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RANDOMIZED-CONTROLLED TRIAL TO EVALUATE A 12-WEEK APP- AND BRACE-ASSISTED EXERCISE INTERVENTION IN PATIENTS WITH KNEE OSTEOARTHRITIS

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Abstract:
Purpose: Exercise therapy is recommended by the international guidelines as a core treatment in patients with knee osteoarthritis (OA). However, there is a significant gap between recommendations and practice in health care. In this context, fully automated, digital applications (apps) could be increasingly used to allow participation in exercise programs independent of time and space. As knee braces increase the functional stability of the knee joint, they may be valuable as an exercise supportive device.
The aim of the study therefore was to evaluate the efficacy of a 12-week app-assisted exercise intervention with and without supporting knee brace compared to a control group without intervention in patients with knee OA. For the primary outcome, superiority of exercises versus control in terms of patient-reported pain reduction was examined. Secondary outcomes included further OA-specific complaints. An explorative sub-analysis was used to explore whether a brace may be useful as a treatment-supporting device.
Methods: Subjects with moderate or severe unicondylar painful knee OA were included. Randomization was 1:1:2 into an intervention group (IG) with two subgroups (IG-A: app-assisted training, IG-AB: app-assisted training and axis-correcting knee brace) and a wait-list control (C). IG-AB had to wear the brace during training, further use was optional. The intervention included a 12-week home training program with three sessions per week. A total of five exercises including strengthening, mobilization, stretching and balance were performed in each session. Exercises were guided via an app and movement performance was monitored with two accelerometers placed below and above the affected knee joint. OA-specific complaints were recorded using the Knee Osteoarthritis Outcome Score (KOOS, score range 0-100). Intervention effects were calculated using

baseline-adjusted analysis of covariance (ANCOVA). In addition, effect sizes were calculated and interpreted according to Cohen.

Results: N=61 subjects (IG: n=30 thereof IG-A: n=15 and IG-AB: n=15; C: n=31; ♂=31; ♀=30; Ø age: 62.9 ± 8.5 years; Ø BMI: 27.7 ± 4.5 kg/m^2) were included in the study. Baseline-adjusted post intervention scores indicated statistically significant differences for the primary outcome pain ($F(1,52)=20.01$, $p=.000$, $\eta^2=.278$, see Image 1 and Table 1) as well as for the secondary outcomes (see Table 1) symptoms ($F(1,52)=7.01$, $p=.011$, $\eta^2=.119$), activities of daily living ($F(1,52)=15.56$, $p=.000$, $\eta^2=.230$), sports and leisure ($F(1,52)=5.98$, $p=.018$, $\eta^2=.103$) and quality of life ($F(1,52)=19.87$, $p=.000$, $\eta^2=.277$) in favor of the intervention group. Mean differences ranged from 10.0 to 13.2 points compared to the control group. According to Cohens d, effect sizes of 0.76 (pain and quality of life) indicate a moderate to large effect and 0.47 (sports and leisure), 0.53 (symptoms) as well as 0.64 (activities of daily living) a small to moderate effect. The subgroup comparison between IG-A and IG-AB demonstrated baseline-adjusted mean differences ranging from 4.7 to 12.1 points more in favor of the IG-AB group regarding the five KOOS categories, but without statistical between-group significance. Yet, the subgroup analysis provided a first indication for superiority of IG-AB vs. IG-A.

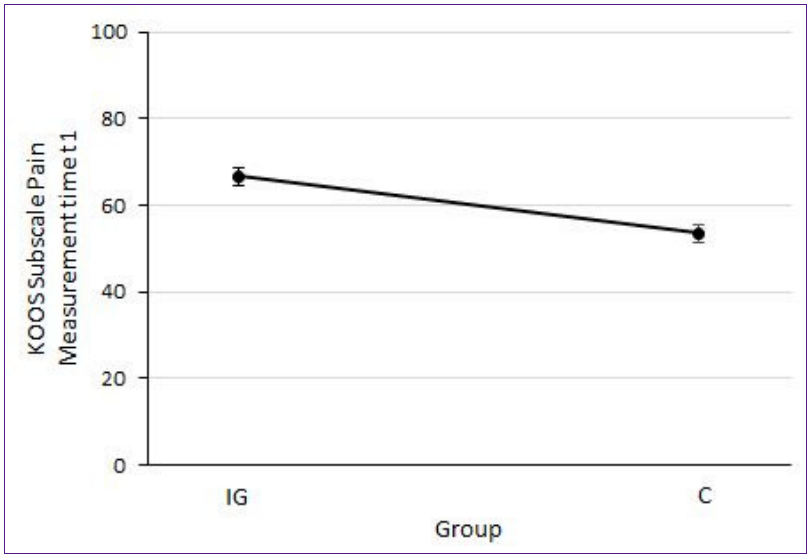

Image 1: Adjusted Mean Knee Osteoarthritis Outcome Score (KOOS) Subscale Pain t1.

Table 1: KOOS subscales (ANCOVA). 0-100 points with higher values reflecting better health status.

Outcome	Group (n)	Baseline (t0)	Post Intervention (adjusted) (t1)		P value	ES
		Mean (SE_{mean})	Mean (SE_{mean})	Difference IG-C (95%CI)		
Pain	C (29)	56.23 (2.94)	53.51 (2.01)	13.2 (7.3 to 19.1)	.000	0.76
	IG (26)	50.96 (3.10)	66.71 (2.13)			
Symptoms	C (29)	58.87 (3.17)	55.16 (2.57)	10.0 (2.4 to 17.5)	.011	0.53
	IG (26)	54.26 (3.47)	65.12 (2.72)			
Activities of daily living (ADL)	C (29)	71.75 (3.48)	67.53 (2.09)	12.0 (5.9 to 18.1))	.000	0.64
	IG (26)	68.89 (3.06)	79.54 (2.21)			
Sports and leisure	C (29)	33.62 (3.96)	37.49 (3.01)	10.7 (1.9 to 19.5)	.018	0.47
	IG (26)	33.85 (4.22)	48.18 (3.17)			
Quality of life (QOL)	C (29)	39.22 (2.79)	35.14 (1.92)	12.5 (6.8 to 18.1)	.000	0.76
	IG (26)	38.70 (3.08)	47.59 (2.03)			
IG Intervention group, C Control group, SE_{mean} Standard error of mean, ES Effect size						

Conclusions: The study was able to demonstrate positive treatment effects of a fully automated, digital health app to guide a 12-week exercise program in terms of pain reduction as well as further OA-specific complaints. Comparable studies in the area of digital exercise therapy also showed statistically significant health effects regarding the outcomes of pain and physical functioning, but with a smaller effect size (0.2) and smaller absolute differences in baseline-adjusted post measures of the intervention group compared to control (3.5 to 7.7 points).

It therefore seems promising to include digital apps in the treatment of knee OA and to support patients in their autonomous home training. Complementary studies should be conducted to examine the robustness of the results based on larger sample sizes. This is also important for first indications of an effective treatment support by wearing a supportive knee brace during training.
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