

Effects of 12-week Digital Treatment in Patients With Hand OA on Pain and Function

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Survey of the field

Musculoskeletal conditions are identified by the Global Burden of Disease Study as a leading cause of global morbidity (1). Estimates of the need for rehabilitation services show that at least one in every three people in the world needs rehabilitation at some point in their life course (2). As disability becomes an increasingly large component of disease burden and health expenditure, greater research and development investment is needed to identify new, more effective intervention strategies (1).

Osteoarthritis (OA) is one of the leading causes of disability worldwide and due to its rising prevalence, the identification of appropriate care and care delivery modalities is a priority for the health care systems (3, 4). Exercise and education constitute the first-line intervention for people with knee, hip and hand OA and have been shown to be effective regardless of symptoms and disease severity (5, 6, 7) International guidelines recommend that first-line interventions for the majority of musculoskeletal conditions should involve nonsurgical management with exercise and education guided by a physiotherapist (PT) and based on a personalised care approach (8, 9).

OA of the hand is probably the most common form of OA and almost 50% of women and 25% of men will be affected during the life course (10). Self-management strategies includes a wide range of strategies such as education for strengthening or stretching exercises, joint protection education for activity and pacing, use of proper body mechanics, and assistive devices to improve pain, reduce inflammation, lower additional risk of deformities, and enhance performance (7). Systematic reviews that compared joint protection strategies to usual care have shown similar effects at short-term and superior effects at mid- and long-term compared to usual care (11).

To implement the guidelines, the Better Management of Patients with OsteoArthritis (BOA), a face-to-face concept including education and an option to exercise, has been developed and is offered at primary care clinics in Sweden since 2008 for patients with hip- knee- and hand OA (12). BOA has previously been found to reduce pain and improve function and quality of life in patients with hip and knee OA (9). Unfortunately, there is a discrepancy between recommended treatment and what patients receive and around 30% of people with OA seeking care go through first line management (13).

Traditional face-to-face interventions present barriers, such as limited access and lack of flexibility, which may limit the patients' adherence with the interventions (14). Digital delivery of the management program may be one way of overcoming such barriers (15, 16). Telehealth, defined as the 'delivery of healthcare at a distance using information and communication technology' could be a solution to many access barriers and has been rapidly adopted by many healthcare professions and accelerating even more throughout the COVID-19 pandemic (17,18).

Literature investigating the use of telehealth for the management of musculoskeletal pain is growing. Systematic reviews have demonstrated that telehealth can provide improvements in pain, physical function and disability that are similar to that of usual face-to-face care for individuals with musculoskeletal conditions such as osteoarthritis for the knee and hip (19, 20). The use of telehealth also seems to increase exercise adherence for a variety of musculoskeletal conditions (21, 22). To our knowledge, digital self-management programs for OA of the hand have not yet been evaluated.

Joint Academy® (JA), a digitally delivered treatment program with exercise and patient education was developed to increase access to and facilitate implementation of guideline derived and evidence-based treatment for OA. The first JA program was introduced in 2016 for persons with hip- and knee OA and participants reported reduced pain and improved function during up to 48 weeks of treatment (23). A recent randomised controlled trial on patients with knee OA showed that the digital program was superior to usual care (24). Since late 2021, a digital program for OA of the hand is also available on the platform.

Project description

This is an observational registry-based study.

Purpose and goal

The overall aim of this project is to evaluate changes in health outcomes during participation in the digitally delivered treatment programme Joint Academy® (JA) containing exercise and education for patients with osteoarthritis (OA) of the hand.

Specific research questions are:

(1) What are the short-term changes in health outcomes of digitally delivered treatment for OA of the hand? Primary outcome is to examine pain and perceived hand function in participants following 3 months of digitally delivered first-line treatment for hand OA

Main exposures and outcomes

All participants answer patient- and disease relevant socio-demographic and outcome questionnaires at baseline and every third month during treatment. Additionally, participants report pain every week.

Pain will be assessed using the Numerical Rating Scale (NRS, discrete boxes 0–10) with the instruction: “Mark on this scale how much pain you had the last week in your hand”, followed by a 0–10 scale where 0 was defined as *No pain* and 10 was defined as *Maximum pain* (25).

To evaluate hand function, the Functional Index for Hand OsteoArthritis (FIHOA) will be distributed. The FIHOA is a 10-item questionnaire based on a semi-quantitative assessment scoring the disease on a 4-point scale. The FIHOA has been shown to be valid, sensitive, clinically relevant for the population and shown consistency and acceptable reliability (26). The literature also suggests it is associated with pain, muscle strength and health related quality of life in people with hand OA (27).

Among other outcomes to be reported are health-related quality of life assessed with the EuroQol – 5 dimension descriptive system (EQ-5D-5L), work situation, medication use (dichotomous reply, yes/no), changes in medications, willingness for surgery (dichotomous reply, yes/no), physical activity, exercise, fear of physical activity (yes/no) and motivation to start exercising using a Numerical Rating Scale (NRS, discrete boxes 0–10).

All outcomes will be self-assessed and self-entered using the digital program interface. Demographic and socioeconomic data and data on the participants’ overall health and characteristics (e. g age, gender, educational level BMI) will be collected at inclusion. The exposure and outcome measures are described in Table 1.

The digital program Joint Academy®

In an attempt to scale and improve implementation of evidence-based guideline-derived first-line treatment for a number of musculoskeletal conditions (education and exercise), the digital self-management and education program Joint Academy® (JA) was developed in Sweden. The first JA program was developed in 2014 for persons with hip- and knee OA (28). The program for hand OA is available for patients since late 2021. The program is part of the health-care system in Sweden.

Participants join the programme through recommendation by their local physiotherapist (PT), occupational therapist (OT) or orthopaedic surgeon, via online advertisements and campaigns placed on search engines and social networks, or through their insurance company. A majority of included participants had a clinical diagnosis of hand arthritis from a PT, OT or physician, and all had a physical visit with a healthcare provider regarding their hand OA prior to joining JA. The clinical diagnosis of OA was confirmed by a PT or OT via telephone, or if deemed necessary the patient was recommended to seek face-to-face care before inclusion in the programme.

The Joint Academy® (www.jointacademy.com) program for people with hand OA consists of video instructed and progressively adaptable daily exercises, patient education through text lessons, possibility for a social chat group with other patients and a continuous asynchronous chat function with a personal reg. physiotherapist who supervises the patient during the full participation period. The program also contains three telephone consultations with a physiotherapist that were compulsory, one at the start, one after six weeks and one after three months. The intervention procedure is similar to that for hip and knee OA, which is thoroughly described in previous studies (23, 28).

Statistical analysis

We will develop a specific statistical analysis plan for each specific sub-study that will be conducted to answer the aforementioned research questions.

To describe the sample, we will use means and standard deviations (SDs), frequencies and percentages. These will follow several general principles. We will aim for the inclusion of all available patients to limit potential selection bias. In the statistical modelling we will aim for

estimation of causal effects and statistical models will be chosen accordingly using direct acyclic graphs (DAGs) to enable proper confounding control. For confounding control, we will use regression models or inverse probability weighting. For analysis of panel data (i.e. longitudinal repeated measurements of the participants and/or data clustered by caregiver) we will use conditional or marginal models. For time-to-event data we will use the Cox regression model, or, if appropriate, a parametric version. For mediation analysis, we will use linear models or maximum likelihood structural equation models when appropriate. For categorical outcomes we will use other approaches such as logit and probit models. We will report the results from all analyses as relevant estimated effect size (such as risk differences, risk ratios or hazard ratios) with 95% confidence intervals and interpret these for clinical relevance, irrespectively of statistical significance.

Power calculation

Power analysis revealed that for the initial short-term follow-up, a sample size of 70 participants will be enough to identify a minimally clinical important change of 1.5 units in pain with a calculated mean pain of 5.2 (sd 2.2) at start, power of 80%, $p<0.05$.

For the other studies, we will not perform any power calculation. This is because the question of power can be considered secondary in such a setting where the sample size is driven by data availability and not decided a priori. Therefore, we will include all the available data from the start.

Ethical considerations

Storage and management of data

The data set will be stored in a database at Arthro Therapeutics head office in Malmö. The platform is designed to securely store, manage and analyse data in accordance with the European Union general data protection regulation (GDPR). The process of linkage, storage and management of data, the role of informed consent in register-based research and safeguarding the integrity of study participants follows the legal and ethical frameworks as described by Swedish law and ethical boards. This has been described by Ludvigsson et al (30).

Data sharing

All information regarding individual patients is subject to confidentiality in accordance with The Public Access to Information and Secrecy Act (SFS 2009:400) chapter 25 article 1. Therefore, no unauthorised person will have access to data.

Significance

Preliminary results

- Initial observational reports on the first digital JA programme for persons with hip or knee OA suggest that participation in JA for six weeks was associated with a clinically relevant decrease in pain and an increase in physical function, as well as a decreased fear of physical activity (23). These effects were maintained up to 48 weeks during participation in the treatment program (29).
- Costing analysis of the JA program for persons with hip or knee OA have shown that the digital model overall costs around 25% of the existing face-to-face model of care (31).
- A Randomised Controlled Trial on patients with knee OA has shown that the digital JA programme was superior to routine treatment in a United Kingdom context (24).

Clinical significance

In the management of OA, overall adherence to clinical guidelines is low and implementation of strategies and removal of existing barriers against the application of evidence-based guidelines could facilitate the transfer of scientific evidence into clinical practice and contribute to optimising the quality of healthcare. Telehealth such as the digital JA program is scalable and has the potential to improve reach and access to evidence-based first-line treatment for a large number of individuals with musculoskeletal conditions who have internet access. Previous results for patients with knee and hip OA also suggest that the digital platform could offer a cost-effective alternative to the existing models of care. Depending on the extent to which the

digital model substitutes for the existing model of care, significant health-care resources can be saved.

Access to personnel

More than 250 physiotherapists are involved in JA and treating patients on a regular basis. Arthro Therapeutics has over 100 employees working with the design, adherence strategies and implementation of the platform, including operational team, research team etcetera.

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Tables

Table 1. Description of the single variables collected from the Joint Academy (JA) database.

	Sign up / Week 0 1	We ek	Every week	Every other week	3 mon ths	6 mon ths	9 mon ths	12 mont hs
Outcomes								
Diagnostic questions (symptoms, red flags etc)		X						
Weight and height / BMI		X						
Age		X						
Gender		X						
Most painful joint (choose one)		X						
pain locations (one or many)	X				X	X	X	X
if arthroscopy has been performed	X							
if patient feels the need for surgery of joint	X				X	X	X	X
if surgery is scheduled	X				X	X	X	X
if surgery has been cancelled due to JA					X	X	X	X
If pain medication the last three months, and if so what type	X				X	X	X	X
If pain medication has been changed since starting JA					X	X	X	X
If so, which are changed and in what way					X	X	X	X
FIHOA hand function score	X				X	X	X	X
If has lung disease (COPD, asthma etc)	X							
If has diabetes	X							

If has cardiovascular disease	X				
If has arthritis (e.g RA)	X				
If has balance problems (e.g. due to neurological disease such as PD)	X				
Free text medical information	X		X	X	X
Level of exercise (defined in category of minutes)	X		X	X	X
Level of activity in daily living (defined in cat of min)	X		X	X	X
If afraid to get hurt during physical activity / exercise (kinesiophobia)	X		X	X	X
30 second chair stand test		X	X	X	X
Specific joint pain (0-10 NRS)	X	X	X	X	X
Overall health (0-10 NRS)	X	X	X	X	X
EQ5D-5L	X		X	X	X
Educational level	X				
Work situation	X		X	X	X
Patient acceptable symptom state	X		X	X	X
If considers treatment failed			X	X	X
Motivation - ready to start exercising (0-10)	X				

FIHOA: Functional index for hand osteoarthritis patients. COPD: Chronic obstructive pulmonary disease, RA: Reumatoid Arthritis, PD: Parkinson's Disease, NRS: Numeric Rating Scale