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ORIGINAL RESEARCH

EducAR: implementing a multicomponent strategy to improve therapeutic adherence in rheumatoid arthritis

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ABSTRACT

Introduction The EULAR points to consider (PtC) for reducing non-adherence need implementation.

Objectives To design, implement and evaluate a strategy based on the PtC to improve treatment adherence in rheumatoid arthritis (RA).

Methods A multidisciplinary panel cocreated an intervention that was subsequently tested in a cluster trial, where centres were randomised to access the developed intervention or follow the standard of care (SOC). 6-month initiation and implementation adherence were measured in consecutive patients with <2 years of RA. The results were discussed among the centres assigned to the intervention to explore barriers and facilitators to implementation.

Results The intervention was a two-sided website. The items on the patient site mainly addressed disease and treatment education, self-management and peer support. The healthcare professional site has tutorials on communication to improve trust and adherence, plus shared decision-making aids. It was tested in 141 RA patients (67 control and 74 intervention). Both groups increased adherence at 6 months, mainly in the control group (48% to 67% vs 42% to 47% in the intervention group). Implementation had been very low in relation to barriers identified as lack of time, inadequate focus (exclusively for nurses) and consideration of the current SOC as adequate.

Conclusion Despite designing an intervention based on the best evidence, the results were inconclusive; the lack of a detected effect could be explained by the limited implementation, which was insufficient for the complexity of the changes required (change of culture).

Trial register number ClinicalTrials.gov ID NCT05425485.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Treatment adherence is a problem in rheumatoid arthritis; therefore, EULAR has recently issued points to consider; however, implementation may be challenging.

WHAT THIS STUDY ADDS

⇒ A group of professionals and patients developed a web that serves both as a patient education tool and as a guide to implementing the EULAR points to consider. The tool was tested in a cluster clinical trial and followed by a discussion with the implementation teams. The results showed that the tool needed additional tuning to be truly implemented.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Implementation of best practices is not easy. A thorough understanding of the reasons for not using a seemingly useful tool is key.

INTRODUCTION

Rheumatoid arthritis (RA) is a systemic autoimmune disease characterised by a form of erosive arthritis that causes severe disability.[1] Numerous currently available treatments have proven effective in controlling and preventing the disease's complications. However, it is estimated that between 20% and 50% of RA patients are not adherent to their treatment.[2] In RA, non-adherence to treatment has been associated with increased disease activity and a higher degree of disability, which in turn has an impact on higher healthcare expenditure, with an increase in both direct and indirect costs.[3 4] In sum, the lack of therapeutic adherence in RA constitutes a problem of great magnitude that requires the development of effective interventions.

Numerous factors involved in adherence to treatment have been identified, some modifiable and others not. To facilitate their study, the WHO proposes classifying them into five groups: socioeconomic, health system-related, disease-related, medication-related and patient-related factors.[5] When developing interventions to improve adherence, it

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is necessary to acknowledge that it is a complex phenomenon that cannot be explained by a single factor but is the result of the interaction of several factors. The results of the "Adherence in RA" (ADHIERA) study, a multilevel analysis conducted in Spain on predictors of adherence in patients with RA, showed that non-adherence is influenced by psychological, communicational and logistic factors to a greater extent than by the sociodemographic and clinical characteristics of the patients.[6]

In 2020, the European Alliance of Associations for Rheumatology (EULAR) published points to consider (PtC) for detecting, preventing and managing non-adherence in rheumatic diseases based on a series of systematic reviews.[7 8] The PtC highlights the need for a multifaceted and tailored approach to non-adherence. Multicomponent interventions, including patient education components, have the largest effect on patient adherence.[8] In 2015, EULAR already published PtC for effective patient education, which not only proposed informing but also empowering the patient to participate in decision-making in the context of a planned and interactive learning process.[9] In fact, the patient's involvement in the decision-making process is critical in adherence to medication.[6 7]

Evidence-based recommendations are useless if not implemented in clinical practice.[10] Implementation is a complex process involving many steps in cycles involving relevant stakeholders, a team, analysis of the context and evaluation, among other components.[10] It is possible that many of the PtC suggested to improve adherence may not be easily implemented in our setting, especially since it takes leadership and resources.

The aim of this work was threefold: (1) to cocreate a multicomponent intervention strategy to improve adherence to pharmacological and non-pharmacological treatments in RA based on the best available evidence; (2) to evaluate its implementation through an intervention study and (3) to analyse barriers and facilitators for the implementation of this strategy in a qualitative study.

METHODS

Development of the multicomponent intervention strategy

A nominal group meeting was held with a multidisciplinary panel including rheumatologists, psychologists, nurses, RA patients, a hospital pharmacist and a graphic designer with two implementation researchers. All participants received prior information on existing interventions and the EULAR PtC for adherence[7] and the results of the ADHIERA study.[6] The objective of this meeting, moderated by a methodologist, was to identify how to translate the PtC into concrete implementable actions. All processes were made transparent and commented on a Miro board,[11] accessible to all. The proposals obtained at the meeting were voted on anonymously in a Delphi survey for prioritisation. The development team then designed a proposal based on a website with two subsites, as suggested by the panel, which was fine-tuned with email iterations and during a second meeting. The time spent on the development of the platform was 8 months.

Cluster randomised intervention study

The efficacy of the multicomponent strategy designed to improve adherence was evaluated in a 6-month randomised intervention cluster study. We invited centres that had already participated in a study of adherence,[6] thinking that their motivation to change behaviour would facilitate demonstrating the effect we were seeking. 15 centres were randomised to receive access to the intervention or not using the RAND() function in Excel. After an informative session with the intervention centres and 3 months to let the centres implement the intervention as preferred, all centres started recruiting consecutive patients with <2 years of RA. All centres were instructed to continue care as usual, plus the intervention group had access to educational videos and aids included on the web, providing patients with access to the information platform.

The outcome variable was adherence at 6 months, defined as a score >80% on both the Compliance Questionnaire on Rheumatology[12] and the Reported Adherence to Medication scale.[13] Secondary outcomes were adherence to healthy habits, such as exercise (Exercise Attitude Questionnaire-18[14]) and Mediterranean diet (Mediterranean Diet Adherence Screener questionnaire[15]), disease activity (Disease activity score, (DAS)28-erythrocyte sedimentation rate (ESR)), cardiovascular risk factors (body mass index, blood pressure, glycated haemoglobin, cholesterol and smoking) and degree of satisfaction with the medical care received (Arthritis Treatment Satisfaction Questionnaire.[16]

The effect of the intervention on adherence was analysed by logistic regression using 6-month adherence as the dependent variable and the study group (intervention or control) as the exposure variable. Crude models were adjusted for baseline adherence, and potential confounders were studied. The efficacy in terms of the secondary outcomes was analysed by creating change variables (6 months minus baseline) and using Student's t-tests or Mann-Whitney U tests, according to the normality of these difference variables. Missing data were not imputed.

Analysis of implementation barriers and facilitators

A focus group explored the level of implementation, the strategies used and the barriers and facilitators to implementing the multicomponent strategy. Rheumatologists and nurses from the centres belonging to the intervention group of the efficacy study participated in the study. A single focus group meeting was held to discuss the difficulties encountered in implementing the tool. The meeting was conducted according to a pre-established guide via Zoom, was recorded, and lasted 1 hour, but it could be extended if the discourse was not saturated. Two rheumatologists with implementation expertise

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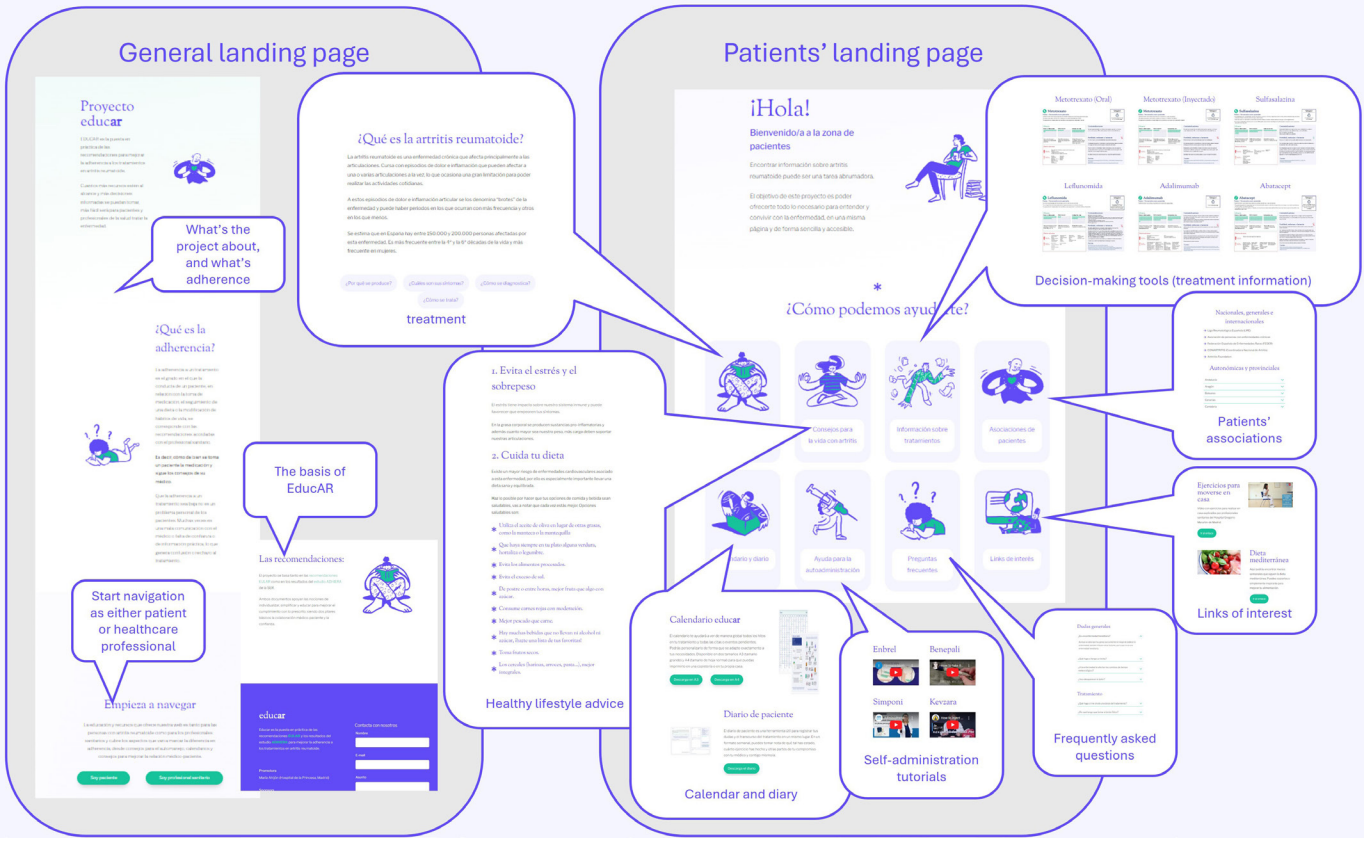

Figure 1 EducAR's general and patients' landing pages with distributing pages.

facilitated the meeting, one of whom was taking notes and cross-checking them with the group.

Participants discussed the dissemination strategies in their departments and how the tool was used. They also discussed potential causes of low implantation, the most useful components, difficulties in using the tool, if they had received feedback from colleagues and patients and any aspect that could be improved in the tool and the implementation process. The content of the discourse was transcribed, transported into bullet points, organised in trees and codes using Word processor tools (headings and subheadings), inductively, and cross-checked with the notes. Once synthesised and organised, it was cross-checked with the group.

The implementation rate was defined as the percentage of uptake, that is, the number of rheumatologists and nurses who used the tool divided by the total number in their department.

RESULTS

Multicomponent intervention strategy

Considering the resources available, the strategy chosen was a website, www.proyectoeducar.es, with two clearly separated sites, one for patients and another for healthcare professionals (figures 1 and 2). Both are freely accessible, but before the clinical trial, we did not disseminate the website, and the physician's part of the website was password-protected. The website offers educational resources for individuals with RA and healthcare professionals, covering aspects that can improve adherence and suggested in the PtC paper, such as self-management tips, calendars and advice to enhance the doctor–patient relationship and make the right adherence questions. The tool includes decision-making tools developed by the graphic designer based on the information contained in the summary of product characteristics and Cochrane reviews. It also contains calendars and diaries. For healthcare professionals, it includes short videos on how (and how not) to show empathy, increase patient confidence, ask open-ended questions, handle relatives, dispel fears and deal with difficult patients and time management, as well as checklists and guides for the clinical interview.

Cluster randomised intervention study

The sample consisted of 141 patients with RA (67 in the control group and 74 in the intervention group). Most were women (76%) with a median age of 56 years and a time since diagnosis of 12 months. Median joint counts were 0 and 2 for swollen and painful joints, respectively. Seropositivity was 75% for both rheumatoid factor and anti-CCP antibodies. In relation to treatment, 77% were receiving first-line conventional synthetic disease-modifying drugs (csDMARDs), 41% corticosteroids, 29% biologic DMARDs and 28% non-steroidal antinflammatory drugs (NSAIDs).

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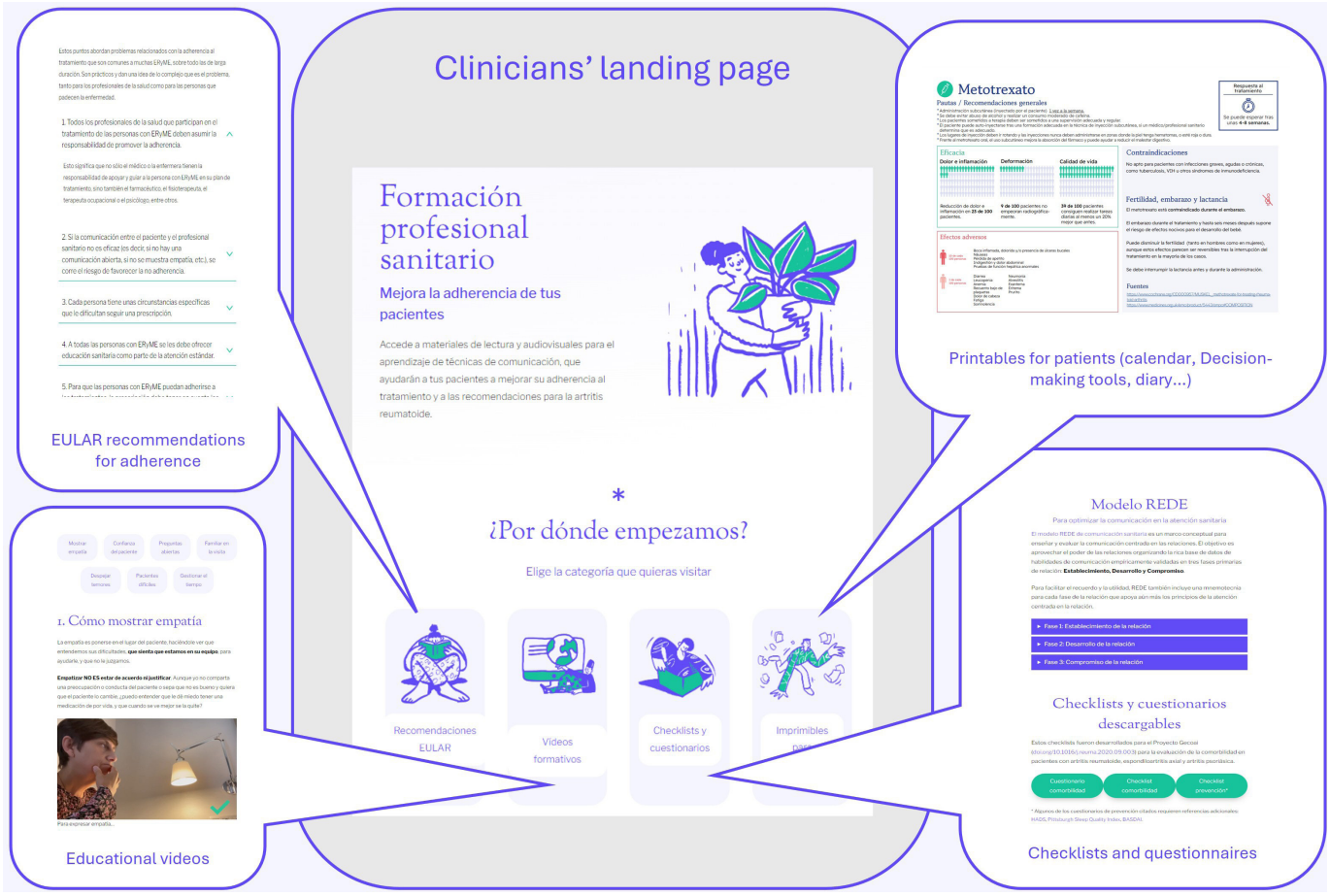

Figure 2 EducAR's health professionals' landing pages with distributing pages.

A baseline comparison of the study groups demonstrated inefficient randomisation with significant differences in disease activity, comorbidity, cardiovascular risk factors and concomitant treatments. The control group had higher disease activity with higher swollen joint count (median 1 vs 0; p=0.026), and visual analogue (VAS) (4 vs 2; p=0.004), as well as higher frequency of biologic treatment (39% vs 20%; p=0.016) and greater cardiovascular (34% vs 19%; p=0.034), respiratory (16% vs 5%; p=0.034) and digestive (19% vs 4%; p=0.006) comorbidity.

At 6-month follow-up, an increase in adherence was observed in both study groups, although of greater magnitude in the control group (from 48% to 67%) than in the intervention group (from 42% to 47%). In addition, there was a decrease in ESR (from 17 to 12 in the control group and from 15 to 11 in the intervention group) and in the count of painful joints in the intervention group and swollen joints in the control group (medians from 1 to 0 in both cases) (table 1).

The analysis of the efficacy of the intervention on adherence is shown in table 2. The crude model showed that the adherence at follow-up decreases with the intervention (OR=0.4; p=0.025) and increased in those patients who were adherent at baseline (OR=4.25; p<0.0001), were receiving biological treatment (OR=2.25; p=0.046) and had respiratory comorbidity (OR=4.95; p=0.043). In the multivariate model, the main determinant of adherence at follow-up was baseline adherence (OR=3.92; p=0.001), while intervention was associated with a decrease in adherence (OR=0.41; p=0.040).

Regarding the efficacy of the intervention on the secondary outcome measures, the only observed differences were the greater decrease in the number of painful joints in the control group than in the intervention group (difference of 1.63 vs 0.42; p=0.004) and the greater decrease in triglyceride concentration in the intervention group (difference of 8.81 vs −7.53; p=0.030) (table 3).

Analysis of implementation barriers and facilitators

Nine participants attended the focus group, representing all but one of the centres where EducAR was implemented. Despite all the intervention team members being invited to participate, the group was attended by two rheumatologists and seven nurses. Notwithstanding a high degree of acceptability, the implementation rate was low overall, ranging from 10% to 66% of the members of the rheumatology departments in the intervention group. The reasons given for the poor implementation were lack of time, redundancy with other existing materials, inadequate focus (exclusively for nurses), specialisation of rheumatologists with little interest in patients with

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Table 1 Evolution of outcome measures over time

	Control		Intervention	
	Baseline	Follow-up	Baseline	Follow-up
Adherence (MPR y CQR >80%)	32 (48.5%)	37 (67.3%)	30 (41.7%)	34 (47.2%)
Adherence to exercise (EAQ-18)	68.5 (53.7–79.6)	68.5 (55.5–79.6)	70.4 (55.5–81.5)	74.1 (61.1–83.3)
Adherence to diet (MEDAS)	7 (5–8)	5 (3–6)	7 (5–9)	5 (3–6)
Satisfaction to treatment (ARTS)	75.3 (67.1–83.6)	80.8 (69.9–87.7)	76.0 (68.5–84.9)	78.8 (67.1–86.3)
Total painful joint count (over 28)	2 (0–6)	2 (0–4)	1 (0–3)	0 (0–2)
Swollen joint count (over 28)	1 (0–3)	0 (0–1)	0 (0–2)	0 (0–1)
ESR (mm/hour)	17 (10–30)	12 (7–27)	15 (7–27)	11 (6–19)
Body mass index	26.6 (24.1–31.3)	27.3 (23.4–30.9)	26.3 (24.1–29.5)	26.6 (24.3–30.0)
Abdominal circumference (cm)	92 (82–105)	94 (87–107)	92 (81–100)	94 (85–101)
Systolic blood pressure	128 (112–139)	128 (113–141)	126 (118–140)	127 (115–135)
Diastolic blood pressure	78 (71–86)	78 (70–90)	81 (73–88)	78 (73–86)
Glycated haemoglobin	5.9 (5.7–6.0)	5.7 (5.3–6.0)	5.8 (5.5–6.8)	5.7 (5.3–7.3)
Triglycerides	105 (74–140)	115 (89–138)	120 (73–155)	106 (71–140)
Total cholesterol	198 (172–221)	191 (174–233)	197 (174–216)	191 (173–209)
Current smoker	17 (25.8%)	10 (19.6%)	21 (28.4%)	17 (25.4%)

Results are presented as median (percentile 25–75) or n (%).
ARTS, Arthritis Treatment Satisfaction Questionnaire; CQR, Compliance Questionnaire on Rheumatology; EAQ-18, Exercise Attitude Questionnaire-18; ESR, erythrocyte sedimentation rate; MEDAS, Mediterranean Diet Adherence Screener; MPR, Medication possesion ratio.

recent onset arthritis and consideration of the standard of care as already adequate.

The materials most used were the videos and the treatment information sheets or decision-making aids. Overall, the aids related to summary information, especially on medications, the printable materials (treatment cards and calendar) and the effective communication videos were considered very useful. In addition, the web format was considered a facilitating element for the young population. Those who used the

Table 2 Efficacy in the multivariate-adjusted model

Baseline variables	Crude model	Adjusted model
Group		
Control	1	1
Intervention	0.43 (0.21–0.90) (0.025)	0.41 (0.17–0.96) (0.040)
Baseline adherence	**4.25 (1.98–9.12) (<0.0001)**	**3.92 (1.75–7.74) (0.001)**
Total painful joint count (over 28)	0.93 (0.84–1.03) (0.154)	0.89 (0.79–1.00) (0.054)
Swollen joint count (over 28)	0.94 (0.82–1.07) (0.340)	
ESR (mm/h)	1.02 (0.99–1.04) (0.140)	
Global VAS	1.02 (0.88–1.19) (0.737)	
Biologic therapy	2.25 (1.01–5.0) (0.046)	2.17 (0.88–5.34) (0.093)
Cardiovascular comorbidity	1.23 (0.56–2.67) (0.605)	
Respiratory comorbidity	4.95 (1.05–23.3) (0.043)	
Digestive comorbidity	0.65 (0.22–1.93) (0.445)	
Concomitant antirheumatic treatment	1.15 (0.49–2.67) (0.738)	
Concomitant nervous system treatment	0.53 (0.16–1.77) (0.302)	
Concomitant respiratory treatment	3.43 (0.70–16.8) (0.129)	
Constant		1.26 (0.51–3.11) (0.613)

Results are presented as OR (95% CI) (p value)). Bold numbers denote statistical significance.
ESR, erythrocyte sedimentation rate; VAS, Visual Analogue Scale.

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Table 3 Efficacy of EducAR on secondary outcomes

Baseline variables	Control	Intervention	P value
Δ EAQ18	1.60±17.5	−5.69±19.8	0.137
Δ MEDAS	2.07±2.39	1.67±2.09	0.227
Δ ARTS	−4.03±15.0	−1.65±16.39	0.521
Δ Total painful joint count (over 28)	1.63±3.66	0.42±1.79	**0.004**
Δ Swollen joint count (over 28)	1.38±5.56	0.79±2.80	0.976
Δ ESR (mm/h)	7.87±19.79	1.98±17.7	0.251
Δ Abdominal circumference	0.03±8.79	−0.63±3.15	0.801
Δ Systolic blood pressure	−1.92±15.98	3.86±18.2	0.127
Δ Diastolic blood pressure	−2.0±10.73	2.63±11.52	0.060
Δ Glycated haemoglobin	1.0±2.15	0.06±0.45	0.497
Δ Triglycerides	−7.53±41.5	6.81±67.4	**0.030**
Δ Total Cholesterol	−4.73±27.7	2.20±28.23	0.201

Results are presented as the mean change (Δ) ± SD from baseline to follow-up. Bold numbers denote statistical significance.
ARTS, Arthritis Treatment Satisfaction Questionnaire; EAQ-18, Exercise Attitude Questionnaire-18; ESR, erythrocyte sedimentation rate; MEDAS, Mediterranean Diet Adherence Screener.

materials were very satisfied with them and found them very useful.

The main difficulties encountered were related to the difficulty of older patients in accessing the internet, the lack of perceived need in the case of patients already diagnosed, despite all being below 2 years of disease duration, and the absence of some important resources, such as a video on how to use MTX.

Other aspects that may influence the implementation fidelity are the delegation of responsibility, for example, believing that EducAR is designed exclusively for nurses, and the lack of motivation to change their current management, which they consider adequate. Interestingly, when confronted with medication adherence results in their centres, the health professionals were surprised at how low they were.

DISCUSSION

We tried to bridge the gap between research evidence in adherence to pharmacological and non-pharmacological treatments in RA and actual practice by combining tailored interventions with user-centred design methodologies. However, the strategy chosen for implementation failed, and adherence at 6 months was only determined by baseline adherence, not by being assigned to the intervention or the control group. Analysing the barriers and facilitators to implementing the EducAR strategy has provided us with valuable insights that allow us to significantly improve both the usability and implementation aspects, potentially enhancing therapeutic adherence in rheumatology in the future.

The research team decided to use a web-based approach for the strategy because they thought the web would be the most adaptable and have a far outreach.[17] However, discrete strategies may not work as effectively as multifaceted ones and have limited sustainability.[17] To underpin our implementation strategy, the barriers analysed after the implementation provided us with very clear messages: (1) physicians see educational websites as mainly for nurses; (2) they may undervalue the power of physician–patient communication to generate desired behaviours and patient satisfaction; (3) they do not see the need to change their behaviour given their time constraints.

Patient education is a core role of nurses.[9] However, nurses are not available in all rheumatology departments, and physicians can enhance patient education without extending visit times by implementing tailored approaches, individualising feedback and using teaching aids, just like the ones proposed in EducAR.

Furthermore, it has been proven that one of the critical steps in reaching optimal treatment adherence is involving the patient in a shared decision-making process, which is difficult for the nurse to be involved.[6 7] The materials designed for EducAR are freely available and can be used to compare therapeutical options with the patient. A QR code has been prepared to get access to the web and compare the options at home. A centre in the project where the rheumatologists downloaded the decision aids, these were used widely, and both patients and the healthcare team were very satisfied.

Time constraints are one of the most common reasons for not implementing PtC in clinical practice.[10 18] Many physicians believe open questions and effective communication are time-consuming. However, it has been shown that training in effective communication, as was the objective of the educational videos in EducAR, can lead to greater patient satisfaction without extending the duration of the visit, ultimately improving the efficiency of medical encounters.[19]

Finally, readiness is critical for health professionals to change behaviour.[20] If rheumatologists think that their patients are adherent enough and that they communicate well, then there is no need to introduce any change. Feedback and measurement are key. A survey that evaluated patient–physician communication and treatment goal understanding in 502 RA patients and 216 physicians found that the perception of short- and long-term treatment goals between patients with RA and physicians treating RA differs, highlighting the importance of aligning treatment goals through effective communication for improved patient satisfaction and treatment outcomes.[21]

We learnt that implementation cannot be achieved with a 1-hour standardisation webinar. It needs dedicated

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follow-up and adaptation in each centre until fidelity can be ensured. The website can be used as a placeholder for an educational programme covering adherence, shared decision-making, patient education and effective communication. Follow-up visits (or virtual meetings) can be planned, thus becoming a true implementation plan with proper evaluation and analysis of the context (eg, already used materials or strategies that can be as useful as the ones included in the programme).

Our take-home message is that a discrete implementation strategy such as the EducAR website, even if it has been cocreated by its end users and is highly acceptable, cannot improve adherence in the short term without an implementation plan. Using the website as the foundation, we must establish a plan that includes (1) feedback on the reality of the patient's adherence and rheumatologist and nurse communication styles, (2) reassurance that training in effective communication does not necessarily increase visit time and (3) an educational programme with follow-up. Finally, as with any implementation plan, it must include periodic evaluation and adaptation. We will now focus on developing an educational programme and using the website for outreach. This will include testimonials from patients and healthcare professionals highlighting the most useful parts and improving the web with the suggestions from the focus group, like creating versions offline and adding videos for methotrexate.

Correction notice This article has been corrected since it was first published online. The ethics approval statement has been updated.

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Contributors MAL and LC developed the concept, produced the protocols for the different substudies and contributed to materials. In addition, MAL was responsible for identifying funding opportunities. All authors codesigned the strategy. MP developed the website and graphic materials. AF-N and FSM participated in the clinical trial, and FSM also participated in the focus group after the trial. MJGdY analysed the trial results and prepared the first draft of the manuscript. TO analysed the focus group. All authors gave comments and reviewed the final version of the manuscript. LC is the guarantor.

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Patient and public involvement statement Patients were involved in codesigning the implementation strategy, which is the trial's intervention; they were, therefore, involved in the design of the study. They participated in two 2-hour online meetings with the rest of the participants and contributed comments online after testing the website. They also facilitated information to add to the website. In addition, OpenReuma, an association that represents professionals and people with RMDs, was involved in disseminating the programme.

Patient consent for publication Not applicable.

Ethics approval The study protocol and materials were reviewed and approved by the Ethics Committee for Research on Medicines at the Hospital Universitario de la Princesa (27/01/2022, #CEIm 02/22).

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Data availability statement Data are available upon reasonable request.

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