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EFFECTIVENESS AND COST-EFFECTIVENESS OF A GROUP-BASED PAIN SELF-MANAGEMENT INTERVENTION FOR PATIENTS UNDERGOING TOTAL HIP REPLACEMENT: FEASIBILITY STUDY FOR A RANDOMISED CONTROLLED TRIAL

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Purpose: Total hip replacement (THR) is a common elective surgical procedure and can be effective for reducing chronic pain. However, waiting times for THR can be considerable, and patients often experience significant pain during this time. A pain self-management intervention may provide patients with the skills to enable them to manage their pain and its impact more effectively during the wait for surgery. However, studies of arthritis self-management programmes have faced challenges because of low recruitment rates, poor intervention uptake, and high attrition rates. Therefore, this study aimed to evaluate the feasibility of a randomised controlled trial (RCT) to assess the effectiveness and cost-effectiveness of a group-based pain self-management course for patients undergoing THR and assess the acceptability of the intervention. Specific objectives were to assess trial design, ascertain recruitment and retention rates, identify barriers to participation, refine data collection methods, and evaluate uptake and patient satisfaction with the course.
Methods: Patients listed for a THR at the Avon Orthopaedic Centre in Bristol were sent a postal invitation about the study. After recruitment, participants were randomised to attend a pain self-management course plus standard care or standard care only using a computer-generated randomisation system (Minim). The pain self-management course was delivered by Arthritis Care and consisted of two half-day group sessions prior to surgery and one full-day group session 2-4 months after surgery. A structured course evaluation questionnaire was completed by participants after the sessions. Outcomes assessment was by postal questionnaire prior to surgery and 1-month, 3-months and 6-months after surgery. Self-report resource use data were collected using a diary prior to surgery and inclusion of resource use questions in the 3-month and 6-month post-operative questionnaires. Brief telephone interviews were conducted with consenting non-participants to explore barriers to participation. NHS ethics approval was obtained (11/SW/0056) and participants provided informed, written consent.
Results: Postal invitations were sent to 385 eligible patients and 88 patients consented to participate (23% recruitment rate). Participants had a mean age of 66 years and 65% were female. Brief interviews with 57 non-participants revealed the most common reasons for non-participation were perceptions about the intervention and difficulties in getting to the hospital to attend the course. Of the 43 patients randomised to the intervention group, 28 attended the pre-operative pain self-management sessions and 11 attended the post-operative sessions. Participant satisfaction with the course was high, and patients enjoyed the group format of the course.Retention of participants was acceptable, with 83% completing follow-up. Questionnaire return rates were high at all assessment times (76-93%), with the exception of the pre-operative resource use diary (35%). Completion rates for the resource use questions varied by category and allowed for an economic perspective from the health and social care payer to be taken.
Conclusion: Undertaking feasibility work for a RCT is labour-intensive; however this study highlights the importance of conducting such work. Postal recruitment resulted in a low recruitment rate and brief interviews with non-participants provided valuable information on barriers to participation. Embedding collection of resource use data within questionnaires resulted in higher completion rates than using resource use diaries. While patients who attended the course gave positive feedback, attendance was low. Findings from this feasibility study enable us to design successful definitive group-based RCTs in the future, ensuring the delivery of effectiveness and cost-effectiveness evidence to inform service provision for patients undergoing THR.

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CAPSAICIN TREATMENT FOR OSTEOARTHRITIS PAIN: A META-ANALYSIS

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Background: Capsaicin appears to be effective for osteoarthritis pain but it is uncertain whether the effect has a dose response, is consistent across joints, or changes over time.
Purpose: To perform a quantitative overview the use of topical capsaicin in the therapy of painful osteoarthritis (OA) in adults, and to assess whether effects vary by formulation strength, joint site, or treatment duration.
Methods: Literature databases (PubMed, EMBASE, ISI Web of Knowledge) were searched for randomized controlled trials for use of topical capsaicin (or capsaicin-like therapies) in OA using the keywords: “capsaicin”, “osteoarthritis” “double-blind method”, “randomized controlled trial [publication type]” or “controlled clinical trial [publication type]” up to 2012. Studies not in English were excluded. Trials were compared for pain scores (assessed using visual analog scales (VAS)), patient global evaluation of treatment effectiveness and application site burning using standardised mean differences (SMD), using RevMan.
Results: Five double-blind randomized controlled trials and one case-crossover trial were identified, testing topical capsaicin four times daily. Formulations ranged from 0.025% - 0.075%, and trial durations from 4-12 weeks. Trials assessed OA of the knee ($n = 3$), hand ($n = 1$), and a mix of joints ($n = 2$). Patients were typically required to have at least moderate pain and either radiologically or clinically defined OA, or both. Treatment efficacy of capsaicin (compared to placebo) for change in VAS pain score was moderate, at 0.44 (95% CI 0.25-0.62) over 4 weeks of treatment. There was no heterogeneity between studies, indicating no between-study differences, including effect of OA site or treatment concentration. There was disagreement on effectiveness over time. Two studies reported treatment beyond 4 weeks, with the first study reporting an effect size of -9mm after 12 weeks, with the maximum difference between groups occurring at 4 weeks. The second study reported that between-group differences increased over time, up to 20 weeks.
Capsaicin was reported as being safe and well-tolerated, with no systemic toxicity. The most common side effect reported was mild application site burning, affecting 35-100% of capsaicin-treated patients; the risk ratio was 4.22 (95% CI 3.25-5.48), reported in 5 trials. Incidence of burning peaked in week 1, with incidence rates declining over time, plateauing from weeks 2-12.
Conclusions: Topical capsaicin treatment four times daily is moderately effective in reducing pain intensity up to 20 weeks regardless of site of application and dose in patients with at least moderate pain and clinical or radiologically defined OA. Capsaicin treatment is also generally well tolerated, suggesting that capsaicin should be used early in the OA treatment algorithm, especially for superficial joints such as the hand and knee.

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EFFECT OF TISSUEGENE-C, A NOVEL CELL AND GENE THERAPY, ON PAIN AND CARTILAGE REGENERATION IN A RAT OSTEOARTHRITIS MODEL

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Purpose: TissueGene-C(TG-C) has been developed as a cell and gene therapy for patients withosteoarthritis. It is a mixture of non-transduced human chondrocytes (hChonJ) and genetically modified chondrocytes expressing TGF-β1 (hChonJb#7). Phase 2b clinical trials have shown that TG-C significantly improved IKDC and 100 mm VAS scores over placebo when administered to the knee joints of osteoarthritic patients. In this study, a rat model of osteoarthritis was used to identify the role of individual components of TG-C.
Methods: A rat model of osteoarthritis was induced by injection of monosodium iodoacetate (MIA) into the left knee joint, which resulted