be
19
20 262 reported at the stage of full-text screening. Finally, the process of study selection will
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22 263 be shown by using a PRISMA flow chart.

23 24 264 Data extraction

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28 265 The following data will be extracted by two authors independently from all selected
29
30 266 trials and disagreements will be resolved by a senior researcher if required.

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32
33 267 Study characteristics include study title, study authors, publication year, publication
34
35 268 type, publication journal, country and source of funding, study design, randomization,
36
37 269 and blinding.

38
39
40 270 Participant characteristics include age, gender, race/ethnicity (if it was reported in the
41
42 271 study), socioeconomic status (if it was reported in the study), sample size, diagnostic
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44 272 criteria for DBDs, age of onset of DBDs symptoms, comorbidities, baseline severity,
45
46 273 maternal mental health, parent-child relationship, parenting skills, parent readiness for
47
48 274 treatment and the total number of participants.

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51 275 Intervention characteristics include the type of psychosocial therapy, delivery
52
53 276 condition (child-focused, parent-focused, or both parent and child involved), delivery
54
55 277 medium (Internet-based or face-to-face), delivery format (group, individual or group
56
57 278 plus individual), treatment setting, duration of a session, number of sessions,
58
59 279 frequency of treatment, length of treatment, fidelity (ie., the average implementing
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4 280 sessions divided by the total sessions of the program), people who delivered the
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6 281 treatment, follow-up duration, and co-interventions.
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8
9 282 Outcome measures include scores of mean and standard deviation, number of
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11 283 participants, and people who rated the outcome (i.e. children, parents, teachers,
12
13 284 clinicians, or researchers) for each predefined outcome.
14

15
16 285 Adherence measures include the total number of subjects at pre- and post-treatment
17
18 286 and at follow-up measurements, and reasons for attrition to treatment.
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21 287 Data at the closest time point to six-month follow-up will be extracted if data for
22
23 288 multiple follow-up time points were provided in the studies. We will contact the
24
25 289 corresponding authors by sending emails if any information that we want to extract
26
27 290 was not provided in their studies.
28

29 291 Risk of bias assessment 30 31

32
33 292 The risk of bias assessment will be assessed by two authors independently according
34
35 293 to the revised Cochrane Collaboration's risk of bias tool (RoB 2.0) for RCTs.²⁶ Any
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37 294 disagreement will be resolved by a senior researcher if required. The overall risk of
38
39 295 bias will be rated as 'low risk' (i.e. low risk of bias in all domains), 'high risk' (i.e.
40
41 296 high risk of bias in at least one domain, or having some concerns in multiple domains),
42
43 297 or 'some concerns' (i.e. having some concerns in at least one domain and no high risk
44
45 298 of bias in any domain). Specifically, we will answer the signaling questions following
46
47 299 available algorithms and judge the risk of bias as low, high, or some concerns for each
48
49 300 domain: (1) bias deriving from the randomization process (e.g. sequence generation
50
51 301 and allocation concealment), (2) bias arising from the blinding (e.g. blinding of
52
53 302 participants and blinding of outcome assessors), (3) bias caused by incomplete
54
55 303 outcome data, (4) bias due to the measurement of outcome and (5) bias due to the
56
57 304 selective reporting. The result of the assessment of the risk of bias will be presented in
58
59 305 a risk of bias summary graph.
60

306 **Data analysis**

307 Bayesian NMA with random-effects model will be performed by using WinBUGS
308 V.1.4.3 to synthesize all evidence for each outcome. Compared with frequentist
309 approach, Bayesian framework can benefit decision making, which can help create
310 stable estimates and their credible intervals, which is further advantageous for making
311 probabilistic statements and predictions on the treatment effects more
312 straightforward.²⁷ Besides the Bayesian NMA, conventional pairwise meta-analyses
313 with random-effects model will be employed for the comparison between active
314 treatments and control arms by using Stata V.16. as a reference for the results of
315 NMAs.

316 For continuous outcomes, standardized mean difference (SMD) will be used as a
317 measurement of effect size. We will use published mean values and standard
318 deviations (SDs), if not available, we will estimate values by conversion from
319 standard errors (SEs), *p* values, confidence intervals (CIs), or *t*-values. We will
320 contact the authors of the study to obtain information if none of the above values is
321 provided in the published paper. If we cannot obtain the information using this
322 approach, missing SDs will be derived from those of the other studies using a
323 validated imputation technique.²⁸ For the dichotomous outcome, the risk ratio (RR)
324 and its 95% CIs will be calculated as effect sizes. Missing data will be managed with
325 respect to the intention to treat (ITT) principle. Participants who drop out after
326 randomization are regarded as non-responders.

327 In order to assess the transitivity assumption of NMA, we will assess the distribution
328 of clinical and methodological variables.²⁹ Concerning clinical variables, we have
329 assured the transitivity by limiting our samples to participants with DBDs and
330 excluding participants with comorbid psychiatric disorders (autism spectrum disorder,
331 depressive disorder, anxiety disorder, etc.), or intellectual, or neurological, or physical
332 disability. Other clinical or methodological variables that may influence the efficacy
333 of psychosocial treatments include age, number of sessions, length of treatment.

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4 334 Heterogeneity will be assessed using the I^2 statistic and its 95% confidence interval
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6 335 (CI). For visualization, the overlap of the CIs will be shown with forest plots. For the
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8 336 NMA, we assume a common heterogeneity variance across the various treatment
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10 337 comparisons and assess it with τ^2 . Possible reasons for heterogeneity will be examined
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12 338 by subgroup analysis.

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15 339 Furthermore, we will assess the global inconsistency as well as local inconsistency.
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17 340 Global consistency will be evaluated by calculating the design-by-treatment
18
19 341 interaction test. The local inconsistency will be evaluated by comparing the
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21 342 disagreement between direct and indirect evidence in evidence loops. The results of
22
23 343 the inconsistency test will be interpreted with caution because the test is known to
24
25 344 have low power.³⁰

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28 345 Finally, the surface under the cumulative ranking curve (SUCRA) and mean ranks
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30 346 will be used to summarize the probabilities of treatments and provide a hierarchy of
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32 347 competing treatments.

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35 348 Subgroup analyses, meta-regression, and sensitivity analyses

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38 349 If there are sufficient data in each subgroup, we will conduct a subgroup analysis to
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40 350 examine how treatment efficacy varies across different subgroups: (1) study setting
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42 351 (clinic, school or community), (2) age group (3-10 years, 11-14 years or 15-17 years),
43
44 352 The age group is divided according to NICE-guidelines, in which parenting training
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46 353 programmes were recommended for 3-11 years, cognitive behavioural approaches
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48 354 were recommended for 9-14 years, and multimodal programmes were recommended
49
50 355 for 11-17 years. (3) socioeconomic status, (4) outcome rater (composite, mother,
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52 356 father, teacher, child or observer) (5) age of onset of DBDs symptoms (3-10 years or
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54 357 11-17 years) (6) diagnosis (formal diagnosis of ODD, formal diagnosis of CD or
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56 358 scale-assessed DBDs) and (7) country. Besides, we will conduct network
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58 359 meta-regression meta-analyses of data on the outcome of efficacy at post-treatment to
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60 360 evaluate the influence of the following potential moderators: (1) number of sessions,

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4 361 and (2) length of treatment, (3) fidelity (ie., the average implementing sessions
5 362 divided by the total sessions of the program), (4) baseline severity (SDQ, ASEBA,
6 363 ECBI or RBPC score at baseline) (5) maternal mental health, (6) parent-child
7 364 relationship, (7) parenting skills, and (8) parent readiness for treatment. Moreover, we
8 365 will explore the sensitivity analyses by excluding: (1) studies in which missing data
9 366 have been imputed, (2) studies in which high risk of bias rating have been assessed,
10 367 and (3) studies in which participants comorbidity with ADHD have been included.

18 368 Publication bias

21 369 First, if ten or more studies are included in the NMA, funnel plots of pairwise NMAs
22 370 will be examined. Moreover, comparison-adjusted funnel plots will be used to
23 371 examine the association between study size and effect size. Furthermore, Egger's test
24 372 will be used to examine the significance of publication bias.

30 373 Quality of the evidence

33 374 Grading of Recommendations Assessment, Development, and Evaluation framework
34 375 specifically developed for NMA will be applied to evaluate the quality of evidence.³¹
35 376 Specifically, we will characterize the credibility of a body of evidence on the basis of
36 377 within-study bias, reporting bias, indirectness, imprecision, heterogeneity, and
37 378 incoherence by using the CINeMA software.³² The starting point for confidence in
38 379 each network estimate is high but will be downgraded according to the assessments of
39 380 the above six domains.

48 381 Ethics and dissemination

51 382 The NMA does not need ethical approval as no primary data are collected, and none
52 383 human nor animal participants will be involved directly. Findings of the present
53 384 research are planned to be published at national or international psychological
54 385 conferences, or in a reputable scientific journal.

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4 386 Patient and public involvement

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7 387 No patient involved.

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10 388 **DISCUSSION AND SUMMARY**

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13 389 The systematic review and NMA will provide an overview and information on the
14 390 comparative efficacy and acceptability of psychosocial treatments for children and
15 391 adolescents with DBDs. The results will show a hierarchy of comparative efficacy
16 392 with regard to symptoms of DBDs at post-treatment and follow-up, as well as in terms
17 393 of acceptability, improvement of internalizing problems, and improvement of social
18 394 functioning. Moreover, the results of subgroup analysis and meta-regression can help
19 395 personalize the information to the youth, setting or other factors. To the best of our
20 396 knowledge, this study will be the first NMA focusing on the treatment types rather
21 397 than the delivery conditions in investigating the hierarchy of effectiveness and
22 398 acceptability of psychosocial treatments for DBDs. The findings are expected to assist
23 399 psychological counselors, psychotherapists, and social workers to make a better and
24 400 evidence-based treatment choice.

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26
27 401 It is worth noting that the findings need to be understood in light of study limitations.
28 402 First, because of the fact that DBDs have high comorbidity with ADHD, we will not
29 403 exclude trials with participants suffering DBDs comorbid with ADHD. Although
30 404 results will reflect the real situation and contribute to more generalizable inferences,
31 405 the risk of bias for outcomes will be raised. Second, when interpreting the results of
32 406 NMA, we have to consider the heterogeneity of some variables (e.g. duration of the
33 407 treatment), which are not always the same across psychosocial treatments. Last, it is
34 408 an excessive challenge to determine how to separate psychosocial treatments as
35 409 independent nodes because some psychosocial treatments are multicomponent and
36 410 vary in module, content, etc. In further research, we could conduct component NMA
37 411 for a specific psychosocial treatment (eg CBT) to further investigate whether some
38 412 components are superior to others in the DBDs treatment.

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4 413 **Contributors** LZ designed this study and drafted the protocol. ZR, XM, DR, GJ
5 414 critically revised the protocol. LZ will screen search results for inclusion, conduct
6 415 data extraction and data analysis and draft the final manuscript. XM, CZ will assist
7 416 with data extraction and analysis and revise the final manuscript. ZZ and QL will
8 417 screen search results for inclusion and conduct data extraction. All authors contributed
9 418 to and have approved the final manuscript.

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15 419 **Competing interests** The authors declare that the research was conducted in the
16 420 absence of any commercial or financial relationships that could be construed as
17 421 potential competing interests.

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19
20
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22 423 China (16CSH051).

24
25 424 **Patient consent** Not required.

26
27 425 **Provenance and peer review** Not commissioned; externally peer-reviewed.

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Table S1 Descriptions and examples of common psychosocial treatment types and control conditions

Treatments	Abbreviation	Description	Example (review or meta-analysis or trails)
Art Therapy	AT	AT uses art medium, including drawing, painting, clay to enable psychological change and personal growth of children and adolescents.	Moula ¹
Behavioral Therapy	BT	BT trains participants (children and adolescents, parents, teachers, etc.) using behavior management techniques such as differential reinforcement.	Axberg and Broberg ²
Cognitive Behavioral Therapy	CBT	CBT combines BT with CT. CBT techniques commonly involve social skill training, cognitive restructuring, problem-solving, anger management.	Chen et al. ³
Family Therapy	FT	FT works with youths and their families, in order to address family dysfunction by changing maladaptive patterns of interaction between family members, like parent-child interaction therapy.	van der Pol et al. ⁴
Mindfulness	MBT	MBT trains youths' attentional awareness, strengthens the capacity of emotional and behavioral regulation and generates a shift in one's view of self.	Simpson et al. ⁵
Multisystemic Therapy	MST	MST targets to address problems regarding environmental systems.	Tan and Fajardo ⁶
Narrative Therapy	NAT	NAT uses narrative techniques like storytelling to cope with children and adolescents' aggression and anger.	Hosseini et al. ⁷
Play Therapy	PT	PT copes with aggressive behavior, hostility, anger, etc. in recreational activities.	Bagherizadeh et al. ⁸
Psychodynamic Therapy	DYN	DYN emphasizes youths' unconscious feelings and the effect of unconscious feelings on their behavior and emotions.	Weitkamp et al. ⁹
Psychoeducation	PE	PE provides education or information to participants.	van der Put ¹⁰
Control Conditions			
Treatment as Usual	TAU	TAU represents an usual treatment. It may involve in some components of psychosocial treatment and have some treatment effects, but is not a structured or formal psychosocial treatment.	-

Table S1 Descriptions and examples of common psychosocial treatment types and control conditions

Treatments	Abbreviation	Description	Example (review or meta-analysis or trails)
Waitlist	WL	WL means that participants in this control group receive any psychosocial treatments during the study, but are told they will receive one when the study finishes.	-
No treatment	NT	NT stands for that neither during the study nor the study finishes, participants in this control group will not receive any psychosocial treatments.	-

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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on Page
Administrative information			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	1
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	3
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	1, 16
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	
Support:			

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5	Sources	5a	Indicate sources of financial or other support for the review
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7	Sponsor	5b	Provide name for the review funder and/or sponsor
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9	Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
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12	Introduction		
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15	Rationale	6	Describe the rationale for the review in the context of what is already known
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18	Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)
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21	Methods		
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24	Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
25			6-10
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29	Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
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33	Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
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36	Study records:		
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Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	11-12
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	11-13
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	11-12
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	12-13
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	9-10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	12-13
	15a	Describe criteria under which study data will be quantitatively synthesised	13-16
Data synthesis	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I ² , Kendall's τ)	13-16
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	14-15

	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	13-16
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies or selective reporting within studies)	15
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	15

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BMJ Open

Comparative efficacy and acceptability of psychosocial treatments for disruptive behaviour disorders in children and adolescents: study protocol for a systematic review and network meta-analysis

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Primary Subject Heading:	Mental health
Secondary Subject Heading:	Mental health
Keywords:	Child & adolescent psychiatry < PSYCHIATRY, MENTAL HEALTH, Impulse control disorders < PSYCHIATRY

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Comparative efficacy and acceptability of psychosocial treatments for disruptive behaviour disorders in children and adolescents: study protocol for a systematic review and network meta-analysis

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Word count: 3959

Keywords: disruptive behaviour disorders, psychosocial treatment, children and adolescents, network meta-analysis, protocol

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4 29 acceptability and help make a clinical treatment choice.
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7 30 **PROSPERO registration number** CRD42020197448
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10 31 **Strengths and limitations of this study**

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13 32 Bayesian network meta-analysis can synthesize all direct and indirect evidence and
14 33 allows the comparison of multiple treatments simultaneously within a single analysis.
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18 34 We investigate psychosocial treatment types rather than delivery conditions for
19 35 treating disruptive behaviour disorders, which contributes to complement the
20 36 guidelines of National Institute for Health and Care Excellence.
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25 37 Bayesian network meta-analysis will provide a hierarchy of effectiveness and
26 38 acceptability of all psychosocial treatment types for disruptive behaviour disorders,
27 39 which can help clinical practitioners make optimal and evidence-based decisions.
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33 41 comorbid with attention deficit and hyperactivity disorder, which may raise the risk of
34 42 bias for outcomes.
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39 43 The generalizability may be impacted by the differences between treatments within
40 44 categories/nodes.
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43 45 **BACKGROUND**

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48 46 Disruptive behaviour disorders (DBDs), which include conduct disorder (CD) and
49 47 oppositional defiant disorder (ODD),¹ are common mental and behavioral problems
50 48 among children and adolescents (more common in boys than in girls), affecting more
51 49 than 50 million children and adolescents worldwide according to the survey by Global
52 50 Burden of Disease Study 2013 Collaborators.² According to the Diagnostic and
53 51 Statistical Manual of Mental Disorders, fifth edition (DSM-5), CD is characterized by
54 52 repetitive and persistent patterns of antisocial, aggressive, or rule-breaking behaviour.
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4 53 ODD is characterized by irritable mood, argumentative behaviour, or vindictiveness.³
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6 54 Patients with DBDs have a high rate of comorbidity with other mental health
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8 55 problems such as attention deficit hyperactivity disorder (ADHD).⁴ DBDs are costly
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10 56 and can persist over time and bring about many serious consequences to the
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12 57 individual, school, family, and society, including poor physical health, poor school
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14 58 performance, social disadvantage, family conflicts, and criminal behaviors.⁵ Besides,
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16 59 untreated CD not only can influence the functioning and quality of life of children and
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18 60 adolescents during their childhood and adolescence but also may develop into
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20 61 antisocial personality in their adulthood.⁶ On the contrary, an effective treatment
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22 62 could increase adaptive behaviours, improve social functioning and further save 128
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24 63 disability-adjusted life years (DALY) per 100,000 boys and 90 DALY per 100,000
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26 64 girls in the United States.⁷ Given the adverse influence of DBDs and the benefits of
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28 65 effective treatment, researchers and practitioners have devoted their efforts to
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30 66 providing professional treatments effectively and timely to children and adolescents
31
32 67 with DBDs.

33
34 68 Several disciplines, such as developmental psychopathology, child psychiatry, and
35
36 69 social psychology, have contributed to understanding the course, causes, and
37
38 70 development of DBDs, and have yielded different perspectives for treating DBDs.
39
40 71 Among the evidence-based interventions, psychosocial treatment is an important
41
42 72 approach for treating DBDs, taking priority over pharmacological treatment.
43
44 73 Although some medications (e.g. risperidone) may have beneficial effects for DBDs,
45
46 74 they have side effects and are not suggested for routine management.⁴ Evidence from
47
48 75 previous meta-analyses indicates that psychosocial treatment can significantly
49
50 76 improve DBDs,^{1 8 9} thence, this study will focus on psychosocial treatment for youth
51
52 77 with DBDs. To date, there are many types of psychosocial treatments available for
53
54 78 treating DBDs, such as behavior therapy (BT),¹⁰ cognitive-behavioural therapy
55
56 79 (CBT),¹¹ psychodynamic therapy (DYN),¹² and play therapy (PT).¹³ These
57
58 80 psychosocial treatments can be delivered with diverse conditions, including parent
59
60 81 training programmes, foster carer/guardian training programmes, child-focused

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3
4 82 programmes, multimodal interventions.⁴ National Institute for Health and Care
5
6 83 Excellence (NICE) has suggested suitable delivery conditions for different age groups.
7
8 84 NICE has recommended (1) parent and foster carer or guardian training programmes
9
10 85 or (2) child-focused programmes or (3) parent and child training programmes, for
11
12 86 children and adolescents with DBDs aged 3-14. Meanwhile, for children and
13
14 87 adolescents aged 11-17 NICE has recommended multimodal interventions. Previous
15
16 88 research has not checked the comparative effectiveness of all the psychosocial
17
18 89 treatment types yet, therefore, the current research will focus mainly on treatment
19
20 90 types rather than delivery conditions unless there are enough numbers of included
21
22 91 trials to distinguish between them. Another concern for psychotherapists,
23
24 92 psychological counselors, and social workers is the acceptability of these
25
26 93 psychosocial treatments. Some treatments are not easily accepted by participants due
27
28 94 to high demands, long durations, stigmatization, etc., even though they can
29
30 95 significantly reduce symptoms of DBDs.¹⁴ Besides, due to methodological restrictions
31
32 96 of conventional meta-analyses, it is still unclear which are the most efficacious and
33
34 97 the most acceptable psychosocial treatments for DBDs. Fully investigating the
35
36 98 comparative effectiveness and acceptability of all psychosocial treatments is
37
38 99 beneficial for clinical practitioners to make an optimal and evidence-based decision
39
40 100 on the treatment of DBDs.

41
42 101 Network meta-analysis (NMA), which can consider both direct (head-to-head
43
44 102 comparison) and indirect (comparison of treatments via a common comparator)
45
46 103 evidence, is an appropriate method to answer the questions above.¹⁵ The standard
47
48 104 pairwise meta-analysis cannot be used to assess relative effects across treatments if
49
50 105 the comparisons have not been evaluated in head-to-head trials. Instead, NMA allows
51
52 106 the comparison of multiple treatments simultaneously within a single analysis as long
53
54 107 as every treatment is connected to at least one of the other treatments under evaluation
55
56 108 through direct comparisons.¹⁶ Some researchers have compared the efficacy of
57
58 109 psychotherapies or psychosocial therapies for the treatment of mental illnesses in
59
60 110 children and adolescents, including depression,¹⁷ acute anxiety disorders,¹⁸ and

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2
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4 111 post-traumatic stress disorders (PTSD).¹⁹ One NMA has investigated the comparative
5
6 112 effects of psychosocial and pharmacologic interventions for disruptive behavior in
7
8 113 children and adolescents.²⁰ However, the previous NMA grouped the same delivery
9
10 114 conditions of psychosocial interventions (i.e. child component, parent component, and
11
12 115 multi-component) into a node. With an increasing body of research investigating the
13
14 116 effectiveness of treatment for DBDs, it is possible to group the same types of
15
16 117 psychosocial treatments into a node and conduct NMA. Besides, the previous research
17
18 118 has not explicitly made a distinction between prevention and treatment, though their
19
20 119 backgrounds, places, and intervention methods are different.²¹ Therefore, the present
21
22 120 protocol aims to address the above limitations and synthesize all direct and indirect
23
24 121 evidence for identifying the optimal psychosocial treatment for children and
25
26 122 adolescents with DBDs.

123 **OBJECTIVES**

124 The purpose of this study is to evaluate and compare the effectiveness and
125 acceptability of psychosocial treatments for DBDs. Specifically, we aim to

- 126 1. assess the relative psychosocial treatment effects at post-treatment for DBDs, in
127 comparison to one another.
- 128 2. determine the acceptability of these psychosocial treatments.
- 129 3. assess the relative psychosocial treatment effects at follow-up for DBDs, in
130 comparison to one another.
- 131 4. compare the effectiveness of psychosocial treatments on the improvement of
132 internalizing problem outcomes at post-treatment in children and adolescents with
133 DBDs.
- 134 5. compare the effectiveness of psychosocial treatments on the improvement of
135 social functioning outcomes at post-treatment in children and adolescents with

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4 136 DBDs.
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7 137 **METHODS AND ANALYSIS**
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10 138 The systematic review and NMA is registered in the PROSPERO database
11
12 139 (registration number: CRD42020197448) and has been developed according to the
13
14 140 Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols
15
16 141 (PRISMA-P) checklist, the extension statement for NMA (PRISMA-NMA), and
17
18 142 proposed additional considerations for protocols of systematic reviews including
19
20 143 NMA.²²⁻²⁴ The planned start and end dates are June 07, 2020 and August 31, 2021,
21
22 144 respectively.
23
24

25 145 **Eligibility criteria for study design, participants, treatments and outcomes**
26
27

28 146 Designs of studies
29
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31 147 All randomized controlled trials (RCTs), including cluster RCTs and first phase of
32
33 148 cross-over studies, will be included. Quasi-randomized trials (e.g. randomization by
34
35 149 the last number of the date of birth, or day of the week) will be excluded. Moreover,
36
37 150 according to many previous NMA,^{18 25} if the sample size is less than ten per arm, the
38
39 151 trials will be excluded for ensuring the power. Because the psychosocial treatments
40
41 152 are difficult to be conducted in a double-blind design, we will include single-blind
42
43 153 RCTs (i.e. raters were blinded) or trials in which participants were assessed by
44
45 154 self-rating scales. Considering the validity of young children's reports, we will
46
47 155 exclude trials in which outcomes were only reported by children younger than 11
48
49 156 years old. Language, year of publication, and publication status will not be restricted.
50
51

52 157 Types of participants
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55 158 Children and adolescents with DBDs, who were no more than 18 years old when they
56
57 159 enrolled in trials, will be included. We will identify DBDs by either a formal
58
59 160 diagnosis of DBDs on the basis of the Diagnostic and Statistical Manual (DSM) or the
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4 161 International Classification of Diseases (ICD) or a standardized rating scale on DBDs.
5
6 162 The common scales measuring DBDs and their clinical cut-off values are shown in
7
8 163 Table 1. Trials in which participants have a secondary diagnosis of comorbid
9
10 164 psychiatric disorders (autism spectrum disorder, depressive disorder, anxiety disorder,
11
12 165 etc.), or intellectual, or neurological, or physical disability will be excluded. We will
13
14 166 also exclude trials in which participants are at risk of other mental disorders (learning
15
16 167 disorder, substance-related disorders, etc). It is noteworthy that trials in which
17
18 168 participants have comorbidity with ADHD or emotional problems (i.e., do not meet
19
20 169 diagnostic criteria for mood disorders, anxiety disorder, etc.) will be included. All
21
22 170 treatment settings (i.e. outpatient, inpatient services, community clinics, and schools)
23
24 171 will be included.

25
26 **Table 1 Hierarchy of DBDs severity scales and their clinical cut-off values**

Hierarchy	Scales	Abbreviation	Clinical Range
1	Eyberg Child Behavior Inventory	ECBI	Norway version: > 90th percentile US version: > 15 for the Problem score scale or/and > 132 for the Intensity score scale (> 93th percentile), problem score > 15
2	Achenbach System of Empirically Based Assessment	ASEBA	> 98th percentile (T score > 70) for oppositional defiant problems or conduct problems in DSM-oriented scales
3	Strengths and Difficulties Questionnaire	SDQ	conduct problems subscale score > 5
4	Revised Behavior Problem Checklist	RBPC	T score > 70 for conduct disorder subscale

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53 173 Types of treatments

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56 174 According to NICE guidelines, psychosocial interventions for DBDs can be delivered
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58 175 through parent training programmes, parent and child training programmes for
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4 176 children with complex needs, foster carer/guardian training programmes,
5
6 177 child-focused programmes, and multimodal interventions.⁴ Psychosocial interventions
7
8 178 are categorized according to the delivery conditions but not treatment types. Table S1
9
10 179 shows descriptions and examples of common psychosocial treatment types and
11
12 180 control conditions on the topic. The effects of many types of psychosocial treatments
13
14 181 on DBDs have been explored in several reviews, traditional meta-analyses, or RCTs.
15
16 182 Because CBT is the most common treatment type for DBDs, CBT with different
17
18 183 treatment focuses (social skills training, anger coping/management training, or
19
20 184 problem-solving skills-training) different delivery conditions (child-focused,
21
22 185 parent-focused, or both parent and child involved), delivery mediums (Internet-based
23
24 186 or face-to-face) and delivery formats (group, individual or group plus individual) will
25
26 187 be separated as independent nodes if data are available. For the other treatment types,
27
28 188 trials comparing the same treatment types will be grouped into the same node no
29
30 189 matter which delivery conditions, delivery mediums, and delivery formats they used.
31
32 190 Control groups include no treatment, waitlist, and treatment as usual.

33 34 191 Types of outcome measures

35 36 37 192 *Primary outcomes*

- 38
39
40 193 1. Efficacy at post-treatment, measured using the change score between baseline and
41
42 194 end-point (at post-treatment) from scales assessing the severity of DBDs.²⁶ Where
43
44 195 multiple scales are reported, we will extract data from the DBDs severity scales in
45
46 196 a hierarchical fashion (table 1). Besides, when multiple raters report a DBDs
47
48 197 severity scale, we will calculate the composite score according to
49
50 198 NICE-guidelines.⁴
- 51
52
53 199 2. Acceptability of psychosocial treatment, defined as the dropout rate for any reason
54
55 200 during psychological treatments.

56 57 58 59 201 *Secondary outcomes*

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4 202 Besides the primary outcomes, we will also assess relative psychosocial treatment
5
6 203 effects at follow-up for DBDs because we want to know whether the short-term
7
8 204 effects of the psychosocial types are different from the long-term effects. Moreover,
9
10 205 we will also compare the effectiveness of psychosocial treatments on the
11
12 206 improvement of internalizing problems and social functioning. We focus on these
13
14 207 questions because DBDs are always complied with internalizing problems and
15
16 208 impairment of social functioning. It would be valuable to examine whether treatments
17
18 209 that are effective in decreasing DBDs symptoms are equally effective in improving
19
20 210 internalizing problems and social functioning.

21
22
23 211 1. Efficacy at follow up, measured by the change score of DBDs severity scales
24
25 212 between baseline and 6-month follow up/ nearest 6-month follow-up.

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27
28 213 2. Internalizing problems, measured by the change score between baseline and
29
30 214 end-point (at post-treatment) from internalizing problem scales, such as
31
32 215 Achenbach System of Empirically Based Assessment (i.e. Child Behavior
33
34 216 Checklist, Teacher's Report Form and Youth Self-Report), Revised Behavior
35
36 217 Problem Checklist, Child and Adolescent Functional Assessment Scale, Revised
37
38 218 Children's Manifest Anxiety Scale, State Trait Anxiety Inventory for Children,
39
40 219 Beck Depression Inventory, Children's Depression Rating Scale Revised,
41
42 220 Hamilton Depression Rating Scale. If the above scales are not available, other
43
44 221 valid scales on internalizing problems will be used.

45
46
47 222 3. Social functioning, measured by the change score between baseline and end-point
48
49 223 (at post-treatment) from social functioning scales, such as Children's Global
50
51 224 Assessment Scale, Social Competence Inventory, Matson Evaluation of Social
52
53 225 Skills with Youngsters, School Social Behavior Scales, Social Skills Improvement
54
55 226 System Rating Scales. If the above scales are not available, other valid scales on
56
57 227 social functioning will be used.

58
59 228 **Search strategy**
60

229 Ten electronic databases, including Web of Science, PubMed, PsycINFO, MEDLINE,
230 APA PsycArticles, Psychology and Behavioral Sciences Collection, Open
231 Dissertations, The Cochrane Library, Embase, and CINAHL will be searched without
232 restriction on language, publication status, or publication period. We take Web of
233 Science as an example, the following search terms are applied:

234 TS=("conduct problem*" OR "conduct disorder*" OR "oppositional behavior*" OR
235 "oppositional behaviour*" OR "oppositional defiant disorder*" OR "externalizing
236 behavior*" OR "externalizing behaviour*" OR "externalizing disorder*" OR
237 "disruptive behavior disorder*" OR "disruptive behaviour disorder*" OR "disruptive
238 behavior*" OR "disruptive behaviour*" OR agressi* OR antisocial* OR
239 callous-unemotion* OR delinquen* OR devian* OR hostile OR hostility OR bully*
240 OR bullie*)

241 AND TS=(youth* OR child* OR adolescent* OR juvenile* OR boy* OR girl* OR
242 parent* OR teenage*)

243 AND TS=(intervention OR therapy OR treatment OR evaluation OR "randomized
244 controlled trial" OR "controlled clinical trial" OR effectiveness OR efficacy OR
245 "controlled trial" OR randomized OR trial)

246 NOT TS=(animal*)

247 In order not to omit any relevant research, we will search eligible studies of reviews
248 and meta-analyses on related topics, and further search reference lists of all eligible
249 studies manually. Moreover, we will contact the corresponding author to complement
250 incomplete data.

251 **Selection of studies and data extraction**

252 All results generated from systematic searches will be imported in Noteexpress and
253 duplicates will be excluded. Two independent authors will identify initially 10% of

1
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3
4 254 studies from the titles and abstracts according to the predefined eligibility criteria for
5
6 255 ensuring consistency. If a high level of inconsistency occurs, the eligibility criteria of
7
8 256 the studies will be clarified through a discussion with a senior researcher. If there is a
9
10 257 high degree of consistency, all potentially eligible articles will be identified from titles
11
12 258 and abstracts by the two authors independently and disagreements will be resolved by
13
14 259 a senior researcher. Then, all full-text potentially eligible articles will be obtained and
15
16 260 screened by the two independent authors according to the same criteria and
17
18 261 disagreements will be resolved as aforementioned. Additional information will be
19
20 262 obtained from study authors if required. Reasons for exclusion for each trial will be
21
22 263 reported at the stage of full-text screening. Finally, the process of study selection will
23
24 264 be shown by using a PRISMA flow chart.

265 Data extraction

266 The following data will be extracted by two authors independently from all selected
267 trials and disagreements will be resolved by a senior researcher if required.

268 Study characteristics include study title, study authors, publication year, publication
269 type, publication journal, country and source of funding, study design, randomization,
270 and blinding.

271 Participant characteristics include age, gender, race/ethnicity (if it was reported in the
272 study), socioeconomic status (if it was reported in the study), sample size, diagnostic
273 criteria for DBDs, age of onset of DBDs symptoms, comorbidities, baseline severity,
274 maternal mental health, parent-child relationship, parenting skills, parent readiness for
275 treatment and the total number of participants.

276 Intervention characteristics include the type of psychosocial therapy, delivery
277 condition (child-focused, parent-focused, or both parent and child involved), delivery
278 medium (Internet-based or face-to-face), delivery format (group, individual or group
279 plus individual), treatment setting, duration of a session, number of sessions,

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4 280 frequency of treatment, length of treatment, fidelity (ie., the average implementing
5 281 sessions divided by the total sessions of the programmes), people who delivered the
6
7 282 treatment, follow-up duration, and co-interventions.
8
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11 283 Outcome measures include scores of mean and standard deviation, number of
12
13 284 participants, and people who rated the outcome (i.e. children, parents, teachers,
14
15 285 clinicians, or researchers) for each predefined outcome.
16

17
18 286 Adherence measures include the total number of subjects at pre- and post-treatment
19
20 287 and at follow-up measurements, and reasons for attrition to treatment.
21

22
23 288 Data at the closest time point to six-month follow-up will be extracted if data for
24
25 289 multiple follow-up time points were provided in the studies. We will contact the
26
27 290 corresponding authors by sending emails if any information that we want to extract
28
29 291 was not provided in their studies.
30

31 32 292 Risk of bias assessment 33

34
35 293 The risk of bias assessment will be assessed by two authors independently according
36
37 294 to the revised Cochrane Collaboration's risk of bias tool (RoB 2.0) for RCTs.²⁷ Any
38
39 295 disagreement will be resolved by a senior researcher if required. The overall risk of
40
41 296 bias will be rated as 'low risk' (i.e. low risk of bias in all domains), 'high risk' (i.e.
42
43 297 high risk of bias in at least one domain, or having some concerns in multiple domains),
44
45 298 or 'some concerns' (i.e. having some concerns in at least one domain and no high risk
46
47 299 of bias in any domain). Specifically, we will answer the signaling questions following
48
49 300 available algorithms and judge the risk of bias as low, high, or some concerns for each
50
51 301 domain: (1) bias deriving from the randomization process (e.g. sequence generation
52
53 302 and allocation concealment), (2) bias arising from the blinding (e.g. blinding of
54
55 303 participants and blinding of outcome assessors), (3) bias caused by incomplete
56
57 304 outcome data, (4) bias due to the measurement of outcome and (5) bias due to the
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4 305 selective reporting. The result of the assessment of the risk of bias will be presented in
5
6 306 a risk of bias summary graph.
7

8 9 307 **Data analysis**

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12 308 Bayesian NMA with a random-effects model will be performed by using WinBUGS
13
14 309 V.1.4.3 to synthesize all evidence for each outcome. Compared with the frequentist
15
16 310 approach, the Bayesian framework can benefit decision making, which can help
17
18 311 create stable estimates and their credible intervals, which is further advantageous for
19
20 312 making probabilistic statements and predictions on the treatment effects more
21
22 313 straightforward.²⁸ Besides the Bayesian NMA, conventional pairwise meta-analyses
23
24 314 with a random-effects model will be employed for the comparison between active
25
26 315 treatments and control arms by using Stata V.16. as a reference for the results of
27
28 316 NMAs.

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31 317 For continuous outcomes, standardized mean difference (SMD) will be used as a
32
33 318 measurement of effect size. We will use published mean values and standard
34
35 319 deviations (SDs), if not available, we will estimate values by conversion from
36
37 320 standard errors (SEs), *p* values, confidence intervals (CIs), or *t*-values. We will
38
39 321 contact the authors of the study to obtain information if none of the above values is
40
41 322 provided in the published paper. If we cannot obtain the information using this
42
43 323 approach, missing SDs will be derived from those of the other studies using a
44
45 324 validated imputation technique.²⁹ For the dichotomous outcome, the risk ratio (RR)
46
47 325 and its 95% CIs will be calculated as effect sizes. Missing data will be managed with
48
49 326 respect to the intention to treat (ITT) principle. Participants who drop out after
50
51 327 randomization are regarded as non-responders.

52
53
54 328 In order to assess the transitivity assumption of NMA, we will assess the distribution
55
56 329 of clinical and methodological variables.³⁰ Concerning clinical variables, we have
57
58 330 assured the transitivity by limiting our samples to participants with DBDs and
59
60 331 excluding participants with comorbid psychiatric disorders (autism spectrum disorder,

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4 332 depressive disorder, anxiety disorder, etc.), or intellectual, or neurological, or physical
5
6 333 disability. Other clinical or methodological variables that may influence the efficacy
7
8 334 of psychosocial treatments include age, number of sessions, length of treatment.
9

10
11 335 Heterogeneity will be assessed using the I^2 statistic and its 95% confidence interval
12
13 336 (CI). For visualization, the overlap of the CIs will be shown with forest plots. For the
14
15 337 NMA, we assume a common heterogeneity variance across the various treatment
16
17 338 comparisons and assess it with τ^2 . Possible reasons for heterogeneity will be examined
18
19 339 by subgroup analysis.

20
21
22 340 Furthermore, we will assess the global inconsistency as well as local inconsistency.
23
24 341 Global consistency will be evaluated by calculating the design-by-treatment
25
26 342 interaction test. The local inconsistency will be evaluated by comparing the
27
28 343 disagreement between direct and indirect evidence in evidence loops. The results of
29
30 344 the inconsistency test will be interpreted with caution because the test is known to
31
32 345 have a low power.³¹

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35 346 Finally, the surface under the cumulative ranking curve (SUCRA) and mean ranks
36
37 347 will be used to summarize the probabilities of treatments and provide a hierarchy of
38
39 348 competing treatments.

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42 349 Subgroup analyses, meta-regression, and sensitivity analyses

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44
45 350 If there are sufficient data in each subgroup, we will conduct a subgroup analysis to
46
47 351 examine how treatment efficacy varies across different subgroups: (1) study setting
48
49 352 (clinic, school, or community), (2) age group (3-10 years, 11-14 years, or 15-17 years),
50
51 353 The age group is divided according to NICE-guidelines, in which parenting training
52
53 354 programmes were recommended for 3-11 years, cognitive behavioural approaches
54
55 355 were recommended for 9-14 years, and multimodal programmes were recommended
56
57 356 for 11-17 years. (3) socioeconomic status, (4) outcome rater (composite, mother,
58
59 357 father, teacher, child or observer) (5) age of onset of DBDs symptoms (3-10 years or
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4 358 11-17 years) (6) diagnosis (formal diagnosis of ODD, formal diagnosis of CD or
5 359 scale-assessed DBDs) and (7) country. Besides, we will conduct network
6 360 meta-regression meta-analyses of data on the outcome of efficacy at post-treatment to
7 361 evaluate the influence of the following potential moderators: (1) number of sessions,
8 362 and (2) length of treatment, (3) fidelity (ie., the average implementing sessions
9 363 divided by the total sessions of the programme), (4) baseline severity (SDQ, ASEBA,
10 364 ECBI or RBPC score at baseline) (5) maternal mental health, (6) parent-child
11 365 relationship, (7) parenting skills, and (8) parent readiness for treatment. Moreover, we
12 366 will explore the sensitivity analyses by excluding: (1) studies in which missing data
13 367 have been imputed, (2) studies in which high risk of bias rating have been assessed,
14 368 and (3) studies in which participants comorbidity with ADHD have been included.

369 Publication bias

370 First, if ten or more studies are included in the NMA, funnel plots of pairwise NMAs
371 will be examined. Moreover, comparison-adjusted funnel plots will be used to
372 examine the association between study size and effect size. Furthermore, Egger's test
373 will be used to examine the significance of publication bias.

374 Quality of the evidence

375 Grading of Recommendations Assessment, Development, and Evaluation framework
376 specifically developed for NMA will be applied to evaluate the quality of evidence.³²
377 Specifically, we will characterize the credibility of a body of evidence on the basis of
378 within-study bias, reporting bias, indirectness, imprecision, heterogeneity, and
379 incoherence by using the CINeMA software.³³ The starting point for confidence in
380 each network estimate is high but will be downgraded according to the assessments of
381 the above six domains.

382 Ethics and dissemination

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4 383 The NMA does not need ethical approval as no primary data are collected, and none
5
6 384 human nor animal participants will be involved directly. Findings of the present
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8 385 research are planned to be published at national or international psychological
9
10 386 conferences, or in a reputable scientific journal.

11
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13 387 Patient and public involvement

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15
16 388 No patient involved.

17 18 19 389 **DISCUSSION AND SUMMARY**

20
21
22 390 The systematic review and NMA will provide an overview and information on the
23
24 391 comparative efficacy and acceptability of psychosocial treatments for children and
25
26 392 adolescents with DBDs. The results will show a hierarchy of comparative efficacy
27
28 393 with regard to symptoms of DBDs at post-treatment and follow-up, as well as in terms
29
30 394 of acceptability, improvement of internalizing problems, and improvement of social
31
32 395 functioning. Moreover, the results of subgroup analysis and meta-regression can help
33
34 396 personalize the information to the youth, setting or other factors. To the best of our
35
36 397 knowledge, this study will be the first NMA focusing on the treatment types rather
37
38 398 than the delivery conditions in investigating the hierarchy of effectiveness and
39
40 399 acceptability of psychosocial treatments for DBDs. The findings are expected to assist
41
42 400 psychological counselors, psychotherapists, and social workers to make a better and
43
44 401 evidence-based treatment choice.

45
46
47 402 It is worth noting that the findings need to be understood in light of study limitations.
48
49 403 First, because of the fact that DBDs have high comorbidity with ADHD, we will not
50
51 404 exclude trials with participants suffering DBDs comorbid with ADHD. Although
52
53 405 results will reflect the real situation and contribute to more generalizable inferences,
54
55 406 the risk of bias for outcomes will be raised. Second, when interpreting the results of
56
57 407 NMA, we have to consider the heterogeneity of some variables (e.g. duration of the
58
59 408 treatment), which are not always the same across psychosocial treatments. Last, it is
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4 409 an excessive challenge to determine how to separate psychosocial treatments as
5
6 410 independent nodes because some psychosocial treatments are multicomponent and
7
8 411 vary in module, content, etc. In further research, we could conduct component NMA
9
10 412 for a specific psychosocial treatment (eg CBT) to further investigate whether some
11
12 413 components are superior to others in the DBDs treatment.

13
14
15 414 **Contributors** LZ designed this study and drafted the protocol. ZR, XM, DR, GJ, FY
16
17 415 critically revised the protocol. LZ will screen search results for inclusion, conduct
18
19 416 data extraction and data analysis and draft the final manuscript. XM, CZ will assist
20
21 417 with data extraction and analysis and revise the final manuscript. ZZ and QL will
22
23 418 screen search results for inclusion and conduct data extraction. All authors contributed
24
25 419 to and have approved the final manuscript.

26
27 420 **Competing interests** The authors declare that the research was conducted in the
28
29 421 absence of any commercial or financial relationships that could be construed as
30
31 422 potential competing interests.

32
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34
35 424 China (16CSH051).

36
37 425 **Patient consent** Not required.

38
39 426 **Provenance and peer review** Not commissioned; externally peer-reviewed.

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46
47 430 their derivative works on different terms, provided the original work is properly cited,
48
49 431 appropriate credit is given, any changes made indicated, and the use is
50
51 432 non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

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53 433

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Table S1 Descriptions and examples of common psychosocial treatment types and control conditions

Treatments	Abbreviation	Description	Example (review or meta-analysis or trails)
Art Therapy	AT	AT uses art medium, including drawing, painting, clay to enable psychological change and personal growth of children and adolescents.	Moula ¹
Behavioral Therapy	BT	BT trains participants (children and adolescents, parents, teachers, etc.) using behavior management techniques such as differential reinforcement.	Axberg and Broberg ²
Cognitive Behavioral Therapy	CBT	CBT combines BT with CT. CBT techniques commonly involve social skill training, cognitive restructuring, problem-solving, anger management.	Chen et al. ³
Family Therapy	FT	FT works with youths and their families, in order to address family dysfunction by changing maladaptive patterns of interaction between family members, like parent-child interaction therapy.	van der Pol et al. ⁴
Mindfulness	MBT	MBT trains youths' attentional awareness, strengthens the capacity of emotional and behavioral regulation and generates a shift in one's view of self.	Simpson et al. ⁵
Multisystemic Therapy	MST	MST targets to address problems regarding environmental systems.	Tan and Fajardo ⁶
Narrative Therapy	NAT	NAT uses narrative techniques like storytelling to cope with children and adolescents' aggression and anger.	Hosseini et al. ⁷
Play Therapy	PT	PT copes with aggressive behavior, hostility, anger, etc. in recreational activities.	Bagherizadeh et al. ⁸
Psychodynamic Therapy	DYN	DYN emphasizes youths' unconscious feelings and the effect of unconscious feelings on their behavior and emotions.	Weitkamp et al. ⁹
Psychoeducation	PE	PE provides education or information to participants.	van der Put ¹⁰
Control Conditions			
Treatment as Usual	TAU	TAU represents an usual treatment. It may involve in some components of psychosocial treatment and have some treatment effects, but is not a structured or formal psychosocial treatment.	-

Table S1 Descriptions and examples of common psychosocial treatment types and control conditions

Treatments	Abbreviation	Description	Example (review or meta-analysis or trails)
Waitlist	WL	WL means that participants in this control group receive any psychosocial treatments during the study, but are told they will receive one when the study finishes.	-
No treatment	NT	NT stands for that neither during the study nor the study finishes, participants in this control group will not receive any psychosocial treatments.	-

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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on Page
Administrative information			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	1
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	3
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	1, 16
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	
Support:			

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5	Sources	5a	Indicate sources of financial or other support for the review	16
6				
7	Sponsor	5b	Provide name for the review funder and/or sponsor	16
8				
9	Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	16
10				
11				
12	Introduction			
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15	Rationale	6	Describe the rationale for the review in the context of what is already known	3-6
16				
17	Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
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21	Methods			
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24	Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	6-10
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29	Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	10-11
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33	Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	10-11
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36	Study records:			
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Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	11-12
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	11-13
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	11-12
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	12-13
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	9-10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	12-13
	15a	Describe criteria under which study data will be quantitatively synthesised	13-16
Data synthesis	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I ² , Kendall's τ)	13-16
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	14-15

	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	13-16
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies or selective reporting within studies)	15
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	15

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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