



Title	Effectiveness and Cost Effectiveness of Arthroscopic Lavage in the Treatment of Osteoarthritis of the Knee: A Mixed Methods Study of the Feasibility of Conducting a Surgical Placebo-Controlled Trial (The KORAL Study)
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Aim

To ascertain the acceptability of a randomized controlled trial comparing arthroscopic lavage with a placebo-surgical procedure in managing osteoarthritis of the knee; and to assess the practical feasibility (via a formal, pilot study) of mounting such a multicenter placebo-controlled trial.

Conclusions and results

Stakeholder groups generally accepted the need to learn more about the effectiveness of arthroscopic lavage. However, opinions varied within all groups about *how* researchers should approach this and whether or not it would be acceptable to use placebo surgery. Health professional groups tended to be split between those who were strongly opposed to including a placebo surgery arm (on the grounds that it could lead to potential harm in individuals who could expect no personal benefit) and those who were more in favor (on the grounds that the potential benefit outweighed the perceived small risks to relatively few people in a placebo surgery trial arm). For prospective trial participants who had osteoarthritis of the knee, the acceptability of the trial reflected more their personal reasons for or against participating. The majority in this group said they would consider taking part. As well as expressing a desire to help others through participation, they tended to downplay any potential risk of harm from their participation while emphasizing the potential to gain some form of personal benefit. Given the nature of the proposed design, the health professionals and MREC chairs recognized that particular attention should be paid to the informed consent process when attempting to recruit participants. The pilot study showed that, in principle, a placebo-controlled trial could be conducted and that patients were willing to participate in a trial involving a placebo-surgical arm. Further, it was possible to undertake placebo surgery successfully and to blind patients to their allocation (although once patients knew their allocation, some patients allocated to surgery withdrew due to their concern about the possibility of undergoing

placebo surgery). The experience of the pilot showed, however, that despite full MREC approval the study required major discussion and negotiation before local clinical approvals could be obtained. The fact that ethics approval had been granted did not mean that clinicians would automatically accept that the process was ethical. Recent national trend data show a slow, continuing decline in the utilization of arthroscopic lavage.

Recommendations

See Executive Summary link at www.hta.ac.uk/project/1448.asp.

Methods

See Executive Summary link at www.hta.ac.uk/project/1448.asp.

Further research/reviews required

Researchers need to investigate: the impact of different terminology referring to placebos (eg, placebo, sham, dummy) on understanding the role and function of a placebo; the usefulness of formal decision aids in facilitating participant consent in the context of a placebo-controlled trial; and the impact of individual versus collective ethics in conducting placebo-controlled trials.