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Assistive devices: an effective strategy in non-pharmacological treatment for hand osteoarthritis—randomized clinical trial

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Abstract

This study aims to evaluate the use of assistive devices as a strategy in non-pharmacological treatment for hand osteoarthritis (HOA). This is a randomized, prospective, parallel, assessor-blinded clinical trial, in which patients with a diagnosis of HOA were randomly allocated to an intervention group (IG), where they received assistive devices for daily life activities, or to a control group (CG), where they received a guideline leaflet with information on joint protection and disease features. The primary outcomes considered were occupational performance, measured by the Canadian Occupational Performance Measure (COPM), and hand function was evaluated through the Score for the Assessment and Quantification of Chronic Rheumatoid Affections of the Hands (SACRAH). The secondary outcomes were pain, measured by the visual analog scale (VAS), and quality of life, measured by the World Health Organization Quality of Life Instrument, Short Form (WHOQOL-BREF). We compared both outcomes before and after interventions and outcomes between groups. Participants from the two groups were assessed at the time of inclusion in the study, 30, and 90 days after initial evaluation. Out of the 39 patients included, 19 were allocated to the IG and 20 to the CG. Only two patients from the CG did not complete the follow-up period. The patients' hand function and occupational performance improved after intervention (30 days—SACRAH—$p < 0.05$; COPM—$p < 0.05$; VAS—$p < 0.05$). When comparing results between the groups, there was a statistical difference in COPM (performance—$p < 0.001$; and satisfaction—$p < 0.001$), in the first reevaluation carried out. The use of assistive devices has proved to be an effective alternative in non-pharmacological treatment for HOA.
Clinical Trial Registration: NCT02667145.

Keywords Osteoarthritis · Hands · Assistive devices · Daily life activities · Occupational therapy

Introduction

Hand osteoarthritis (HOA) is a chronic disease that deserves attention due to its high incidence and its limiting potential [1, 2]. When symptomatic, there is a condition of joint pain, deficit in joint mobility, and impaired hand skills [3]. People who are affected often become dependent on others to perform their daily life activities (DLAs) or keep fulfilling activities, but they feel pain and stress the joints [4]. Occupational performance and quality of life are also affected [5].

The combination of pharmacological and non-pharmacological treatments, adapted to the needs of each person, is indicated to minimize symptoms and improve functionality [6]. A non-pharmacological treatment includes: thermal modalities; guidelines based on the principles of joint protection and energy conservation; physical exercise programs;

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indication of assistive technology (AT) resources, which highlight orthoses and assistive devices [7], among others.

Assistive devices are strategies frequently used by individuals with HOA [8]. Their main purpose is promoting alignment and minimizing stress on the joints during the activities. In the case of patients with HOA, a common indication is to adapt utensils by increasing the ergonomically designed grip, something which can decrease the grip strength used and minimize joint wear [7]. Assistive devices are available in a variety of forms, materials, and purposes and they may be made by the therapist or purchased in a common store or in a store specialized in rehabilitation, such as ergonomic bottle openers and electric can openers.

Despite the increased number of studies focusing on HOA and its treatments, much still needs to be investigated [9]. The need for high-quality clinical trials that assess the individual efficacy of each treatment mode is clear [10]. In the case of assistive devices, it is known that their use associated with the use of orthoses, by individuals with HOA, besides promoting greater participation in the activities, are resources widely accepted by patients [11]. However, there are still few studies that analyze the benefits of assistive devices alone [12, 13].

The occupational therapist aims to optimize the occupational performance of an individual with HOA, promoting functionality and quality of life [14]. This is the practitioner recommended to evaluate orthoses and assistive devices, joint protection and hand function training, as well as to evaluate the ability to fulfill DLAs, when providing care for patients with HOA [1]. AT is used as a major resource in the clinical practice of these professionals, to favor participation in DLAs [15]. The inclusion of AT resources in the daily routine of an individual is key to achieve the expected goals [13]. Training the use of this resource and creating self-care groups are possible strategies for this purpose [1].

Knowing the effects and possible benefits of using assistive devices in the daily routine of individuals with HOA may ground the intervention by occupational therapists in clinical practice, drive treatment to the specific need of each person, improve the quality of care provided to these patients, and enrich the literature on the theme. In this scenario, the study aims to identify the effects of using an assistive device on occupational performance and on hand function among individuals with HOA, by raising awareness of the relevance of self-care and training to use this AT.

Method

Study design

This is a randomized, prospective, parallel, assessor-blinded clinical trial, in which, the outcomes before and after interventions were compared, as well as the outcomes between the groups and possible associations between numerical variables (occupational performance, hand function) and categorical variables (diagnostic time, school education level, occupation, presence of nodules, and frequency of analgesic drug use) were also verified after the intervention. The study was carried out at the Rheumatology Outpatient Clinic of the Clinics Hospital of Pernambuco, in Recife, Pernambuco, Brazil.

The Research Ethics Committee of the Health Sciences Center of the Federal University of Pernambuco (UFPE) approved this study on March 9, 2014, under the Brazilian Certificate of Submission for Ethical Assessment (CAAE) 349169143000528, and all participants signed the free and informed consent term to formalize their participation.

Participants

Between November 2014 and 2015, participants were selected having convenience as a basis, through direct invitation, when they attended routine appointments with a rheumatologist. The inclusion criteria were diagnosis of HOA, according to the American College of Rheumatology (ACR) [16], and report of difficulties in DLAs, this information was accessed through a question asked by the researcher and an answer according to the patient's self-perception. Patients who underwent surgical treatment or hand infiltration, occupational therapy and/or physical therapy, or those who used some AT (assistive device or orthosis) device within the last 6 months were excluded; or also subjects with a diagnosis of another rheumatic or musculoskeletal disease affecting the hands.

Outcomes

Participants were evaluated at three moments: a first evaluation, before randomization and the beginning of the intervention, and two additional evaluations, conducted 30 and 90 days after the first one.

The primary outcomes of this study were occupational performance and hand function, evaluated 30 days after the intervention's onset. To verify whether the results were maintained, a new evaluation was performed 90 days after initial assessment. Occupational performance is the outcome of interaction between the person, the environment, and the activity, where self-care, productive, and leisure activities stand out [17]. It was assessed using the COPM, which is an individualized, standardized, measurement designed to be used by occupational therapists, to identify the problem area in occupational performance and to assess performance and customer satisfaction, aiming to obtain a better basis for clinical practice [18]. The COPM is not a benchmarked test, this is a standardized instrument, created as an outcome

measurement to capture changes perceived in occupational performance over time. By measuring the problems identified by each customer, the individuals' scores are compared to their own scores on reassessment. Based on research, the instrument's handbook indicates that a change of 2 or more points, when subtracting the second assessment from the first one is regarded as clinically relevant [17]. Considering as key, the individuality and particularity of each one, this instrument was chosen to identify the areas of performance and DLAs affected, pointed out and seen by each patient as the most significant ones. Another issue considered for this choice was the type of intervention used, since the effects of TA resources are directly linked to performance and accomplishment of activities. To apply the instrument, the individual reports the DLAs affected, then she/he evaluates the degree of importance (1–10) of each one, the five activities regarded as most significant are selected and the patient evaluates her/his performance (1–10), and her/his satisfaction in accomplishing them (1–10), where one means that it does not matter, she/he cannot fulfill, or she/he gets no satisfaction, and ten means extremely significant, she/he can fulfill without any difficulty and gets great satisfaction, this gradation is provided with cards having a ruler-shaped scale, to facilitate the response [13]. The COPM has been translated into Portuguese [19].

Hand function, directly affected by HOA, was assessed by means of the SACRAH, which consists of a 23-item questionnaire, which proposes to assess hand function, pain, and stiffness in individuals with rheumatic diseases. Its measurement is provided through the VAS, where 0 is painless, with no stiffness and no difficulty to fulfill activities, and 100 represents maximum pain, maximum stiffness, and maximum difficulty in fulfilling activities. The SACRAH has been translated and validated into Portuguese [20].

As secondary outcomes, pain and quality of life were also assessed 30 days after the intervention's onset and, to verify the maintenance of results, a new assessment was performed 90 days after the initial evaluation. They were assessed, respectively, by means of the VAS, which is a tool that evaluates the degree of self-perceived pain and it has gradation from 0 to 100, where 0 means absolute absence of pain and 100 means maximum pain [21, 22], and using the WHOQOL-Bref instrument, which evaluates quality of life, consisting of 4 domains: physical; psychological; social relationships; and environment. It is formed by 26 questions, taking as reference the last 2 weeks in a person's life. The results are given in percentage from 0 to 100, considering that the closer to 100, the better quality of life. The WHOQOL-BREF has been translated and validated into Portuguese [23].

Also, an initial interview was conducted with sociodemographic and clinical information, including age, sex, education level, occupation, medication for disease control, diagnosis time, presence of nodules and frequency of analgesic use.

Randomization

The patients included in the study underwent initial assessment, then they were randomly allocated (en bloc) to the intervention group (IG) or control group (CG). The patients allocated to the IG were informed about the days scheduled for group appointments, this group had as its main aim stimulating the use of a daily assistive device as a joint protection way. Those who were allocated to the CG, at the same time, received from the researcher in charge the guideline leaflet, which contained information about the disease and guidelines on how to apply the joint protection and energy conservation principles to daily life, and the explanations needed about the written information were provided. In this study, the patients and the main researcher, responsible for the intervention, knew the treatment concerned. Assessors were blinded and patients were instructed not to tell the assessors which treatment they received. In addition, the statistician responsible for the analyses has not participated in the research.

Interventions

Participants allocated to the IG participated in a self-care group, consisting of four meetings that happened once a week with an average length of 60 min. On the first day, the guidelines on physiopathology, clinical aspects, and treatment for HOA were provided, as well as joint protection and energy conservation guidelines, focusing on the use of assistive devices, through lectures, group discussion, and guideline leaflet. On the second day, about ten assistive devices were selected and given to each participant. Indications were based on the COPM and the SACRAH results pointing out the activities where patients had difficulties to fulfill the opinion of each patient regarding which possible resources might benefit them in daily life. The assistive devices used in this study, made of several materials and having various prices, were devised by the main researcher or bought in a common store or a store specialized in rehabilitation. On the third and fourth days, there was training for DLAs using the resources and adjustments, when needed. Thus, patients, besides being involved in the selection and choice of devices, were also trained to use them appropriately and stimulated to include these resources effectively in their daily routine. Self-care and lifestyle changes were motivated during all meeting, so that the use of devices became part of each individual's routine. Participants in this group had to achieve a minimum attendance of 80% in the assistive program. During the 3-month follow-up period, there were two phone calls to each participant to reinforce the guidelines.

Participants in the CG received the guideline leaflet with information about HOA, including physiopathology, most affected areas, treatment, and primary guidelines on joint protection and energy conservation in DLA and they were guided as for the information contained in the leaflet at the time it was handed out, individually.

An occupational therapist specialized in AT was responsible for the interventions performed, including group visits, selection of assistive devices, preparation of the guideline leaflet, and the guidelines provided. All participants had an appointment with a rheumatologist during the follow-up period. Participants in the CG, upon completion of the survey, received assistive devices, as well as training for their use.

Sample size

Scores were obtained from a study conducted in Norway with the same audience and similar purposes. The sample size was determined considering a 5.0% margin of error, power of 80.0%, and a 2.00 minimum detectable difference in the COPM performance score, a value suggested in the COPM handbook as a clinically relevant change. Based on a standard deviation value combined between the two groups equal to 1.95, a figure obtained by Kjeken et al. [24], sample size was calculated in 16 patients from each group, but considering an expected loss of 20% within the 3-month follow-up period, it was concluded that each group would consist of 20 patients [19].

Statistical analysis

As for data analysis, descriptive statistics was used for continuous variables, through central tendency measurements (mean), dispersion measurements (standard deviation), and probability distribution (percentage analysis). The normal distribution test (Kolmogorov–Smirnov) was performed. For inferential analyses, Student's *t* test was used in case of normal distribution, and for comparing more than two groups, ANOVA (normal distribution) was used. For the categorical variables, the Chi-square test or Fisher's exact test was used. For the tests between paired groups, the Wilcoxon test was used. For all tests, a 95% confidence interval was used. Data was analyzed through the softwares Stata/SE, version 12.0, and Microsoft Excel, version 2010.

Results

Participants

Fifty-three patients were invited to participate in the study, 39 accepted and they met the eligibility criteria. Participants were randomized and allocated to the IG ($n = 19$) and CG ($n = 20$). The 19 patients from the IG concluded the 3-month follow-up period as proposed, in turn, the CG had 2 losses within this period (Fig. 1).

The sample consisted of women with an average age of 59.59 (6.75) years. IG and GC patients had baseline characteristics without a significant statistical difference, except for the use of symptomatic slow-acting drugs for osteoarthritis (SYSADOAs), where the IG had 8 patients who used this medicine and the CG had 17 patients ($p = 0.014$). For the variable 'use of analgesic medicine,' the groups showed to be comparable. HOA severity was considered in this study by the presence of nodules and rhizarthrosis. It is noteworthy that the variable rhizarthrosis was considered in patients with symptoms and changes on physical examination compatible with the clinical status, and Rx was not performed. The sample's baseline characteristics are described in detail in Table 1.

Intervention

According to the COPM, the 39 participants reported limitations in 60 different activities. Out of these, 28 were indicated as the most relevant, and the most frequent were: knife cutting (66.6%), washing clothes (64.1%), sweeping the house (51,3%), washing dishes (46,1%), handling the clothing complements (zipper, buttons, belts) (43.5%), and opening pots/bottles/cans (38.4%), something which shows that among the performance areas, productivity was the most affected, represented by domestic activities, and then self-care, represented by personal care. All participants in the IG underwent the planned group care, with 100% attendance. The assistive devices were indicated according to each person's specific need, and ten devices were delivered to each participant in average. Eighteen different types of assistive devices were offered, see the supplementary material. The most commonly used in order of frequency were: pot openers, zipper and push button adapters, and cutters (100%), followed by adaptations for the broom (78.9%), adapters of various utensils (63.1%), and adaptation for bath (63.1%).

Primary and secondary outcomes

The primary outcomes occupational performance and hand function improved over time using daily assistive devices (SACRAH—$p \leq 0.05$; COPM—$p \leq 0.05$). For secondary outcomes, pain showed a significant statistical difference ($p \leq 0.05$) and quality of life (physical domain) showed a significant statistical difference ($p \leq 0.05$) after intervention (90 days). The results were also positive for the control group, however, with lower scores (Table 2).

When comparing results between the groups, significant statistical difference was observed for COPM performance ($p < 0.001$) and COPM satisfaction ($p < 0.001$) in the first reevaluation (30 days after baseline or initial assessment)

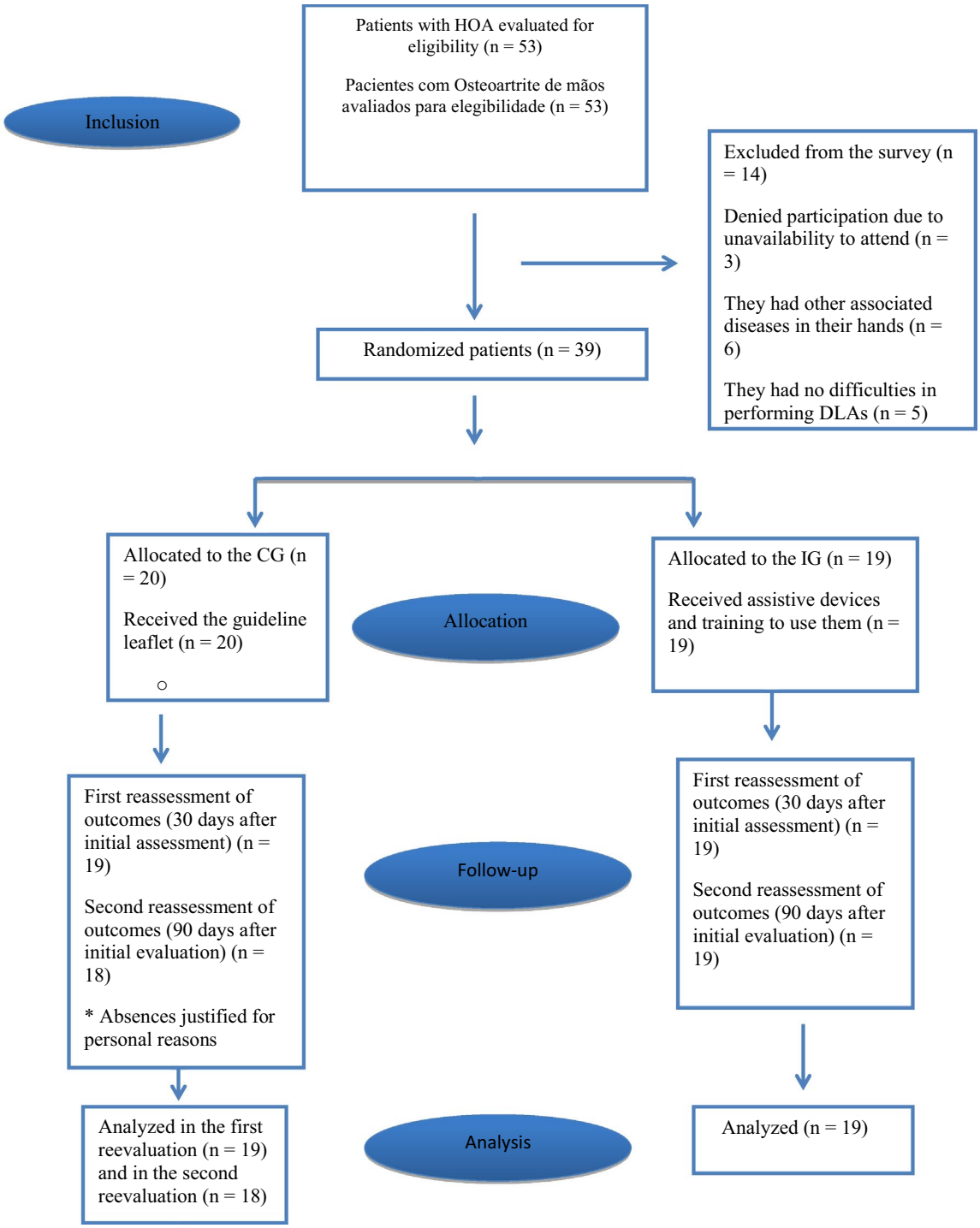

Fig. 1 Flowchart

performed (Table 3). In the second reassessment, where the 90-day follow-up was completed, there was a trend towards this significant difference. For the other outcomes, no statistical difference was observed between the groups.

We found an association between the variables 'occupational performance' and 'hand function' and the categorical variable 'diagnostic time', revealing that those patients with a shorter diagnostic time had worse results regarding hand function ($p < 0.036$), occupational performance, performance ($p < 0.020$), and satisfaction ($p < 0.051$) after the intervention. There was no association between the other variables.

Table 1 Baseline characteristics of the 39 patients, randomly allocated to the IG (received an assistive device) and to the CG (guideline leaflet), displayed in number and proportion, or mean and standard deviation

Variables	Total ($n=39$)	Group		p value
		Case ($n=19$)	Control ($n=20$)	
Sociodemographic variables				
Age	59.59 ± 6.75	59.00 ± 9.02	60.15 ± 6.21	0.644***
Education level				
Up to 8 years	28 (71.8)	13 (68.4)	15 (75.0)	0.920*
More than 8 years	11 (28.2)	6 (31.6)	5 (25.0)	
Occupation				
Housewife	21 (53.8)	8 (42.1)	13 (65.0)	0.266*
Work outside home	18 (46.2)	11 (57.9)	7 (35.0)	
Clinical variables				
Diagnostic time				
Up to 8 years	20 (51.3)	7 (36.8)	13 (65.0)	0.150*
More than 8 years	19 (48.7)	12 (63.2)	7 (35.0)	
Nodal osteoarthritis	32 (82.1)	14 (73.7)	18 (90.0)	0.235**
Rhizarthrosis	25 (64.1)	13 (68.4)	12 (60.0)	0.831*
SYSADOAs	25 (64.1)	8 (42.1)	17 (85.0)	0.014*
Type of medication				
HCQ	10 (40.0)	4 (50.0)	6 (35.3)	0.680**
Diacerhein	10 (40.0)	2 (25.0)	8 (47.0)	
Glucosamine	4 (16.0)	2 (25.0)	2 (11.8)	
Others	1 (4.0)	0 (0.0)	1 (5.9)	
Frequency of analgesic drug				
Daily	14 (35.9)	4 (21.1)	10 (50.0)	0.201**
Weekly	18 (46.1)	11 (57.9)	7 (35.0)	
Monthly	4 (10.3)	3 (15.8)	1 (5.0)	
Does not use	3 (7.7)	1 (5.3)	2 (10.0)	
Outcome variables				
VAS	76.53 ± 18.71	79.68 ± 14.02	74.30 ± 22.20	0.374***
SACRAH	69.63 ± 14.25	68.86 ± 16.89	69.33 ± 12.13	0.920***
COPM performance	3.36 ± 1.39	3.56 ± 1.43	3.32 ± 1.48	0.613***
COPM satisfaction	2.73 ± 1.25	2.98 ± 1.23	2.68 ± 1.50	0.494***
W PHYSICAL	34.50 ± 15.08	34.97 ± 15.35	35.90 ± 17.00	0.860***
W PSYCHO	51.86 ± 20.10	54.60 ± 17.22	50.00 ± 22.49	0.480***
W SOCIAL	64.03 ± 17.87	64.47 ± 16.17	64.99 ± 20.34	0.931***
W ENVIRONMENT	46.32 ± 14.01	49.20 ± 14.04	44.86 ± 14.81	0.354***

VAS visual analog scale for pain, *SACRAH* hand function assessment, *COPM* Canadian Occupational Performance Measure, *W* WHOQOL-BREF physical, psychological, social, and environmental domains, *SYSADOAs* symptomatic slow-acting drugs for osteoarthritis, *HCQ* hydroxychloroquine, *HOA* hand osteoarthritis

*Chi-square test

**Fisher's exact test

***Student's *t* test

Discussion

Using the assistive device in the daily routine has proved to be an effective alternative as a non-pharmacological treatment for HOA. After intervention, the individuals showed gains in occupational performance and hand function, as well as in pain relief and quality of life (physical domain).

A clinical trial conducted by Kjeken et al. [24], in Norway, studied the effects of AT with a patient with HOA, however, they evaluated the orthoses and assistive devices together. We believe that studying the effect of these various types of AT combined may not make clear what actually improved individuals' performance. The aim of orthoses differs in some points from the purposes of the assistive

Table 2 Values of the continuous variables related to evaluation of pain, hand function, occupational performance, and quality of life, in each group, before and after intervention (30 and 90 days)

Variables	Case group			Control group		
	Baseline	30 days	90 days	Baseline	30 days	90 days
VAS*	79.68 ± 14.02	53.58 ± 23.02[a]	47.37 ± 28.79[a]	73.37 ± 22.41	59.95 ± 18.46	59.06 ± 23.27[a]
SACRAH*	68.86 ± 16.89	55.15 ± 15.99[a]	46.47 ± 21.73[a]	70.40 ± 11.44	56.22 ± 15.76[a]	53.23 ± 17.64[a]
COPM P*	3.56 ± 1.43	6.15 ± 1.53[a]	6.24 ± 2.06[a]	3.17 ± 1.35	4.47 ± 1.37[a]	4.92 ± 2.05 [a]
COPM S*	2.98 ± 1.23	6.72 ± 1.75[a]	6.29 ± 2.34[a]	2.48 ± 1.25	4.46 ± 2.02[a]	4.77 ± 2.46[a]
W PHYSICAL*	34.97 ± 15.35	42.29 ± 14.14	43.79 ± 16.79[a]	34.03 ± 15.21	40.78 ± 8.61[a]	40.88 ± 12.31[a]
W PSYCHO*	54.60 ± 17.22	58.99 ± 15.35	55.05 ± 16.53	49.12 ± 22.76	55.70 ± 16.51[a]	51.85 ± 19.08
W SOCIAL*	64.47 ± 16.17	64.48 ± 17.32	66.68 ± 16.44	63.58 ± 19.87	65.34 ± 16.96	58.80 ± 20.30
W ENVIRONMENT*	49.20 ± 14.04	47.70 ± 13.82	48.20 ± 17.28	43.44 ± 13.73	48.35 ± 12.22	46.01 ± 11.69

Displayed in mean and standard deviation

VAS visual analog scale for pain, *SACRAH* hand function assessment, *COPM* Canadian Occupational Performance Measure, *W* WHOQOL-BREF physical, psychological, social, and environmental domains

*Wilcoxon test

[a]Significant statistical difference from baseline (p value ≤ 0.05)

Table 3 Values of the continuous variables related to evaluation of occupational performance, in the comparison between groups

Variables	Groups		p value
	Case	Control	
	Mean ± SD	Mean ± SD	
COPM P (baseline)	3.56 ± 1.43	3.32 ± 1.48	0.613*
COPM P (30 days)	6.15 ± 1.53	4.47 ± 1.37	0.001*
COPM P (90 days)	6.24 ± 2.06	4.92 ± 2.05	0.059*
COPM S (baseline)	2.98 ± 1.23	2.68 ± 1.50	0.494*
COPM S (30 days)	6.72 ± 1.75	4.46 ± 2.02	0.001*
COPM S (90 days)	6.29 ± 2.34	4.77 ± 2.46	0.061*

Displayed in mean and standard deviation

COPM Canadian Occupational Performance Measure, *P* performance, *S* satisfaction

*Student's *t* test

device, such as carpometacarpal joint stabilization in cases of rhizarthrosis. Clinical trials have already been performed to evaluate the effect of a good-quality orthosis for rhizarthrosis, showing that they relieve pain and improve hand function [25, 26]. In this context, we chose to study only the assistive devices.

The assistive device is considered as a method to implement joint protection (JP), which in turn is based on respect for pain, balance between activity and rest, a position restriction that stimulate deformity, preferential use of the larger and stronger joints, and decreased joint stress and strength [7]. The main resource's purpose is expanding the grip contact area to reduce the strength used during movement and to promote joint alignment, since during DLAs minor trauma to the cartilage may intensify damage to degraded tissues, hence the importance of reducing the effort of hand joints when doing the activities using the mechanical means of assistive devices for joint protection [7, 25]. Some joint protection studies have advised and even trained the use of assistive devices, but they did not provide the resources [11, 27], however, in our study, just as in Kjeken's [24], such devices were provided.

When comparing results between the groups, only the COPM showed some statistical difference, benefiting those who underwent the intervention. For the analysis of this result, we take two major aspects into account: the first is that occupational performance, since it is related to the individual's interaction with the activity, may have been more sensitive to changes brought by the benefit of using the assistive devices. Using such adaptations during activities, patients with limiting HOA can re-engage in an activity independently, or perform it more comfortably and safely [8]; the second issue is that responses from the CG were better than expected, suggesting that the guideline leaflet should be considered relevant as a low-cost and user-friendly treatment choice. We observed that many participants in this group were interested in the guidelines provided, even in a single moment, and they began a process of change on a daily basis, resulting in improved functionality and quality of life, thus what we planned to be a 'placebo group' became a group that also underwent an intervention. A third comparison group, where participants were exempt from any intervention or guidelines, has not been proposed in our study for ethical reasons.

Data suggested that the activities most affected by the impact of this disease were those in the fields of productivity and self-care. This fact corroborates the activities observed in previous studies [4, 28]. Regarding the assistive devices,

a study has shown through patient accounts that using assistive devices among the most frequently used strategies with a view to improving performance in DLAs. The accounts also mentioned that pot openers and food cutters were the most frequently used [8]. In our study, these two devices were used by 100% of the participants in the IG.

Quality of life is a complex outcome, from its definition to its measurement. It involves many fields with physical, psychological, social, cultural, and environmental representations, something which may require a longer follow-up period to achieve significant results in all of its domains and this may also be influenced by independent variables, such as education level, social status, aesthetic changes [29]. We believe that, for this reason, in our study, only the physical domain showed improvements after intervention, which may be justified by the fact that this domain is related to pain, fatigue, performance in DLAs, and work capability, where using the assistive device might have a direct effect.

Another aspect that must be taken into account is the relevance of caution and attention to select these resources, rather than just delivering the resource to individuals in a decontextualized way. In this study, group appointments were used as a strategy, with guidance on disease and joint protection and energy conservation techniques, as well as workshops with experiences related to these DLAs in an adequate and safe way, discussions to exchange experiences and motivation to change lifestyle and include the resources in daily life. We notice the relevance of these strategies when there is no loss in this group, in addition to 100% attendance among the participants, which reflects their interest and commitment to the intervention.

This study has put its results to test in other contexts. Although the sample has come from a university hospital specialized in the area, the eligibility criteria were not very restrictive. Also, the city's primary health care (PHC) network has a few rheumatologists, referring these patients to reference hospitals, something which makes the characteristics of this sample similar to those of patients from the community as a whole. Thus, we may use this type of treatment in other healthcare levels.

For the internal validity of this study, the systematic biases that characterize clinical trials were minimized as far as possible. The selection bias was avoided through randomization. The calibration bias was minimized by blinding assessors, and the friction bias was minimized by the small number of losses that occurred in the study. However, there was a performance bias, due to the impossibility of blinding the main researcher and the patients, because this is a non-pharmacological intervention, which made it impossible to apply a placebo. Another potential limitation seems not to be sure of the actual description of how, for how long, and in which activities assistive devices were used in patients' daily lives, i.e., if patients used and followed the guidelines provided.

Thus, we conclude that using assistive devices may be regarded as a good strategy in non-pharmacological treatment for HOA, since in this study patients showed significant functional gains, with major improvements in terms of occupational performance. Including this kind of assistance in the protocols of care for these patients is reinforced by the possibility to minimize the impact of disease and contribute to better performance in DLAs. For the clinical practice of occupational therapists, this study suggests reflection not only on the benefits of resources but about the importance of concern with selection strategies that can make the difference for a real change in users' lifestyle.

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Author contributions All authors contributed in some way to conduct this study and approved the final version for publication. Study conception and design: DA, CM, SB and VL. Data acquisition: DA, SC, AR, AD, AO, PS and JA. Data analysis and interpretation: DA, CM and ÂD. Manuscript preparation: DA and CM.

Compliance with ethical standards

Funding All study costs were paid by the main researcher.

Conflict of interest The authors declare there is no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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