Research Week 2023

Shared decision making in rheumatoid arthritis: study protocol for a stepped wedge, cluster-randomized trial

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Keywords

Rheumatoid arthritis, shared decision making

Abstract

Background:

Rheumatoid arthritis (RA) impacts quality of life causing disability and increased mortality. Treatment decisions are complex and require individualized decisions. Shared decision making (SDM) is the first principle of RA treat-to-target guidelines but uptake is suboptimal. We aim to evaluate the effectiveness of a multicomponent SDM intervention on RA disease activity and explore the early implementation of the intervention within three geographically diverse rheumatology services.

Methods/design:

We will use a stepped-wedge, cluster-randomized trial design at 3 U.S. Veterans Health Administration rheumatology clinics. The multicomponent SDM intervention will consist of three parts: 1) rheumatology clinician training on SDM and choice awareness, 2) RA patient activation using the AskShareKnow questions, and 3) a point of care decision aid (RA Choice) and medication summary guide. We will conduct a mixed methods outcomes and process evaluation. Outcome will be evaluated during a pre-intervention and intervention period. The primary outcome is disease activity as measured by validated measure, with secondary outcomes of RA knowledge and medication adherence. SDM will be measured by two well-validated patient-reported measures: CollaboRATE and SURE. A subgroup of clinic visits will be audio-recorded and SDM will be assessed by the OPTION-5 scale. The implementation process will be evaluated using stakeholder interviews and field notes at each of the three sites.

Discussion:

This study is the first multi-site study of a multicomponent intervention to facilitate SDM among Veterans with RA. We expect to improve uptake of SDM across three geographically distinct rheumatology clinics and hypothesize that patients exposed to the interventions will have a greater decrease in disease activity, and increase in knowledge of RA medications compared to controls. Insights gained from this study will inform broader dissemination and implementation of SDM across VA rheumatology clinics and beyond with the goal of improving quality of care for all persons with RA.