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Randomized trial of the effectiveness of a non-pharmacological multidisciplinary face-to-face treatment program on daily function compared to a telephone-based treatment program in patients with generalized osteoarthritis

N. Cuperus † *, T.J. Hoogeboom ‡, C.C. Kersten †, A.A. den Broeder †, T.P.M. Vliet Vlieland §, C.H.M. van den Ende †

† *Department of Rheumatology, Sint Maartenskliniek, Nijmegen, The Netherlands*
‡ *Department of Epidemiology, CAPHRI School for Public Health and Primary Care, CCTR Centre for Care Technology Research, Maastricht University, The Netherlands*
§ *Department of Orthopaedics, Leiden University Medical Centre, Leiden, The Netherlands*

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SUMMARY

Objective: To compare the effectiveness of a non-pharmacological multidisciplinary face-to-face self-management treatment program with a telephone-based program on daily function in patients with generalized osteoarthritis (GOA).
Design: A pragmatic single-blind randomized clinical superiority trial involving 147 patients clinically diagnosed with GOA, randomly allocated to either a 6 week non-pharmacological multidisciplinary face-to-face treatment program comprising seven group sessions or a 6 week telephone-based treatment program comprising two group sessions combined with four telephone contacts. Both programs aimed to improve daily function and to enhance self-management to control the disease. The programs critically differed in mode of delivery and intensity. Daily function (primary outcome) and secondary outcomes were assessed at baseline, 6, 26 and 52 weeks. Data were analyzed using linear or logistic multilevel regression models corrected for baseline, sex and group-wise treatment.
Results: No differences in effectiveness between both treatment programs were observed on the primary outcome (group difference (95% CI): −0.03 (−0.14, 0.07)) or on secondary outcome measures, except for a larger improvement in pain in the face-to-face treatment group (group difference (95% CI): 1.61 (0.01, 3.21)). Within groups, significant improvements were observed on several domains, especially in the face-to-face group. However, these benefits are relatively small and unlikely to be of clinical importance.
Conclusions: We found no differences in treatment effect between patients with GOA who followed a non-pharmacological multidisciplinary face-to-face self-management program and those who received a telephone-delivered program. Besides, our findings demonstrated limited benefits of a self-management program for individuals with GOA.
Dutch Trial Register trial number: NTR2137.

Introduction

Osteoarthritis (OA) can affect multiple joints, but is most common in the hand, spine and the weight-bearing joints i.e., the hip and knee[1,2]. In recent years, clinically relevant OA subpopulations or so called phenotypes have been classified whereby different joint groups are generally seen as distinct phenotypes[1,3,4]. A commonly used and widely accepted phenotype is generalized osteoarthritis (GOA)[3,4], describing a subset of patients with

* Address correspondence and reprint requests to: N. Cuperus, Department of Rheumatology, Sint Maartenskliniek, PO Box 9011, 6500 GM Nijmegen, The Netherlands. Tel: 31-243272726.
E-mail addresses: n.cuperus@maartenskliniek.nl (N. Cuperus), thomashoogeboom@gmail.com (T.J. Hoogeboom), c.kersten@maartenskliniek.nl (C.C. Kersten), a.denbroeder@maartenskliniek.nl (A.A. den Broeder), t.p.m.vliet_vlieland@lumc.nl (T.P.M. Vliet Vlieland), e.vandenende@maartenskliniek.nl (C.H.M. van den Ende).

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clinically polyarticular OA[5]. To date, a wide variety of GOA definitions have been described in the literature, however no agreed and validated definition is available so far[5]. Most definitions of GOA include at least three joints or joint groups, but there is little agreement on the necessity or appropriateness of including a specific joint or combination of joints. It has been suggested that individuals with GOA might represent a relatively large subgroup of patients with OA. In knee OA, approximately 50% of patients can be classified as GOA [6–8].

Several international guidelines for the management of OA are available emphasizing the effectiveness of non-pharmacological, non-surgical interventions, such as education, self-management, weight reduction and exercise therapy[9–14]. However, these guidelines all focus on single joint involvement (i.e., hand, hip or knee), without considering the involvement of multiple joints. Recently, the Osteoarthritis Research Society International (OARSI) was the first to publish recommendations for the non-surgical management of OA for several subpopulations, including multiple joint OA (i.e., OA in other joints in addition to the knee)[12]. However, due to the limited research on the management of multiple joint OA, the authors only considered balneotherapy (defined as the use of baths containing thermal mineral waters) appropriate for patients with multiple joint OA, whereas no other recommendations could be formulated. Yet, it is likely that recommendations for hip and knee OA also apply for individuals with GOA.

Considering the substantial group of patients with GOA, the lack of knowledge on the non-pharmacological management of GOA and the high physical and psychological burden associated with GOA[7,8,13,15,16], the development and evaluation of a treatment program for patients with GOA is warranted. Therefore, our research group systematically developed a non-pharmacological, multidisciplinary face-to-face treatment program for individuals with GOA based on recommendations for the management of hip and knee OA[14] and tailored to the needs of patients with GOA[17]. Treatment components of the program included education, self-management and exercises. Besides, a less intensive telephone-based treatment program was developed since increasing evidence shows telephone-based interventions to be cost-efficient[18] and to improve symptoms and promote lifestyle changes[19,20]. The aim of the current study was to compare the effectiveness of both treatment programs on daily function during the first year after treatment. We hypothesized the face-to-face treatment program to be superior in effect on daily function, since this program is more extensive and more strictly supervised.

Methods

Study design

This study was a pragmatic parallel group, single-blind randomized clinical superiority trial comparing the effectiveness of a 6 week non-pharmacological multidisciplinary supervised face-to-face treatment program with a 6 week telephone-based treatment program on daily function in patients with GOA. The effectiveness over 1 year was examined. Details of the trial development and design have been published previously[17]. The protocol adhered to the CONSORT guidelines for non-pharmacological interventions[21]. The study was performed at the outpatient rheumatology departments of the Sint Maartenskliniek Nijmegen and Woerden, the Netherlands from January 2010 to April 2014 and was approved by the local ethics committee (CMO region Arnhem, Nijmegen) and registered in the Dutch Trial Register (trial number NTR2137). All participants signed informed consent prior to the baseline data collection.

Setting and participants

During an outpatient visit, patients clinically diagnosed with GOA and referred by their rheumatologist for treatment were invited for a screening visit to consider eligibility for the trial. Patients were included when: (1) having at least two objective signs indicating OA in $\geq$2 joint areas on the basis of the patient's medical record (objective signs included: malalignment, crepitation, limited range of motion, palpable osteophytes or nodules or radiographic signs including the presence of joint space narrowing and/or osteophytes); (2) having complaints in $\geq$3 out of 8 joint areas (i.e., feet, knees, hips, lumbar spine, neck, shoulders, elbows and hands); (3) being limited in the performance of daily activities (Health Assessment Questionnaire Disability Index (HAQ-DI) score $\geq$ 0.5); and (4) motivated to alter their lifestyle and willing to participate in a group (assessed by a standardized set of questions). Excluded were patients who were: (1) diagnosed with another rheumatic disease; (2) awaiting surgery; (3) already participated unsuccessfully in a self-management program; (4) having psychosocial problems interfering with the scope of the treatment; (5) incapable of coming to the hospital; or (6) unable to write and or understand the Dutch language.

Interventions

The overall goals of both treatment programs were to improve daily function and to enhance self-management skills to control the disease. The face-to-face treatment was provided by a multidisciplinary team comprising a physical therapist, occupational therapist, specialized rheumatology nurse and dietician. The telephone-based treatment was provided by a specialized rheumatology nurse and physical therapist. The most critical differences between both treatments were the mode of care delivery, the number of involved healthcare providers, the number of group sessions and the number of sessions including an exercise program. For an overview of the content of both programs see Appendix 1. The healthcare providers were trained in techniques of motivational interviewing[22] and were specialized in treating patients with musculoskeletal disorders and teaching self-management principles. To standardize both programs, slide presentations for all sessions and manuals for healthcare providers and patients were used. Protocol adherence of healthcare providers was maintained by meetings during the trial.

Face-to-face treatment group

The multidisciplinary face-to-face program comprised six therapeutic group sessions (6–8 patients and 2–4 h) and a group evaluation delivered during 6 weeks, supervised by a physical therapist. In the first session information about the treatment program was given, expectations were discussed and patients filled in activity and diet diaries. Information about GOA, pain management and medication was also provided in this session. Additionally, patients participated in a general exercise program to improve the quality of movement and posture (i.e., walking, sitting) and to implement exercises in the home situation. This exercise program was continued in session two (standing, kneeling, lifting) and three (stair climbing, lying). Information on physical activity and activity pacing was given in session two and information on food consumption was given in sessions three and four. Furthermore, in session three patients were asked to set personal goals regarding pain management, physical activity and activity pacing which were closely monitored and discussed in the next three sessions. Besides, patients participated in a specific exercise program based on the principles of graded activity and tailored to the patient's health problems in sessions four, five and six. Acceptance as a strategy to

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