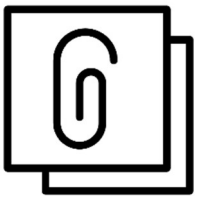

educAR

Validation of a strategy to improve therapeutic adherence in rheumatoid arthritis.

Study protocol and statistical analysis plan

Version: v2 27/12/2021

Study Protocol

Study design: We have designed a cluster clinical trial of 6-month duration.

Randomization and allocation: Fifteen centres will be randomised to receive access and instruction on the strategy or to continue standard care. Centre recruitment is on a voluntary basis, understanding that access to the educational tool will be delayed in case of being assigned to the control group.

Intervention: The intervention is a web-based tool with educational and practical materials for the patient and for the physician (this part will be protected with a password during the duration of the trial). Physicians (prescribers or non-prescribers) in centres assigned to the intervention will be invited to be instructed on the materials (text, videos, checklists, calendars, etc). Control will be standard care.

Accessible population: The study will be conducted in specialized care centres in Spain. Each centre will recruit 15 consecutive adult patients with rheumatoid arthritis (as stated in the clinical records), less than 2 years since diagnosis and living independently.

Variables and measures: The primary outcome will be therapeutic adherence (patient-level), defined as a score ≥ 80% in the Compliance Questionnaire on Rheumatology (CQR) and in the Adherence Medication Scale (RAM).

Secondary outcomes will be adherence to physical activity, a Mediterranean diet, lifestyle changes and disease activity.

Statistical Analysis Plan

Sample size: Accepting an alpha risk of 0.05 and a beta risk of 0.20 in a bilateral contrast, 79 patients per group are required, assuming that the initial proportion of adherent patients is 70% and at the end of the intervention, it would increase to 90% (only in the intervention group, in the control it would not change). A lost-to-follow-up rate of 25% has been estimated.

If 10 centres are selected to have at least 5 clusters for each group, this would correspond, rounding up, to 16 patients per centre, or a total of 160 patients.

Statistical analysis: The effect of the intervention on adherence to treatment will be refuted by the chi-square test and measured by relative risk (RR) and difference of proportions.

The effect of the intervention on RA disease activity and on adherence to healthy habits will be refuted by Student´s t test and the effect will be measured by the difference of means.

In all cases, statistical significance will be inferred at a value of $p < 0.05$