

Table 3
Comparison of change in inflammatory biomarkers between vitamin D status over 24 months

	Not consistently sufficient (N = 61) change, mean (95% CI)	Consistently sufficient (N = 139) change, mean (95% CI)	Between-group difference mean (95% CI)	P value
hs-CRP (ug/ml)	-0.1 (-0.7, 0.6)	0.2 (-0.2, 0.7)	0.3 (-0.5, 1.1)	0.46
IL-6 (pg/ml)	1.3 (-3.0, 5.6)	-2.8 (-5.7, 0.0)	-4.1 (-9.3, 1.0)	0.12
IL-8 (pg/ml)	1.4 (-3.1, 6.0)	-3.0 (-6.0, -0.0)	-4.5 (-9.9, 1.0)	0.11
IL-10 (pg/ml)	2.9 (-6.8, 12.6)	-3.3 (-9.6, 3.1)	-6.2 (17.8, 5.4)	0.29
Resistin (pg/ml)	1.9 (-0.4, 4.3)	3.8 (2.3, 5.4)	1.9 (-0.9, 4.7)	0.18
Leptin (ng/ml)	-1.3 (-5.5, 2.9)	-0.1 (-2.9, 2.7)	1.1 (-3.9, 6.2)	0.66
Adiponectin (ng/ml)	-0.01 (-0.06, 0.03)	0.02 (-0.01, 0.04)	0.03 (-0.02, 0.08)	0.26
Adipsin (ng/ml)	0.1 (-0.1, 0.3)	0.3 (0.1, 0.4)	0.2 (-0.1, 0.4)	0.13
Apelin (ng/ml)	-0.1 (-0.1, 0.0)	-0.0 (-0.1, 0.0)	0.0 (-0.1, 0.1)	0.72

619 EVALUATION OF THE BEHAVIOURAL PROCESS AND SECONDARY OUTCOMES OF THE SELF-MANAGEMENT OF OSTEOARTHRITIS AND LOW BACK PAIN THROUGH ACTIVITY AND SKILLS CLUSTER RANDOMISED CONTROLLED FEASIBILITY TRIAL

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Purpose: The Self-management of Osteoarthritis and Low back pain through Activity and Skills (SOLAS) theory-driven group-based complex intervention was developed through the intervention mapping process for evaluation within the SOLAS cluster randomised controlled feasibility trial (ISRCTN49875385) primarily in terms of its acceptability to patients and physiotherapists and the feasibility of trial procedures and sample size for a definitive trial. It has been established that SOLAS is acceptable and feasible to deliver provided sufficient participants can be enrolled and retained. The secondary objectives were to explore the 1) process of change in selected mediators and target self-management (SM) behaviours and 2) medium term changes in secondary outcomes which are reported here.

Methods: This assessor-blinded multicentre two-arm non-inferiority parallel cluster randomised controlled feasibility trial comparing the six week SOLAS intervention to usual individual physiotherapy (UP) was conducted in 14 publicly funded primary care PT clinics (i.e., clusters) in Dublin, Ireland between September 2014 and June 2016. At baseline, consenting participants completed measures to assess (1) selected mediators: i.e., perceived competence to engage in physical activity and SM (Perceived Competence Questionnaires, PCQ), motivation to participate in exercise (Behaviour Regulation Exercise Questionnaire, BREQ) and SM (Treatment Self-Regulation Questionnaire, TSRQ), pain catastrophizing (Pain Catastrophizing Scale, PCS), and fear (Tampa Scale of Kinesiophobia-Avoidance Subscale, TSK), (2) engagement in physical activity (International Physical Activity Questionnaire, IPAQ) and target SM strategies (SM Behaviour Questionnaire), and (3) secondary measures: i.e., Short-Form 12 physical component score, Roland-Morris Disability Questionnaire (RMDQ), WOMAC Function Daily Living Hip and/or Knee Subscale, Numeric Rating Scales for pain intensity and bothersomeness, Hospital Anxiety and Depression Scale, EuroQol-5D, and Global Ratings of Improvement. Phone follow-up was at 6 weeks (process of change outcomes only), 2 and 6 months. Analysis was by intention-to-treat and conducted by the blinded statistician. A linear mixed model was used to contrast change over time in participant outcomes between treatment arms, while adjusting for study waves and clusters. Treatment effects are reported as the difference between groups in mean changes (95% confidence interval) from baseline for continuous variables, and group ratios of odds ratios (ORs) for categorical outcomes.

Results: 120 participants (83.3%; of n = 144 expected) were recruited (Intervention n = 59, Control n = 61), with follow up data obtained from 80.8% (n = 97) of participants at 6 weeks, 84.2% (n = 101) at 2 months and 71.7% (n = 86) at 6 months. At 6 weeks there were improvements in the selected mediators with the between group mean difference in change from baseline in favour of SOLAS for the measures of perceived competence [mean, 95% CI: PCQ-physical activity = -0.37, -0.99, 0.25; PCQ-SM = -0.46, -1.07, 0.16], motivation [TSRQ = -1.19, -2.96 to 0.59; BREQ = -0.71, -1.78, 0.36], and pain catastrophizing [PCS = -1.02; -2.96, 5.00], and in favour of UP for fear (TSK = -0.71, -1.99, 0.56). At 2 and 6 months, the intervention effects on perceived competence and motivation gradually reduced, while the effects on pain catastrophizing and fear increased in both groups, with small between group mean differences evident. Similarly, at 6 weeks the group ratio of ORs were in favour of

SOLAS for engaging in at least moderate physical activity (1.02), setting goals (2.82), exercising in line with goals (3.23), not using pain relief (0.52), using mental relaxation techniques (4.34) and healthy eating (100% SOLAS v 96% control), with smaller ORs at 2 and 6 months for most outcomes. There were improvements in the majority of secondary outcomes at 2 and 6 months with small between group differences, apart from the RMDQ at 6 months in favour of the UP group (-1.94; -4.59, 0.70). **Conclusions:** There were some SOLAS intervention effects evident for the process map of behaviour change which had influence on the physical activity and SM behaviour outcomes compared to UP at 6 weeks but these effects reduced over time and the effects on the majority of secondary outcomes were similar to the UP control group. The relationship between these outcomes and PT fidelity to the SOLAS intervention content and behaviour change elements of the programme is being evaluated to identify how the intervention could be optimised if proceeding to a definitive trial.

620 ADHERENCE TO IN-HOME GAIT RETRAINING USING FEEDBACK FROM A SMARTPHONE APP

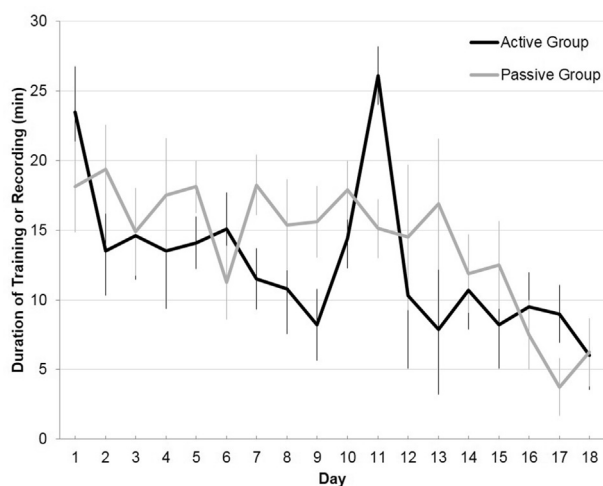
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Purpose: A high knee adduction moment (KAM) has repeatedly been linked to progression and severity of medial knee osteoarthritis (OA). It places higher than normal loads on the medial compartment of the knee and has become a target for biomechanical intervention. To lower KAM and slow OA progression, gait modification and retraining have been explored. However, the challenge has been incorporating feasible, longitudinal methods for gait retraining. We recently demonstrated that healthy subjects can quickly respond to auditory feedback from a pressure-detecting shoe insole to lower their KAM by shifting their foot pressure medially. Encouraged by these findings, we started a randomized clinical trial enrolling subjects with medial knee OA and outfitting them with a sensor shoe insole and a smartphone feedback kit. Here, we report about our initial experience with adherence to a three-week long program using this technology for daily in-home gait retraining. We were specifically concerned that negative feedback may cause training avoidance and decreased adherence over time and therefore sought to evaluate if there were differences in adherence between this active group and one that handles similar technology without receiving feedback.

Methods: Subjects with mild to moderate clinical and radiographic knee OA, BMI <38, and age >40 yrs were recruited and informed consent was obtained. At the beginning of their lab visit, all subjects received a standardized pair of flexible shoes, a pair of pressure-detecting shoe insoles (Moticon GmbH, Munich, Germany), which communicate wirelessly with a smartphone that generates auditory cues for subjects to follow. Subjects were randomized into two groups, Group 1 ('active group') which received and trained with auditory feedback cues, and Group 2 ('passive control') that interacted with the smartphone without receiving feedback. Both groups learned to connect the insole with the smartphone via a smartphone application. After lab-based instructions, subjects in Group 1 and Group 2 were sent home to complete a three-week, six-days-per-week self-directed feedback training or recording, respectively. All subjects were asked to document the duration of each session in their journal. Subjects were instructed to log a total of 15 min per day, which could be broken into smaller increments (e.g., 5-5-5 min). After 3 weeks of training, the journals were returned to study staff and daily logged minutes were summed. Missing entries were treated as "0". Statistical analyses were performed using chi-square and repeated measures ANOVA.

Results: The journal entries of the first 22 subjects were reviewed. Four subjects were excluded from analysis: one because he withdrew from the study (Group 1), two because journals were not returned (Group 1), and one because excessive training times were logged (143 min daily; Group 2). This left 18 subjects for analysis: 10 were in Group 1 (2M/8F, 61+/-11 yrs, KL = 2.4), and eight were in Group 2 (2M/6F, 62+/-9 yrs, KL = 2.6) ($P > .343$). On average, Group 1 trained 12.6 min/day, while Group 2 recorded 14.2 min/day during the three week period ($P = .679$). There was no Group effect on daily logged journal entries ($P = .578$), and both groups started similarly motivated (17.2 and 17.4 min/day during the first three days); however, with time, the logged journal times decayed ($P = .003$). Regression analysis suggested a daily reduction of 32 s (Group 1) and 38 s (Group 2), finishing clearly under 10 min/day on Day 18 (Figure).

Conclusions: Our initial experience with self-driven, in-home gait retraining using a pressure insole and negative feedback is promising in terms of overall adherence. Although we saw a decrease in adherence over time, the difference was likely not related to negative feedback from training since the no-feedback group also experienced a similar trend in decreased adherence rates over 3 weeks. In that 'no journal entry' was treated equally to 'no training', a worst case scenario has been created. Treating 'no journal entries' as 'lost data' would increase the daily average session times to 17.3 and 16.7 min for Group 1 and 2, respectively, with both groups finishing at 12.5 min on Day 18. Nevertheless, continued follow up and encouragement techniques may be necessary to help maintain adherence.



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EFFECTS OF SUPERVISED EXERCISE IN OLDER POPULATION HAVING OSTEOARTHRITIS OF KNEE: A RANDOMISED CONTROL TRIAL

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Purpose: The objective of the study was to determine whether the supervised knee exercise and supervised aerobic walking training can decrease symptoms, improve quality of walking, functional ability and the quality of life in older adults with knee osteoarthritis (OA) dwelling in a city having limited facility of physical activity in and around their home.

Methods: Total eighty six adults (both male and female) age between 58 and 72 years having mechanical pain in the knee joints, difficulty in some of their activities of daily living (due to dysfunction of knee joint) and mild to moderate degree of radio-graphic changes of knee OA were included in the study. None of them had practiced an exercise program in home or in a center during the previous year or had any co-morbidity that significantly impairs their muscular ability and/or cardio-pulmonary capacity. They were randomly divided into three groups. Group 1 ($n = 29$) was given knee exercise program three times a week. Group 2 ($n = 28$) was given regular walking program three times a week starting with 10–15 min duration and increasing gradually. Group 3 ($n = 29$) was given health education only, was accepted as the control group. Exercise intervention groups exercised under supervision of Doctors or physical therapists 3 days in a week for 3 months. 21 from Group 1 and

20 from Group 2 continued the program for 3 months and 24 from the control group accepted to come to the hospital at the end of the therapy. Condition of the patients was assessed according to pain, functional capacity, and quality of life parameters. Visual analogue scale (VAS) and Western Ontario McMaster osteoarthritis index (WOMAC) of pain score were used to evaluate pain. While WOMAC physical function index was used to measure the functional capacity. Quality of life was assessed by the Nottingham Health Profile questionnaire (NHP).

Results: VAS scores and WOMAC pain and physical functional scores were statistically lower in both Group 1 and Group 2 than in the control group ($P < 0.001$), but difference in the pain parameters between groups 1 and 2 was not statistically significant ($P > 0.05$). But the result of the NHP showed a statistically significant improvement in the group 2 when compared to the Group 1 and Group 3 ($P < 0.05$).

Conclusions: From the findings of this study we conclude that regular knee exercise and regular walking program have a definite role in decreasing pain, improving functional capability and providing better quality of life in older population with OA. Supervision of the exercise and walking program ensures regularity and perfection of the program as well as better monitoring of exercise induced pain during and after exercise.

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CLINICAL EFFECT OF ACUPUNCTURE AT HUATUO JIAJI POINTS COMBINED WITH TRADITIONAL CHINESE MEDICINE IN TREATMENT OF LUMBAR DEGENERATIVE OSTEOARTHRITIS

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Purpose: Lumbar degenerative osteoarthritis (LDO), is a degenerative disease, more common in middle age, more men than women. Clinically, Low back pain is the first symptom with back pain, heavy and inflexible. The pain can sometimes radiate to the buttocks, thighs, and occasionally to the calf, which is increased after the activity, mitigated rest after. Physical examination showed tenderness, limited waist activity. Although many methods, but the effect is very general. Wherein the surgery is a relatively effective method, but expensive, and the surgical trauma will bring psychological pressure to patients. In recent years, Acupuncture therapy plays an increasingly important role in clinical treatment. Therefore, in order to systematically evaluate the clinical effect of acupuncture therapy in the treatment of patients with Lumbar degenerative osteoarthritis (LDO), This study will explore the effect of acupuncture therapy on patients with Lumbar degenerative osteoarthritis (LDO) based on Huatuo Jiaji points (EX-B2) combined with traditional Chinese medicine.

Methods: Eighty-four patients with different symptoms in accordance with the diagnostic criteria of lumbar degenerative osteoarthritis were randomly divided into acupuncture group and control group, with 42 cases in each group. The acupuncture group was treated with acupuncture in order to find the Huatuo jiaji points (EX-B2) and positive Tender point for the acupuncture points, weekly treatment once a week for a course of treatment. Acupoints: The first lumbar spine next to the fifth lumbar spine to open 0.5–1 inch bilateral Huatuo Jiaji points (EX-B2) (a total of 10 points) the main point, according to the disease with other points, such as the Huantiao (GB30), Yinmen (GL37), Weizhong (BL40), Yanglingquan (GB34), Zusanli (ST36), Xuanzhong (GB39), Taichong (LR3), Hegu (LI4) and other points. Acupuncture: Acupoint skin disinfection, using a diameter of 0.35 mm × 60 mm disposable acupuncture needle vertical rapid needle, acupuncture depth due to patients with different fat and thin, the average depth of about 50 mm acupuncture. The rest of the acupuncture points acupuncture operation, acupuncture needle 10–15 min. After acupuncture with traditional Chinese medicine (Take Chuanwu, Zhicaoowu, Shengjincao, Niuxi and other drugs placed in a gauze bag about 30 cm long and evenly sprayed around the sandbag vinegar, into the pressure cooker, 20 min Remove, until the temperature is reduced about 40°C deposited in the affected area), each 30–40 min. Control group using conventional massage, and oral administration of a small amount of painkillers, such as celecoxib and so on.

Results: After one course of treatment, the ODI score and the JOA score improved in both groups ($P < 0.05$), and the improvement in the treatment group were both better than that in the control group ($P < 0.05$).

Conclusions: Acupuncture therapy refers to the needle under the guidance of traditional Chinese medicine theory (usually refers to the filiform needle) pierced into the patient's body at a certain angle, the use of