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Original article

# Randomised study versus control group of customised therapeutic education for patients in follow-up for rheumatoid arthritis



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#### ABSTRACT

*Objective:* We have evaluated customized objectives, predefined during a therapeutic education session for rheumatoid arthritis (RA).

*Methods*: Fifty-four RA patients were randomised into patient therapeutic education (PTE) group versus waiting list (WL). The final comparative evaluation involved solving 3 predefined problems.

Results: Fifty-four were evaluated after 6 months. The main criterion was defined for all three of the chosen themes at 76.9% in the PTE group and 42.4% in the WL group. Among the other positively evaluated criteria were: less corticotherapy, more occupational therapy, more demand for social aid, more physical activity, knowledge of the recognition of an RA attack and how to cope with it. On the other hand, knowledge of the treatments did not differ between the 2 groups nor did the RAPID scores, fatigue, stiffness, depression, compliance, number of consultations and hospitalisations. Patient satisfaction was excellent (between 85.3 and 93.9%).

Conclusion: This study is a good illustration of the position occupied and value of PTE in solving the problems specific to each RA case, the resulting high level of patient satisfaction and its independently complementary aspects relative to the purely medical treatment of RA. Customized PTE could better respond to specific patients problems in RA.

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#### 1. Introduction

Rheumatoid arthritis (RA) is the most common of the chronic inflammatory rheumatisms, with prevalence in France estimated at between 0.25 and 0.50% [1]. It usually starts in women between the age of 40 and 50, but can be found at any age. Chronic pain and functional limitations generated by the disease, their effects on quality of life, evolution with flares, treatments and their side effects justifying long-term monitoring, are the events with the greatest influence on a patient's daily life [2]. Therefore, patient therapeutic education (PTE) is recognised to be a key part of treatment in chronic diseases [3–5]. It is "a recognised process for training patients in the skills of self-treatment or adapting their treatment to their chronic disease". "It is used in addition to the usual treatments [...] so that a patient can take charge of his or her treatment and prevent avoidable complications while maintaining or improving quality of life" [3].

Beside medical treatment itself, the Haute Autorité de Santé (HAS) (High Health Authority) in France recognises a grade B level of proof of therapeutic education, which corresponds to an intermediate level [5]. Indeed, a literature analysis finds arguments in favour of the efficacy of therapeutic education in terms of acquisition of skills and psychological improvement, but also emphasises the low level of methodological quality in studies: education objectives rarely defined, education strategies rarely described [6–10]. Randomised studies are rare, and meta-analyses note the mediocre quality of the methodology used [6-12]. One Cochrane metaanalysis finds PTE to be effective on the function, number of painful joints, patient's overall opinion and certain psychological aspects such as depression [13]. However, these effects remain modest and short-term only, disappearing in the long term. Moreover, no efficacy was noted on RA activity or pain. Albano et al. also published a meta-analysis of 37 articles published between 2003 and 2008 [6]. Most of the studies are not randomised. An effect was also found in the short term, notably for socioeconomic and cultural problems. Fautrel et al. issued 8 recommendations for PTE in RA, but, above all, with a consensus of experts, the recommendations themselves being scored as grade D [8]. Therefore, Li wonders why the results

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are so disappointing [14]. She notes that it is better to understand patients' real needs.

In this context, our objective was to reveal the individual added value provided by a course of therapeutic education, strictly based on treating RA patients. For this, we had to determine what the efficacy of a course of therapeutic education meant to us. In previous evaluative studies, criteria used to evaluate efficacy of therapeutic education in inflammatory rheumatisms were varied: usual markers for monitoring rheumatism (pain, fatigue, quality of life (health assessment questionnaire [HAQ]), activity scores, functional scores), educational criteria (acquisition of knowledge, skills in self-care relative to pain, physical exercise), patient satisfaction, psychosocial criteria (self-efficacy, coping, depression, anxiety, compliance...) and economic criteria (visits to the GP, using a treatment system) [6,15]. These interesting criteria do not, in our opinion, represent the essential purpose of a therapeutic education course based on a customised educational diagnosis which leads to setting appropriate objectives with the patient, to meet his or her specific needs (education contract) [16]. In so far as, at the end of the educational diagnosis, the patient defines with the nurse which subjects are problematic, it seems logical to check that the patient does actually find appropriate solutions for his/her situation, for these subjects in particular.

The main objective of our work was therefore to make sure that the patient can easily find solutions applicable to his/her particular situation for those aspects which pose problems after therapeutic education sessions, compared with no therapeutic education at all.

By including an evaluation of the impact of therapeutic education in treating RA patients, we have structured our programme in accordance with the HAS requirement ("like any health intervention, patient therapeutic education deserves to be evaluated") [5,9]. Our work also meets the requirements of the PTE section of the Société Française de Rhumatologie (French Rheumatology Society) created in 2008 for which one of the main issues of therapeutic education in rheumatology is the evaluation of its efficacy [14].

#### 2. Methods

#### 2.1. Patients

We recruited 62 patients between April and October 2011. We randomised the patients who had given their written consent into 2 groups, using an electronic system (Interactive Voice Response System [IVRS]), one to follow a course of PTE for 6 months and the other placed on a waiting list (WL) for 6 months before being able to benefit from this PTE, considering our available human ressources to provide these PTE sessions. These were patients attending the Rheumatology department at Nantes University Hospital (in western France), men or women aged over 18, meeting the diagnostic criteria of RA (ACR 2009), capable of understanding a PTE action and who had signed their informed consent form. The RA had to have been stabilised for at least 6 months (no variation in DAS28 > 1.2). We excluded women who were pregnant or planning to become pregnant, those with projected surgery, patients under guardianship or who could not fully understand the information given, as well as patients with a major functional problem (Steinbroker IV). All types of treatment were authorised, with or without biotherapy, disease modifying anti-rheumatic drugs, corticotherapy, NSAIDs, analgesics.

#### 2.1.1. Methods

The patients were all given an educational diagnosis by a nurse trained and qualified in PTE, with more than 3 years experience. A specific tool, called "Become familiar" ("Apprivoiser" in French), was used, which had been developed by a medical and paramedical task force specialising in PTE, combining arthritic associations

[17]. A first version was given to the patient in advance so that he/she could get to know it, along with instructions for use and the purpose of the tool: situation relative to the disease, principles of coordination of this treatment with the referring physician and town specialist, and 4 chapters (how to improve my quality of life considering my disease, understanding my disease, talking about my disease and stating my needs, taking advantage of the care and treatment available), illustrated by 51 images so that the patient can think about the main 3 problems currently represented by the disease. They were then randomised into 2 groups, the first placed on a WL with routine treatments including the usual medical information about treating their RA, and a second group enrolled in a course of PTE for 6 months.

The course was split into 3 stages:

- Stage 1: private interview with a therapeutic education nurse, used to make an educational diagnosis and, with the patient, choose 3 subjects which cause problems, out of the 10 suggested;
- Stage 2: allocation to an educational route leading in 6 months to communal workshops (maximum of 3) and/or private interviews for the 3 subjects chosen;
- Stage 3: final interview with a therapeutic education nurse specialising in training evaluation, leading to production of a report.

The patients had the choice between the possibility of individual treatment (social worker, occupational therapy, dietician, psychologist, chiropodist) and joint workshops:

- understand my disease and talk about it (presented by a rheumatologist and a PTE instructor);
- living with my treatment (presented by a rheumatologist and a PTE instructor);
- maintain my mobility and save my joints (presented by an occupational therapist and a physiotherapist);
- identify my rights (presented by a social worker and a PTE instructor);
- Diet: between balance and pleasure (presented by a dietician and a PTE instructor):
- self-image, emotion and morale (presented by a psychologist and a PTE instructor).

The average time for educational diagnosis was 1 h and the 3 communal sessions of about 1 and half to 2 h each, with a 1 h final evaluation.

All the patients were reassessed at 6 months using the same schedule. The main objective was to check whether the patients had found solutions applicable to their situations for the three themes selected at the end of the initial evaluation. Evaluation was made using a visual analogue scale for the 3 items chosen. The question asked was: "For 6 months I have found solutions applicable to my situation for subject 1/2/3: "do not agree at all" to "totally agree" on a visual analogue scale (VAS) from 0 to 10". The solution found could be technical or financial aid, exercises carried out regularly, a new contact which positively influenced their problem (health professional, association or social worker), a personal procedure or any other factor making a contribution to improving the situation for the 3 subjects chosen.

The secondary evaluation criteria selected included several areas.

The evaluation of skills acquired (knowledge and management of treatments, ability to cope with a side effect of the treatment, identification and management of a flare of RA), taking medication (corticoids, analgesics, Girerd adherence scale) and medical treatment (number and type of medical visits, hospitalisations, transport coupons, social aid) and paramedical visits (physiotherapy, occupational therapy, diet, physical activity, development of a

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