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Newly diagnosed with inflammatory arthritis – A protocol for a self-management intervention (NISMA)

NCT number: Not yet assigned

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Introduction

Despite the increasing number of new drugs and treatment regimes, complete long-term disease remission is not achieved for many patients with inflammatory arthritis (IA) [1–3]. In addition, even in remission, patients with IA will experience symptoms, and due to the fluctuating nature of the arthritis, symptoms will come and go throughout life with varying intensity [2]. Therefore, an important but often insufficient aspect of care in patients with IA is empowering patients to acquire a good understanding of their disease and build their ability to deal effectively with its practical, physical, and psychological impacts of it. Self-management skills can be helpful in [4].

Background

Inflammatory arthritis (IA) covers diseases caused by an overactive immune system. These diseases manifest mainly with inflammation of the joints felt as joint pain and stiffness, but IA can also affect other connective tissues, including the lungs, heart, eyes, skin, and other organs. Importantly, when inflammation affects any part of the body, it can result in irreversible damage [5–9]. The most common types of IA are Rheumatoid Arthritis (RA), Spondyloarthritis (SpA), and Psoriatic Arthritis (PsA) [5], and all have a major impact on patient's life and health.

These three types of IA affect more than 2% of the population with considerable variation worldwide, depending on ethnicity [5–9]. IA can occur at any age and in both sexes. The cause of IA is poorly understood, but we know that it involves both genetic and lifestyle factors [8,10,11]. Approximately 2,000 people are diagnosed annually with RA, SpA, or PsA [12,13].
The newly diagnosed are particularly challenged. They are about to begin a life with lifelong pharmacological treatment, regular blood tests, symptoms as pain, fatigue, sleep disturbances and increased risk of developing co-morbidities such as depression, cardiovascular disease, diabetes, and osteoporosis. Some experience of reduced quality of life, altered body image and changes in family, work, and social life, and struggles with the fluctuation of the disease. Several studies have shown that newly diagnosed patients require regular consultations and available support from healthcare professionals (HPs) to deal with emotional, social, and physical challenges [14–20]. In addition, they have a wide range of educational needs, such as knowledge and management of the disease, knowledge of adverse effects and risk factors, non-pharmacological treatment including strategies for lifestyle, pain control and self-help methods, as well as activity regulation, physical activity, behavior change and psychological support especially immediately following IA diagnosis.

Self-management

Previous research suggests that increased self-management - defined as the individual's ability to manage symptoms, treatments, lifestyle changes and psychosocial and cultural consequences of illness - can improve the quality of life in patients with chronic illness. However, in patients with arthritis, self-management interventions have produced small to medium effect sizes, and the content, settings, and outcomes of the tested interventions have been very heterogeneous [21–25]. Thus, these interventions are difficult to compare and transfer to another setting. Also, the mechanisms of impact in these interventions remain relatively unclear [21–25]. After a thorough review of the literature, there is a lack of research on self-management interventions that are specifically targeted at newly diagnosed patients with inflammatory arthritis.

Rationale for NISMA project

Our hypothesis is that a self-management intervention can improve patients' ability to monitor their arthritis and respond to symptoms, reduce the risk of co-morbidities, and improve adherence. And also, that they can develop cognitive, behavioral, emotional strategies to manage life with arthritis. There is to our knowledge, a lack of disease specific evidence, in integrated interventions with multiple components targeting patients

with a newly diagnosed IA. Therefore, we developed a self-management intervention. The development I reported elsewhere [26].

Aim

The overall aim of this study is to determine whether a full-scale randomized controlled trial, which aims to increase self-management in patients with newly diagnosed IA, is possible.
We wish to identify methodological, clinical, and procedural uncertainties in delivering a self-management intervention. Furthermore, we wish to investigate outcomes related to recruitment, including adherence, retention, accrual rate, characteristics of the sample, and reliable recruitment methods.

Design

This feasibility study is designed as a randomized controlled feasibility trial (allocation ratio 1:1) to assess the method proposed for use in the definitive RCT.

Overall Setting
The intervention will take place at the Center for Rheumatology and Spine Diseases, Rigshospitalet, Denmark.

Participants
Patients with IA covering following diagnoses: SpA, PsA or RA according to the International Classification of Disease and Related Health Problems.
Inclusion criteria: IA diagnosis within 6 months, 18 years of age or older and able to discuss the topics in the intervention in Danish.
Exclusion criteria: Patients in kemo-therapy treatment for malignancies.

Recruitment
A rheumatologist or rheumatology nurse from the outpatient clinic will briefly inform possible eligible patients about the trial.

Allocation and blinding: Randomization will be performed after baseline data collection and conducted using a computerized random number generator algorithm. Participant and clinician blinding are not possible due to the nature of the intervention.

Usual care
Usual care consists of planned sessions with a rheumatologist and occasionally a nurse.
Participants in the control group receive usual care, and participants in the intervention group receive both usual care supplemented with the intervention.

Intervention
NISMA is a nine-month intervention and consist of four individual sessions and two group sessions. The theoretical frame is Social Cognitive Theory (25,26), along with Acceptance and Commitment Therapy (ACT) (27), to support the enhancement of self-efficacy. It involves four individual sessions with a nurse and two group sessions (5-7 patients) with a nurse, an occupational therapist (OT), and a physiotherapist (PT), with the nurse being the facilitator. Every session has a specific topic and in every session a person-centered approach is used to secure relevance (23).
For further details see Figure 2. Or the development study (23).

Training of health professionals involved in delivering the intervention

The research team developed a comprehensive manual, describing each session and the overall intervention strategy and framework. Also, we held a two-day competence program in October 2021 to train HPRs in delivering the intervention to secure fidelity and acceptance.

Table 1. The NISMA self-management intervention (sessions, topics, timeline, duration, aims and activities)

Session type	Topic	Timeline	Duration	Aim	Activity
First individual session with a nurse	Medical management	14 days after baseline	1.5 hours	To establish a partnership between patient and nurse, based on patient values, and health history. To increase knowledge about self-management and physical state.	○ Introduction to self-management and the frame of the sessions. ○ What is arthritis – education and information about principles of medical treatment. ○ Management of individual problems – help to achieve performance accomplishment through problem-solving and action planning.
Second individual session with the nurse	Emotional management	6 weeks after baseline	1 hour	To increase knowledge about emotional reactions.	○ Normal emotional reactions including acceptance and crisis theory. ○ Management of individual problems – help to achieve performance accomplishment through problem-solving and action planning.
Third individual session with a nurse	Role management	3 months after baseline	1 hour	To help prioritize and address challenges related to work and social life.	○ Social relationships, identity, and loneliness. The outside world's expectations versus own expectations. ○ Management of individual problems – help to achieve performance accomplishment through problem-solving and action planning.
First group session with a nurse, occupational-	Symptom management	4 months after baseline	2 hours	To help patients meet other patients and make a room for	○ Symptoms such as flare, pain, fatigue, and sleep problems. Symptom interactions.

and physiotherapist				observational learning about symptom management.	○ Each patient tells a little about themselves and shares their experiences with IA and IA symptoms.
Second group session with a nurse, occupational- and physiotherapist	Lifestyle and co-morbidity	6 months after baseline	2 hours	To help patients meet other patients and make a room for observational learning in relation to lifestyle management.	○ Each participant shares their experiences since the last session. ○ Lifestyle. What is good and what is bad - why? Identify the need for lifestyle changes and possible barriers and solutions. Patients share previous experiences with lifestyle changes. ○ Management of individual problems – problem-solving and action planning.
Fourth individual session with a nurse	Future use of the healthcare system and round up	9 months after baseline	1 hour	To increase health literacy.	○ Use of healthcare and future collaboration with healthcare professionals. ○ Management of individual problems – problem-solving and action planning.

Participants in the control group receive usual care, and the intervention group receives both usual care supplemented with the intervention.

Sample size considerations
As this is a feasibility study, sample size calculation is not relevant [27]. However, the steering committee anticipates that 20 patients (10 in the intervention group and 10 in the control group) will give us sufficient data to answer questions related to feasibility outcome measures, including estimation of potential recruitment rates, intervention adherence and rates of completion of data outcome tools.

Outcomes

In this feasibility study we will explore different feasibility outcomes and patient reported outcome measures (PROMS) to find suitable outcome measures for the definitive RCT.

Data collection, measurements and follow up (Figure 3)
Socio-demographic and lifestyle data will be collected at baseline. Data of the outcome measures described below will be measured at baseline and by the end of the intervention (9 months). The self-administered questionnaires are entered in the electronic project manager tool REDCap.

The patient reported outcome measures
- Physical Activity and Sedentary Time (FAST)
- Functional status measured by Modified Health Assessment Questionnaire (MHAQ)

- Pain measured by VAS
- Fatigue measured by Bristol Rheumatoid Arthritis Fatigue Questionnaire (BRAF) and VAS
- Health literacy measured by Health Literacy Questionnaire (HLQ)
- Quality of Life measured by European Quality of Life (EQ5D)
- Anxiety and Depression measured by The Hospital Anxiety and Depression Scale (HADS)
- Illness intrusiveness measured by Illness Intrusiveness Rating Scale (IIRS)
- Self-efficacy measured by Arthritis specific Self-Efficacy measurement tool (ASES).

Blood samples and blood pressure measurement

Lifestyle regulation measured by total cholesterol, and glycated hemoglobin HbA1c, height, weight and blood pressure.

Information from patient journals

Diagnosis (including IgM-reumafaktor and Anti-CCP) and disease duration will be obtained in the electronic database DANBIO.

Pharmacological treatment, joint-score DAS28, CDAI, BASDAI or DAPSA depending on the rheumatic diagnosis (number of tender joints, swollen joints and VAS-global), and structural damage will be obtained from both DANBIO and SundhedsPlatformen to achieve baseline and follow-up information.

Analysis

Quantitative analyses of feasibility outcome measures

The primay analysis will be of feasibility outcomes. We will report the numbers of eligible participants seen over the recruitment period, and the resulting rates of recruitment, retention, and data completion. Non-completers will be characterized. Also, data collection methods will be evaluated.

Patient reported outcome analysis

We will assess the performance of potential outcome measures to determine the appropriate sample size for a definitive trial. In addition, we will ascertain data completeness of the instruments and any potential bias in the completion of follow-up data to inform the choice of instruments in a future trial. The outcome data will be presented in simple descriptive tables presenting percentages, means and standard deviations.

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