Community occupational therapy for older patients with dementia and their care givers: cost effectiveness study

Maud J L Graff,[1,3] Eddy M M Adang,[2] Myrra J M Vernooij-Dassen,[3] Joost Dekker,[4] L Jönsson,[5] Marjolein Thijssen,[1,3] Willibrord H L Hoefnagels,[6] Marcel G M Olde Rikkert[6]

[1]Alzheimer Centre Nijmegen, Department of Occupational Therapy 897, Radboud University Nijmegen Medical Centre, PO Box 9101, 6500 HB Nijmegen, Netherlands
[2]Department of Epidemiology, Biostatistics and Health Technology Assessment, Radboud University Nijmegen Medical Centre
[3]Alzheimer Centre Nijmegen, Department of Quality of Care Research, Radboud University Nijmegen Medical Centre
[4]Department of Rehabilitation Medicine, Free University Medical Centre Amsterdam, Amsterdam, Netherlands
[5]Division of Geriatric Epidemiology, Neurotec Department, Karolinska Institute, Stockholm, Sweden
[6]Alzheimer Centre Nijmegen, Department of Geriatrics 925, Radboud University Nijmegen Medical Centre

Correspondence to: M J L Graff
m.graff@pmd.umcn.nl

BMJ 2008;336:134-8
doi:10.1136/bmj.39408.481898.BE

This article is an abridged version of a paper that was published on bmj.com on 2 January 2008. Cite this article as: *BMJ* 2 January 2008, doi: 10.1136/bmj.39408.481898.BE

ABSTRACT

Objective To assess the cost effectiveness of community based occupational therapy compared with usual care in older patients with dementia and their care givers from a societal viewpoint.

Design Cost effectiveness study alongside a single blind randomised controlled trial.

Setting Memory clinic, day clinic of a geriatrics department, and participants' homes.

Patients 135 patients aged ≥65 with mild to moderate dementia living in the community and their primary care givers.

Intervention 10 sessions of occupational therapy over five weeks, including cognitive and behavioural interventions, to train patients in the use of aids to compensate for cognitive decline and care givers in coping behaviours and supervision.

Main outcome measures Incremental cost effectiveness ratio expressed as the difference in mean total care costs per successful treatment (that is, a combined patient and care giver outcome measure of clinically relevant improvement on process, performance, and competence scales) at three months after randomisation. Bootstrap methods used to determine confidence intervals for these measures.

Results The intervention cost €1183 (£848; $1738) (95% confidence interval €1128 (£808; $1657) to €1239 (£888; $1820)) per patient and primary care giver unit at three months. Visits to general practitioners and hospital doctors cost the same in both groups but total mean costs were €1748 (£1279; $2621) lower in the intervention group, with the main cost savings in informal care. There was a significant difference in proportions of successful treatments of 36% at three months. The number needed to treat for successful treatment at three months was 2.8 (2.7 to 2.9).

Conclusions Community occupational therapy intervention for patients with dementia and their care givers is successful and cost effective, especially in terms of informal care giving.

INTRODUCTION

The world prevalence of dementia has recently been estimated at 24.3 million people. This is expected to double over the next 20 years.[1] In the Netherlands in 2003, 5.3% of the total healthcare budget was spent on dementia.[2] Because of an ageing population, the numbers of patients and the related healthcare costs will increase substantially in the next five decades.[3-5] In the Netherlands in 2002, 39% of people with dementia needed continuous care, and 60% of those living in the community needed daily or continuous care.[6]

In Scandinavia, informal care costs, valued at the opportunity costs of the care giver's time, made up about a third of the total annual costs in dementia.[7] It is therefore important to implement new effective and efficient healthcare interventions that increase independence and wellbeing of the patients and decrease the burden on care givers.[8]

Occupational therapy can improve daily functioning, social participation, and wellbeing in people with dementia living in the community and improve the sense of competence and wellbeing of their primary care givers.[9-14] Recent research has looked at the efficacy and cost effectiveness of community occupational therapy in patients with dementia and their primary care givers.[9-12 14-19] In one study of an efficient preventive nine month occupational therapy programme there was a trend towards lower medical costs and more independent living.[16] Brodaty and Peters found that an intensive 10 day training programme for care givers was cost effective and was associated with patients being able to live at home for longer and decreased psychological morbidity in care givers.[19]

We determined the cost effectiveness of community occupational therapy for people with dementia and their primary care givers from a societal viewpoint.

METHODS

Participants

From April 2001 to January 2005, we recruited people with dementia and their care givers from the memory clinic and the day clinic of a department of geriatrics. Patients were included if they were aged 65 or over, had been diagnosed with mild to moderate dementia, were living in the community, and had a primary care giver who cared for them at least once a week.

Randomisation and procedures

Patients were randomly assigned to the intervention (10 sessions of occupational therapy at home over five weeks) or control group (usual care with no occupational therapy), which was stratified by level of dementia (mild or moderate). Patients and care givers were aware of the treatment assigned. The assessors were blinded to group allocation. The total study period per patient was three months.

Intervention

The study intervention was developed in a consensus process and was implemented by experienced trained occupational therapists.[9 10 20 21] Treatment consisted of 10 one hour sessions held over five weeks and focused on

both patients and their primary care givers. In the first four sessions of diagnostics and goal defining, patients and primary care givers learnt to define their problems and choose and prioritise meaningful activities they wanted to improve.

In the remaining six sessions, patients were taught to optimise the compensatory and environmental strategies identified in the first four sessions. Primary care givers were trained to use effective supervision, problem solving, and coping strategies. The total time spent for the intervention was about 18 hours per patient and care giver.

Outcome assessments of effects

We assessed patients and their primary care givers at baseline before the intervention and six weeks and three months later. Our primary outcome measure for patients was daily functioning assessed with the process scale of the assessment of motor and process skills,[22] and the performance scale of the interview of deterioration in daily activities in dementia.[23] The primary outcome for care givers was assessed with the sense of competence questionnaire.[24]

Over a three month period these three primary outcomes were combined in one measure. The treatment was judged successful if the process, performance, and competence scale scores showed improvements of ≥0.5 points, ≥20%, and ≥5 points, respectively.[22-24]

Outcome measures collected at baseline included information on patients' comorbidity, depressive mood, cognition, and behaviour. For carers we collected information on the relationship to the patient and depression.

Cost analysis

We evaluated costs from a societal viewpoint and included both direct costs inside and outside the healthcare service and indirect costs outside the healthcare service. This societal viewpoint includes all costs our society met as a consequence of this community occupational therapy[25] and includes the estimated costs for gains and losses in productivity of the care givers.[26] Because the study lasted only three months we did not expect a discount effect and therefore did not correct for inflation. We performed an incremental analysis in which we analysed in detail only costs that potentially differed between the two groups.

We used several instruments to measure the consumed resources. The primary care givers kept a diary to record the patients' visits to healthcare suppliers specifically related to the dementia, and their own visits to healthcare services. They recorded the number of hours the patients received professional care at home. Finally, they noted the days of illness in the patients and the number of days patients had spent in day care or were admitted to hospital or nursing homes.

The quantities measured were multiplied by unit costs (prices) to obtain the costs involved. The costs for community occupational therapy sessions were based on outpatient price for employee costs (that is, a defined price for outpatient occupation therapy per hour), additional costs for home visits, and travelling costs.[27] The additional costs of occupational therapy were based on the employee costs per hour. We based prices for visits to the general practitioner, day care, home care or household support on Dutch guidelines.[26] Costs for the hospital social worker and hospital physician were calculated from the employee costs. Hours invested by care givers were counted according to Dutch guidelines, which reflect an average of costs for care givers still in paid employment and care givers not working any more.

Statistical analysis

We analysed differences in outcome by analyses of covariance of the primary outcome measures based on an intention to treat analysis. The covariates were age, sex, relationship between the patient and the care giver, other care givers, and baseline scores for cognitive functioning,[28] depression,[29] comorbidity,[30] behaviour and behavioural problems checklist,[23] and the outcome variable.

We computed the proportion of patients and care givers achieving a clinically relevant improvement for each of the primary outcome measures separately and for all three together, which was the fraction with successful treatment outcome. We calculated the difference in treatment effect as the difference in successfully treated patients and care givers combined. Incremental treatment costs were calculated as the difference in mean total care costs. We calculated an incremental cost effectiveness ratio, which was expressed as total costs per successful treatment. Bootstrap methods were used to explore the uncertainty in the estimates of cost effectiveness and determine confidence intervals. We used one way sensitivity analyses to examine the robustness of the findings of the cost effectiveness analysis. We assessed cost effectiveness with an acceptability curve.

Table 1 | Effect of treatment and mean (SD) costs per patient at 3 months of follow-up

	Occupational therapy (n=67)	Usual care (n=65)	Difference (95% CI)
Effect			
No (%) of "successful treatments"	25 (37)	1 (1.5)	36% (23% to 47%)
No with missing data	1	2	—
NNT (95% CI)	2.8 (2.7 to 2.9)	—	—
Costs (€)*			
Total care costs	12 563 (6628)	14 311 (7833)	−1748 (−4244 to 748)
Intervention (OT):			
Visits	774 (151)	0	774 (737 to 810)
Additional	409 (78)	0	409 (391 to 429)
Total	1183 (228)	0	1183 (1128 to 1239)

NNT=number needed to treat.
*Costs per patient averaged over all patients in each group.

RESULTS

Effects

We evaluated 275 people with dementia who were living in the community. Of the 135 eligible patients

randomised, three stopped the trial immediately after randomisation. This left 132 patients with care givers. The baseline characteristics of patients and care givers were well matched between the two groups. The occupational therapist visited those in the intervention group an average of nine times at home for one hour and spent an additional seven hours per patient and care giver couple.

Table 2 | Effect on costs of health care at 3 months of follow-up. Figures are mean (SD) costs (€) per patient

	Occupational therapy (n=67)	Usual care (n=65)	Difference in cost (95% CI)
Physiotherapy:			
Average cost*	152 (290)	188 (363)	−36 (−149 to 77)
No (%) who used service	27 (40)	18 (28)	—
Costs if used†	377	679	—
Social worker:			
Average cost*	26 (68)	34 (90)	−8 (−35 to 20)
No (%) who used service	11 (16.9)	13 (20)	—
Costs if used†	158	170	—
General practitioner:			
Average cost*	3 (11)	3 (17)	0 (−5 to 4)
No (%) who used service	5 (7.5)	3 (4.6)	—
Costs if used†	40	65	—
Hospital specialist:			
Average cost*	5 (16)	4 (16)	1 (−5 to 6)
No (%) who used service	6 (9)	5 (7.6)	—
Costs if used†	56	52	—
Nurse home care:			
Average cost*	1512 (2469)	1929 (3201)	−417 (−1399 to 566)
No (%) who used service	40 (59.7)	33 (50.8)	—
Costs if used†	2533	3800	—
Domestic home care:			
Average cost*	413 (990)	504 (1056)	−91 (−443 to 262)
No (%) who used service	26 (38.8)	29 (44.6)	—
Costs if used†	1064	1130	—
Day care:			
Average cost*	408 (1178)	605 (1291)	−197 (−622 to 228)
No (%) who used service	9 (13.4)	17 (26.2)	—
Costs if used†	3037	2513	—
Meals-on-wheels:			
Average cost*	134 (273)	142 (278)	−8 (−103 to 87)
No (%) who used service	14 (20.9)	16 (24.6)	—
Costs if used†	641	577	—
Admitted to hospital:			
Average cost*	739 (3215)	981 (4114)	−242 (−1512 to 1027)
No (%) who used service	6 (9.0)	7 (10.8)	—
Costs if used†	8252	9109	—
Admission to institution			
Nursing home:			
Average cost*	335 (1635)	501 (2731)	−166 (−938 to 607)
No (%) who used service	5 (7.5)	5 (7.7)	—
Costs if used†	4489	6513	—
Home for elderly:			
Average cost*	71 (582)	77 (590)	−6 (−208 to 196)
No (%) who used service	1 (1.5)	4 (6.2)	—
Costs if used†	4757	1251	—
Informal care:			
Average cost	7582	9344	−1762 (−3919 to 395)
No (%) who used service	67 (100)	65 (100)	—
Costs if used†	7582	9344	—

*Costs per patient averaged over all patients in each group.
†Costs of specific service when averaged over those patients who actually used it.

At three months 53 of the 68 patients in the intervention group and 52 of the 67 in the control group remained in the study. There were significant differences between the groups on all primary outcome variables at three months. In the intention to treat analysis (n=132), treatment was considered as successful in 26 patients and their care givers, of whom 25 (37%) were in the intervention group (n=67) and one (1.5%) was in the control group (n=65). The number needed to treat for a successful treatment outcome was 2.8 (95% confidence interval 2.7 to 2.9) (table 1). No adverse events were reported in either group.

Costs

The occupational therapy intervention cost €1183 (£848; $1738) per patient and care giver couple (95% confidence interval €1128 to €1239) (table 2). The costs for visits to a general practitioner and hospital doctor were equal in both groups. Costs for other healthcare services were lower in the intervention group (table 2), as were costs for admission to hospital (−€242) and nursing homes and homes for the elderly (−€172). The main cost savings were from reduced informal care in the intervention group (−€1762).

The economic evaluation showed average savings of €1748 (£1279; $2621) per couple successfully treated with occupational therapy. The probability of occupational therapy being the dominant intervention was estimated to be 94%. The acceptability curve shows that if society is willing to pay €2000 (£1473; $2933) or more for a successful treatment then there is 99% probability that occupational therapy is efficient.

DISCUSSION

Community occupational therapy intervention for people with dementia and their primary care givers is cost effective, at a cost of about €1200 (£859; $1790) per patient and care giverover a three month period. The intervention was associated with a 35% higher proportion of successful treatment. The mean costs per patient and care giver of all care for the three months were €12 563 (£8994; $18 433) for the intervention group and €14 311 (£10 246; $20 998) for the control group. From a societal viewpoint community occupational therapy is an effective and efficient intervention strategy. On average it saved €1748 (£1279; $2641) over three months (with a probability of 95%), and yielded significant and clinically relevant improvements in daily functioning in patients and sense of competence in care givers.

Hay et al looked at cost effectiveness of a preventive occupational therapy for independent living older adults in a randomised controlled trial with an occupational therapy group, a social activity group, and a control with no treatment.[16] The costs for the nine month preventive

WHAT IS ALREADY KNOWN ON THIS TOPIC

Community occupational therapy improves daily functioning in patients with dementia and reduces the burden on care givers

Dementia is categorised as one of the three major diseases in healthcare costs and is a major cause of disability and burden of care in elderly people

WHAT THIS STUDY ADDS

Community occupational therapy intervention is cost effective and specifically reduces costs of informal care giving

occupational therapy programme ($548 per person) and the follow-up costs at 15 months for the occupational therapy group ($967) were lower than for the social activity group ($1726) and the control ($3334). The authors concluded that the programme was cost effective.

Strengths and limitations

We used a randomised controlled design and carried out the economic analysis from a societal perspective. Another strong point is the new outcome measure "successful treatment outcome" which combines the effect of occupational therapy on outcome in both patient and care giver. We did not include a generic measure for quality of life on which QALYs could be computed, which limits comparability with other interventions. Given the results (an average cost saving and a 95% probability of being the dominant strategy) the conclusion that occupational therapy is cost effective would not be altered if we included quality of life as an outcome measure.

A second limitation of our study design is that we could not carry out a double blind study. We tried to maintain masked conditions when possible when it came to assessment, which succeeded for 80% of the cases.[31]

The study took place over a relatively short time, with a three month follow-up.[25] Based on the remaining effects on the primary outcomes of the randomised controlled trial at three months,[10] we expect that the savings at six months would be even greater, with no more costs incurred.

Our participants might not be representative of all patients with mild to moderate dementia in our health region as they were recruited primarily from the outpatient clinics of the university hospital and because we excluded those who lived alone. Another issue is the costs for informal care giving, which were computed with the "friction cost method.[26] In our study most of the care givers were retired. If other informal care givers had been used (for example, more employed sons or daughters or neighbours) another value would have been plausible.

We expect that this intervention might also be cost effective for older people with dementia without an informal care giver but who have the help of a professional home care worker with relevant training.

Community occupational therapy is a highly effective non-pharmacological therapy for older people with dementia and their care givers.[9 10 32] As this community occupational therapy intervention was also cost effective we recommend it in all community health services, primary care services, and outpatient services for people with dementia and their care givers. A multicentred study would determine the cost effectiveness in different settings and healthcare regions.

We thank all participants for their contribution and Jana Zajec and Patricia Verstraten for occupational therapy treatments.
Contributors: See bmj.com.
Funding: Fund VCVGZ, the Dutch Alzheimer Association with financial support of the Radboud University Nijmegen Medical Centre, and the Dutch Occupational Therapy Association.
Competing interests: None declared.
Ethical approval: Medical ethics committee of the Radboud University Nijmegen Medical Centre of Nijmegen and Arnhem, No CWOM0012-0292.
Provenance and peer review: Not commissioned; externally peer reviewed.

1 Ferri CP, Prince M, Brayne C, Brodaty H, Fratiglioni L, Ganguli M, et al. Global prevalence of dementia: a Delphi consensus study. *Lancet* 2005;366:2112-7.
2 Slobbe LCJ, Kommer GJ, Smit JM, Groen J, Meerding WJ, Polder JJ. *Kosten van Ziekten in Nederland 2003*. [Costs of illnesses in the Netherlands 2003.] Bilthoven: RIVM, 2006. (In Dutch.)
3 Wimo A, Winblad B, Aguero Torres H, von Strauss E. The magnitude of dementia occurrence in the world. *Alzheimer Dis Assoc Disord* 2003;17:63-7.
4 Meerding WJ, Bonneux L, Polder JJ, Koopmanschap MA, van der Maas PJ. Demographic and epidemiological determinants of healthcare costs in the Netherlands: cost of illness study. *BMJ* 1998;317:111-5.
5 Dutch Health Council. Gezondheidsraad. *Rapport: dementie*. Hague: Gezondheidsraad, 2002 (publication No 2002/04). (In Dutch.)
6 Raad voor de Volksgezondheid en Zorg (RVZ). *Arbeidsmarkt en zorgvraag. Achtergrondstudies*. [Labour market and care demand. Background studies.] Hague: RVZ, 2006. (In Dutch.)
7 Jönsson L, Eriksdotter Jönhagen M, Kilander L, Soininen H, Hallikainen M, Wimo A, et al. Determinants of costs of care for patients with Alzheimer's disease. *Int J Geriatr Psychiatry* 2006;21:449-59.
8 Karlsson G, Wimo A, Jönsson B, Winblad B. Methodological issues in health economic studies of dementia. In: Wimo A, Karlsson G, Jonsson B, Winblad B, eds. *Health economics of dementia*. Chichester: John Wiley, 1998.
9 Graff MJL, Vernooij-Dassen MJM, Thijssen M, Dekker, J, Hoefnagels Whl, OldeRikkert MGM. Effects of community occupational therapy on quality of life, mood, and health status in dementia patients and their caregivers: a randomized controlled trial. *J Gerontol A Biol Sci Med Sci* 2007;62:1002-9.
10 Graff MJL, Vernooij-Dassen MJM, Thijssen M, Dekker J, Hoefnagels WHL, Olde Rikkert MGM. Community based occupational therapy for patients with dementia and their care givers: randomised controlled trial. *BMJ* 2006;333:1196.
11 Gitlin LN, Corcoran M, Winter L, Boyce A, Hauck WW. A randomised, controlled trial of a home environment intervention: effect on efficacy and upset in caregivers and on daily function of persons with dementia. *Gerontologist* 2001;41:4-14.
12 Gitlin LN, Hauck WW, Dennis MP, Winter L. Maintenance of effects of the home environmental skill-building program for family caregivers and individuals with Alzheimer's disease and related disorders. *J Gerontol A Biol Sci Med Sci* 2005;60:368-74.
13 Steultjens EMJ, Dekker J, Bouter L, Jellema S, Bakker, EB, vandenEnde CHM. Occupational therapy for community dwelling elderly people: a systematic review. *Age Ageing* 2004;33:453-60.
14 Graff MJL, Vernooij-Dassen MJFJ, Hoefnagels WHL, Dekker J, Witte de LP. Occupational therapy at home for older individuals with mild to moderate cognitive impairments and their primary care givers: a pilot study. *Occup Ther J Res* 2003;23:155-64.
15 Burgener SC, Bakas T, Murray C, Dunahee J, Tossey S. Effective caregiving approaches for patients with Alzheimer's disease. *Geriatr Nurs* 1998;19:121-6.
16 Hay J, LaBree l, Luo R, Clark F, Carlson M, Azen SP, et al. Cost-effectiveness of preventive occupational therapy for independent-living older adults. *J Am Ger Soc* 2002;50:1381-8.
17 Knapp M, Thorgrimsen L, Patel A, Spector A, Hallam A, Orrel M, et al. Cognitive stimulation therapy for people with dementia: cost-effectiveness analysis. *Br J Psychiatr* 2006;188:574-80.

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 MJFJ, 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 geriatrische 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 Zorgverzekeringen (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

[1]Centre for Health Sciences, Barts and The London, Queen Mary, University of London, London E1 2AT
[2]Wolfson Institute of Preventive Medicine, Barts and The London, Queen Mary, University of London, London EC1M 6BQ
[3]MRC General Practice Research Framework, London NW1 2ND
[4]Department of Primary and Social Care, London South Bank University, London SE1 6EN
[5]Clinical 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 µmol/l less favourable (0.9 µmol/l to 6.5 µmol/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