

INPLASY PROTOCOL

To cite: Xiao et al. Effect of acceptance and commitment therapy to improve psychological wellbeing for parents of children and adolescent with chronic conditions: A protocol for systematic review and meta-analysis of randomized controlled trial. Inplasy protocol 202170101. doi: 10.37766/inplasy2021.7.0101

Received: 31 July 2021

Published: 31 July 2021

Corresponding author:

Na Xiao

554343940@qq.com

Author Affiliation:

Hunan Traditional Chinese Medical College.

Support: XJ201704.

Review Stage at time of this submission: Preliminary searches.

Conflicts of interest:

None declared.

Effect of acceptance and commitment therapy to improve psychological wellbeing for parents of children and adolescent with chronic conditions: A protocol for systematic review and meta-analysis of randomized controlled trial

Xiao, N¹; Yi, LJ²; Lei, JM³; Shi, SN⁴; Nie, WJ⁵.

Review question / Objective: The aim of this systematic review and meta-analysis is to identify the application of Acceptance and Commitment Therapy (ACT) to improve psychological wellbeing in the parents of children and adolescent with chronic conditions. The article aims to determine effectiveness in parental psychological flexibility, mindfulness and psychological symptoms (i.e. depression, anxiety and/or stress).

Information sources: Eight databases (i.e. PubMed, Embase, Cochrane Library, CINAHL, PsychINFO, China national knowledge infrastructure (CNKI), Chinese Biomedical Literature database (CBM) and WanFang Data) were systematically searched from inception to August 2021. In addition, data from gray literature (such as clinical trial registry website) will be searched in case of omissions of potential studies.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 July 2021 and was last updated on 31 July 2021 (registration number INPLASY202170101).

INTRODUCTION

Review question / Objective: The aim of this systematic review and meta-analysis is to identify the application of Acceptance and Commitment Therapy (ACT) to improve

psychological wellbeing in the parents of children and adolescent with chronic conditions. The article aims to determine effectiveness in parental psychological flexibility, mindfulness and psychological

symptoms (i.e. depression, anxiety and/or stress).

Rationale: Acceptance and Commitment Therapy (ACT) as a transdiagnostic intervention, has broad applicability (Dindo et al., 2017). Numerous systematic reviews and meta analyses support its efficacy in multiple conditions including mental health, physical health and behavioural problems (Fischer M et al., 2021; Bai et al., 2020; Law et al., 2019). Acceptance and commitment therapy is an emerging evidenced-based practice, but no systematic review regarding the effects of ACT on parents of children and adolescent with chronic conditions has been conducted. However, systematic reviews about ACT of randomized controlled trial in parents of children with chronic conditions are limited. Limited randomized controlled trials (RCTs) were included in previous reviews because most ACT interventions applied to parents of children with chronic conditions were case studies, pre-post designs or controlled clinical trials (CCTs) (Graham et al., 2016; Han et al., 2020; Jin et al., 2021). Given the lack of systematic review and meta-analysis regarding RCT design, whether the promising results are due to ACT intervention, placebo effect or other non-specific treatment factors is unclear. Thus, A systematic review and meta-analysis of randomized controlled trial of the application of ACT to identify psychological well-being such as psychological flexibility, mindfulness and psychological symptoms (i.e. depression, anxiety and/or stress) among parents of children with chronic conditions is of great significance.

Condition being studied: Pediatric chronic conditions represent a central event constituting a major challenge for families. Parents of children and adolescent with chronic conditions face various challenges after their child's diagnosis, such as the related medical risks, demanding treatment regimens and daily health-related monitoring or tasks with a higher prevalence of anxiety disorders (Pinquart et al., 2019). These diseases have physical, psychological, socioeconomic, and

behavioral effects on patients and their family caregivers that translate into vulnerability and decreased quality of life and family functioning (Toledano et al., 2019). Acceptance and Commitment Therapy (ACT) based on building psychological flexibility is a promising approach for parents of children with chronic conditions (Chong et al., 2019; Muscara et al., 2020; Douma et al., 2020; Lappalainen et al., 2021). ACT posits that difficult experiences are unavoidable; accepting them nonjudgmentally, fully focusing on the present moment and engaging in value-consistent behaviours are probably to result in optimal functioning (Hayes et al., 2004). Yet, much of these studies up to now have not focused on the systematic review (SR) and meta-analysis (MA) of randomized controlled trial, which can provide convincing evidence to verify the effect of psychological well-being in parents of children and adolescent with chronic conditions.

METHODS

Search strategy: Data sources: Eight databases (i.e. PubMed, Embase, Cochrane Library, CINAHL, PsychINFO, China national knowledge infrastructure (CNKI), Chinese Biomedical Literature database (CBM) and WanFang Data) were systematically searched from inception to August 2021. MeSH terms and keywords were used as follows: (1) parents, parent*, caregivers, caregiver*, mothers, mother*, fathers, father*, family, famil*; (2) Acceptance and Commitment Therapy, acceptance-based, commitment-based, psychological flexibility. (3) randomized controlled trial, controlled clinical trial, clinical trials as topic, Random*, Placebo, trial. Other search resources of related websites (e.g. Association for Contextual Behavioural Science: <https://contextualbehavioural.org/>) and the reference lists of relevant papers were manually searched to supplement the database.

Participant or population: Parents were operationally defined as primary caregivers who were responsible for parenting the child, including biological parents and

adoptive parents. Children and adolescents, aged three months to 19 years, with chronic medical conditions that had an expected duration of at least three months. chronic conditions can be any physical, mental, behavioural, or other health condition. We selected chronic conditions from the list of “Current Health Conditions and Functional Difficulties” from the National Survey of Children with Special Health Care Needs 2009 to 2010 (Data Resource Center 2010).

Intervention: Studies involving Acceptance and Commitment Therapy as intervention; Acceptance and Commitment Therapy can be delivered solely or combined with other components.

Comparator: Studies that used any type of comparators, such as waitlist, usual care, or active intervention.

Study designs to be included: Studies that were randomized controlled trials or clinical controlled trials; Studies published in peer-reviewed journals; Studies published in English or Chinese.

Eligibility criteria: Our study will only consider RCT published in English or Chinese without any regional restrictions. All search records will be imported into the EndNote, and the automatic deduplication function will be used to eliminate duplicate records. Two reviewers will independently access the title and abstract of all unique records. Then, reviewers will obtain the full-text publications of all studies that considered to be potentially relevant. Full-text studies that do not meet the inclusion criteria will be excluded, and a list of reasons for excluded will be provided. The two reviewers will check the studies that each other thinks should be included. Any disagreements will be resolved by consensus or with a third reviewer. We will complete a PRISMA flow diagram to summaries the screen process.

Information sources: Eight databases (i.e. PubMed, Embase, Cochrane Library, CINAHL, PsychINFO, China national knowledge infrastructure (CNKI), Chinese

Biomedical Literature database (CBM) and WanFang Data) were systematically searched from inception to August 2021. In addition, data from gray literature (such as clinical trial registry website) will be searched in case of omissions of potential studies.

Main outcome(s): Studies that covered at least one of the following outcomes on parents: parental psychological flexibility, mindfulness ,and psychological symptoms (i.e. depression, anxiety and/or stress).

Additional outcome(s): Studies that covered at least one of the following outcomes on parents: parental psychological flexibility, mindfulness ,and psychological symptoms (i.e. depression, anxiety and/or stress).

Data management: A pre-designed and calibrated standardized data sheet will be used to extract and summarize details of the eligible studies. The calibration process is as follows: using a random sample of three of the included studies, the data extraction form will be pilot-tested, and revised as necessary. We will extract data on the following items: name of the first author, year of publication, study location, study design, participants(Parents and Children), sample size, interventions (intensity, format, providers, setting), follow-up period, outcomes of interest and interpretation. Two reviewers will extract data independently and will resolve disagreements by discussion, drawing on a third review author when required. If the data is incomplete, the authors of the studies will be contacted through email or telephone. Data will be extracted by two author and double-checked by a third author.

Quality assessment / Risk of bias analysis: The Cochrane Risk of Bias(RoB) Tool for RCT s will be used to evaluate the risk of bias of each included RCT s. The RoB tool has seven domains and each aspect is judged as three levels: high risk of bias, unclear risk of bias, and low risk of bias. All domains will be considered, including sequence generation and allocation

sequence concealment(selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment(detection bias), incomplete outcome data(attrition bias), selective reporting(reporting bias), and other biases considered relevant to the review topic. Two reviewers will independently assess the quality of included studies. Any disagreements will be resolved by consensus or with a third reviewer.

Strategy of data synthesis: Direct comparisons of outcomes will be performed using Review Manager 5.4. The outcomes will be mainly represented by the mean difference (MD) or odds ratio (OR) with 95% confidence intervals. For continuous data, the pooled standardized mean differences(SMDs) and their corresponding 95% confidence intervals (95% CIs) were used to assess the strength $P < 0.05$ was considered as statistically significant. The Cochrane Q-test and I^2 statistics were used to assess heterogeneity. When $I^2 > 50\%$, which indicates statistical heterogeneity, a random-effects model will be used to calculate the outcomes; otherwise, a fixed-effects model will be considered.

Subgroup analysis: If heterogeneity is high, we will perform a subgroup analysis(such as different patients, interventions). And if cannot perform subgroup analysis, we will perform a descriptive analysis.

Sensitivity analysis: To ensure robustness of the combined results, sensitivity analyses will be performed to assess the impact of studies with a high risk of bias. We will compare the results to determine whether lower-quality studies should be excluded.

Language: English and Chinese.

Country(ies) involved: China.

Other relevant information: No.

Keywords: Acceptance and Commitment Therapy, chronic conditions, parents,

psychological symptoms, psychological flexibility, mindfulness, meta-analysis.

Dissemination plans: July 2021:Preliminary searches; July 2021:Piloting of the study selection process; August 2021:Formal screening of search results; August 2021>Data extraction; September 2021:Risk of bias assessment; September 2021>Data analysis; October 2021:Writing-review & editing; October 2021:submit a paper.

Contributions of each author:

Author 1 - Na Xiao - Formal analysis; Resources; Validation; Writing-original draft.

Email: 554343940@qq.com

Author 2 - LiJuan Yi - Conceptualization; Project administration; Writing-review & editing.

Email: 940576567@qq.com

Author 3 - JinMei Lei - Software; Validation; Visualization.

Email: 361945735@qq.com

Author 4 - ShaoNan Shi - Supervision; Visualization.

Email: 1394410791@qq.com

Author 5 - WenJie Nie - Formal analysis; Investigation.

Email: 1138631849@qq.com