

## A proposed placebo-controlled trial of arthroscopic lavage for osteoarthritis: The KORAL Study



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The author accepts full responsibility for this talk.

## Background

- Osteo-arthritis most common form of arthritis in Western populations
- Disabling OA of the knee affects approx 10% of people over 55
- Associated with pain and functional disability
- Leads to limited activities for sufferers
- Range of treatments for knee OA



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## Arthroscopic lavage

- Common procedure: 650,000 performed each year in the US; 34,000 in UK in financial year 2002/3
- Annual cost to NHS estimated at over £34m



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## Evidence for benefit

- Weak!
- Mainly uncontrolled studies of poor quality
- Small number of randomised controlled trials
- Systematic reviews provide little evidence to support routine use of arthroscopic lavage
- Most controversial trial conducted by Moseley and colleagues in the US



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## Moseley trial

- 180 patients randomised to either:
  - arthroscopic lavage
  - arthroscopic debridement, or
  - sham procedure
- At 24 months, no evidence of difference between either active group compared with sham
- Trial conclusion – any benefit resulted from a placebo effect



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## Perceived problems with Moseley trial

- Limited generalisability:
- Most patients had severe OA
  - Limited age range
  - Almost all were men
  - Only one surgeon
  - VA hospital setting



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## UK NHS HTA Programme call

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- Identified the need to conduct another well-designed randomised controlled trial (given the limitations of the Moseley trial)
- Want to investigate whether any benefit is due to placebo
- Led to .... a call for a placebo-controlled randomised controlled trial of arthroscopic lavage +/- debridement



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## However ...

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- They recognised that the inclusion of a placebo procedure might be problematic
- So..
- Commissioned the work in two stages:
    1. Feasibility phase to explore ethical issues around the proposed placebo ... and if placebo found to be acceptable
    2. Formal randomised controlled trial



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## Result of call

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- Aberdeen-led bid successful
- Team includes: surgeons, anaesthetists, health services researchers, triallists, qualitative researchers, consumer representation, an ethicist, a health psychologist, health economists, statisticians
- Study started July 2005



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## Feasibility study

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## Research questions

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- Which procedures might be used as 'placebos' for arthroscopic lavage?
- What do key stakeholder groups think about the use of placebo procedures in the context of a randomised controlled trial to evaluate arthroscopic lavage?



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## Key stakeholder groups

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- Orthopaedic surgeons
- Anaesthetists
- People with osteoarthritis of the knee
- Members of research ethics committees



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- Extra slides about Moseley placebo



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## How Moseley did it (1)

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### Debridement / lavage groups

- "received standard general anaesthesia with endotracheal intubation"

### Placebo group

- "received a short-acting intravenous tranquilizer and an opioid and spontaneously breathed oxygen enriched air"



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## How Moseley did it (2)

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### To preserve blinding ...

A standard arthroscopic debridement procedure was simulated. After the knee was prepped and draped, three 1cm incisions were made in the skin. The surgeon asked for all instruments and manipulated the knee as if arthroscopy were being performed. Saline was splashed to simulate the sounds of lavage. No instrument entered the portals for arthroscopy. The patient was kept in the operating room for the amount of time required for a debridement ...



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## How Moseley did it (3)

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Patients spent the night after the procedure in the hospital and were cared for by nurses who were unaware of the treatment group assignment...

Postoperative care was delivered according to a protocol specifying that all patients should receive the same walking aids, graduated exercise program and analgesics.



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