Official Title: Effects of a Rheumatoid Arthritis Self-management program-a Randomized Controlled Trial
NCT number: NCT03470740
Date of the document: 20160801

Background

Rheumatoid arthritis (RA) is a persistent systemic disease (Flurey et al., 2014; WHO, 2003). The prevalence of RA is 0.3% - 1% worldwide (WHO, 2003), and 0.6% in Taiwan (Chou, 2003). Within a decade of its onset, RA leads to work disability defined as a total cessation of employment in between 51% and 59% of patients (WHO, 2003). In Taiwan, the Ministry of Health and Welfare (2014) emphasized that people suffer from knee joint degeneration is up to 15% prevalence, and the most common cause including RA. WHO (2003) commented that although the mortality rate of RA is low, a decreased life expectancy is associated with some musculoskeletal disorders, inflammation of the multi-system, and ischemic heart disease. The impact of RA including reduction of patients' daily activities, effects on the different dimensions of the quality of life, reduce work capacity (Lee et al., 2010; WHO, 2003), and significant increase health care costs (Furner et al., 2011). Epidemiological data indicate that individuals with RA are most often diagnosed in their 40s (Lin et al., 2004). With the disease continuing into old age, we can anticipate that the number of older patients with RA is increasing on a worldwide basis. In Taiwan, the life expectancy is increase and the average life span achieves 79.84-year (Ministry of the Interior, 2015), and indicate that individuals with RA need to live with the disease for more than 40 years.

Patients' involvement in the management of their care is referred to as self-management, which has been defined by Barlow and colleagues (2002, p.178) as "the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition". Barlow further states that for SM to be effective, it needs to encompass the ability to monitor one's condition and to affect the behavioral and emotional responses necessary to maintain a satisfactory quality of life. This definition implies that SM is more than simple adherence to treatment guidelines because it incorporates the psychological and social management of living with a chronic illness. SM involves, on the patient's part, acquiring the knowledge, practicing the skills and developing the confidence to deal with disease-related problems, and making and maintaining behavioral changes to maximize well-being (Dures & Hewlett, 2012). Chronic diseases such as RA and related conditions have no 'cure', the goal of intervention is to minimize disease impact and optimize physical, emotional, and social health (Keysor et al., 2001). Day-to-day SM is extremely important in achieving optimal health outcomes, and people with arthritis use a variety of strategies to relieve symptoms or manage disease consequences (Keysor et al., 2001). Hence, SM in arthritis tends to adopt a more holistic approach including management of psychosocial consequences and life style changes (Barlow et al., 2002).

Methods

Research Design

An ***experimental design*** was used to examine the effectiveness of a SM intervention for RA patients.

Sample and Setting

A medical center in northern Taiwan was selected as the research setting to ensure sufficient numbers of RA patients are able to be recruited for this study, and the teaching hospital is constantly striving to improve their services, and is readily accessible to the researcher. Patients who visited the rheumatology departments of the medical center was eligible for the study and the inclusion criteria include: (1) diagnosed with RA, (2) age of 20 years or over, (3) disease considered by the treating rheumatologist to have been stable for at least 3 months, and (4) able to understand and comply with the study treatment. Patients were excluded if they are suffering from other terminal illnesses, severe dementia or another debilitating psychiatric disorder, living in a long-term care facility, and participation in another research protocol. All patients were under the medical care of their rheumatologist during the study.

Sampling Procedure

Patients were approached for recruitment when they visit in the medical center rheumatology departments. If the patients meet the inclusion criteria and agree to participate in the study then randomly assigned to the experimental and control groups were proceeded using a computerized allocation procedure in SPSS 17.0 for Windows by an independent researcher. A numbered envelope was given. The big and opaque envelopes were numbered from 1 to 260 and contained the baseline data collection questionnaires and another sealed of small opaque envelope. The small opaque envelope contained a randomly determined using the computer-generated sequence of random numbers: number zero is for the control group and number one is for the experimental group. The researcher opened the big envelop and collect the baseline data, and then open the small sealed envelope to randomly assign participants to two groups. If the patient is random assigned to the control group, the usual care of the RA was received. Another experimental group received the program. For this sampling procedure, neither the researcher nor the participant is aware of treatment group assignment until after the baseline questionnaire has been collected. The CONSORT (Consolidated Standards of Reporting Trials) flow diagram (Moher et al., 2001) will be followed to manage the random allocation.

Intervention Program

The intervention program was based on self-efficacy theory (Bandura, 1977, 1986, 2004), and the four resources of self-efficacy such as mastery experience, social modeling, social persuasion, and physical and emotional states will be incorporate to emphasize patients' knowledge, skill, and responsibility in managing their RA situations. Various sources of information affect efficacy judgments and influence how people weigh and integrate them into actions.

Instruments and Outcome Measurements

Many of the standard measuring instruments selected have been used in previous studies of people with arthritis, and have established reliability and validity. Outcome data were collected at the baseline, and 2, 3, and 6 months including RA disease activity (DAS-28), arthritis self-efficacy (ASE), physical functioning (MHAQ), quality of life (SF-36), self-management behaviors, and and health care utilization.

Procedure and Data Collection

The researcher contacted the RA patients if they meet the inclusion criteria, and a face-to-face interview started. The researcher explained the purpose and procedure of the project, as well as the participants' rights and the benefits of participating. Next, participants agreeing to participate signed consent forms. Regarding collection the data, the baseline data was collected including background information, disease activity, arthritis self-efficacy, quality of life, physical functioning, self-management behaviors, and health care utilization. It followed questionnaire guide to collect data, and the person who collected the data and the researcher who visit the patient for the intervention was never the same. After completion of baseline data, patients were randomly allocated to the intervention or control group by an independent researcher. Control patients received usual care, and the intervention group received the 6-week RA self-management program. All participants were followed up for 6 months, and the data were all collected at the RA OPD when patients were back to the clinic.

Data Analysis

Data were double entered for verification and the level of significance was set at alpha of .05 using SPSS Version 17.0. D***escriptive statistical analyses*** were used to establish baseline characteristics of RA patients using means, ranges, standard deviations, frequencies, and percentages. Background characteristics and outcomes at baseline were compared between two groups by means of chi-square tests and t-tests for independent samples. To evaluate the effect of the intervention over the total follow-up period, we used the multiple linear regression method used in the ***GEE*** (Liang & Zeger, 1986) to take into account of internal dependencies within subjects (due to the repeated measurements) and to adjust for the effects of certain factors. Effects evaluated included the main effects of time and group and two-way interaction effect(s) of time by group. A significant interaction effect of time by group would indicate a significant change from baseline to a specific later time point between the two groups. Significant interaction effect(s) in GEE results would provide evidence of intervention effects.

Ethical Considerations

The study was reviewed and approved by the Institutional Review Boards of the hospitals of the PI prior to data collection. The participants were informed both orally and in writing about the purpose of the study, assured that participation was voluntary, and the benefits of participating. To ensure the security of the intervention, the researcher discussed with the physician about the potential participants' condition and their self-management. They signed the informed consent, was guaranteed confidentiality, and was assured an anonymous presentation of the findings.

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