INPLASY PROTOCOL

To cite: Guo et al. Effect of transitional care on rheumatoid arthritis patients after discharge: A protocol for systematic review and meta-analysis of randomized controlled trial. Inplasy protocol 202160020. doi: 10.37766/inplasy2021.6.0020

Received: 07 June 2021

Published: 07 June 2021

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Support: **Yes.**

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

Conflicts of interest:
None declared.

Effect of transitional care on rheumatoid arthritis patients after discharge: A protocol for systematic review and meta-analysis of randomized controlled trial

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Review question / Objective: **After RA patient is discharged from the hospital, transitional care can to understand the psychological and physical state of patients, and to guide patients in rehabilitation training and medication, enhance the trust of doctors and patients, eliminate patients' worries, and meet their needs.**
Condition being studied: **As a chronic and debilitating disease, Rheumatoid Arthritis(RA) can greatly impede usual activities of daily living. Transitional care is a kind of extended out-of-hospital comprehensive care. Yet, much of these studies up to now have not focused on the systematic review(SR) and meta-analysis(MA), which can provide convincing evidence to verify the effect of transitional care in RA patients.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 June 2021 and was last updated on 07 June 2021 (registration number INPLASY202160020).

INTRODUCTION

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a kind of extended out-of-hospital comprehensive care. Yet, much of these studies up to now have not focused on the systematic review(SR) and meta-analysis(MA), which can provide convincing evidence to verify the effect of transitional care in RA patients.

METHODS

Search strategy: A systematic search will be performed in eight public domain electronic databases from inception to April 2021. These databases are as follows: PubMed, Cochrane Library, Embase, Web of Science, Chinese National Knowledge Infrastructure, WanFang database, China Biology Medicine Database and Chongqing VIP Chinese Scientific Journals Full-text Database. We will do not apply any restrictions or filters. The Medical Subject Heading(MeSH) and free-text terms will be applying a combination, and the search strategies will incorporate the database-specific controlled vocabularies and text words.

Participant or population: Patients who met the 2010 ACR/European League Against Rheumatism(EULAR) classification criteria. The patient must be an adult (age≥18 years) and have been treated to meet discharge requirements. There will no restriction on gender, race, economic and education status.

Intervention: Intervention is that using transitional care on RA patients, whether or not combined with other therapies. In the control group, interventions were consistent with the experimental group except that transitional care was not received. There are no restrictions on the type, frequency, length, and stage. A variety of different models of transitional care will be studies, such as the Omaha system, 4C continuous nursing model, Reengineered Discharge.

Comparator: Intervention is that using transitional care on RA patients, whether or not combined with other therapies. In the control group, interventions were consistent with the experimental group except that transitional care was not received. There are no restrictions on the type, frequency, length, and stage. A variety of different models of transitional care will be studies, such as the Omaha system, 4C continuous nursing model, Reengineered Discharge.

Study designs to be included: We plan to included randomized controlled trials(RCTs) that assessed the effects of transitional care on RA patients. Qualitative studies, case control studies, observational studies, case reports, reviews, conference proceeding and non-random studies will be excluded. If the data cannot be obtained by contacting the author, the studies reported in abstract form that without presenting the outcome will be excluded.

Eligibility criteria: The literature management software of EndNote X9(Thomson Reuters [Scientific] LLC, Philadelphia, PA) will be used for study screening. All search records will be imported into the EndNote X9, 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.

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incorporate the database-specific controlled vocabularies and text words. Reference lists in the relevant publications, such as reviews conducted on of transitional care for RA patients, will also be hand checked for search additional eligible trials. In addition, we will search in the clinical trial registry website to ensure that the most recent trials will be included.

Main outcome(s): Primary outcomes. (1)Self-Efficacy, defined as the patient's confidence in implementing disease management, which is assessed by the Chinese version of the Arthritis Self-Efficacy Scale-8(ASES-8);(2)Health Status and Physical Function, is been evaluated by the Health Assessment Questionnaire-Disability Index (HAQ-DI);(3)Hospital Readmission Rates.

Additional outcome(s): Second outcomes. (1)Joint pain, which is assessed by the Visual analogue scale (VAS);(2)Quality of life, which is assessed by the Quality-of-Life Scale(SF-12) developed by Boston Health Education Institute;(3)Quality of sleep, which is assessed by the Pittsburgh Sleep Quality Index(PSQI).

Data management: We will extract and summarize details of the eligible studies using a pre-designed and calibrated standardized data extraction sheet. 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, study setting, participants, sample size, follow-up period, outcomes of interest, risk and prognostic factors, missing data, summary statistics, outcomes 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 one author and double- checked by a second author.

Quality assessment / Risk of bias analysis: The Cochrane Risk of Bias(RoB) Tool for RCTs will be used to evaluate the risk of bias of each included RCTs. 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: Firstly, we will perform pairwise meta-analysis using a random-effects model in Stata 14.0 software for every direct treatment comparison with at least two primary studies. About the study effect size, we will calculate the odds ratios for binary outcomes and standardized mean differences for continuous outcomes, with 95% confidence interval. And we will estimate the heterogeneity for each comparison by Cochran Q test and I2 test. I2≤25% is considered to reflect low heterogeneity, 25% high heterogeneity. We will prespecifies meta-regression analyses to explore the sources of heterogeneity. If heterogeneity is high, we will perform a subgroup analysis(such as different patients, interventions). And if cannot perform subgroup analysis, we will performer a descriptive analysis.

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 performer a descriptive analysis.

Sensitivity analysis: We will prespecifies meta-regression analyses to explore the sources of heterogeneity.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: Transitional care, Rheumatoid arthritis, Systematic review, Randomized controlled trial.

Contributions of each author:

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