INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The general public's attitude towards participating in pediatric clinical trials: a qualitative evidence synthesis

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Review question / Objective: **What is the general public 's attitude towards participating in pediatric clinical trials?**
Condition being studied: **All conditions tested by pediatric trials.**
Information sources: **Electronic databases [Pubmed, Embase, APA PsycInfo (EBSCOhost), CINAHL Plus with Full Text (EBSCOhost)], contact with authors, grey literature (Dissertation).**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 October 2020 and was last updated on 16 October 2020 (registration number INPLASY2020100055).

INTRODUCTION

Review question / Objective: **What is the general public 's attitude towards participating in pediatric clinical trials?**

Rationale: **Problematic recruitment is the most common cause of delays, increased costs, and failure to complete trials. Recruitment issues are thought to differ for adults and children, with children's recruitment being more difficult. The attitudes of children, relatives and even trusted friends could influence parents' decision, though children's participation greatly depends on parents.Therefore, our study aims not only to explore the attitudes of parents and children to participate in**

pediatric trials, to identify factors that influence the decision for participation and perceived risks and benefits for parents, but also to further synthesize public attitudes and opinions towards pediatric clinical trials. Up to now, a plenty of relevant qualitative interview studies have published, and there is no qualitative evidence synthesis. Therefore, we planned this qualitative evidence synthesis to provide up-to-date thorough evidence of the knowledge, attitude, experience, and suggestion to pediatric clinical trials. We hope the results of the study will not only help the researchers to design and implement of future pediatric clinical trials, but also improve general public's perception and attitude of clinical trials and eventually facilitate recruitment.

Condition being studied: All conditions tested by pediatric trials.

METHODS

Search strategy: #1: (infant*):ti,ab,kw OR (newborn*):ti,ab,kw OR (neonat*):ti,ab,kw OR (baby) :ti,ab,kw OR (babies):ti,ab, kw OR (pre-school):ti,ab,kw OR (kindergarten*) :ti,ab,kw OR (nursery school*):ti,ab,kw OR(toddler*):ti,ab,kw OR (school-age):ti,ab,kw OR (pubescent*):ti,ab,kw OR (juvenile*):ti,ab,kw OR (child*):ti,ab,kw OR (teen*) :ti,ab,kw OR (adolescent*):ti,ab,kw OR (pupil*):ti,ab,kw OR (boy):ti,ab,kw OR (girl):ti,ab,kw OR (boys):ti,ab,kw OR (girls):ti,ab,kw OR (primary school*):ti,ab,kw OR (middle school*):ti,ab,kw OR (high school*):ti,ab,kw OR (parent*):ti,ab,kw OR (pediatr*):ti,ab,kw OR (paediatr*):ti,ab,kw OR (mother*): ti,ab,kw OR (father*):ti, ab, kw OR (caregiver*):ti,ab,kw OR (guardian*): ti,ab,kw. #2: (clinical research*):ti,ab,kw OR (clinical study):ti,ab,kw OR (trial*):ti,ab,kw OR(clinical studies):ti,ab,kw #3: (consent*):ti,ab,kw OR (recruit*):ti,ab,kw OR (enroll*):ti,ab,kw OR (involve*):ti,ab,kw OR (participat*):ti,ab,kw #4: #2 AND #3 #5: (attitude*):ti,ab,kw OR (perception*): ti,ab,kw OR (perspective*):ti,ab,kw OR (concern*):ti,ab,kw OR (view*):ti,ab,kw OR (barrier*):ti,ab,kw OR (motivat*):ti,ab,kw OR (knowledge):ti,ab,kw OR (value*):ti,ab,kw OR (preference*):ti,ab,kw OR (opinion*):ti,ab,kw OR (thought*):ti,ab,kw OR (feeling*):ti,ab,kw OR (belief*):ti,ab,kw #6:(interview*):ti,ab,kw OR (qualitative) : ti,ab,kw OR (focus group*) :ti,ab,kw OR (consultation*):ti,ab,kw #7: #5 AND #6 . #8: #1 AND #4 AND #7

Participant or population: General public.

Intervention: No restrict.

Comparator: No restrict.

Study designs to be included: Interviews, mixed method research with Interview component.

Eligibility criteria: Include criteria: (1)The study's method must include interview and based on an existed or hypothetical pediatric clinical trials, and the participants in the clinical trials aged between birth to 18 years old. In view of that different countries have discrepancy in age of majority and it shall not exceed 22 years old by principle, as long as these studies use children or adolescents to describe their participants, we consider them could be included. (2)The study's main aim must be exploring knowledge, attitude and experience of children, parents or relatives or adolescents or other general public, towards pediatric clinical trials. No restrictions will be placed on setting, social status, ethnic background, or country of recruitment. Exclude criteria: (1)The study's main aim is to investigate the experience, feasibility or acceptability of a set intervention (preventive, cure, care measures, etc.) rather than knowledge, attitude and experience of participating in pediatric trials. (2)Employed mixed methods and it was not possible to extract qualitative data separately. (3)Included data from medical workers and clinical researchers , and data from general public could not be extracted separately. (4)Editorials, commentaries, opinion papers, and studies that do not provide a transparent descriptions of the methods used.

Information sources: Electronic databases [Pubmed, Embase, APA PsycInfo (EBSCOhost), CINAHL Plus with Full Text (EBSCOhost)], contact with authors, grey literature (Dissertation).

Main outcome(s): General public's attitudes to pediatric clinical trials and the factors that influence their attitudes.

Data management: We use NoteExpress V3.0 to screen, Excel to conduct data extraction.

Quality assessment / Risk of bias analysis: 1. Assessment of methodological limitations in primary studies: The Critical Appraisal Skills Programme (2018), CASP Qualitative Checklist tool was chosen as it is widely used and fit the purpose of these type of studies. A score of zero is given if the criteria is not met, one if it is unclear and two where it is definitely met. Paired authors conduct quality appraisal independently (blinded to each other's assessments) and if there is disagreement on scores awarded then the third author will compare the two appraisals and discuss with former two authors until reaching an agreement. 2. Assessment of confidence in the review findings: Appraisal of review findings. This review will use the GRADE-CERQual approach, to appraise the review findings, which involves examining four main elements: the limitations of included studies, how relevant the studies are to the review question, the coherence of the review finding and how adequate that data is in supporting the review finding. This will include a sensitivity analysis to examine the contribution of the poorer quality studies to the overall findings (Houghton et al,2017). The appraisal of review findings will be carried out by one author (YMR) and reviewed by a second (RYX).

Strategy of data synthesis: Authors use pre-designed structure Excel to extract data independently and cross-check the data. In the Excel, the first line is to put 'original data' which is usually in the form of quotations from the interviewees. Then the second line is to put 'descriptive data' which are usually researchers' summaries and comments of findings. After data extraction, two authors use thematic synthesis approach to identify themes which includes three stages: free coding of the findings of primary studies included in the sample; the organization of these 'free codes' into related areas to construct 'descriptive' themes; and the development of 'analytical' themes (Thomas 2008).

Subgroup analysis: 1. Subgroup of the type of diseases: acute diseases, chronic diseases, seriously diseases and lightly/ mild disease, etc. 2. Subgroup of the settings: different countries, geographic regions and ethnic origins.

Sensibility analysis: Not involved.

Language: No Language limit.

Country(ies) involved: China.

Keywords: children, adolescent, pediatric, clinical trial, general public, knowledge, attitude, recruit, interview, qualitative evidence synthesis.

Contributions of each author:
Author 1 - Yiming Ren conceived this study, constructed search strategy, ran the searching, exported Bibliographic Reference, developed eligibility criteria, designed the structure Excel of data extraction, conducted initial screening, full-text screening.
Author 2 - Ruyu Xia is academic advisor who developed eligibility criteria and design the structure Excel of data extraction.
Author 3 - Jiaxi Tong exported bibliographic reference and conducted initial screening, full-text screening.
Author 4 - Si Tang exported bibliographic reference and conducted initial screening, full-text screening.
Author 5 - Leying Zhao exported bibliographic reference and conducted initial screening, full-text screening.
Author 6 - Zelin Qin exported bibliographic reference and conducted initial screening, full-text screening.

Author 7 - Mingkun Yu conceived this study.
Author 8 - Rui Li exported bibliographic reference and conducted initial screening, full-text screening.
Author 9 - Yuxuan Chen exported bibliographic reference and conducted initial screening, full-text screening.
Author 10 - Jiaqi Gao exported bibliographic reference and conducted initial screening, full-text screening.
Author 11 - Ziyi Lin contributed to the development of search strategy and ran the searching.
Author 12 - Yutong Fei, generated the idea, conceived this study, and is the supervisor of whole program, developed eligibility criteria and give advice to every procedure.