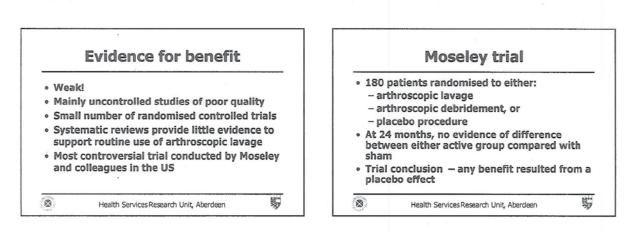


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Perceived problems with Moseley trial

Limited generalisability:

- Most patients had severe OA
- Limited age range
- Almost all were men
- · Only one surgeon

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VA hospital setting

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UK NHS HTA Programme call

- · Identified the need to conduct another welldesigned 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

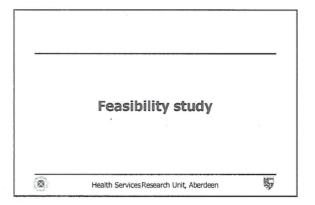
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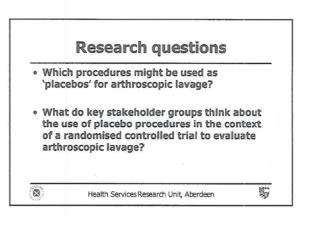
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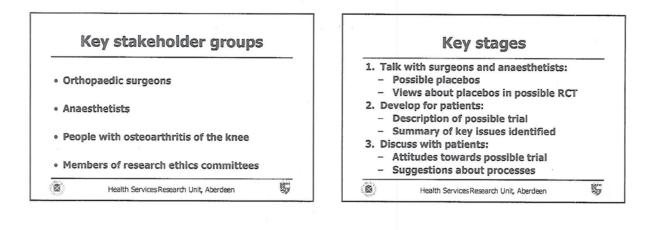
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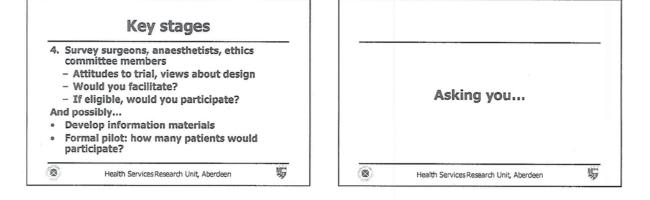
Result of call However ... · They recognised that the inclusion of a Aberdeen-led bid successful!! placebo procedure might be problematic · Team includes: surgeons, anaesthetists, So... health services researchers, triallists, Commissioned the work in two stages: qualitative researchers, consumer 1. Feasibility phase to explore ethical issues representation, an ethicist, a health around the proposed placebo ... and if psychologist, health economists, placebo found to be acceptable statisticians 2. Formal randomised controlled trial Study started July 2005 弱 . 1 Health Services Research Unit, Aberdeen Health Services Research Unit, Aberdeen

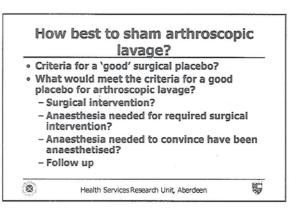
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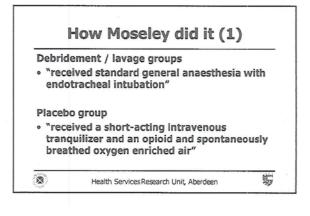












How Moseley did it (2)

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 amoutn of time required for a debridement ...

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How Moseley did it (3)

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, gradated exercise program and analgesics.

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Should there be a placebo-controlled trial?

- Arguments for?
- Arguments against?
- Essential features sine qua non

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