INPLASY PROTOCOL

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None.

Effectiveness of social skills intervention for the management of children with autism spectrum disorder: a protocol for systematic review and meta-analysis

Shuai, FR[1]; Lin, ZY[2].

Review question / Objective: **Is social skills intervention (SSI) effective and safety for the management of children with autism spectrum disorder (ASD)?**
Condition being studied: **Social skills intervention; autism spectrum disorder.**
Information sources: **We will search all related randomized controlled trials (RCTs) on assessing effectiveness and safety of SSI for children with ASD from Cochrane Library, MEDLINE, EMBASE, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure from inception to the present with no limitations of language and publication time. Search terms will include autism, autism spectrum disorder, Asperger, childhood disintegrative disorder, difficulty with communication, social interactions, imagination, creativity, obsessive interests, repetitive behaviors, social skills training, and education. A search strategy example of Cochrane Library is presented. We will also adapt similar search strategies to the other electronic databases. In addition, any other potential studies will be searched from relevant conference proceedings, dissertations, and reference lists of associated reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 April 2020 and was last updated on 15 April 2020 (registration number INPLASY202040090).

INTRODUCTION

Review question / Objective: **Is social skills intervention (SSI) effective and safety for the management of children with autism spectrum disorder (ASD)?**

Condition being studied: **Social skills intervention; autism spectrum disorder.**

METHODS

Participant or population: **All children (less than 18 years old) with ASD will be included**

in analysis, regardless their ethnicity, gender, and economic status.

Intervention: Any forms of SSI utilized for the treatment of children with ASD will be included as an experimental group.

Comparator: Any other interventions, except SSI used to the children with ASD will be set as a control group in this study.

Study designs to be included: All randomized controlled trials (RCTs) that assess the use of SSI in the treatment of children with ASD will be included.

Eligibility criteria: This study will consider RCTs that examined the use of SSI vs. other treatments for children with ASD.

Information sources: We will search all related randomized controlled trials (RCTs) on assessing effectiveness and safety of SSI for children with ASD from Cochrane Library, MEDLINE, EMBASE, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure from inception to the present with no limitations of language and publication time. Search terms will include autism, autism spectrum disorder, Asperger, childhood disintegrative disorder, difficulty with communication, social interactions, imagination, creativity, obsessive interests, repetitive behaviors, social skills training, and education. A search strategy example of Cochrane Library is presented. We will also adapt similar search strategies to the other electronic databases. In addition, any other potential studies will be searched from relevant conference proceedings, dissertations, and reference lists of associated reviews.

Main outcome(s): The primary outcomes are adaptive behaviors, as measured by Vineland Adaptive Behavior Scale, or other relevant scales.

Additional outcome(s): The secondary outcomes are motor skills, visual reception, communication and language, as assessed by Mullen Scales for Early Learning or others; joint attention, joint engagement, repetitive behaviors, social skills, as checked by Autism Diagnostic Observation Schedule or other associated tools; child anxiety, child distress, parental distress, parental self-efficacy, parent child relationship, self-regulation, and symptom severity, as identified using Aberrant Behavior Checklist, or Autism Treatment Evaluation Checklist, Social Communication Questionnaire and Autism Behavior Checklist, or other scales; and any adverse events.

Data management: Two investigators will independently utilize a previous designed data extraction sheet to collect data. Any discrepancies between two investigators will be solved by a third investigator via consultation. The extracted information on study characteristics (such as title, first author, time of publication, et al), patient characteristics (such as age, gender, diagnostic criteria, et al), study setting, study methods (such as details of randomization, blind, et al), treatment and control details (such as management types, dosage, frequency, et al), outcomes, and conflicts of interest. When there are inadequate or missing data, we will attempt to contact primary corresponding authors by email or telephone to obtain such information. Incomplete data will be regarded if we can not achieve such information.

Quality assessment / Risk of bias analysis: Two investigators will independently assess the study quality using Cochrane Risk of Bias Tool based on the 7 domains, and each one is further assessed as low, unclear or high risk of bias. Any disagreements between two investigators will be solved by a third investigator.

Strategy of data synthesis: RevMan 5.3 software will be applied for statistical analysis according to the homogeneity among eligible studies. Mean difference or standardized mean difference and 95% confidence intervals (CIs) will be calculated for continuous data, while risk ratio and 95% CIs will expressed for dichotomous data. The I^2 statistic will be used for checking heterogeneity among included

studies. I^2 ≤50 means homogeneity, while I^2 >50% means significant heterogeneity. If I^2 ≤50, a fixed-effects model will be used, and meta-analysis will be performed if sufficient studies are included which focus on the similar study and patient characteristics, interventions, controls and outcomes. Conversely, if I^2 >50%, a random-effects model will be applied, and subgroup analysis will be conducted to explore the potential reasons for the significant heterogeneity.

Subgroup analysis: If we detected significant heterogeneity among included studies, subgroup analysis will be carried out according to the different characteristics of study and patient, interventions, comparators, and outcomes.

Sensibility analysis: If sufficient data are available, we will conduct sensitivity analysis to determine whether the merged outcome results are robust by excluding high risk of bias studies.

Country(ies) involved: China.

Keywords: Social skills intervention; autism spectrum disorder; effectiveness; safety.