

- 18 Melis RJF, Adang EA, Teerenstra S, van Eijken MIJ, Wimo A, Achterberg T, et al. The cost-effectiveness of a multidisciplinary intervention model for community-dwelling frail older people. *J Gerontol A Biol Sci Med Sci* (in press).
- 19 Brodaty H, Peters KE. Cost effectiveness of a training program for dementia carers. *Int Psychogeriatr* 1991;3:11-22.
- 20 Graff MJL, Vernooij-Dassen MJF, Zajec J, OldeRikkert, MGM, Hoefnagels WHL, Dekker J. How can occupational therapy improve the daily performance and communication of an older patient with dementia and his primary caregiver? *Dementia* 2006;5:503-32.
- 21 Graff MJL, Melick van MBM. Het ontwikkelen, testen en implementeren van een ergotherapeutische standaard. De standaard voor de ergotherapeutische diagnostiek en behandeling van geriatische patiënten met niet-ernstige cognitieve stoornissen. [The development, testing and implementation of an occupational therapy guideline. The guideline for the OT diagnosis and treatment of older persons with cognitive impairments.] *Ned Tijdschr Ergother* 2000;28:169-74. (In Dutch.)
- 22 Fisher AG. *Assessment of motor and process skills*. Fort Collins, CO: Three Stars Press, 2003.
- 23 Teunisse S, Derix MM. The interview for deterioration in daily activities in dementia: agreement between primary and secondary caregivers. *Int Psychogeriatr* 1997;9(suppl 1):155-62.
- 24 Vernooij-Dassen MJM, Persoon JM, Felling AJ. Predictors of sense of competence in caregivers of demented persons. *Soc Sci Med* 1996;43:41-9.
- 25 Drummond MF, O'Brien B, Stoddart GL, Torrance GW. *Methods for the economic evaluation of health care programmes*. Oxford: Oxford Medical Publications, 1997.
- 26 Oostenbrink JB, Koopmans MA, Rutten FFH. *Handleiding voor kostenonderzoek. Methoden en richtlijnen voor economische evaluaties in de gezondheidszorg*. [Guideline for cost evaluation.] Amsterdam: College voor Zorgverzekering (CVZ), 2004. (In Dutch.)
- 27 Dutch Occupational Therapy Association. NVE. *Richtlijn voor declaraties verrichtingen Eerstelijns Extramurale Ergotherapie (EEE)*. [Guideline for the declaration of community occupational therapy visits.] Utrecht: NVE, 2006. (In Dutch.)
- 28 American Psychiatric Association (APA). *Diagnostic and statistical manual of mental disorders*. 4th edn. Washington, DC: American Psychiatric Association, 1994.
- 29 Brink TL, Yesavage JA, Lum O, Heersema P, Adey MB, Rose TL. Screening tests for geriatric depression. *Clin Gerontol* 1982;1:37-43.
- 30 Miller MD, Paradis CF, Houck PR, Mazumdar S, Stack JA, Rifai AH, et al. Rating chronic medical illness in burden in psychogeriatric practice and research: application of the cumulative illness rating scale. *Psychiatry Res* 1992;41:237-48.
- 31 Siemonsma PC, Walker MF. Practical guidelines for independent assessment in randomized controlled trials (RCTs) of rehabilitation. *Clin Rehabil* 1997;11:273-9.
- 32 Rockwood K, Gauthier S. *Trial designs and outcomes in dementia therapeutic research*. London: Taylor & Francis, 2006.

Accepted: 4 November 2007

Advice to use topical or oral ibuprofen for chronic knee pain in older people: randomised controlled trial and patient preference study

Martin Underwood,¹ Deborah Ashby,² Pamela Cross,¹ Enid Hennessy,² Louise Letley,³ Jeannett Martin,⁴ Shahrul Mt-Isa,² Suzanne Parsons,¹ Madge Vickers,⁵ Ken Whyte,¹ on behalf of the TOIB study team

EDITORIAL by Dieppe

¹Centre for Health Sciences, Barts and The London, Queen Mary, University of London, London E1 2AT

²Wolfson Institute of Preventive Medicine, Barts and The London, Queen Mary, University of London, London EC1M 6BQ

³MRC General Practice Research Framework, London NW1 2ND

⁴Department of Primary and Social Care, London South Bank University, London SE1 6EN

⁵Clinical Trials Co-ordinating Centre, University of Hertfordshire, Hatfield, Herts AL10 9LB

Correspondence to: M Underwood
m.underwood@warwick.ac.uk

BMJ 2008;336:138-42

doi:10.1136/bmj.39399.656331.25

This article is an abridged version of a paper that was published on bmj.com on 4 December 2008.

Cite this article as: *BMJ*

4 December 2008, doi: 10.1136/bmj.39399.656331.25

ABSTRACT

Objective To determine whether older patients with chronic knee pain should be advised to use topical or oral non-steroidal anti-inflammatory drugs (NSAIDs).

Design Randomised controlled trial and parallel patient preference study.

Setting 26 general practices.

Participants People aged ≥ 50 with knee pain: 282 in randomised trial and 303 in preference study.

Interventions Advice to use topical or oral ibuprofen.

Primary outcome measures WOMAC (Western Ontario and McMaster Universities) osteoarthritis index, major and minor adverse effects.

Results Changes in global WOMAC scores at 12 months were equivalent. In the randomised trial the difference (topical minus oral) was two points (95% confidence interval -2 to 6); in the preference study, it was one point (-4 to 6). There were no differences in major adverse effects in the trial or study. The only significant differences in secondary outcomes were in the randomised trial. The oral group had more respiratory adverse effects (17% v 7%, 95% confidence interval for difference -17% to -2%), the change in serum creatinine was 3.7 $\mu\text{mol/l}$ less favourable (0.9 $\mu\text{mol/l}$ to 6.5 $\mu\text{mol/l}$); and more participants changed treatments because of adverse effects (16% v 1%, -16% to -5%). In the topical group more participants had chronic pain grade III or IV at three

months, and more participants changed treatment because of ineffectiveness.

Conclusions Advice to use oral or topical preparations has an equivalent effect on knee pain over one year, and there are more minor side effects with oral NSAIDs. Topical NSAIDs may be a useful alternative to oral NSAIDs.

INTRODUCTION

Oral and topical non-steroidal anti-inflammatory drugs (NSAIDs) have some short term beneficial effects on chronic knee pain.¹⁻⁵ If topical NSAIDs are as effective as oral NSAIDs but produce fewer adverse effects, then topical treatment might be preferred. As the route of administration is different, non-pharmacological factors may affect the response to treatment, and patients' preferences might have an important effect on perceived benefit and the incidence of subjective adverse effects. We compared the effect of advice to older patients to use oral or topical NSAIDs on knee pain and disability, minor adverse effects related to use of NSAIDs, overall pain, and health related quality of life.

METHOD

We have described our methods in detail elsewhere.⁶

Recruitment—We recruited general practices from the Medical Research Council general practice research

framework. We sent postal invitations to patients who had consulted these practices with osteoarthritis or knee or leg pain in the preceding five years or who had had a prescription for a topical or an oral NSAID or a rubefacient over the preceding year. To be included participants had to be aged ≥ 50 , have had troublesome pain in or around the knee on most days for at least a month as well as knee pain for more than three months in the preceding year; have consulted or been prescribed treatment by the general practitioner for knee pain in the preceding three years; have no current or planned knee replacements; and meet our safety criteria. See [bmj.com](#). A general practitioner assessed each participant and recorded the physical components of the American College of Rheumatologists' clinical criteria for knee osteoarthritis. At study entry research nurses collected baseline data. Potential participants were asked not to use any topical or oral NSAIDs for one week before the assessment at study entry. Participants were offered a choice of joining the randomised trial or joining the preference study, in which participants selected their treatment. Randomisation was stratified by practice and troublesomeness of knee pain.⁷ We provided participants with a starter pack of their chosen or allocated treatment. After this participants were either prescribed medication by the practice or they could purchase their own over the counter.

Participant flow and follow-up—We followed up participants with postal questionnaires at 3, 6, 12, and 24 months after study entry. There were nurse assessments and blood tests at 12 and 24 months. Because recruitment was slow, not all participants could be followed for 24 months; participants with 16-24 months of follow-up at the end of data collection underwent 24 month (end of study) assessments at this time; for those with 12-16 months of potential follow-up we did the end of study assessments after 12 months. We collected data on health service activity and prescribing from randomisation to 24 months or end of study.

Intervention—In the randomised trial we compared a recommendation to use either a topical or an oral NSAID, preferably ibuprofen, as required for knee pain. In the preference study the recommendation was to use the route of delivery preferred by the patient. If a change of medication was required, participants were encouraged, when appropriate, to use an alternative NSAID with the same route of administration.

Masking—The study was not blinded at the general practice or participant level. All other members of the study team involved in data collection were blind to the participants' chosen or allocated treatment.

Outcome measures—Our primary efficacy analyses used the WOMAC (Western Ontario and McMaster Universities) VA 3.1 questionnaire, which measures knee pain and disability in the preceding 48 hours and produces individual measures of pain, stiffness, and physical function and a global assessment.⁸ Our secondary efficacy outcomes were the chronic pain grade, which measures overall pain and disability related to pain over the preceding six months and the SF-36v2,

reported as physical and mental component scores. All were collected with a postal questionnaire.

Adverse effects—We defined a major adverse effect as an unplanned hospital admission or death during follow-up. We defined a minor adverse effect as a change in one or more selected variables that a Delphi panel of general practitioners considered serious enough to entail advising a change of treatment. See [bmj.com](#). We also report the differences in clinical and laboratory study measures, participants' reports of changing treatment because of adverse effects, and, when appropriate, the results of laboratory tests initiated by the practice. We used questionnaire data at 3, 6, and 12 months, results of blood tests taken up to and including those taken at the 12 month nurse assessment, and medical record data up to 12 months.

Prescribing data—We calculated the number of defined daily doses of oral ibuprofen, other oral NSAIDs, rescue analgesia (paracetamol or opioids), treatments for dyspepsia, and respiratory and cardiovascular drugs (except aspirin) prescribed with standardised values. For oral ibuprofen the defined daily dose is 1.2 g. For topical NSAIDs and rubefacients we defined a daily dose for one knee as 1.5 g.

Sample size—To show equivalence, defined as 95% confidence that difference in WOMAC score was less than 10 mm between oral and topical groups, we needed 275 participants in the randomised trial, and 368 in the preference study. See [bmj.com](#) for further details.

Analysis—We analysed the two studies separately. When appropriate we adjusted for baseline values using regression models. For other analyses we used *t* tests, differences in proportions, and rates with 95% confidence intervals with corrections for small numbers.

RESULTS

Participant recruitment—We recruited 25 practices plus two pilot practices of which one contributed to our analyses. Participants in the other pilot also took part in a nested qualitative study.⁹ Recruitment took place from April 2003 to May 2005. Follow-up finished in May 2006. We approached 22 870 (89%) of the 26 866 potential participants identified. Of those eligible and interested at the end of the first assessment, 585/745 (79%) eventually joined the study; 282 joined the randomised trial and 303 the preference study.

Baseline characteristics—Participants' mean age was 64 years (SD 8.5) and median 64 years (range 50-89). Participants in the topical group in the preference study, were older and of lower social class than those in the controlled trial. The remainder of participants' main baseline characteristics were broadly similar across all four groups. Participants in the preference study generally expected their chosen medication to be effective or very effective. More participants in the preference study who chose to use oral NSAIDs had at least moderately troublesome pain in one or more additional body area (difference topical minus oral 11% (95% confidence interval -21% to -1%).

Follow-up—We obtained at least an 83% response to follow-up questionnaires, nurse assessment, and blood test data at 12 months. We obtained at least 55% of these data at 24 months (82% of those eligible for a 24 month follow-up). See [bmj.com](#).

Primary outcome—WOMAC scores changed little between baseline and the 12 month follow-up. For the global scores these were -0.5 (SD 17) in the oral group and 1.1 (SD 17) in the topical group in the randomised trial and 0.1 (SD 18) and 1.1 (SD17), respectively, in the preference study. Only for pain at 24 months in the randomised trial did the limits of the confidence intervals for the difference between oral and topical groups exceed our predefined limits for equivalence. For the WOMAC pain scores in the randomised trial 24 month and end of study analyses, there was a difference of borderline significance in favour of oral medication (table).

Adverse effects—We found no differences in major adverse effects. There were two deaths before the end of follow-up, both in the topical group in the preference study. One participant in the oral group in the preference study had an upper gastrointestinal haemorrhage during a planned admission to hospital. The only difference in defined minor adverse effects was that fewer participants in the topical group in the randomised trial had a respiratory adverse effect -9% (-17% to -2%). The only significant mean difference in our clinical and laboratory measurements was in the randomised trial, where the change in creatinine concentrations at 12 months in the topical group was more favourable by $3.7 \mu\text{mol/l}$ ($0.9 \mu\text{mol/l}$ to $6.5 \mu\text{mol/l}$). See [bmj.com](#).

Secondary outcomes—We found no significant differences in the overall proportion with chronic pain grade III or IV at any time point or in the SF-36 physical component scores. There were some differences in the disability component of the chronic pain grade at three months and in the end of study analyses in the randomised trial. Those in the oral group had slightly less pain related disability at three months and in the end of study analysis but not at 12 months. After we corrected

for baseline differences there was a difference in the odds of having chronic pain grade III or IV at three months and in the end of study assessment, but not at 12 months, favouring the oral group. See [bmj.com](#).

Adherence with treatment route—There were no significant differences in the proportions in either study who reported in the 12 month questionnaire that they had changed treatment. In the randomised trial this apparent similarity masks important differences: 11% (95% confidence interval 2% to 20%) more of the topical group reported changing treatment because of inadequate pain relief and 10% (5% to 16%) more of the oral group reported changing treatment because of adverse effects. This was not seen in the preference study. Only 5% of those randomised to the oral group, and nobody who chose oral treatment, had any prescriptions for topical NSAIDs. More of the topical group had prescriptions for oral NSAIDs (37% in the randomised trial and 26% in the preference study). In the preference study, however, more of the oral group were prescribed “rescue medication”; this difference approaches significance (-14% , -26% to 0.4%).

DISCUSSION

Main findings

We found that advising patients to use either oral or topical NSAIDs produced equivalent clinical outcomes for knee pain over one year in both studies. Only for the pain subscale in the randomised trial at 24 months did limits of the confidence interval breach our definition of equivalence; this may be because of small numbers. There were no differences in the secondary patient centred outcomes except for suggestions, in the randomised trial, that those in the topical group were more likely to have more severe overall pain and disability as measured by the chronic pain grade at three months and in the end of study analysis adjusted for the baseline values, and that more people in the topical group stopped treatment because it was ineffective.

Mean difference (95% CI for difference) in change in WOMAC* from baseline, for topical minus oral treatment with NSAIDs for knee pain in elderly people (adjusted by regression for baseline values)

	3 months	6 months	12 months	24 months	End of study†
Randomised trial					
No in oral/topical group‡	133/129	128/121	125/121	80/87	139/132
Pain	-2 (-6 to 2)	1 (-3 to 5)	1 (-4 to 6)	6 (0 to 12)	5 (0 to 9)
Stiffness	-3 (-8 to 2)	-4 (-9 to 1)	0 (-6 to 5)	-1 (-8 to 6)	-2 (-7 to 4)
Difficulty	-2 (-5 to 2)	1 (-3 to 5)	3 (-2 to 7)	5 (-1 to 10)	3 (-2 to 7)
Global	-2 (-5 to 2)	0 (-3 to 4)	2 (-2 to 6)	4 (-1 to 10)	3 (-1 to 7)
Preference study					
No in oral/topical group‡	71/198	66/194	70/184	65/162	75/209
Pain	-2 (-7 to 3)	-2 (-7 to 3)	-1 (-7 to 4)	0 (-6 to 6)	-1 (-7 to 5)
Stiffness	0 (-6 to 6)	-3 (-9 to 3)	-2 (-8 to 4)	-2 (-9 to 5)	-3 (-9 to 3)
Difficulty	2 (-3 to 6)	3 (-2 to 7)	2 (-3 to 7)	1 (-5 to 7)	1 (-4 to 6)
Global	1 (-3 to 5)	1 (-3 to 5)	1 (-4 to 6)	0 (-6 to 6)	0 (-5 to 5)

*Each WOMAC score has potential range of 0-100; 0=no symptoms, 100=maximum symptoms. Positive differences favour oral treatment.

†End of study value is last value carried forward or 24 month follow-up.

‡No of analysable WOMAC questionnaires.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Oral and topical non-steroidal anti-inflammatory drugs (NSAIDs) have short term beneficial effects for people with osteoarthritis

Oral NSAIDs have a high incidence of adverse effects

WHAT THIS STUDY ADDS

Advice to use oral or topical NSAIDs has an equivalent effect on knee pain in the long term

Topical NSAIDs may be a useful alternative to oral NSAIDs

Although we found no differences in the overall numbers having major or defined minor adverse effects in either study, in the randomised trial we found an excess of respiratory adverse effects and a less favourable change in creatinine concentration in the oral group. These may be chance findings caused by multiple comparisons or they may represent real differences. The size of these differences could be clinically important; 9% more in the oral group had an adverse respiratory effect that could justify stopping NSAIDs. At a population level, a difference in creatinine of 3.7 $\mu\text{mol/l}$ might have important health consequences. Participants' reports in the randomised study showed that 11% of those in the oral group stopped taking NSAIDs because of adverse effects. Our data suggest that in the randomised trial oral NSAIDs caused more adverse effects. These differences were not seen in the preference study, even though the differences in daily doses of oral NSAIDs prescribed between the oral and topical groups were much greater than in the trial. Possibly participants who chose oral treatment did so because of previous experience and so were more likely to tolerate adverse effects.

Preferences

Participants who wanted a choice predominantly selected topical rather than oral treatment, although those with more severe or widespread pain chose oral rather than topical treatment. Those who chose topical treatment tended to be older and of lower social class than those in the other three groups.

Those who chose oral NSAIDs seemed to be more tolerant of their adverse effects than those randomly allocated to the oral group, even though the oral group in the preference study took substantially more oral NSAIDs.

Applicability to routine practice

Our results are relevant to the management of knee pain in primary care. All our participants were receiving care from their general practitioner for knee pain, and their general practitioner would still have considered prescribing NSAIDs if the study were not taking place. Further, as the choice of treatment in routine practice is not random but is affected by preferences of the clinician and patient, the preference

study arm increases the relevance of our findings to routine practice.

Our participants may differ from typical patients presenting in general practice in two important areas. Firstly, our results may not be directly applicable to the very elderly. Secondly, although most participants were identified because they had used NSAIDs, nearly half (763/1691, 45%) of those we assessed were deemed ineligible because they failed our safety criteria. The selection procedure may have produced a study population with a comparatively low risk of adverse effects related to NSAID use. Our results may not therefore be directly applicable to those who have most to gain from avoiding the toxicity of oral NSAIDs. The counter-argument is that in very elderly people and those who would fail our safety criteria the risks of using oral NSAIDs are always too great.

Statistical power

We had ample power for our primary effectiveness analyses at 12 months. The conclusions for 24 months, however, are weaker, particularly in the randomised trial, because of the smaller numbers available for follow-up.

Potential for bias

We did not attempt to blind the participants or practices, but this might have introduced bias in the questionnaires. The measurements taken by the research nurses and the data from medical records should be less prone to bias.

Use of prescribed medication

The amount of NSAID consumed in this trial was lower than in many controlled trials, thus, the clinical effects and rates of adverse effects observed in some other trials may overestimate what happens when these drugs are used in routine practice. The pattern of drug use we observed is more likely to be representative of how NSAIDs are prescribed in routine practice. One caveat is that we were not able to measure the use of topical or oral NSAIDs purchased over the counter, nor to estimate the proportion of prescribed medication the participants actually used.

Meaning of the study

What is clear is that the outcome for knee pain at one year is equivalent, whether patients are initially advised to use oral or topical treatment. This is a consistent finding in both the randomised trial and the preference study. We cannot use these data to conclude that advice to use either preparation is superior to paracetamol, placebo, or no treatment. Indeed, the absence of clear change in WOMAC scores between baseline and follow-up, in both arms of either study, is consistent with several hypotheses including the notion that neither preparation is particularly effective. Advice to use topical NSAIDs might, however, be a useful alternative to advice to use oral NSAIDs for knee pain in older people

We thank all the people who took part in the study and the hospital laboratories for processing blood tests, Lynette Edwards for comments on earlier drafts of this paper, and Dawn Carnes for assistance in preparing this paper. Full details of the study team and the general practice research framework are on bmj.com.

Contributors: See bmj.com.

Funding: This study was commissioned by the NHS Health Technology Assessment Programme, project reference 01/09/02. Goldshield Pharmaceuticals supplied the starter packs of topical ibuprofen.

Competing interests: MU has received speaker fees from Pfizer, the manufacturers of celecoxib.

Ethical approval: Northern and Yorkshire multi-centre research ethics committee (MREC 2/3/1). The 28 local research ethics committees also gave approval.

Provenance and peer review: Not commissioned; externally peer reviewed.

- 1 Pendleton A, Arden N, Dougados M, Doherty M, Bannwarth B, Bijlsma JWJ, et al. EULAR recommendations for the management of knee osteoarthritis: report of a task force of the standing committee for international clinical studies including therapeutic trials (ESCISIT). *Ann Rheum Dis* 2000;59:936-44.
- 2 Towheed TE, Hochberg MC. A systematic review of randomized controlled trials of pharmacological therapy in osteoarthritis of the knee, with an emphasis on trial methodology. *Semin Arthritis Rheum* 1997;26:755-70.

- 3 Mason L, Moore RA, Edwards JE, Derry S, McQuay HJ. Topical NSAIDs for chronic musculoskeletal pain: systematic review and meta-analysis. *BMC Musculoskelet Disord* 2004;5:28.
- 4 Lin J, Zhang W, Jones A, Doherty M. Efficacy of topical non-steroidal anti-inflammatory drugs in the treatment of osteoarthritis: meta-analysis of randomised controlled trials. *BMJ* 2004;329:324-6.
- 5 Towheed TE. Pennsaid therapy for osteoarthritis of the knee: a systematic review and meta-analysis of randomized controlled trials. *J Rheumatol* 2006;33:567-73.
- 6 Cross PL, Ashby D, Harding G, Hennessy EM, Letley L, Parsons S, et al. TOIB Study. Are topical or oral ibuprofen equally effective for the treatment of chronic knee pain presenting in primary care: a randomised controlled trial with patient preference study. *BMC Musculoskelet Disord* 2005;6:55.
- 7 Parsons S, Carnes D, Pincus T, Foster N, Breen A, Vogel S, et al. Measuring troublesomeness of chronic pain by location. *BMC Musculoskelet Disord* 2006;7:34.
- 8 Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988;15:1833-40.
- 9 Carnes D, Anwer Y, Harding G, Underwood M, Parsons S, on behalf of the TOIB study team. Influences on older people's decision making regarding choice of topical or oral NSAIDs for their knee pain: qualitative study. *BMJ* 2007 doi: 10.1136/bmj.39401.699063.BE.

Accepted: 7 November 2007

Influences on older people's decision making regarding choice of topical or oral NSAIDs for knee pain: qualitative study

Dawn Carnes,¹ Yasir Anwer,¹ Martin Underwood,¹ Geoff Harding,² Suzanne Parsons,¹ on behalf of the TOIB study team

EDITORIAL by Dieppe

¹Centre for Health Sciences, Barts and The London, Queen Mary University of London, London E1 2AT

²Peninsula College of Medicine and Dentistry (Primary Care), Royal Cornwall Hospital, Truro TR1 3LJ

Correspondence to: M Underwood m.underwood@warwick.ac.uk

BMJ 2008;336:142-5
doi:10.1136/bmj.39401.699063.BE

This article is an abridged version of a paper that was published on bmj.com on 4 December 2007. Cite this article as: *BMJ* 4 December 2007, doi: 10.1136/bmj.39401.699063.BE

ABSTRACT

Objective To explore the factors that influence older people's decision making regarding use of topical or oral ibuprofen for their knee pain.

Design Qualitative interview study nested within a randomised controlled trial and a patient preference study that compared advice to use oral or topical non-steroidal anti-inflammatory drugs (NSAIDs) for knee pain in older people.

Setting 11 general practices.

Participants 30 people aged ≥50 with knee pain.

Results Participants' decision making was influenced by their perceptions of the associated risk of adverse effects, presence of other illness, nature of their pain, advice received, and practicality. Although participants' understanding of how the medications worked was sometimes poor, their decision making about the use of NSAIDs seemed logical and appropriate. Participants' model for treatment was to use topical NSAIDs for mild, local, and transient pain and oral NSAIDs for moderate to severe, generalised, and constant pain (in the absence of other more serious illness or risk of adverse effects). Participants showed marked tolerance and normalisation of adverse effects.

Conclusion Participants had clear ideas about the appropriate use of oral and topical NSAIDs. Taking such views into account when prescribing may improve

adherence, judgment of efficacy, and the doctor-patient relationship. Tolerance and normalisation of adverse effects in these patients indicate that closer monitoring of older people who use NSAIDs might be needed.

INTRODUCTION

In a randomised controlled trial and parallel patient preference study we found that advice to, or the decision to, preferentially use topical or oral NSAIDs for knee pain had equivalent effects on the pain.¹⁻³ To help set the results of that study in context we conducted a nested qualitative study to examine what influenced participants' decisions about taking part in the study and their use of topical or oral ibuprofen for their knee pain.

METHOD

Details of our methods and the clinical results are available elsewhere.¹⁻³ Participants for the qualitative study came from 11 practices across the UK.

Rationale behind the decisions—We explored the rationale behind patients' decisions to take part in the preference study or the randomised trial and, for those in the preference study, their decisions to choose topical or oral medication. We conducted telephone