INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The Process factors and improvement strategies of patient compliance and retention in clinical trials: a synthesis of qualitative research

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Review question / Objective: **In clinical trials, what are the process factors and improvement strategies that may affect patient compliance and retention based on qualitative research? What is the quality of the evidence from these qualitative studies?**
Condition being studied: **The patient compliance and retention (PCR) in RCTs are the ability to avoid non-compliance with medication and attendance appointments and loss of follow-up visits, including loss of contact with the research team (including subsequent loss of follow-up during the study and failure of the research team to re-establish contact).PCR is critical to determining the efficacy of drugs in clinical trials. Poor PCR may result in missing essential data, which affect the authenticity of clinical trial results. Since the understanding of process factors and improvement measures is highly personal, the use of qualitative interviews is very useful for investigating these because they allow patients and researchers in clinical trials to express their experiences in their own words. Although there are some qualitative studies on process factors and improvement strategies, no systematic reviews of qualitative research exploring process factors and improvement strategies has been found. Thus a synthesis and rigorous evaluation of the available data is still very necessary.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 February 2021 and was last updated on 06 February 2021 (registration number INPLASY202120024).

INTRODUCTION

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METHODS

Participant or population: Patients in clinical trials.

Intervention: Not limited.

Comparator: Not limited.

Study designs to be included: The type of research is limited to Qualitative research (in-depth interviews, serial ethnographic interviews, and focus group discussions, etc.).

Eligibility criteria: Qualitative research with the main purpose of exploring influencing factors and improvement measures will be included. The population is restricted to patients in clinical trials. The type of research is limited to Qualitative research (in-depth interviews, serial ethnographic interviews, and focus group discussions, etc.). The publication date and language of the study was not restricted.

Information sources: Four English database and three Chinese database were searched before 2020.12: Pubmed, Cochrane Library, Embase, PsycINFO, CNKI, Vip ,and Wanfang database. The reference lists of included articles and existing systematic reviews were also re-checked.

Main outcome(s): Strategies to improve patient compliance and retention in clinical trials; Factors affecting patient compliance and retention in clinical trials.

Data management: Noteexpress was used to manage the included studies. Firstly, it was used to eliminate duplicate articles. Two reviewers (MK Yu and CH Liang) independently screened the abstract and title. They double-checked their respective articles and included studies which may meet the inclusion and exclusion criteria as fully as possible. Finally, They screened the full text of these articles. All disagreements were resolved by discussion or arbitration by senior author(YT Fei).

Quality assessment / Risk of bias analysis: Critical Appraisal Skills Programme(CASP) was used to assess the quality of qualitative study in the following areas:1. Was there a clear statement of the aims of the research?; 2.Is a qualitative methodology appropriate?3.Was the research design appropriate to address the aims of the research? 4.was the recruitment strategy appropriate to the aims of the research? 5.Was the data collected in a way that addressed the research issue? 6.Has the relationship between researcher and participants been adequately considered? 7.Have ethical issues been taken into consideration? 8.Was the data analysis sufficiently rigorous? 9.Is there a clear statement of findings? 10.How valuable is the research? GRADE-Confidence in the Evidence from Reviews of Qualitative research(CERQual) which included the methodological limitation component; coherence

component; adequacy component; relevance component; dissemination bias was used to assess the quality of the synthesis of qualitative evidence. Two reviewers independently assess the quaility and double-checked their results.

Strategy of data synthesis: Thematic analysis was independently applied by two groups of researchers (MK Yu and KX Liu, CH Liang and Q He) to extract qualitative findings and integrated them. After data was re-checked, discrepancies were discussed and resolved, then the list of topics were finalized. Open coding was accomplished through multiple readings of research results. The theme and overall concept was also determined. The extracted content included:(1)The information of studies(First author; publication date; country; funding);(2)The information of participants(the number, the region, the age, and gender);(3)The methods of interview;(4)The methods of data collection;(5)The methods of data analysis;(6)The process factors and improvement strategies. In the process of open coding of articles by researchers, each concept is summarized into multiple fields related to one central theme.

Subgroup analysis: Not applicable.

Sensitivity analysis: Not applicable.

Language: The language of the included study was not restricted.

Country(ies) involved: China.

Keywords: qualitative research; factors; strategies; compliance; retention.

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