Digitally Delivered First-line Osteoarthritis Treatment - Effects on Pain and Function in Different Age Groups.

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Study questions:

Primary:

Do the mean outcomes for these 3 age groups differ (as they are, unadjusted, and using JA 'as prescribed' by the Swedish national Board of Health and Welfare (Socialstyrelsen)?

To what extent does adherence and other covariates explain the potential differences in outcomes?

Secondary:

Does the adherence to JA treatment differ across age groups?

Does the JA uptake differ by age when comparing age distribution of JA participants with age distribution of OA in the Skåne population?

Background

Osteoarthritis (OA) is among 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. Exercise and education constitute the first-line intervention for people with knee and hip OA and are effective regardless of symptoms and disease severity. This first-line intervention is available as face-to-face programs, or digital programs via eHealth apps. No published studies have yet examined if, among the OA population, the uptake, or the outcomes of the program, differ between younger or older participants in a digital first-line OA intervention. Our understanding of how background (demographic) factors interact with uptake and outcomes is incomplete.

Methods

This is an observational, retrospective register-based study of participants in a digital osteoarthritis self-management program.

All participants signed informed consent digitally upon registration. The regional ethics committee of Lund University and the Swedish Ethical Review Authority provided ethical approval (Dnr: 2018/650, 2019-02232 and 2020-05431). The study adheres to the STROBE guidelines for observational studies.

Setting and participants

Participants joined the digital OA self-management and education program (see Intervention below for details), through recommendation by their local orthopaedic surgeon or physiotherapist, and via online advertisements and campaigns placed on search engines and social networks. Included participants had a radiographic and or clinical diagnosis of hip or knee OA from a physical therapist or physician (95% of all patients at the date of data extraction). Individuals without a prior diagnosis had clinical OA confirmed by an orthopaedic surgeon or physiotherapist via telephone (diagnosis according to NICE UK criteria and Swedish National Guidelines, and confirming the absence of any red flag symptoms), or if deemed necessary were recommended to seek face-to-face care before inclusion in the program.

All data for the present study were extracted from the digital self-management program data registry on the 22nd of March 2021. Criteria for inclusion in the primary data extraction were:

- Having registered in the program and had the first telephone contact with the physiotherapist assigned to the patient, and enrolled between March 1, 2018 and November 30, 2020.
- Having reported hip or knee as most symptomatic (index) joint
- Having provided 3-month follow-up data on or before February 28, 2021

These selection criteria resulted in 14006 eligible participants.

Adherence was defined as the percentage of completed activities (exercises, and text or video lessons on OA, with quizzes on lesson material) per the pre-defined period of 12 weeks. A cut-off of 80% or higher adherence corresponds to the National Recommendations for first-line knee and hip OA treatment by the Swedish National Board of Health and Welfare (1).

Intervention

The intervention consisted of a digital, structured and individualized first-line treatment program for people with hip or knee OA (Joint Academy®; www.jointacademy.com). The physiotherapist-led program consists of instructions for neuromuscular exercises appropriately adjusted to each patient in regard to degrees of complexity and difficulty. Exercises are distributed daily during the whole participation period, in general two per day, for a total of 163 exercise sessions over 12 weeks. While rating perceived difficulty and adding comments, patients also indicate when exercises are completed. Program progression is halted until all exercises for the day are marked as completed. Information (based on current national OA management guidelines and research) in the form of text or video lessons (with quizzes on the material after each episode) on subjects related to OA, OA symptoms and management is also distributed to each participant. The lessons come packed in themes, with each theme containing 1–5 lessons where participants receive one theme per week the first six weeks, and then every other week, for a total of 31 lessons over 12 weeks. Completion of a lesson is indicated by the patient answering the quiz correctly. Additionally, continuous access to, and dialogue with, is provided by a physiotherapist through an encrypted chat function and telephone.

Main exposure & outcomes

Exposure

Age (categorized in 3 groups) is the main exposure of the interest.

Outcomes

For research question 1:

1. Joint pain will be assessed at baseline and at week 12 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 hip/knee”, followed by a 0–10 scale where 0 was defined as No pain and 10 was defined as Maximum pain.

2. As a measure of physical function, the 30 second chair rise will be measured at baseline and week 12, performed by the participant with the help of an instruction video with a coupled visual timer. The patient enters the performed number of repetitions after each test.
3. Among other outcomes to be reported are changes between baseline and 12 weeks follow-up in self-reported KOOS-12 and HOOS-12, KOOS-PS, HOOS-PS, response to anchor questions, response to questions on satisfaction or not with treatment, fear of movement, and walking difficulties (Table 1).

All outcomes will be self-assessed and self-entered using the digital program interface and selected based on the International Consortium for Health Outcomes Measurement Standard Set for Hip & Knee Osteoarthritis (ICHOM) (2).

For research question 2:

Adherence as measured (between 0 to 100%) and desirable adherence ≥80% (i.e. ≥80% completed exercises, text or video lessons on OA, with quizzes on lesson material offered in the digital program) between 0 and 12 weeks of first-line OA treatment delivered digitally.

For research question 3:

Registration in JA is the outcome of interest.

Endpoints

Main endpoints

a) Self-reported change in index joint (knee or hip) pain on the NRS-scale between baseline and 12 weeks of follow-up for the three age groups <=59, 60-69, and >=70
b) Self-reported change between baseline and 12 weeks in 30-second chair rise test for the three age groups <=59, 60-69, and >=70

Other endpoints

Outcomes will be compared for the three age groups >=59, 60-69, and >=70 for the following

KOOS-12 questionnaire
HOOS-12 questionnaire
KOOS-PS questionnaire
HOOS-PS questionnaire
Physical activity
Responder criteria and patient responses to questions on satisfactory health state and treatment failure.

Covariates

We will examine to what extent the potential differences across age groups in research questions 1 & 2 can be explained by the baseline demographic, socioeconomic (employment status and education level) and clinical (BMI, co-morbidity, overall health status, index joint) characteristics.

Sample size

This being a registry-based study of prospectively collected data, no formal power calculation will be provided. However, with the number of patients providing data, statistical power will be more than sufficient to analyze conclusively relevant group differences for the main endpoints.

Statistical analysis

Data description

Summary data by age groups will be described by the mean value, standard deviation and number of observations or the number and percent of the categories of interest.

For research question 1, we perform ordinary least squares (OLS) regressions of the outcome of interest on age group and the baseline value of that outcome. Next, we adjust for all other covariates including adherence. Finally, we will employ the Oaxaca-Blinder (OB) decomposition technique to understand the reasons for potential differences across age groups in the outcome of interest. OB decomposition decomposes differences between groups into “explained” and “unexplained” portions. The explained part estimates the amount of the differences in the outcome attributable to age group differences in the means of explanatory variables. The unexplained part originates from the differences in the associations between the outcome and explanatory variables across age groups. This latter part represents the magnitude of difference which will remain even if the age groups had identical means of covariates. In addition to decomposition of mean differences between age groups, we will also decompose the difference in variance of the outcome using OB technique. In interpreting the findings, we will take into account the minimal clinically important difference for each outcome (e.g. differences above 10 (scale 0-100), or 1 (scale 0-10) in pain).

For research question 2, we will use OLS regression (with adherence as measured) and logistic regression (for desirable adherence: adherence≥80%) to investigate age group differences in these outcomes. Similar to research question 1, we will use OB technique to decompose the potential gap between age groups in these two outcomes. In interpreting the findings, we will take into account the minimal clinically important difference of 2.0 in repetitions"

For research question 3, we will obtain data on doctor-diagnosed knee and/or hip OA among the Skåne population by age group and contrast this with the JA participants resident in the Skåne. This comparison will reflect what proportion of people with doctor-diagnosed OA in each age group registered in JA.

In all studies we will conduct subgroup analyses by index joint (knee & hip) if data allows. Moreover, since the rate of dropout between the baseline and 3 months follow up might be different across age groups, we will apply inverse probability weighting to account for this.

References

1. https://www.socialstyrelsen.se/en/regulations-and-guidelines/national-guidelines/
2. https://www.ichom.org/standard-sets/#musculoskeletal

Table 1

Reported only at follow-up
Reported at both baseline and follow-up

		JA-ages-usage-outcomes	
	QUESTIONS	**Baseline**	**3 months**
	Total number of participants	14006	14006
Demographics	work_situation	14006	0
	educational_level	14006	0
Comorbitities	other_health_problems.diabetes	14006	0
	other_health_problems.lung_disease	14006	0
	other_health_problems.balance_troubles	14006	0
	other_health_problems.rheumatoid_arthritis	14006	0
	other_health_problems.cardiovascular_disease	14006	0
	other_health_problems.causing_walking_difficulties	14006	0
Health	overall_health	14006	14006
	specific_joint	14006	14006
	specific_joint_pain	14006	14006
	pain_in_other_joints	14006	0
	pain_improved	0	4329
	pain_locations	0	
	exercise_choice	14006	14006
	physical_activity_choice	14006	14006
	difficulty_walking	14006	14006
	afraid_to_get_hurt_by_movement	14006	14006
	patient_acceptable_symptom_state	14006	14006
	motivation_readiness	14006	0
	overall_health_improved	0	4329
	physical_function_improved	0	4329
	considers_treatment_failed	0	8857
Willingness for surgery	wants_operation	14006	14006
	invasive_operation_scheduled	2337	2176
	arthroscopy_performed_on_specific_joint	14006	0
	invasive_operation_type_scheduled	299	0
	invasive_operation_cancelled	0	1571
~~**Medication**~~	~~invasive_medicines_selections~~		
	~~invasive_medicines_changed~~		
EQ-5D	eq5d.mobility	14006	14006
	eq5d.self_care	14006	14006

	eq5d.pain_discomfort	14006	14006
	eq5d.usual_activities	14006	14006
	eq5d.anxiety_depression	14006	14006
HOOS-PS	hoos.running_difficulty		
	hoos.sitting_difficulty		
	hoos.descending_stairs_difficulty		
	hoos.getting_out_of_bath_difficulty		
	hoos.pivoting_loaded_leg_difficulty		
KOOS-PS	koos.squatting_difficulty		
	koos.sitting_up_difficulty		
	koos.bending_over_difficulty		
	koos.twisting_knee_difficulty		
	koos.laying_on_knee_difficulty		
	koos.putting_on_socks_difficulty		
	koos.rising_out_of_bed_difficulty		
~~**Work productivity**~~	~~wpai.employed~~		
	~~wpai.hours_actually_worked~~		
	~~wpai.oa_productivity_effect~~		
	~~wpai.oa_regular_activities_effect~~		
	~~wpai.missed_working_hours_due_to_oa~~		
	~~wpai.missed_working_hours_due_to_other_reasons~~		
~~**JA**~~	~~ja_like~~		
	~~recommend_others~~		
	~~therapist_appreciation~~		
Other	free_text_medical_information		
HIP new	hip_satisfaction_now	0	3956
	hip_satisfaction_quality	0	3956
	hip_satisfaction_performance	0	3956
	hip_satisfaction_symptoms_now	0	3956
	hip_satisfaction_sports_performance	0	3956
HOOS-12 new	hoos.standing	3541	3956
	hoos.in_out_car	3541	3956
	hoos.hip_aware	3541	3956
	hoos.going_stairs	3541	3956
	hoos.sitting_lying	3541	3956
	hoos.rising_sitting	3541	3956
	hoos.hip_confidence	3541	3956
	hoos.hip_difficulty	3541	3956
	hoos.hip_pain_duration	3541	3956
	hoos.walk_flat_surface	3541	3956
	hoos.modified_lifestyle	3541	3956

	hoos.walk_uneven_surface	3541	3956
KNEE new	knee_satisfaction_now	0	5721
	knee_satisfaction_quality	0	5721
	knee_satisfaction_performance	0	5721
	knee_satisfaction_symptoms_now	0	5721
	knee_satisfaction_sports_performance	0	5721
KOOS-12 new	koos.standing	5026	5721
	koos.in_out_car	5026	5721
	koos.knee_aware	5026	5721
	koos.going_stairs	5026	5721
	koos.sitting_lying	5026	5721
	koos.rising_sitting	5026	5721
	koos.knee_confidence	5026	5721
	koos.knee_difficulty	5026	5721
	koos.knee_pain_duration	5026	5721
	koos.walk_flat_surface	5026	5721
	koos.modified_lifestyle	5026	5721
	koos.twisting_injured_knee	5026	5721

Fig. 1 Flowchart