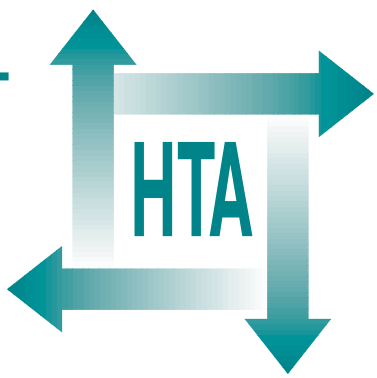
Health Technology Assessment 1999; Vol. 3: No. 23

Economic evaluation of a primary care-based education programme for patients with osteoarthritis of the knee

J Lord
C Victor
P Littlejohns
FM Ross
JS Axford

Health Technology Assessment
NHS R&D HTA Programme



Standing Group on Health Technology

Current members

Chair:
Professor Kent Woods
Professor of Therapeutics,
University of Leicester

Professor Martin Buxton
Director & Professor of
Health Economics,
Health Economics
Research Group,
Brunel University

Professor Shah Ebrahim
Professor of Epidemiology
of Ageing, University of Bristol

Professor Francis H Creed
Professor of
Psychological Medicine,
Manchester Royal Infirmary

Professor John Gabbay
Director, Wessex Institute
for Health Research
& Development

Professor Sir John
Grimley Evans
Professor of Clinical Geratology,
Radcliffe Infirmary,
Oxford

Dr Tony Hope
Clinical Reader in Medicine,
Nuffield Department of
Clinical Medicine,
University of Oxford

Professor Richard Lilford
Regional Director of R&D,
NHS Executive West Midlands

Dr Jeremy Metters
Deputy Chief Medical Officer,
Department of Health

Professor Maggie Pearson
Regional Director of R&D,
NHS Executive North West

Mr Hugh Ross
Chief Executive,
The United Bristol
Healthcare NHS Trust

Professor Trevor Sheldon
Joint Director, York Health
Policy Group, University of York

Professor Mike Smith
Faculty Dean of Research
for Medicine, Dentistry,
Psychology & Health,
University of Leeds

Dr John Tripp
Senior Lecturer in Child Health,
Royal Devon and Exeter
Healthcare NHS Trust

Professor Tom Walley
Director,
Prescribing Research Group,
University of Liverpool

Dr Julie Woodin
Chief Executive,
Nottingham Health Authority

Past members

Professor Sir Miles Irving*
Professor of Surgery,
University of Manchester,
Hope Hospital, Salford

Dr Sheila Adam
Department of Health

Professor Angela Coulter
Director, King's Fund,
London

Professor Anthony Culyer
Deputy Vice-Chancellor,
University of York

Dr Peter Doyle
Executive Director, Zeneca Ltd,
ACOST Committee on Medical
Research & Health

Professor John Farndon
Professor of Surgery,
University of Bristol

Professor Charles Florey
Department of Epidemiology
& Public Health, Ninewells
Hospital & Medical School,
University of Dundee

Professor Howard
Glennester
Professor of Social Science
& Administration, London
School of Economics &
Political Science

Mr John H James
Chief Executive,
Kensington, Chelsea &
Westminster Health Authority

Professor Michael Maisey
Professor of
Radiological Sciences,
Guy's, King's & St Thomas's
School of Medicine & Dentistry,
London

Mrs Gloria Oates
Chief Executive,
Oldham NHS Trust

Dr George Poste
Chief Science & Technology
Officer, SmithKline Beecham

Professor Michael Rawlins
Wolfson Unit of
Clinical Pharmacology,
University of Newcastle-
upon-Tyne

Professor Martin Roland
Professor of General Practice,
University of Manchester

Professor Ian Russell
Department of Health Sciences
& Clinical Evaluation,
University of York

Dr Charles Swan
Consultant Gastroenterologist,
North Staffordshire
Royal Infirmary

* Previous Chair

Details of the membership of the HTA panels, the NCCHTA Advisory Group and the HTA Commissioning Board are given at the end of this report.

How to obtain copies of this and other HTA Programme reports.
An electronic version of this publication, in Adobe Acrobat format, is available for downloading free of charge for personal use from the HTA website (http://www.hta.ac.uk). A fully searchable CD-ROM is also available (see below).

Printed copies of HTA monographs cost £20 each (post and packing free in the UK) to both public **and** private sector purchasers from our Despatch Agents.

Non-UK purchasers will have to pay a small fee for post and packing. For European countries the cost is £2 per monograph and for the rest of the world £3 per monograph.

You can order HTA monographs from our Despatch Agents:

– fax (with **credit card** or **official purchase order**)
– post (with **credit card** or **official purchase order** or **cheque**)
– phone during office hours (**credit card** only).

Additionally the HTA website allows you **either** to pay securely by credit card **or** to print out your order and then post or fax it.

Contact details are as follows:

HTA Despatch
c/o Direct Mail Works Ltd
4 Oakwood Business Centre
Downley, HAVANT PO9 2NP, UK

Email: orders@hta.ac.uk
Tel: 02392 492 000
Fax: 02392 478 555
Fax from outside the UK: +44 2392 478 555

NHS libraries can subscribe free of charge. Public libraries can subscribe at a very reduced cost of £100 for each volume (normally comprising 30–40 titles). The commercial subscription rate is £300 per volume. Please see our website for details. Subscriptions can only be purchased for the current or forthcoming volume.

Payment methods

Paying by cheque
If you pay by cheque, the cheque must be in **pounds sterling**, made payable to *Direct Mail Works Ltd* and drawn on a bank with a UK address.

Paying by credit card
The following cards are accepted by phone, fax, post or via the website ordering pages: Delta, Eurocard, Mastercard, Solo, Switch and Visa. We advise against sending credit card details in a plain email.

Paying by official purchase order
You can post or fax these, but they must be from public bodies (i.e. NHS or universities) within the UK. We cannot at present accept purchase orders from commercial companies or from outside the UK.

How do I get a copy of *HTA on CD*?

Please use the form on the HTA website (www.hta.ac.uk/htacd.htm). Or contact Direct Mail Works (see contact details above) by email, post, fax or phone. *HTA on CD* is currently free of charge worldwide.

The website also provides information about the HTA Programme and lists the membership of the various committees.

Economic evaluation of a primary care-based education programme for patients with osteoarthritis of the knee

J Lord[1*]
C Victor[1]
P Littlejohns[1]
FM Ross[2]
JS Axford[3]

[1] Department of Public Health Sciences,
[2] Department of Healthcare Sciences and
[3] Department of Immunology, St George's Hospital Medical School, London, UK

* Corresponding author

Competing interests: none declared

Published December 1999

This report should be referenced as follows:

Lord J, Victor C, Littlejohns P, Ross FM, Axford JS. Economic evaluation of a primary care-based education programme for patients with osteoarthritis of the knee. *Health Technol Assess* 1999;**3**(23).

Health Technology Assessment is indexed in *Index Medicus*/MEDLINE and *Excerpta Medica*/EMBASE. Copies of the Executive Summaries are available from the NCCHTA web site (see overleaf).

NHS R&D HTA Programme

The overall aim of the NHS R&D Health Technology Assessment (HTA) programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and work in the NHS. Research is undertaken in those areas where the evidence will lead to the greatest benefits to patients, either through improved patient outcomes or the most efficient use of NHS resources.

The Standing Group on Health Technology advises on national priorities for health technology assessment. Six advisory panels assist the Standing Group in identifying and prioritising projects. These priorities are then considered by the HTA Commissioning Board supported by the National Coordinating Centre for HTA (NCCHTA).

This report is one of a series covering acute care, diagnostics and imaging, methodology, pharmaceuticals, population screening, and primary and community care. It was identified as a priority by the Primary and Community Care Panel and funded as project number 94/39/01.

The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for the recommendations for policy contained herein. In particular, policy options in the area of screening will be considered by the National Screening Committee. This Committee, chaired by the Chief Medical Officer, will take into account the views expressed here, further available evidence and other relevant considerations.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

Series Editors: Andrew Stevens, Ruairidh Milne and Ken Stein
Monograph Editorial Manager: Melanie Corris

The editors have tried to ensure the accuracy of this report but cannot accept responsibility for any errors or omissions. They would like to thank the referees for their constructive comments on the draft document.

ISSN 1366-5278

Published by Core Research, Alton, on behalf of the NCCHTA.
Printed on acid-free paper in the UK by The Basingstoke Press, Basingstoke.

Copies of this report can be obtained from:

The National Coordinating Centre for Health Technology Assessment,
Mailpoint 728, Boldrewood,
University of Southampton,
Southampton, SO16 7PX, UK.
Fax: +44 (0) 23 8059 5639 Email: hta@soton.ac.uk
http://www.hta.nhsweb.nhs.uk

Contents

List of abbreviations

AHI	Arthritis Helplessness Index
AIMS2	Arthritis Impact Measurement Scales, version 2
BNF	British National Formulary
CI	confidence interval
CIPFA	Chartered Institute for Public Finance Accountants
com	complementary therapy*
CPD	continuing professional development*
DP	day patient*
ECR	extra contractual referral*
GHQ	General Health Questionnaire
GP	general practitioner
HCHS	hospital and community health services
HFMA	Health Finance Management Association
IP	inpatient*
NSAID	non-steroidal anti-inflammatory drug
OA	osteoarthritis
OAK	Osteoarthritis of the Knee Study (randomised controlled trial carried out by researchers from St George's Hospital, London)
OP	outpatient*
PAM	professions allied to medicine
PSSRU	Personal Social Services Research Unit
RA	rheumatoid arthritis
SEM	standard error of the mean*
SE	standard error*
SF-36	short form 36-item version of the Medical Outcomes Survey questionnaire
SSD	Local Authority Social Services Department*
WOMAC	Western Ontario and McMaster Universities Arthritis Index

* Used only in tables and figures

Executive summary

Objectives

This study is an economic evaluation of a general practice-based nurse-led education programme for patients with osteoarthritis of the knee. The objectives were:

- to measure the clinical effectiveness of the intervention over 1 year of follow-up
- to estimate the mean cost per participant of providing the intervention in the Osteoarthritis of the Knee (OAK) study
- to estimate the impact of the programme on the direct and indirect costs of health care related to knee arthritis over the year of follow-up.

Methods

The OAK study

In the OAK study, local general practices were randomised to an intervention or control group. Patients with confirmed knee osteoarthritis were recruited between November 1995 and May 1997, and were initially assessed by interview. Those in the intervention practices were then invited to take part in four 1-hour group sessions led by a research nurse. The sessions took place at weekly intervals at the general practitioners' (GPs') surgeries. The patients were assessed by postal questionnaire at 1, 3, 6 and 12 months. Health outcome measurement instruments included the Western Ontario and McMaster Universities Arthritis Index, the Arthritis Helplessness Index (AHI), the Short Form 36 (SF-36) and the General Health Questionnaire.

Economic analysis

Analysis was conducted on an intention-to-treat basis. Firstly, tests were carried out for differences in baseline characteristics by level of follow-up and by study group. Baseline values of each socio-demographic and outcome variable were regressed against a dummy follow-up variable and against a dummy study group variable. The significance of the relationships was tested using robust estimates of variance with adjustment for clustering by practice. Tests were then carried out for between-group differences in clinical outcomes at 1 year using (robust cluster-adjusted) linear regression with adjustment for the baseline value of the variable. Further explanatory variables were added to correct for baseline differences in practice or patient characteristics.

Additional information for the economic evaluation was collected from two sources: patients were re-interviewed at 1 year, and GP case notes were reviewed. Information was collected for each cost-generating event over a 2-year period (from 1 year before baseline to 1 year after). Events were excluded from the cost analysis if they were clearly not related to knee osteoarthritis. Total costs, including all relevant health care and the cost of the educational sessions, were then estimated for each patient for the 2 study years.

The unit costs used to estimate costs were derived from published national sources wherever possible. All costs are reported in 1996/1997 pounds sterling. The social direct cost of the OAK programme was estimated to be £240 per participant. This is based on the recruitment of 20 practices, 38 teaching groups and 174 patients – the numbers that could be expected to be recruited within a single health district in 1 year. If a nurse were to be employed to deliver an existing programme, the social direct cost would be about £140 per participant.

Patient costs were analysed in two ways. Firstly, between-group cost differences were tested for using robust cluster-adjusted linear regression, as for the outcome data. Secondly, confidence intervals for incremental costs were estimated by bootstrap regression with re-sampling of residuals. The effect of uncertainty over unit cost estimates was investigated through simple one-way and probabilistic sensitivity analyses.

Results

The control practices recruited significantly fewer patients than the intervention practices: 65 patients were recruited from 12 control practices, compared with 105 patients from ten intervention practices ($p = 0.02$). There were no significant differences between the control and intervention groups in follow-up rates at 1 year by questionnaire, interview or case-note review. Overall, 85% of patients

completed the questionnaire (full or brief version) at 1 year, 74% were interviewed at 1 year, and case notes were reviewed for 81%.

There was evidence of selective withdrawal from the trial, as patients with complete follow-up had higher AHI scores at baseline ($p < 0.001$).

Some differences in baseline characteristics remained after randomisation. The control practices had more partners ($p = 0.02$). A greater proportion of patients in the control group than in the intervention group came from non-white ethnic groups ($p = 0.007$), and the control group also had a greater proportion of patients who lived alone ($p = 0.005$). The control group had higher baseline scores for the physical dimension of the SF-36 ($p = 0.008$).

There were no significant differences between the control and intervention groups in health outcome at 1 year after adjustment for baseline scores and practice clustering. This remained so after further adjustment for initial patient and practice differences.

Over the year after baseline, costs were greater for the intervention group than for the control group. After adjusting for baseline costs and clustering, the mean difference in social direct costs was £239 ($p < 0.001$). The results of the cost analysis did not change after further adjustment for other baseline differences.

The results were also robust to changes in unit costs. The cost of the education programme had to fall to below £15 per participant before the significance of the difference in social direct cost was lost. The 95% confidence interval for incremental social direct costs was similar when estimated by parametric methods (£138 to £259) or non-parametric bootstrapping (£150 to £263). When probabilistic sensitivity analysis was introduced along with non-parametric bootstrapping, to include additional uncertainty due to unit costs, the 95% bias-corrected percentile uncertainty range was slightly wider (£133 to £274).

Conclusions

The OAK study failed to demonstrate improvements in knowledge, self-efficacy in arthritis management, or health outcomes after 1 year. Not only were the differences not statistically significant, they were not consistent in direction. Of course this does not mean that clinical equivalence has been proved. The study suffered from a number of limitations. There was a lack of statistical power, and some differences in patient and practice characteristics remained after randomisation. There was also evidence of selective loss to follow-up. Fortunately this was unlikely to introduce bias, since the study groups had similar follow-up rates.

The cost analysis showed a highly significant increase in costs for the patients randomised to receive the education programme. There was no evidence that the costs of the educational intervention were offset by reduced utilisation of other health services during the period of follow-up. These results were robust to the method of analysis, and to the level of unit costs.

This evidence lends support to the contention that general practice-based patient education programmes for knee osteoarthritis are not a cost-effective use of healthcare resources. However, further evidence is required before this can be confirmed. The study may have failed to detect significant clinical effects due to lack of power. The generalisability of the clinical and economic findings might be limited for a number of reasons. The study sample was drawn from a particular locality (an ethnically mixed urban population) that might not be representative of the wider UK population. Outcomes are likely to vary between patient groups, and better targeting of the intervention might have been beneficial. The effectiveness of such interventions is also likely to be sensitive to the specific content and mode of delivery.

Recommendations for further research

There are difficulties in designing studies to evaluate the cost-effectiveness of primary care-based patient education programmes for knee osteoarthritis. These include the selection of appropriate control groups and outcome measures, estimating the power of trials involving cluster randomisation, possible bias due to selective withdrawal, and the generalisability of the results to a wider population. Further research to address these issues and to confirm or contradict the findings of the study reported here would be valuable.

Chapter 1
Background

The burden of osteoarthritis

Osteoarthritis (OA) is the most common cause of disability among adults in the UK.[1] Its prevalence rises with age, and is higher in women than in men.[2] It has been estimated that between 1.6 and 3.4 million people aged over 45 years in England and Wales have symptomatic radiological knee OA, and between 0.9 and 1.9 million of these have associated disability.[3]

OA affects many people's activities and quality of life, and it has a great personal cost. Healthcare utilisation and expenditure due to OA are also high. Each general practitioner (GP) can expect about 117 OA consultations in a year, 35 of which will be with people consulting with this problem for the first time.[2] In a population survey conducted in West Yorkshire,[4] 82% of respondents reporting arthritis symptoms had visited their doctor in the last year, 72% had attended an outpatient clinic, and 17% had received inpatient care. A US study conducted in 1984[5] estimated the average yearly direct cost for attendees at a primary care arthritis centre at $683 per patient (roughly £900 in current prices). With the spread of more expensive treatments, including non-steroidal anti-inflammatory drugs (NSAIDs) and arthroplasty, costs will have increased in recent years.[6] The gastrointestinal side-effects of NSAID therapy are also very costly.[7]

In addition to these direct costs, OA has substantial indirect costs because of its impact on work and productivity. In a US population survey,[8] 18% of people with OA and no musculoskeletal co-morbidities reported that they could no longer do their major activity, in comparison with 8% in an age-matched population sample without OA. The proportion of people with OA who reported that that they were not limited in any way (30%) was much smaller than in the age-matched population sample of people without OA (70%). Twenty-nine per cent of the OA sample with a history of labour-force participation reported work disability (compared with 6% of the general population sample). The OA group reported a mean extra 14.2 bed days, and 5.2 lost working days, due to the condition over the previous year. The total annual loss of earnings due to OA has been estimated at US$1500 per person (roughly £2500 at current prices).[9]

The impact of patient education for OA

Patient education programmes have been proposed as a means of limiting the impact of a range of chronic conditions, including arthritis. Patient education has been defined as:[10]

> "... any set of planned educational activities designed to improve patients' health behaviours and/or health status ... in addition to teaching patients **what** he or she should do, patients also should be instructed on **how** to approach situations and to make adjustments which are appropriate for each **individual** and his or her **own** needs."

Patient education is a low-technology intervention, which may be conducted in a community setting. The intention is to enable patients to manage better their own conditions – to use medication and health services more appropriately, and to use pain management, joint protection techniques, relaxation and exercise to improve health status. The mechanisms through which patient education works are not well understood. The intuitive pathway from knowledge, to behaviour, to improved health is not well supported by research.[11] For example, Lorig and colleagues found that reductions in pain were not related to changes in taught behaviours.[12] Instead they suggest that it is patients' perceived self-efficacy in managing their disease that is the mediating factor. This has important implications for the nature of educational interventions, suggesting that the transfer of knowledge is less important than engendering positive attitudes and confidence. This may account for the apparent success of psychological interventions in this area, particularly cognitive behavioural therapy.[13]

Studies over two decades and more have suggested that educational interventions can lead to significant benefits in a range of chronic diseases. In a meta-analysis of 30 controlled trials (24 of which were randomised), Mazzuca found that educational interventions were associated with significant improvements in regimen

compliance, physiological progress, and long-term outcomes.[14] The largest effects were observed in trials of 'behavioural' rather than 'didactic' styles of intervention – with less emphasis on standardised delivery of information, and more on patients' individual circumstances.

However, evidence for the efficacy of patient education for OA is still inconclusive. Many studies have been conducted, but the quality of the research is generally poor. Some investigators have failed to discriminate between patients with different forms of arthritis, who might be expected to have very different needs and responses to educational interventions. Further problems have arisen through failures in basic study design, as investigators have not controlled or randomised adequately. Where research is of reasonable quality, it is often not relevant to a UK primary care environment. Much of the research has focused on the more severely affected individuals, with selection of participants from specialist outpatient clinics. When community-based studies have been conducted, they have often relied on self-selected subjects recruited through advertising. Such volunteers are likely to be quite different from the population of patients consulting GPs in this country.

A number of literature reviews have been published, but secondary analysis in this area is complicated by differences in interventions, patient populations, methods of assessment, and length of follow-up. Mullen and colleagues[15] conducted a meta-analysis of 15 controlled educational and psychological interventions for OA and rheumatoid arthritis (RA). They concluded that the average effect size for treatment groups compared with controls was equivalent to a 16% reduction in pain, a 22% reduction in depression, and an 8% reduction in disability – although these benefits did not occur consistently across the studies. More recently, evidence on patient education for arthritis (OA and RA) has been systematically reviewed by Hirano and colleagues.[10] They identified 25 intervention studies, of variable quality (not all were controlled), published since 1987. Overall, the studies showed some evidence that educational interventions improved knowledge, behaviour, and psychosocial and health status. Significant improvements were reported for four out of eight measurements of knowledge, 12 out of 34 measurements of behaviour, 12 out of 25 measurements of psychosocial status, and 27 out of 52 measurements of health status.

It is difficult to interpret the results of the above two reviews,[10,15] since they include studies of variable quality, and do not differentiate between OA and RA. Two other reviews that do make this distinction have been published. However, they are not restricted to randomised controlled trials, and so their findings may not be robust or generalisable. Hawley reviewed psycho-educational interventions for arthritis.[16] She identified 34 trials (of varying designs) published between 1985 and 1995. Mean effect sizes (weighted for sample size) immediately after intervention for clinic samples of OA patients were 0.44 for pain, 0.28 for functional ability and 0.56 for depression. For community samples, in which it was not always possible to distinguish OA from RA patients, the corresponding effect sizes were 0.21, 0.08 and 0.12. Effects were weaker at 3 months. Superio-Cabuslay and colleagues[17] conducted a formal meta-analysis of 19 controlled trials of patient education for OA and RA (not all of which were randomised). There was no significant benefit from education for the OA patients either for pain (mean effect size 0.16, 95% confidence interval (CI) –0.69, 1.02), or for functional disability (mean effect size 0.0, 95% CI, –0.61, 0.61).

The cost-effectiveness of patient education

Patient education does not come free. It has costs over and above existing treatments, and if resources are used for arthritis patient education, they cannot be used for other healthcare programmes. This additional expenditure may well be justified if it can be shown to improve health outcomes sufficiently, to reduce the use of health care, and/or to get patients back to productive activities. However, there is very little evidence in the literature about the cost-effectiveness of patient education for arthritis.[10,18,19]

No full economic evaluation has been conducted. Lorig and colleagues conducted a very limited cost–benefit analysis of their original Arthritis Self-Management Programme.[12] They found a 39% reduction in self-reported physician visits among programme participants with OA, which was sustained over 4 years, irrespective of whether there was any reinforcement of the educational programme. In contrast there was a 6% increase over the same period for a **retrospective** comparison group. Lorig and colleagues estimated a net saving of US$189 for each OA patient over 4 years. It is difficult to generalise from these findings, since the control group was recruited for another study and so is not directly comparable with the intervention group. The scope of the

economic evaluation was also quite narrow. Only the costs of the educational programme and physician visits were evaluated, and no attempt was made to estimate indirect costs.

Another study, by Lindroth and colleagues, found increased service usage among their intervention group.[20] This was a non-randomised controlled trial of an education programme for people with RA or OA in Sydney, Australia. At 5-year follow-up, it was found that the intervention group was significantly more likely to have had regular contact with physiotherapists, occupational therapists and rheumatologists than the control group. This finding might, however, be explained by selection bias due to the non-randomised nature of the study.

Weinberger and colleagues assessed the cost-effectiveness of regular telephone contact for OA patients.[21] They conducted a randomised controlled trial with 1-year follow-up, and found no significant differences in inpatient, outpatient or emergency costs, but significant differences in the physical function and pain scores in the Arthritis Management Scales (version 2; AIMS2),[22] giving an annual cost for a 1-unit improvement of US$70.86 and US$31.00, respectively. Again this was a limited economic analysis, with no consideration of indirect costs or patient out-of-pocket expenses.

Chapter 2
Methods

Objectives

This study is an economic evaluation of a general practice-based nurse-led education programme for patients with OA of the knee. It is based on a randomised controlled trial in which the controls received conventional management alone. The objectives were:

- to measure the clinical effectiveness of the intervention over 1 year of follow-up
- to estimate the mean cost per participant of providing the intervention in the Osteoarthritis of the Knee (OAK) study
- to estimate the impact of the programme on the direct and indirect costs of health care related to knee arthritis over the year of follow-up.

The primary outcome measure was a disease-specific health measurement instrument, the Western Ontario and McMaster Universities Arthritis Index (WOMAC).[23] Our intention was to conduct a cost-effectiveness analysis by estimating the incremental cost per unit gain in the WOMAC score (taking an overall mean of the three WOMAC dimensions – pain, stiffness and disability). However, it is shown below that there were no significant differences between the education and control groups in the WOMAC or any other outcome measures, and so an analysis of costs is sufficient. The analysis may thus be classified as a **cost-minimisation analysis**. The incremental cost of the intervention was estimated by subtracting costs for the control group from those for the intervention group (including the cost of the OAK intervention itself).

The main **perspective** for the cost analysis was that of society, but costs were also estimated from the perspectives of the NHS, and the individual patient. We estimated both direct costs (related to the use of healthcare resources) and indirect costs (related to patients' time off work). However, indirect costs are presented separately because of the controversy over their inclusion in economic evaluations.[24]

Sources of data

The OAK study

The OAK study was a randomised controlled trial conducted by a multidisciplinary group of researchers at St George's Hospital Medical School, London. It was funded by the Arthritis and Rheumatism Council. General practices in the Merton, Sutton and Wandsworth Health Authority area were invited to take part. The practices that agreed were randomised to the intervention or control group. The GPs then invited patients consulting with symptoms of knee OA to participate in the trial. After obtaining the patients' written consent, GPs referred them to the study team. Radiographic evidence of knee OA was obtained, using recent or specially obtained knee X-rays, before patients were included in the study. Recruitment began in November 1995 and finished in May 1997.

The included patients were first assessed in their own homes by a trained interviewer. A summary of the areas covered in the baseline interview is shown in *Box 1*. A more detailed list of items included in the interview schedule is given in appendix 1.

BOX 1 Summary of items in the baseline interview schedule for the OAK study

- Demographic and socio-economic data
- History of disease and co-morbidity
- Satisfaction with GP care
- The social activity and support sections of AIMS2[22]
- Sources of information and knowledge of OA management and outcomes. This included a scale developed for the study, comprising ten true/false questions about knee arthritis. Correct responses scored 2 points, 'don't know' scored 1 point, and incorrect responses scored 0 points
- Self-efficacy in arthritis management: Arthritis Helplessness Index (AHI)[25]
- Disease-specific health status: WOMAC[23]
- Generic health status: Short Form 36 (SF-36), UK version[26]
- Psychological well-being: General Health Questionnaire (GHQ)[27]
- Medication, health and social service utilisation: using questions from the General Household Survey[28]

After their baseline assessment, patients in the intervention practices were invited to join an educational group. Each group involved up to six patients, and was led by a research nurse. They met for four 1-hour sessions at weekly intervals at the GPs' surgeries. The content of the sessions was developed by the research nurses and other members of the OAK team, and included general information about OA, and information on pain prevention, exercise, joint protection, diet and relaxation techniques. Patients were visited at home by the research nurse before the first group session to assess their individual concerns. They were also given a diary to complete. A description of the intervention methods has been published elsewhere.[29]

Patients from both intervention and control practices were sent outcome questionnaires by post 1, 3, 6 and 12 months after their baseline interviews. These four postal outcome questionnaires contained a subset of the questions asked at baseline, including the knowledge scale, AHI, WOMAC, SF-36 and GHQ (see appendix 1). If patients refused to complete the 1-year outcome questionnaire, or if they had failed to respond after 1 month, they were sent a reminder with a brief outcome questionnaire, comprising the WOMAC questions. A second reminder was sent to non-responding participants 1 month later.

After their final assessment, patients in the control practices were invited to attend group sessions by the research nurse. Consequently it is not possible to obtain controlled follow-up beyond 1 year.

The OAK baseline interview included some questions relating to health care and social care utilisation, and the impact of arthritis on paid work. However, these data were not sufficient to enable quantification of direct or indirect costs, and so two additional sources of data were used for the economic evaluation:

- repeat patient interviews 1 year after baseline
- a review of GP case notes.

It was the collection of this additional information that was funded through the NHS HTA programme.

Patient interviews

Face-to-face interviews were conducted in the patients' homes after their final postal outcome assessment. The interview schedule was based on the OAK baseline schedule. Questions about resource utilisation and impact on work were repeated, to enable a direct comparison of changes over the study period. Further questions were added on the impact of knee OA on paid and unpaid work, and on out-of-pocket expenditure (see appendix 1).

The interview schedule was first piloted on two patients who were attending an outpatient rheumatology clinic at St George's Hospital, and who were not participating in the OAK study. Revisions were made to the schedule, and then it was tested on ten of the patients in the OAK study. Further changes were then made to the interview schedule, and assessments were conducted for the remaining study participants. Patients were first contacted by telephone to arrange a date and time for the interview. When they could not be contacted by telephone, an attempt was made to contact them by post. Interviews were conducted by one of two interviewers, each of whom conducted roughly half of the interviews.

GP case-note review

A review of GPs' case notes was also conducted to collect detailed information on medication and healthcare utilisation. GPs were contacted and asked for permission to review the notes for patients in the OAK study. All agreed, except one GP from the intervention group. Two investigators visited the GP surgeries together. They recorded the following information for each participant over a 2-year period (1 year before baseline to 1 year after baseline) from written case notes (GP cards and referral/discharge letters):

- the date and cause of each GP or practice nurse consultation, including home visits and telephone consultations
- the date, name, dose and quantity of each prescribed medication
- the date and cause of each outpatient, day-patient, and emergency hospital visit
- the dates of admission and discharge and cause of each inpatient stay
- the dates and causes of consultations with members of the professions allied to medicine (PAM: physiotherapists, occupational therapists, chiropodists) and complementary therapists (acupuncturists, homeopathic practitioners, osteopaths).

The cause of each 'cost-generating event' was coded as due to knee OA, partly due to knee OA, not due to knee OA, or unknown. A cause was attributed only if it was specifically mentioned in the notes.

Where practices had a computer system containing prescribing or clinical information, details obtained from the written notes were checked against this, and additional information was recorded if necessary. In most practices there were differences between the information recorded in the paper and electronic notes. The use of computer systems by GPs varies widely. In some cases the computer system is used primarily by receptionists and practice nurses. Many GPs do not record details of repeat prescriptions on the patient cards. In these cases, the dates and quantities of repeat medications were obtained from the computer. Some of the computer systems recorded only the dose and date on which repeat medications were last issued. The date on which repeat medications were first prescribed was usually available in the written notes, in which case quantities of repeat medications over the 2-year period were estimated. This was difficult for some items such as creams or gels, or for items for which the only dosage instructions were 'as directed' or 'as required'. Such items were omitted from the database of cost-generating events. Similarly, information on the use of over-the-counter or complementary medicines from the patient interviews was included only if estimates of the quantities used could reasonably be made.

Methods of analysis

Adjustment for cluster randomisation

The OAK study was a **cluster randomised trial**, because whole practices rather than individual patients were allocated to the study arms. This was considered necessary because of the possibility of 'contamination': the treatment of the control patients might have changed if their doctors were also treating intervention patients. However, a cluster-randomised trial is less powerful than an equivalent trial in which individual patients are randomised. Statistical inference based on the observed variation between patients would tend to over-emphasise the significance of any differences between the groups, since patients within a practice are likely to be more similar to each other than to patients in other practices.[30] Thus, we analysed the data at the patient level, but using regression with adjustment for clustering. The Stata statistical software package (Stata Corp)[31] includes a facility for such cluster-adjusted regression, in which the standard error estimates are based on robust estimates of variance. This allows for independence between, but not within, practices.

Differences in baseline characteristics

Randomisation does not guarantee perfect matching of the study groups. We tested for differences between practices in the number of partners and patients, and in recruitment and follow-up rates. We also used cluster-adjusted regression to test for baseline differences at the patient level. The value of each socio-demographic and outcome variable was regressed against a dummy study group variable (0 = control group, 1 = intervention group). Logistic regression was used for the dichotomous variables, and linear regression for the continuous variables. Where significant differences in practice or patient characteristics were found, we attempted to correct for these in further analysis.

Loss of patients to follow-up is another potential problem. Patients with complete follow-up are likely to be different from those without, and if the study groups differ in their follow-up rates then this may introduce bias. Further, intervention group patients who do not attend the teaching sessions, or who do not find them useful, are less likely to complete follow-up. It is difficult to exclude fully the possibility of such selective withdrawal. However, we did test for baseline socio-demographic and outcome differences between patients with and without complete 1-year follow-up.

Clinical effectiveness

The primary outcome measure selected for the economic evaluation was the WOMAC index.[23] This was chosen because it was assumed to be more responsive than a generic measure of health status.[32] In addition to the WOMAC we also considered the SF-36, the AHI, the knowledge scale and the GHQ. Each of these five outcome scales was transformed to a 0–100 score, with a higher score representing a more positive outcome.

We used linear regression with cluster-adjustment to test for differences in the outcome variables at 1 year. The value of each outcome variable at 1 year was regressed against the value of the variable at baseline, and against a dummy study group variable (0 for the control group and 1 for the intervention group). We also introduced further explanatory variables to adjust for differences in practice size and patient socio-demographic characteristics.

Intention-to-treat analysis

Some of the intervention patients did not attend teaching. Every attempt has been made to follow-up all of the patients who had a baseline interview, including these non-attendees. All analyses have

been conducted on an **intention-to-treat** basis. This will tend to dilute any real clinical effect that might exist. The intention-to-treat assumption will also tend to reduce the estimated incremental cost of education, since intervention group patients who did not attend teaching did not incur the costs of teaching. In order to investigate the possibility of such effects we also analysed the data by attendance, comparing baseline data for patients who did attend at least one educational session with data for those who did not.

Resource utilisation

The quantities of healthcare resources used were estimated for each 'cost-generating event' (for example, visit to the GP, prescription, inpatient stay). In general, case-note data were assumed to be more reliable than patient recall. Case-note data were used to estimate the quantity of prescribed medications and the use of primary care and hospital services. However, one would not expect to find a record of all health care in the GP notes. Consequently, case-note data were supplemented with information from the baseline and 1-year interviews on the use of over-the-counter and complementary medications, and consultations with members of the PAM and complementary therapists. Patients without case-note data were excluded from the cost analysis, since the majority of cost-generating events were identified from case notes. Of the 137 patients whose case notes were reviewed, 33 did not complete a 1-year interview. For these patients it was assumed that the additional resource utilisation identified from the 1-year interview would have been the same as that identified from their baseline interview.

In many cases it was difficult to decide whether a resource-generating event resulted from the patient's knee OA. There were three main causes of this difficulty:

- the reason for the event was not recorded
- the event may have been related to more than one health condition (including knee OA)
- the event was related to a health condition that may have been caused by knee OA (such as a fall) or by a treatment for OA (such as the gastrointestinal effects of NSAIDs).

Consequently, we excluded events from the analysis if they were recorded as **not** due to knee OA, rather than including them only if they were recorded as due to knee OA. This results in the inclusion of some cost-generating events unrelated to knee OA, which will tend to obscure true differences in knee OA-related costs. To reduce this possibility, we also excluded certain types of resource items that were unlikely to be related to knee OA. The **included** resource items are shown in *Box 2*.

Unit costs

Patient costs were estimated by applying unit costs to the estimated quantities of resources used. The sources of the unit cost estimates used in the reference case analysis are shown in *Table 1*. Different unit costs were used for the three different perspectives – that of the patient, the NHS and society. To improve the generalisability of results, whenever possible unit costs were estimated from published national data. All costs were estimated at 1996/1997 levels in pounds sterling, where necessary up-rating using an index of hospital and community health services (HCHS) pay and price inflation.[34] A full list of the unit costs used in the reference case analysis is given in appendix 2.

BOX 2 Items included in estimations of resource utilisation

- Antacids, antispasmodics and ulcer-healing drugs (BNF 1.1, 1.2 and 1.3)
- Hypnotics and anxiolytics, antidepressants, appetite suppressants, drugs used in nausea and vertigo, and analgesics (BNF 4.1, 4.3, 4.5, 4.6 and 4.7)
- Corticosteroids (BNF 6.3)
- Drugs affecting nutrition and blood (BNF 9)
- Drugs used in musculo-skeletal and joint diseases (BNF 10)
- Local anaesthetics (BNF 15.2)
- Wound management products and elastic hosiery (BNF appendix 9)
- Over-the-counter dietary supplements and complementary remedies
- Consultations with the GP and practice nurse, including surgery consultations, home visits and telephone consultations
- Attendance at hospital outpatient clinics, inpatient stays and day-case visits for the following specialities: general surgery, trauma and orthopaedics, accident and emergency, general medicine, gastroenterology, rheumatology, geriatrics, mental illness
- Consultations with members of the PAM: specialist nurses, district nurses, chiropodists, dieticians, physiotherapists and occupational therapists
- Consultations with complementary therapists: acupuncturists, chiropractors, homeopaths and osteopaths
- Radiological tests: knee X-rays

BNF, British National Formulary[33]

TABLE 1 *Sources of unit cost estimates*

		Perspective	
Item	**NHS**	**Patient**	**Society**
Prescribed medications	NHS 'net price',[33] minus prescription charges	Prescription charges	NHS net price[33]
Over-the-counter and complementary medicines	None	Retail price	Same as cost of prescribed medication (if in BNF[33]); otherwise retail price less VAT
Primary and community health services	PSSRU estimates[34]	Mean reported patient expenditure	PSSRU estimates[34]
Complementary therapists	None	Mean reported patient expenditure	Mean reported patient expenditure
Hospital outpatient and inpatient services	HFMA/CIPFA estimates by speciality[36]	None	HFMA/CIPFA estimates[36]
Hospital day-case treatment	PSSRU estimates[34]	None	PSSRU estimates[34]
Radiological investigations	Mean ECR price from three local hospitals (Band A)	None	ECR prices
Transport	PSSRU estimates for hospital transport or emergency ambulance[34]	Reported fares or mileage estimates, excluding journeys made with travel cards etc.	NHS cost plus private cost
Patient time	None	National median wage rates[38]	National median wage rates[38]

ECR, extra contractual referral

Medications

The NHS and social unit costs of prescribed medications were based on BNF[33] net prices. In general it was assumed that non-proprietary medications, or the cheapest brands available, were dispensed, unless a specific brand name was given in the case notes or interviews. Unit costs were based on the largest pack size available. BNF prices do not include dispensing costs, but these are not very large: the average level of pharmacist charges and container allowances, less discounts obtained for bulk purchasing, was estimated from the Prescription Pricing Authority's annual report[35] (10.8% of the average prescription).

The private unit cost of over-the-counter and complementary medications was taken as the retail price obtained from a local chemist's shop. Because of national price agreements, prices will be similar around the country. BNF prices were used, where they were available, for the social cost of over-the-counter medications. Otherwise, retail prices were used.

Prescription charges were included when patients did not report being exempt. The 1996/1997 level of £5.50 per prescription was used. Prescription charges were added to private costs and subtracted from NHS costs, but omitted from social costs, since they represent a transfer within society.

Health services

The NHS and social unit costs of primary and community health care were obtained from Personal Social Services Research Unit (PSSRU) estimates.[34] Unit costs for inpatient and outpatient hospital services at a speciality level were obtained from the Health Finance Management Association (HFMA) and Chartered Institute for Public Finance Accountants' (CIPFA) 1996 Health Database.[36] These costs were up-rated from 1995/1996 to 1996/1997 levels using the HCHS pay and price index (3.4%).[34] The HFMA/CIPFA database does not differentiate between inpatient and day-patient costs, and so the unit cost of day-patient treatment was taken from the PSSRU publication.

For the few patients who reported using private services (mostly chiropody, osteopathy, and acupuncture), averages of the unit costs reported by patients in the 1-year interview were used.

Travel

Private and social direct costs included estimates of the cost of patient travel. The cost of each journey was estimated from 1-year interview data. Where patients reported using public transport, the actual fares reported were used. No travel costs were allocated when patients reported using a travel pass or walking. For private transport, or when data on the method or cost of travel were missing, travel costs were estimated by applying a standard mileage rate (£0.27 per mile). Distances between patients' homes and their GPs' surgeries or St George's Hospital were estimated using the Automobile Association's CD-ROM package.[37] To simplify the calculations it was assumed that all tests, outpatient visits, day-case treatments, inpatient stays and visits to members of PAM or complementary therapists took place at St George's Hospital.

Time off work

The time required for each GP and hospital visit was estimated from 1-year interview data. The average time taken for patients (and their companion if appropriate) to visit their GP was 1.2 hours. Outpatient visits, PAM and complementary therapist consultations and visits to emergency departments were all assumed to take 5.5 hours. Day-patient treatments took an average of 53.5 hours (including convalescence). Patient time lost due to inpatient stays was assumed to be the duration of the stay plus 1 week's convalescence (at 8 hours per day).

Patients' time was valued using the national median wage rate (approximately £8 an hour),[38] irrespective of age, sex, occupation or employment status. This provides an equitable basis for decision making as all patients' time is given the same value. However, this method does not necessarily reflect the true opportunity cost of the intervention to society.

The OAK intervention

The cost of providing the OAK intervention was estimated excluding research costs, so as to improve the generalisability of the results (*Table 2*). In the trial, two part-time nurses were employed to organise and run the sessions, but in costing the programme we have assumed the employment of one full-time nurse. Nineteen groups of between three and six participants (mean 87/19 = 4.6 per group) were recruited from the ten intervention practices over a year. It is assumed that outside a trial situation a similar number could have been recruited from the control practices. Therefore, cost estimates are based on the recruitment of 20 practices, 38 teaching groups, and 174 patients – numbers that the study experience suggests could be recruited within a single health district within

TABLE 2 *Estimated costs of the OAK intervention*

Cost item	Cost (1996/1997 UK£)			
	Total	Per practice (*n* = 20)	Per group (*n* = 38)	Per participant (*n* = 174)
Development	18,100	905	476	104
Training	1230	62	32	7
CPD visit to GPs	1740	87	46	10
Organising the sessions	4674	234	123	27
Visits to patients	2610	131	69	15
Running the sessions	9348	467	246	54
Room at GP surgery	608	30	16	3
Consumables	3480	174	92	20
Nurse travel	400	20	11	2
Patient travel	348	18	9	2
Social direct cost with full development costs	41,000	2050	1080	240
Social direct cost with training costs only for one nurse	24,100	1200	640	140
Indirect cost	8700	440	230	50

CPD, continuing professional development

a single year. More patients could probably be recruited in routine practice, since the study placed a considerable assessment burden on the practices and patients.

If we assume a basic salary of £19,000, 18% salary on-costs (assuming full national insurance and superannuation costs), revenue overheads at 17% of total salary costs,[34] and capital overheads of £976 a year (based on sharing an NHS office[34]), then the annual cost of employing the research nurse is £27,207. Assuming 220 working days a year, at 8 hours a day, this translates to a cost of £123 per day or £15 per hour.

The OAK package took about 8 months of nurse time to develop. This included a literature review, visits to experts, discussion within the project team and production of written materials. Thus development costs are estimated at £18,100. This does not include the time of other members of the OAK team, or of the experts consulted, since these were difficult to estimate. When a new research nurse joined the team, it took her about 4 weeks (half-time) to learn how to deliver the programme (reading up on the package, attending a full series of four sessions led by another nurse, and visiting and talking to experts). Thus, if a nurse was to be employed to deliver an existing programme, initial training would cost roughly £1230.

Each practice was visited by a GP (Jeremy Shindler) or consultant (JA) member of the project team, together with one of the research nurses, and given an hour of continuing professional development training on knee OA. If we allow 0.5 hours travelling time for the nurse and the doctor, each visit took 1.5 hours of doctor time (at £43 per hour[34]) and 1.5 hours of nurse time (at £15 per hour) – a total of £87 per practice recruited.

Encouraging GPs to recruit patients, following-up patients, liaising with practice staff and organising the group sessions was time-consuming. It is assumed that each group would take 1 day of nurse time to arrange (£123). Before the group sessions, patients were contacted by one of the research nurses and visited in their home. This enabled the nurse to introduce herself, and to find out about the patients so that she could be sensitive to their needs. These home visits took from 10 minutes to 1 hour – say 1 hour each including travel time (£15 per participant). The sessions themselves took 1–1.5 hours each, but allowing for preparation and clearing up afterwards, it is assumed that each session took 0.5 days to deliver (£246 per group).

Obtaining the use of a room for the OAK sessions was sometimes difficult. The sessions had to be conducted out of surgery hours, when there was not always somebody available to lock up afterwards. The cost of the room itself is difficult to assess. The marginal cost might be judged to be zero, since the sessions were given in the afternoons when the surgeries were closed and the rooms were not being used. On the other hand, there might be an opportunity cost if by giving group sessions on OA, practices were prevented from providing other services. The new build and land requirements of an NHS office and shared facilities for waiting, interviews and clerical support has been estimated at £1951 per year,[34] or roughly £8 a day. Thus the cost of the GP room is estimated at £16 per group.

Some consumables were used in the programme. Patients were given an information booklet written by the OAK team, with publication paid for by Pfizer (total cost £3000 for 250 copies). Other booklets handed out were: the Health Education Authority's *Enjoy Healthy Eating* and *Getting Active, Feeling Fit,* and *Taking Care With Arthritis* from Arthritis Care. Cushioned insoles, which had been donated by Sorbocare, were given to patients. In addition, knee models were donated to assist with teaching, and samples of knee supports, foot and heel cushioners were supplied to be shown to patients. The cost of consumables has been estimated at £20 per participant.

The 87 patients who attended at least one session attended a mean 3.5 of the four sessions. The mean travel cost for patients to visit their GP was £0.55 (return). Thus patient travel cost about £2 per participant. The cost of travel for the nurse is estimated at £400 over the whole programme.

Finally, the value of patient time to attend the sessions is estimated as £50 per participant: 1 hour for the nurse's home visit and 1.5 hours per session (with an average attendance of 3.5 sessions) at £8 an hour.

The total social direct cost of providing the OAK sessions is estimated at approximately £240 per participant, if we include all of the development costs (*Table 2*). However, if a nurse was to be employed, for example, within a hospital or community trust, to provide an existing educational programme, the social direct cost would be about £140 per participant. In addition, we estimate an indirect cost of £50 per participant.

Incremental cost estimates

The direct costs of healthcare utilisation (including the cost of attendance at the OAK sessions where appropriate) were aggregated for each patient, for each of the 2 study years (the year before and the year after the date of the baseline interview). Patient-level direct costs were estimated from three perspectives – for the NHS, for individual patients, and for society as a whole. The indirect cost of time off paid work was also estimated. Thus, for each patient four summary costs were estimated for each year.

As with health outcome data, we tested for cost differences between the groups by the use of linear regression with adjustment for baseline differences and for clustering at the practice level. Costs over the year after baseline were first regressed against costs over the year before baseline and a dummy study group variable. We also tested the effect of adding further explanatory variables, which differed significantly between the groups at baseline. This process was repeated for each of the four patient-level summary costs: NHS direct, private direct, social direct and indirect costs. The coefficients of the study group variables are estimates of the incremental costs of intervention, that is the cost for the intervention group minus the cost for the control group.

It has been observed that healthcare cost data are often highly skewed, with costs bounded by zero from below, and a small number of patients accounting for a high proportion of costs.[39] In analysing such data, care has to be taken in the use of parametric statistics and tests, particularly when the number of data points is small. The linear regression model used to analyse the OAK cost data assumes that the residuals are normally distributed. This is unlikely to be true. If the subjects had been directly randomised, then the sample size would almost certainly have been sufficient for the central limit theorem to apply, and the errors would have been approximately normal. However, with randomisation at the practice level the effective sample size is much smaller.

Two basic approaches have been suggested in such situations. Firstly, costs might be transformed so that they are more nearly normal, and then standard parametric methods applied.[39] This approach has been criticised for the analysis of cost data, where the objective is to compare mean costs so that policy makers can extrapolate to a population level.[40] Alternatively, non-parametric methods might be used, such as the non-parametric bootstrap.[41–43] Bootstrap methods also have the merit of providing a test for whether parametric results are valid: if the bootstrapped replicates of the test statistic are approximately normal, then we may assume that the sampling distribution is approximately normal.

We used non-parametric bootstrap regression with re-sampling of residuals to test for cost differences between the groups as follows.[42]

- The year-after costs were regressed on the year-before costs and the dummy study group variable.
- A bootstrap sample of size n was randomly drawn with replacement from the residuals.
- A vector of bootstrapped year-after costs was obtained by adding the vector of bootstrapped residuals to the vector of predicted year-after costs.
- The bootstrapped responses were then regressed on the observed exogenous variables to estimate a bootstrap replicate of the regression coefficients.
- The residual re-sampling process was repeated B times, to generate B bootstrap replicates of the regression coefficients.
- A CI was obtained for the coefficient of the study group variable by the bias-corrected percentile method.

Re-sampling of residuals is more complicated than direct re-sampling of cases, but it is more appropriate for a linear regression model where the coefficients are considered as fixed constants and only the error term is stochastic.

For CI estimation by percentile methods, a B of 1000 is usually recommended.[41] To ensure that the CIs had stabilised, B was set at 5000 in our analysis.

Sensitivity analysis

A series of assumptions and parameter estimates were used to estimate costs. In particular, the unit costs of the resources consumed were estimated from various sources (see *Table 1*). These estimates are subject to uncertainty. It is usually recommended that sensitivity analyses should be conducted to assess the implications of such uncertainty.[44] Various methods of sensitivity analysis have been suggested.[45] We used two different methods to explore the robustness of our findings: one-way simple sensitivity analysis and probabilistic sensitivity analysis. For simplicity, we have

restricted the sensitivity analysis to social direct costs.

One-way simple sensitivity analysis

We conducted a simple one-way sensitivity analysis to test the impact of changes in unit costs on the estimated social direct incremental cost. It was not possible to change the unit cost of each separate resource item, because of the large number of such items (as listed in appendix 2). Therefore, we varied unit costs across a number of broad categories of resources:

- medications
- GP consultations
- outpatient appointments
- inpatient and day-patient care
- consultations with other healthcare professionals
- consultations with complementary therapists
- X-rays
- the OAK intervention.

The costs within each of these eight resource categories were varied (one category at a time) by ± 50% around the reference case values. We also tested the effect of reducing the cost per participant of the OAK intervention to £140 (the estimated value without development costs, see *Table 2*).

Probabilistic sensitivity analysis

A multivariate probabilistic sensitivity analysis[46,47] was also conducted to investigate the effect of uncertainty over unit costs. This method requires the specification of a 'prior' probability distribution for each unknown modelling parameter. In this case there were eight model parameters, representing the relative level of unit costs for the eight resource categories, compared to their base-case values. Monte Carlo simulation was used to obtain interval estimates for the statistic of interest (the incremental social direct cost). This method may be called **parametric bootstrapping**, since we re-sample from specified parametric distributions.[41] The results of a probabilistic sensitivity analysis may be presented in a number of ways. Here we present an interval containing 95% of the simulation replications. This interval is called an 'uncertainty range'[48] to avoid confusion with traditional CIs. The treatment of the unknown parameters as random variables fits more easily with a Bayesian interpretation of probability,[49] and suggests that the interval is more appropriately seen as a 'credible interval' rather than a 'confidence interval'.

The prior distributions should encapsulate uncertainty over the true location of the **expected** values of the model parameters (secondary uncertainty), rather than uncertainty about how the parameters might vary between individual patients or institutions (primary uncertainty). Take the cost of a GP consultation: this might be expected to vary at both the GP/practice level, due to variation in consulting habits and cost structures, and at the patient level, due to variation in consultation length. These types of variation are not relevant for the present analysis, since we are attempting to estimate incremental costs at a population level. If we had data on the cost of a GP consultation from a sample of practices and individual consultations, we might estimate secondary uncertainty over the location of the population mean from the standard error. Unfortunately, we do not have standard errors for most unit cost estimates. The unit costs of primary and community services were obtained from PSSRU estimates,[34] which are based on various data sources and assumptions. The mean unit costs of hospital services by speciality were obtained from the HFMA/CIPFA Health Database, but no measure of dispersion is reported.[36]

Since no empirical estimates of uncertainty were available, we made subjective assumptions to represent our uncertainty about the true values of the unit costs. We assumed that the eight categories of unit costs each followed a normal distribution, with means equal to the baseline values and standard errors of 10%. The cost of the OAK sessions was also simulated as a normal distribution, with a mean of £190 and a standard error of £25.25 (so that the CI matched the range of estimates with or without development costs, £140 to £240).

The combined effect of uncertainty over the unit cost estimates and uncertainty over the quantities of resources used may be estimated by a mixture of parametric and non-parametric bootstrapping.[48] We estimated an uncertainty range for the incremental social direct cost by the following process.

- A set of eight relative unit cost parameters was drawn by random sampling from the specified 'prior' distributions.
- The unit cost of each individual resource item was calculated by multiplying the base-case unit cost by the appropriate relative unit cost parameter.
- Social direct costs were estimated for each patient, for the 2 study years, by applying the unit costs to the observed resource utilisation data.

- Non-parametric bootstrap regression was used to obtain *B* replicates of incremental cost, using the same residual re-sampling method described above.
- The process of re-sampling the unit cost parameters was repeated *I* times, so that in total *BI* replicates of incremental cost were obtained.
- A 95% uncertainty range was estimated for the study group coefficient using the bias-corrected percentile method.

To give an accurate estimate of the uncertainty range, *I* was set at 1000 and *B* at 500. This gave a total of 500,000 replicates.

Chapter 3
Results

Practice size, recruitment and follow-up rates

The characteristics of the practices that participated in the study are shown in *Table 3*. The control practices were significantly larger than the intervention practices, with nearly twice as many partners ($p = 0.02$) and patients ($p = 0.02$). This was due to the inclusion of two very large practices in the control group (one of 10,000 patients and one of 14,000 patients). The number of patients per GP did not differ significantly between the groups.

There was no difference between the practices in the percentage of patients who were referred to the study by their GP, but who did not actually enter the study. Overall 13.5% of the referred patients did not participate. Seventeen patients refused a baseline interview, four were excluded on clinical grounds, and six could not be contacted.

Practices in the intervention group recruited significantly more patients than those in the control group: 105 patients from ten intervention practices completed a baseline interview, compared with 65 patients from 12 control practices. Thus the intervention practices recruited about ten patients each, whereas the control practices recruited only about five ($p = 0.02$).

There were no significant differences between control and intervention practices in follow-up rates at 1 year. Overall 125 of the 170 patients (74%) completed a full outcome questionnaire at 1 year, and a further 18 (11%) completed a brief questionnaire. Of the remaining 27 patients, nine had moved with no forwarding address, seven had withdrawn from the study or refused to complete a questionnaire, six had died or were too ill, and five did not respond. In total, 126 patients (74%) were interviewed at 1 year. Case notes were reviewed for 137 (81%) patients.

TABLE 3 *Characteristics of participating practices by study group*

	Intervention group (n = 10)		Control group (n = 12)		
Characteristic	**Mean**	**SEM**	**Mean**	**SEM**	p^*
Number of partners	2.2	0.4	4.0	0.6	0.02
List size	4290	679	7320	1276	0.02
List size/partner	2131	198	1736	125	0.11
Patients referred without baseline interview	13.4%	4.7%	13.6%	5.5%	0.97
No. patients recruited (with baseline interview)	10.5	1.6	5.4	1.0	0.02
Patients recruited who completed 1-year questionnaire (full version)	68.5%	5.4%	73.0%	10.4%	0.70
Patients recruited who completed 1-year questionnaire (full or brief version)	82.8%	4.4%	75.7%	10.6%	0.54
Patients recruited who had 1-year interview	72.5%	4.3%	70.8%	10.5%	0.88
Patients recruited whose case notes were reviewed	82.1%	9.4%	82.1%	8.0%	0.99

* *Two-sample, two-sided,* t *tests for difference of intervention and control group means, with unequal variances*

SEM, standard error of the mean

Patient characteristics at baseline by level of follow-up

One hundred patients had complete follow-up at 1 year: that is they completed the postal outcome questionnaire (full version), they were interviewed, and their case notes were reviewed. Seventy patients did not fully complete follow-up. These two groups were compared with regard to a range of baseline socio-demographic, clinical and outcome variables (*Tables 4* and *5*).

A higher proportion of those with complete follow-up came from non-white ethnic groups (cluster-adjusted odds ratio 3.1, $p = 0.04$). There were no other socio-demographic or clinical differences by level of follow-up. The mean outcome scores were higher for patients with complete follow-up for all fourteen scales tested. Those with complete follow-up had higher AHI scores at baseline ($p < 0.001$). They also had higher mean scores on the following scales: knowledge about knee OA ($p = 0.04$); the SF-36 physical, social and pain dimensions ($p = 0.02$, $p = 0.02$ and $p = 0.04$ respectively); and the GHQ ($p = 0.04$). With 29 tests the significance level is more appropriately around 0.002, rather than the conventional 0.05, and so, after allowing for multiple significance testing, only the difference in the AHI appears to be statistically significant.

These findings suggest that loss to follow-up was selective, with patients being more likely to complete follow-up if they had more positive attitudes towards their own ability to manage their arthritis.

Patient characteristics at baseline by study group

The patients' baseline characteristics by study group are shown in *Tables 6* and *7*. A higher proportion of the control group patients lived alone (cluster-adjusted odds ratio 0.4, $p = 0.005$), and a higher proportion of them came from non-white ethnic groups (cluster-adjusted odds ratio 0.2, $p = 0.007$). The only difference in health outcomes that was statistically significant was for the physical dimension of the SF-36, on which the control group scored more highly (a difference of nearly 10 percentage points after adjustment for clustering, $p = 0.008$).

TABLE 4 *Patient characteristics at baseline by level of follow-up (dichotomous variables)*

Dependent variable	Incomplete follow-up (% of patients)	Complete follow-up (% of patients)	Logistic regression of dependent variable on dummy follow-up variable		
			Odds ratio	Robust SE*	*p*
Female	76	71	0.8	0.3	0.54
Married	50	54	1.2	0.5	0.68
Living alone	29	36	1.4	0.6	0.39
Non-white	44	71	3.1	1.7	0.04
Home owners	69	66	0.9	0.3	0.71
Higher education	39	37	0.9	0.2	0.79
Qualifications	51	41	0.7	0.3	0.27
Employed	39	25	0.5	0.2	0.06
Professional or managerial†	31	36	1.3	0.3	0.37
OA in both knees	56	62	1.3	0.4	0.45
OA in knees for more than 3 years	59	53	0.8	0.2	0.34
OA in other joints	70	58	0.6	0.2	0.10
Long-term illness	58	61	1.1	0.3	0.64
Limiting long-term illness	30	21	0.6	0.2	0.22

* *Standard error (SE) for odds ratio using the robust estimate of variance and adjustment for clustering by general practice*
† *For women who are not employed or actively seeking work, social class is based on occupation of husband*

TABLE 5 *Patient characteristics at baseline by level of follow-up (continuous variables)*

Dependent variable	Incomplete follow-up (mean)	Complete follow-up (mean)	Logistic regression of dependent variable on dummy follow-up variable		
			Coefficient	Robust SE*	*p*
Age	61	65	3.5	1.8	0.07
Knowledge†	73	78	4.6	2.1	0.04
AHI†	57	61	4.0	0.9	< 0.001
WOMAC†:					
pain	61	64	3.7	2.6	0.17
stiffness	57	57	0.3	3.2	0.92
disability	66	68	2.7	3.1	0.40
SF-36†:					
physical	53	63	9.3	3.6	0.02
role physical	42	53	10.9	5.9	0.08
role emotional	66	80	14.1	7.5	0.07
social	72	83	10.9	4.3	0.02
pain	50	57	7.2	3.3	0.04
mental	70	79	8.1	4.0	0.06
vitality	53	59	6.6	3.9	0.11
general health	56	64	7.3	4.7	0.13
GHQ†	78	88	10.1	4.6	0.04

* *SE for coefficient using the robust estimate of variance and adjustment for clustering by general practice*
† *Measured on a scale from 0 to 100, with a higher score representing a more positive outcome*

TABLE 6 *Patient characteristics at baseline by study group (dichotomous variables)*

Dependent variable	Control group (% of patients)	Intervention group (% of patients)	Logistic regression of dependent variable on dummy study group variable		
			Coefficient	Robust SE*	*p*
Female	69	75	1.4	0.5	0.45
Married	45	57	1.7	0.6	0.13
Living alone	46	25	0.4	0.1	0.005
Non-white	80	48	0.2	0.1	0.007
Home owners	62	70	1.5	0.5	0.24
Higher education	34	40	1.3	0.4	0.38
Qualifications	42	48	1.3	0.4	0.43
Employed	28	32	1.2	0.5	0.60
Professional or managerial†	33	34	1.0	0.3	0.91
OA in both knees	63	57	0.8	0.2	0.40
OA in knees for more than 3 years	55	55	1.0	0.3	0.95
OA in other joints	67	61	0.8	0.4	0.61
Long-term illness	62	59	0.9	0.4	0.79
Limiting long-term illness	25	24	0.9	0.4	0.84

* *SE for odds ratio using the robust estimate of variance and adjustment for clustering by general practice*
† *For women who are not employed or actively seeking work, social class is based on occupation of husband*

TABLE 7 *Patient characteristics at baseline by study group (continuous variables)*

Dependent variable	Control group (mean)	Intervention group (mean)	Logistic regression of dependent variable on dummy study group variable		
			Coefficient	Robust SE*	*p*
Age	65	62	–3.5	2.8	0.23
Knowledge†	78	74	–3.4	2.2	0.14
AHI†	61	59	–1.8	1.6	0.29
WOMAC†:					
pain	64	62	–1.4	2.6	0.59
stiffness	57	57	0.0	3.1	0.99
disability	67	67	0.2	2.6	0.94
SF-36†:					
physical	65	55	–9.6	3.3	0.008
role physical	52	47	–4.5	6.2	0.48
role emotional	78	72	–6.2	6.0	0.31
social	81	78	–3.7	4.6	0.43
pain	57	52	–5.0	3.4	0.15
mental	76	75	–0.8	3.0	0.80
vitality	57	57	–0.6	4.7	0.90
general health	65	58	–7.2	4.2	0.10
GHQ†	87	83	–3.7	3.1	0.24

* *SE for coefficient using the robust estimate of variance and adjustment for clustering by general practice*
† *Measured on a scale from 0 to 100, with a higher score representing a more positive outcome*

Although these differences appear to be highly significant at the conventional 0.05 level, they are not significant if we correct for multiple significance testing (significance level 0.002).

Differences in outcomes at 1 year

The mean outcome scores at 1 year for the two study groups are shown in *Table 8*. No significant differences were found between the groups after adjusting for clustering and the baseline values of the variables. Introducing further explanatory variables to correct for practice size, patient ethnicity and the number of patients living alone did not change this finding, except for one dimension of the SF-36. The mean score on the 'vitality' dimension became significantly higher for the control group than for the intervention group ($p = 0.02$). Again, this difference is not significant if we apply a Bonferroni correction for repeated testing (significance level 0.002, rather than the conventional level of 0.05).

Differences in costs over 1 year

The estimated direct cost of knee OA-related health care (excluding the cost of the intervention) over the 2-year study period was £212 per patient for the NHS, £78 per patient for private individuals, and £291 per patient for society as a whole. The breakdown of NHS and private direct costs by broad category of resource is shown in *Figure 1*. The NHS costs of medication and primary care were each about £50 per patient. Outpatient care and inpatient/day-patient care each cost the NHS about £40 per patient, and consultations with members of the PAM and complementary therapists added about £20 per patient. NHS X-rays cost about £12 per patient. Individual patients paid about £43 for consultations with PAM or complementary therapists, and £23 for prescription charges and over-the-counter/complementary medicines. Travel costs amounted to about £12 per patient.

The total cost of knee OA-related health care, excluding the cost of the intervention, was greater for the intervention group patients than for the controls. From an NHS perspective the mean direct cost per patient was £231 for the intervention group and £186 for the control group. The mean cost to the individual was £96 for intervention patients and £54 for control patients. From a societal perspective the mean direct cost was £326 for the intervention group

TABLE 8 *Health outcome scores* at 1 year by study group*

			Linear regression of 1-year outcome variable on dummy study group variable and baseline value of outcome variable			Plus further explanatory variables (no. of partners in practice, patient ethnicity, living alone)		
Dependent variable	**Control group (mean)**	**Intervention group (mean)**	**Coefficient of group variable**	**Robust SE†**	***p***	**Coefficient of group variable**	**Robust SE†**	***p***
Knowledge	77	77	1.1	2.4	0.65	4.4	3.1	0.17
AHI	61	63	2.4	2.0	0.25	0.6	2.7	0.83
WOMAC:								
pain	60	62	3.0	2.9	0.32	1.4	3.1	0.65
stiffness	53	59	6.0	3.5	0.10	3.7	3.1	0.25
disability	61	64	1.0	2.1	0.65	–0.6	2.5	0.82
SF-36:								
physical	52	50	5.5	4.9	0.28	4.6	5.1	0.37
role physical	48	45	–1.5	8.1	0.86	–9.4	9.9	0.36
role emotional	57	56	2.3	8.1	0.78	4.3	10.4	0.68
social	79	71	–4.5	4.0	0.27	–3.4	6.1	0.59
pain	58	51	–2.9	5.1	0.58	–4.3	6.1	0.49
mental	77	75	–0.5	2.0	0.79	–2.0	2.3	0.40
vitality	54	53	–0.5	2.6	0.85	–5.5	2.2	0.02
general health	64	59	0.6	4.8	0.90	0.4	5.2	0.94
GHQ	80	81	2.7	5.4	0.63	–1.2	5.6	0.84

* *All with scales from 0 to 100, with higher scores representing more positive outcomes*
† *SE for coefficient using the robust estimate of variance and adjustment for clustering by general practice*

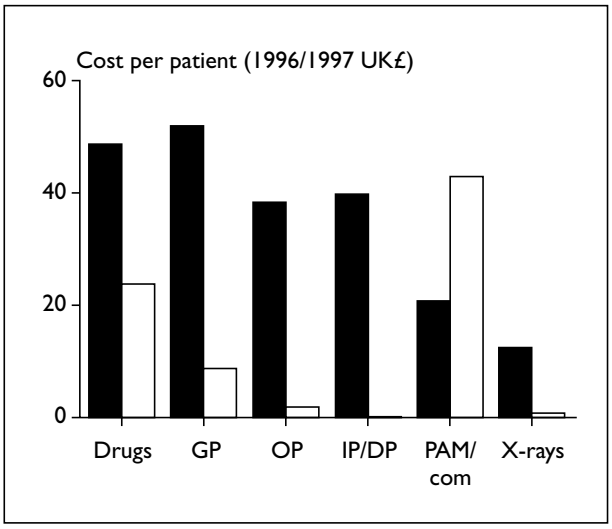


FIGURE 1 *NHS (■) and private (□) direct costs by resource type over the 2-year study period (OP, outpatient; IP/DP, inpatient/day patient; com, complementary therapy)*

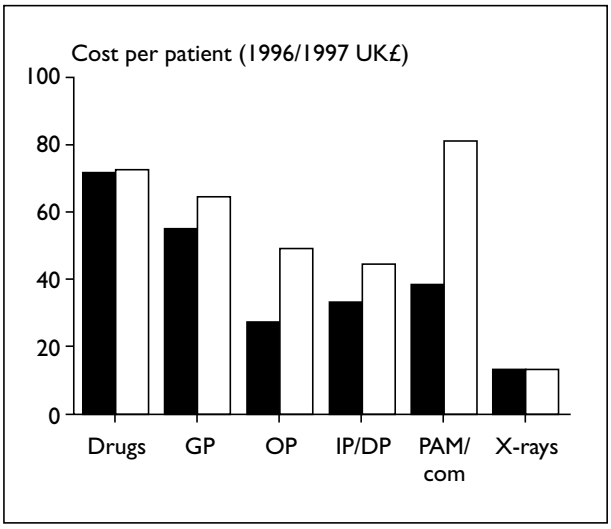


FIGURE 2 *Direct social costs by study group and resource type over the 2-year study period: ■, control group; □, intervention group*

and £240 for the controls. The social direct cost by study group and resource type is shown in *Figure 2*. The biggest difference between the groups related to PAM and complementary therapist consultations.

The costs discussed so far all relate to the whole 2-year study period. Mean social direct costs by month and study group are shown in *Figure 3* (cost items identified from the baseline and 1-year interviews were excluded from this graph,

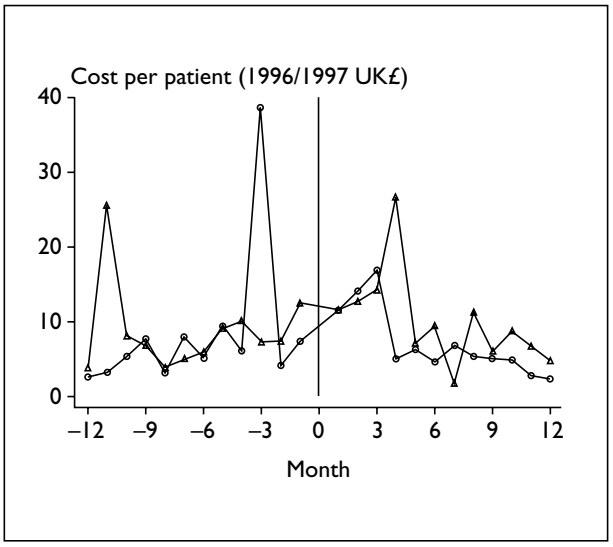


FIGURE 3 *Direct social costs by study group and time, from case-note review: ○, control group; △, intervention group*

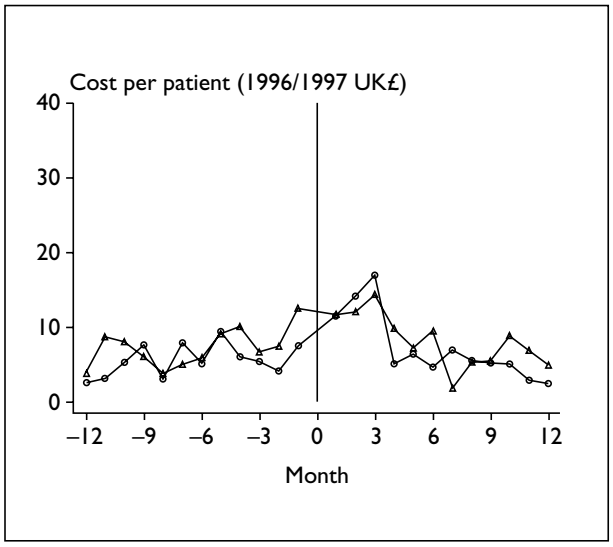


FIGURE 4 *Direct social costs by study group and time, from case-note review, excluding inpatient and day-patient treatment: ○, control group; △, intervention group*

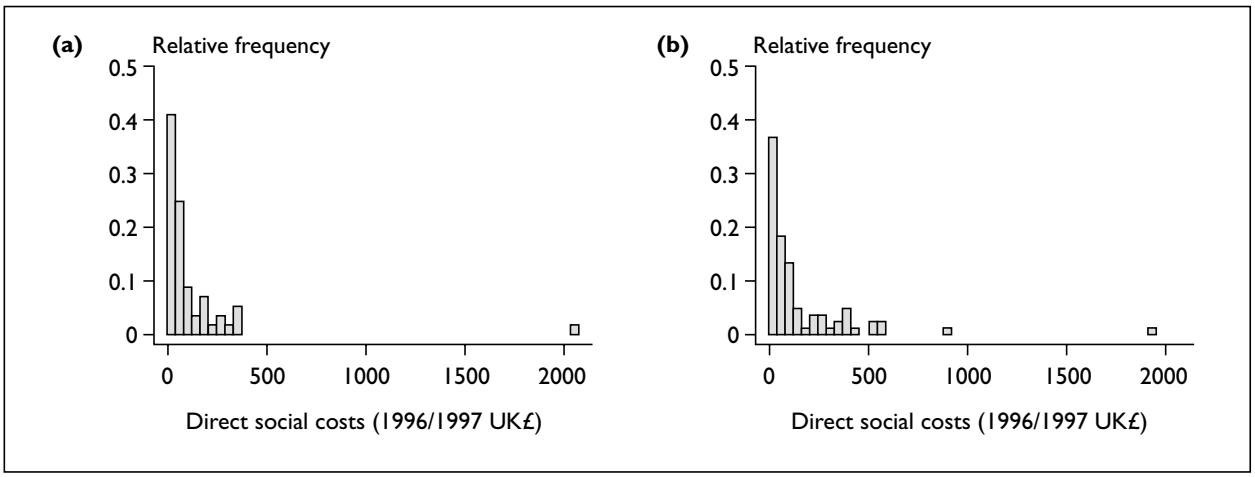


FIGURE 5 *Relative frequency of direct social costs for the year before baseline in (a) the control group and (b) the OAK intervention group*

since the month in which they were incurred could not be reliably ascertained). The volatile nature of the cost estimates results largely from a few expensive episodes of inpatient care. These are excluded from *Figure 4*, and the resulting cost estimates are much more stable over time. There is no clear difference between the groups in the pattern of costs. There does appear to be a slight increase in costs around baseline (month 0), particularly for the control group. This is to be expected, since patients were recruited at month 0 when they consulted their GP with an occurrence or recurrence of knee OA.

As might be expected, the estimated costs were not normally distributed. The frequency distributions for social direct costs over the year before baseline are shown in *Figure 5*. Both groups showed a strong positive skew: the median costs were £50 and £62, respectively, for the control and intervention groups, compared with means of £125 and £159, respectively. For the year after baseline, the distributions were slightly less skewed (see *Figure 6*): the median costs for the control and intervention groups were £91 and £78, respectively, compared with means of £115 and £169, respectively. Including the cost of the OAK sessions (£240 per participant) shifted the distribution of year-after costs to the right for the intervention group (see *Figure 7*). This reduced the skew still further, although the distribution was still far from normal, with a median of £310 and a mean of £362.

The mean costs for the year before baseline are shown in *Table 9*. There was no significant difference between the intervention group and the control group in NHS, private or social direct

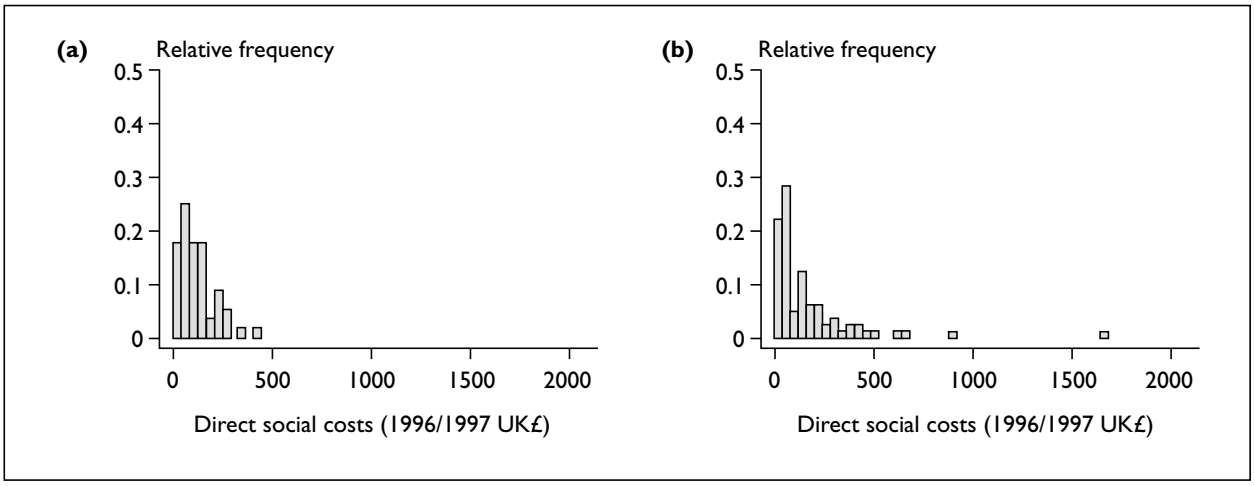


FIGURE 6 *Relative frequency of direct social costs, excluding intervention costs, for the year after baseline in (a) the control group and (b) the OAK intervention group*

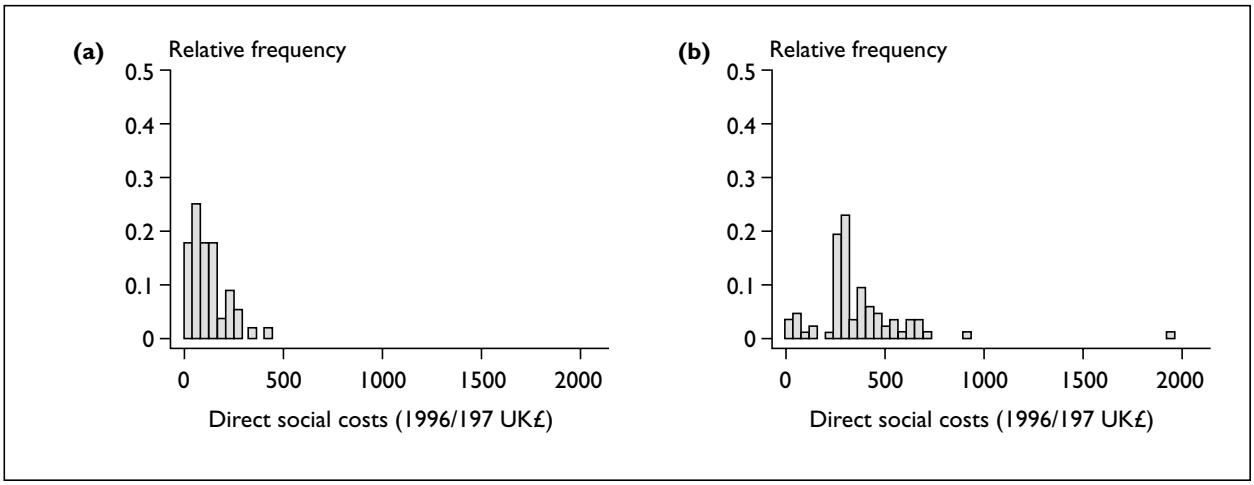


FIGURE 7 *Relative frequency of direct social costs, including intervention costs, for the year after baseline in (a) the control group and (b) the OAK intervention group*

costs, or in indirect costs. The difference in social direct costs remained non-significant when the costs of inpatient and day-patient care were excluded. Introducing additional explanatory variables to correct for baseline differences in socio-demographic and outcome variables did not change these results.

Mean costs for the year after baseline, including intervention costs, are shown in *Table 10*. The four types of mean costs (NHS direct, private direct, social direct, and indirect) were all greater for intervention group patients than for the controls. The coefficient of the study group variable might be interpreted as the incremental cost of intervention (the mean cost for the intervention group patients minus the mean cost for the controls), after adjusting for baseline costs and clustering. The estimated incremental cost was thus £225 for NHS direct costs, £239 for social direct costs, and £98 for indirect costs. These three incremental costs were significantly greater than zero ($p < 0.001$). Excluding the costs of inpatient and day-patient care reduced the estimated incremental social direct cost to £196, but this remained significantly greater than zero ($p < 0.001$). Private direct costs did not differ significantly between the groups. The results did not change after further adjustment for baseline differences in socio-demographic and outcome variables.

One-way simple sensitivity analysis

The effects of changing the unit costs are illustrated in *Table 11*. The unit costs for eight categories of health care were varied, one at a time, from 50% to 150% of their base-case values.

TABLE 9 *Costs over year before baseline by study group (1996/1997 UK£)*

Dependent variable	Control group (mean)	Intervention group (mean)	Linear regression of baseline costs on dummy study group variable: Coefficient of group variable	Robust SE†	*p*	Plus further explanatory variables*: Coefficient of group variable	Robust SE†	*p*
NHS direct cost	101	111	11	45	0.82	–42.5	50	0.41
Private direct cost	24	47	24	19	0.23	46.0	31	0.16
Social direct cost	125	159	34	55	0.55	3.5	61	0.96
Social direct cost, excluding IP/DP costs	91	140	49	30	0.13	49.3	42	0.26
Indirect costs	120	145	26	35	0.48	–16.3	41	0.70

* *Number of partners in practice, patient ethnicity, living alone and baseline SF-36 physical dimension*
† *SE for coefficient using the robust estimate of variance and adjustment for clustering by general practice*
IP, inpatient; DP, day patient

TABLE 10 *Costs over year after baseline by study group (1996/1997 UK£)*

Dependent variable	Control group (mean)	Intervention group (mean)	Linear regression of 1-year costs on dummy study group variable and baseline cost: Coefficient of group variable	Robust SE†	*p*	Plus further explanatory variables*: Coefficient of group variable	Robust SE†	*p*
NHS direct cost	85	312	225	27	< 0.001	234	43	< 0.001
Private direct cost	30	50	9	10	0.38	–12	21	0.58
Social direct cost	115	362	239	29	< 0.001	237	44	< 0.001
Social direct cost, excluding IP/DP costs	115	337	196	16	< 0.001	172	25	< 0.001
Indirect costs	99	204	98	24	0.001	99	39	0.02

* *Number of partners in practice, patient ethnicity, living alone and baseline SF-36 physical dimension*
† *SE for coefficient using the robust estimate of variance and adjustment for clustering by general practice*

The results changed very little, with the difference between the intervention group and controls in social direct costs remaining highly significant under all parameter values tested. The largest change resulted from changes to the cost of the OAK intervention. At £140 per participant (the estimated cost without full development costs, *Table 2*), the estimated incremental cost was £159 ($p < 0.001$). The intervention cost had to fall to below £15 per participant before the significance of the cost difference was lost. Even when the cost of the intervention was set at zero, the mean social direct incremental cost was still positive at £48 ($p = 0.11$).

Interval estimates for cost difference

Taking the mid-point of the two estimates of the cost of the OAK intervention (£190 per participant), the estimated social direct incremental

TABLE 11 *One-way simple sensitivity analysis of incremental social direct costs (1996/1997 UK£)*

Change in cost of resource ...	**+50%**			**–50%**		
Resource	**Estimated incremental cost***	**Robust SE†**	***p***	**Estimated incremental cost***	**Robust SE†**	***p***
Medications	247	29	< 0.001	230	30	< 0.001
GP consultations	239	29	< 0.001	239	30	< 0.001
OP appointments	236	29	< 0.001	242	31	< 0.001
IP/DP care	219	21	< 0.001	255	38	< 0.001
PAM consultations	240	30	< 0.001	238	29	< 0.001
Complementary therapists	234	30	< 0.001	243	29	< 0.001
X-ray	239	30	< 0.001	238	30	< 0.001
OAK attendance	143	28	< 0.001	335	31	< 0.001

* *Derived from linear regression of cost over the year after baseline on a dummy group variable (0 = control group, 1 = intervention group) and on cost over the year before baseline*
† *SE for coefficient using the robust estimate of variance and adjustment for clustering by general practice*

TABLE 12 *Interval estimates for incremental social direct costs (1996/1997 UK£)*

Interval estimate	**Lower limit**	**Upper limit**
Conventional parametric method : 95% CI	138	259
Non-parametric bootstrapping: 95% percentile interval	144	260
Non-parametric bootstrapping: 95% bias-corrected percentile interval	150	263
Non-parametric bootstrapping with probabilistic sensitivity analysis: 95% percentile uncertainty range	132	272
Non-parametric bootstrapping with probabilistic sensitivity analysis: 95% bias-corrected percentile uncertainty range	133	274

cost is £199. Based on the robust standard error estimate with GP-clustering adjustment, a 95% CI of £138 to £259 is obtained (*Table 12*). However, this estimate is based either on the assumption of large sample sizes (which cannot be justified by the number of practices in the trial), or on assumptions of normality and equal variance for the two groups (neither of which is justified here; *Figure 7*).

The frequency distribution for 5000 replicates of the social direct incremental cost, obtained by non-parametric bootstrapping of residuals, is shown in *Figure 8*. A normal distribution of equal mean and variance is displayed over the frequency distribution. It can be seen that the replicates are close to a normal distribution, although a slight skew remains. This point is further illustrated by the standardised normal probability plot in *Figure 9*. This implies that the sampling distribution of the statistic is approximately normal, and that the conventional parametric CI will be reasonably accurate. The 95% CIs obtained by the simple and bias-corrected percentile methods from the bootstrapped replicates are close to those obtained by parametric methods (*Table 12*).

The interval estimates quoted so far make allowance for uncertainty due to sampling variation alone. Additional uncertainty enters cost estimates through the unit cost parameters. A combination of parametric and non-parametric bootstrapping was used to estimate a combined 95% uncertainty range to capture uncertainty due to both sampling variation and the unknown nature of unit costs. The frequency distribution for the 500,000 replicates obtained by the combined bootstrap procedure is shown in *Figure 10*. The 95% percentile and bias-corrected percentile intervals are shown

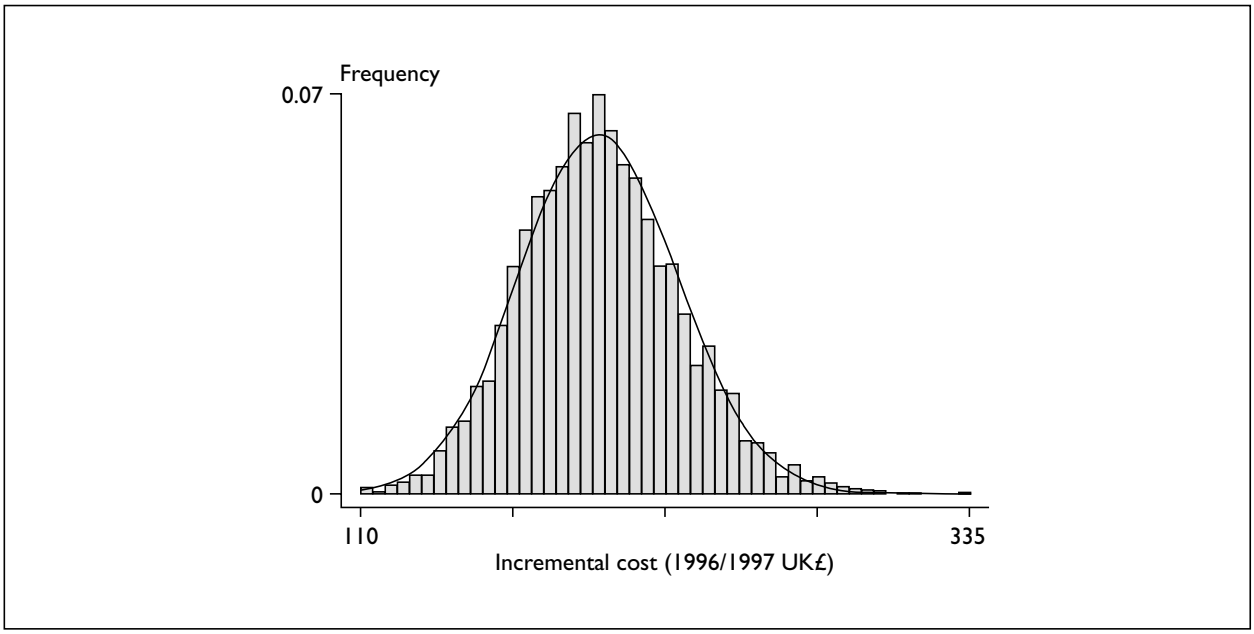


FIGURE 8 *Frequency distribution for social direct incremental cost estimated by the non-parametric bootstrap method (5000 iterations)*

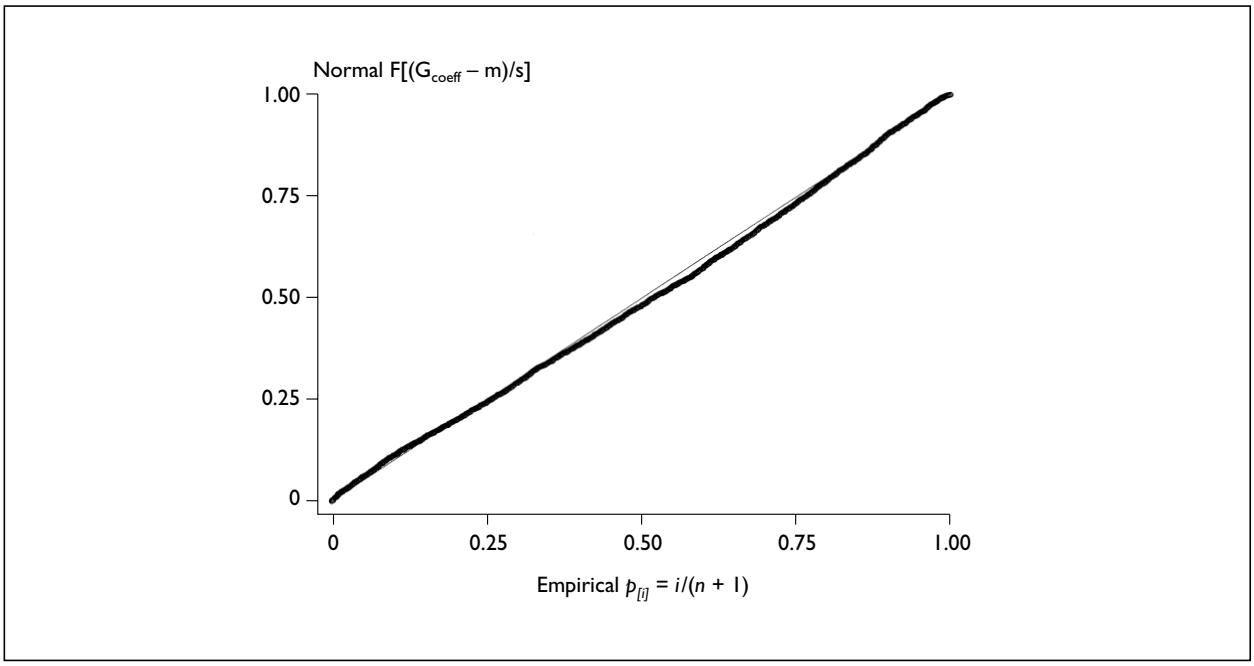


FIGURE 9 *Standardised normal probability plot for social direct incremental costs estimated by the non-parametric bootstrap method (5000 iterations)*

in *Table 12*: these intervals are slightly wider than the intervals obtained by the conventional parametric method or by non-parametric bootstrapping alone. This suggests that uncertainty over unit costs does not greatly add to uncertainty due to sampling variation, as measured in the trial. The lower limit of the uncertainty range remains greater than zero, indicating that year-after costs were greater for the intervention group than for the control group.

Analysis of cost and outcome data by attendance

Eighty-seven of the intervention group patients (83%) attended one or more education sessions. Thus 83 patients (18 'intervention group' patients and 65 controls) did not actually receive the intervention. In order to test the effect of the intention-to-treat assumption we also analysed the 1-year cost and outcome data by actual attendance

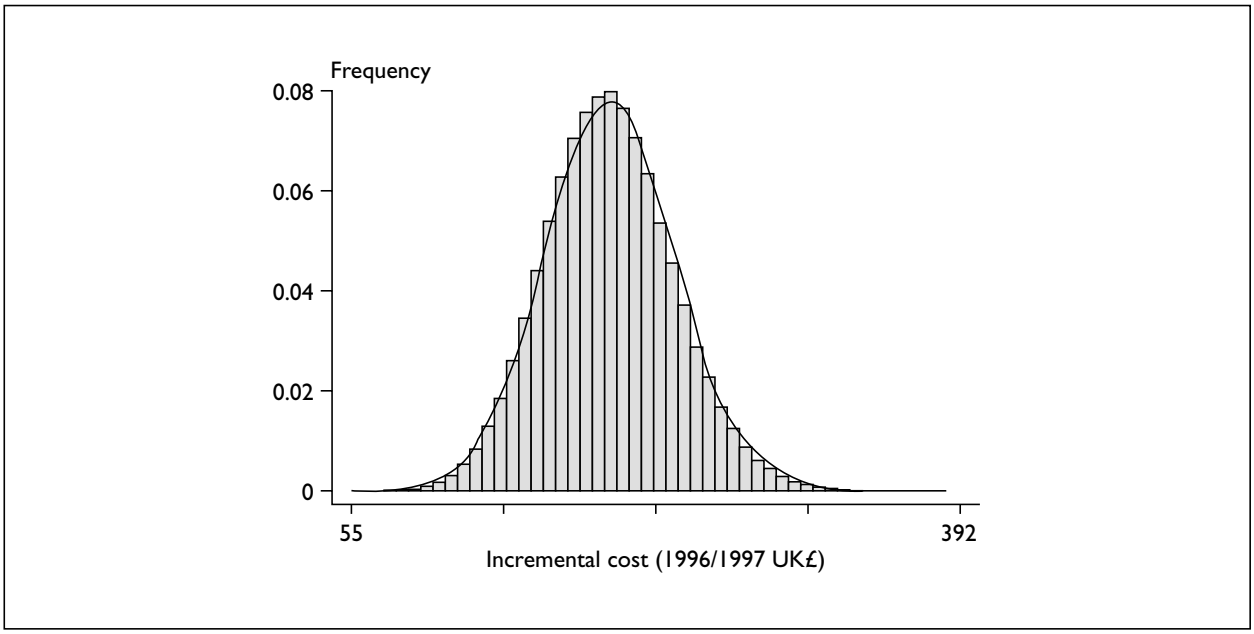


FIGURE 10 *Frequency distribution for social direct incremental cost estimated by the combined parametric/non-parametric bootstrap method (500,000 iterations)*

(see *Table 13*). This did not change any of the results of our initial analysis. None of the outcome differences were significant, whereas the costs were significantly greater for the patients who received the intervention than for those who did not (at least from NHS and societal perspectives).

TABLE 13 *One-year outcomes and costs by attendance at OA education sessions*

Dependent variable	Attended at least one educational session		Linear regression of variable on dummy attendance group variable and baseline value of variable		
	No (mean)	Yes (mean)	Coefficient of group variable	Robust SE*	*p*
Outcomes[†]					
Knowledge	77	77	0.3	2.4	0.92
AHI	60	63	3.2	1.7	0.09
WOMAC:					
pain	60	63	2.5	2.9	0.40
stiffness	53	59	5.1	2.8	0.08
disability	60	64	2.2	1.9	0.25
SF-36:					
physical	50	51	7.5	4.1	0.08
role physical	47	45	0.4	7.6	0.96
role emotional	57	56	3.1	7.7	0.69
social	78	71	–3.8	4.2	0.37
pain	57	52	–2.0	5.0	0.70
mental	76	76	–0.4	1.8	0.81
vitality	53	54	0.6	2.5	0.82
general health	64	59	–0.1	4.8	0.98
GHQ	80	81	2.3	5.5	0.68
Costs[‡]					
NHS direct cost	95	357	258	31	< 0.001
Private direct cost	47	35	–19	13	0.17
Social direct cost	142	392	239	39	< 0.001
Indirect cost	103	226	112	27	< 0.001

* *SE for coefficient using the robust estimate of variance and adjustment for clustering by general practice*
† *Scale from 0 to 100, with a higher score representing a more positive outcome*
‡ *1996/1997 UK£*

Chapter 4
Discussion

There is good evidence for the effectiveness of patient education for some chronic diseases such as asthma.[50] For OA the evidence is still inconclusive. There are methodological flaws in all of the literature reviews that have been conducted so far all. A Cochrane review of the clinical effectiveness of patient education for OA is being conducted.[51] That review should be available soon, and should resolve some of the unanswered questions in this area. However, primary research on the cost implications of patient education for OA is lacking.

The OAK trial measured the effects of a programme of education for primary care patients with knee OA. No improvements were found in knowledge, perceived self-efficacy in OA management, or health outcomes over a year of follow-up, in comparison with a 'routine practice' control group. Furthermore, the economic evaluation presented above suggests that the additional costs of the OAK intervention were not offset by reductions in the use of other health services. On the contrary, the net societal incremental cost of the intervention was estimated at £239 per patient. Patients in the intervention group did not have any less time off work than the controls. The value of lost patient time was estimated at £98 per patient more for the intervention patients than for the controls. These results were robust to a range of assumptions and methods of analysis. We estimate that the cost of the educational intervention would have had to be less than £15 per participant before the significance of the cost difference would have been lost.

However, because a number of difficulties were encountered in the conduct of the study, the results should be interpreted cautiously.

Firstly, recruitment did not meet original targets, despite considerable efforts by the OAK team: the accrual period was extended, participating GPs were contacted, and attempts were made to recruit more GPs. Recruitment was a particular problem for the control practices, possibly because the GPs did not feel that their patients would obtain sufficient benefit, as they would have to wait a year before receiving the educational intervention. It was estimated in the original OAK proposal that ten practices in each arm of the trial, with 12 patients per practice, would be required to detect a difference of half a standard deviation in the AIMS2 index[22] (estimated standard deviation 2.0) with a power of 90% and significance at the 5% level, and allowing for a loss of power due to randomisation of practices rather than patients. In the event the AIMS2 questionnaire was not used.

Estimating the power of the trial was complicated by the cluster randomisation. The 'design effect' (D) is defined as the ratio of the total number of subjects required using cluster randomisation to the number required with individual randomisation.[52] If the clusters are of equal size, the design effect is:

$$D = 1 + (m - 1)I$$

Where m is the number of patients per practice and I is the intracluster correlation coefficient.

With unequal clusters an approximate value for the design effect may be obtained by replacing m in the above equation with the 'average cluster size':[53]

$$\overline{n}_A = \left(\sum_{i=1}^{M} n_i^2 \right) \Big/ \left(\sum_{i=1}^{M} n_i \right)$$

Where n_i is the number of patients in cluster i, ($i = 1, 2, ..., M$).

Great care should be taken in drawing conclusions from *post hoc* power calculations. However, they may be useful for designing similar studies in the future. The 1-year overall WOMAC score had a mean of 60 and a standard deviation of 21. The average cluster size was 8.8, the intracluster correlation was 0.01, and the design effect 1.08. To detect a difference of half a standard deviation in the WOMAC score at 5% significance and 90% power, 85 (individually randomised) patients in each group would be required. This would be equivalent to 92 cluster-randomised patients (with $D = 1.08$). Final WOMAC scores were available for 52 control patients and 82 intervention patients. The design effect was higher for the cost variables. Cost data were available for 56 control and 81 intervention patients, with an average

cluster size of 9.3. The intracluster correlation was 0.32 for social costs over the year after baseline, yielding a design effect of 3.62.

The second reason for advising caution in the interpretation of the study results relates to possible biases due to selective withdrawal. Overall, the follow-up rates at 1 year were reasonable, with 85% of participants completing the primary outcome measure (the WOMAC), 74% being interviewed and 82% having their case notes reviewed. However, the patients who completed full follow-up (the self-completed questionnaire, the interview and the case-note review) did appear to be different from those who did not. At baseline they had more positive attitudes towards their ability to manage their arthritis and they tended to have better scores on a number of outcome measures. Fortunately, this selective loss to follow-up was unlikely to have introduced bias, since the study groups had similar follow-up rates. It might, however, affect the generalisability of the results, if there was a more homogeneous group of patients at the end of the trial than at the beginning.[54]

Thirdly, the randomisation process did not lead to perfectly matched groups. The control practices tended to be larger than the intervention practices (with more GPs and patients). The patients that they recruited were more likely to come from non-white ethnic groups, they were more likely to live alone, and they had better scores on the physical dimension of the SF-36. Once we allow for multiple significance testing, these differences are probably not statistically significant. However, to ensure that they did not influence the results, we analysed the 1-year data with and without corrections for baseline differences. The significance of the outcome and cost differences was not changed by these corrections.

A further issue that might concern some people relates to the intention-to-treat analysis. There is a possibility that this conservative assumption could obscure real clinical effects of intervention. To investigate this possibility, we repeated the analysis by actual attendance, comparing patients who did attend at least one of the education sessions at baseline with those who did not. This did not make any difference to the results.

Chapter 5
Conclusions

The evidence presented in this report lends support to the conclusion that GP-based patient education programmes for knee OA are not a cost-effective use of healthcare resources. The trial showed no evidence of clinical benefit, and costs were greater with the intervention than without. However, the study might have failed to detect a true clinical difference, and so further evidence is required before our conclusions can be confirmed. The forthcoming Cochrane review should provide firmer evidence on the clinical effectiveness of educational interventions for OA.

The generalisability of the clinical and economic findings might also be limited for a number of reasons. The sample was drawn from a particular locality, involving an ethnically mixed urban population, that might not be representative of the wider UK population. Outcomes are likely to differ between patient groups, and better targeting of the intervention might have been beneficial. The effectiveness of such interventions is also likely to be sensitive to the specific content and mode of delivery. Further economic analyses to address these issues and to confirm or contradict the findings of this study would be valuable.

Acknowledgements

This economic evaluation was based upon the Osteoarthritis of the Knee (OAK) study, which was funded by the Arthritis and Rheumatism Council, and conducted by a multidisciplinary team of researchers at St George's Hospital Medical School: John Axford, Heather Cadbury, Fiona Ross, Jeremy Shindler, Eric Triggs and Christina Victor.

The NHS R&D HTA Programme commissioned the economic evaluation. Elizabeth Pendry assisted with additional data collection for the economic evaluation. Alastair Fischer and Sally Kerry provided helpful discussion and advice. The HTA referees also made helpful suggestions that led to substantial revision of the report. Any errors that remain are our own responsibility.

Thanks to all of the patients and primary care staff who generously gave their time to help with this research.

References

1. Martin J, Meltzer H, Elliot D. OPCS surveys of disability in Great Britain. Report 1. The prevalence of disability among adults. London: HMSO; 1988.

2. McCormick A, Fleming D, Charlton J. Morbidity statistics from general practice. Fourth national study 1991–1992. London: HMSO; 1995.

3. Spector TD, Hart DJ. How serious is knee osteoarthritis? *Ann Rheum Dis* 1992;**51**:1105–6.

4. Badley EM, Tennant A. Impact of disablement due to rheumatic disorders in a British population: estimates of severity and prevalence from the Calderdate Rheumatic Disablement Survey. *Ann Rheum Dis* 1993;**52**:6–13.

5. Bloom BS. Direct medical costs of disease and gastrointestinal side effects during treatment for arthritis. *Am J Med* 1988;**84**(2A):20–4.

6. Williams MH, Frankel SJ, Nanchahal K, Coast J. Total knee replacement. In: Stevens A, Raftery J, editors. Health care needs assessment: the epidemiologically based needs assessment reviews. Oxford: Radcliffe Medical Press; 1994.

7. Greene JM, Winickoff RN. Cost-conscious prescribing of nonsteroidal anti-inflammatory drugs for adults with arthritis. *Arch Intern Med* 1992;**152**: 1995–2002.

8. Kramer JS, Yelin EH, Epstein WV. Social and economic impacts of four musculoskeletal conditions. A study using national community-based data. *Arthritis Rheum* 1983;**26**(7):901–7.

9. Pincus T, Mitchell JM, Burkhauser RV. Substantial work disability and earnings losses in individuals less than age 65 with osteoarthritis: comparisons with rheumatoid arthritis. *J Clin Epidemiol* 1989;**42**(5): 449–57.

10. Hirano PC, Laurent DD, Lorig K. Arthritis patient education studies, 1987–1991: a review of the literature. *Patient Educ Couns* 1994;**24**(1):9–54.

11. Daltroy LH, Liang MH. Advances in patient education in rheumatic disease. *Ann Rheum Dis* 1991;**50** Suppl 3:415–17.

12. Lorig K, Mazonson PD, Holman HR. Evidence suggesting that health education for self-management in patients with chronic arthritis has sustained health benefits while reducing health care costs. *Arthritis Rheum* 1993;**36**(4):439–46.

13. DeVellis RF, Blalock SJ. Psychological and educational interventions to reduce arthritis disability. *Baillieres Clin Rheumatol* 1993;**7**(2):397–416.

14. Mazzuca SA. Does patient education in chronic disease have therapeutic value? *J Chronic Dis* 1982;**35**:521–9.

15. Mullen PD, Laville EA, Biddle AK, Lorig K. Efficacy of psychoeducational interventions on pain, depression, and disability in people with arthritis: a meta-analysis. *J Rheumatol* 1987; **14** Suppl 15:33–9.

16. Hawley DJ. Psycho-educational interventions in the treatment of arthritis. *Baillieres Clin Rheumatol* 1995;**9**(4):803–23.

17. Superio-Cabuslay E, Ward MM, Lorig K. Patient education interventions in osteoarthritis and rheumatoid arthritis: a meta-analytic comparison with nonsteroidal antiinflammatory drug treatment. *Arthritis Care Res* 1996;**9**(4):292–301.

18. Mazzuca SA. Education and behavioral and social research in rheumatology. *Curr Opin Rheumatol* 1994;**6**(2):147–52.

19. Ruchlin HS, Elkin EB, Paget SA. Assessing cost-effectiveness analyses in rheumatoid arthritis and osteoarthritis. *Arthritis Care Res* 1997;**10**(6):413–21.

20. Lindroth Y, Bauman A, Brooks PM, Priestley D. A 5-year follow-up of a controlled trial of an arthritis education programme. *Br J Rheumatol* 1995;**34**(7):647–52.

21. Weinberger M, Tierney WM, Cowper PA, Katz BP, Booher PA. Cost-effectiveness of increased telephone contact for patients with osteoarthritis. A randomized, controlled trial. *Arthritis Rheum* 1993;**36**(2):243–6.

22. Meenan RF, Mason JH. AIMS2 users' guide. Boston: Boston University School of Medicine; 1990.

23. Bellamy N, Buchanan W, Goldsmith C, Campbell J, Stitt L. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to anti-rheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988;**15**:1833–40.

24. Koopmanschap MA, van Ineveld BM. Towards a new approach for estimating indirect costs of disease. *Soc Sci Med* 1992;**34**(9):1005–10.

25. Nicassio PM, Wallston KA, Callahan LF, Herbert M, Pincus T. The measurement of helplessness in rheumatoid arthritis. The development of the Arthritis Helplessness Index. *J Rheumatol* 1985;**12**(3):462–7.

26. Ware JE, Snow KK, Kosinski M, Gandek B. SF-36 health survey: manual and interpretation guide. Boston: The Health Institute; 1993.

27. Goldberg D. Manual of the General Health Questionnaire. Windsor: NFER Publishing; 1978.

28. Bennett N, Jarvis L, Rowlands O, Singleton N, Haselden L. Living in Britain: results from the 1994 General Household Survey. Office of Population Censuses and Surveys, Social Survey Division. London: HMSO; 1996.

29. Cadbury H. Self-care in osteoarthritis. *Community Nurse* 1997;November:28–31.

30. Kerry SM, Bland JM. Trials which randomize practices I: how should they be analysed. *Fam Pract* 1998;**15**(1):80–3.

31. StataCorp. Stata user's guide release 5.0. College Station (TX): Stata Press; 1997.

32. Wright JG, Young NL. A comparison of different indices of responsiveness. *J Clin Epidemiol* 1997;**50**(3):239–46.

33. British Medical Association, Royal Pharmaceutical Society of Great Britain. British National Formulary. 34th ed (Sept). London: British Medical Association; 1996.

34. Netten A, Dennett J. Unit costs of health and social care 1997. Canterbury: Personal Social Services Research Unit, University of Kent; 1997.

35. Prescription Pricing Authority. Annual report. Newcastle-upon-Tyne: PPA; 1996.

36. Healthcare Financial Management Association. Introductory guide to NHS finance in the UK. 4th ed. London: HFM; 1998.

37. Automobile Association. Streetmaster London. Basingstoke: AA Multimedia; 1997.

38. Office for National Statistics. New Earnings Survey 1996. London: HMSO; 1996.

39. Rutten-van Molken MP, van Doorslaer EK, van Vliet RC. Statistical analysis of cost outcomes in a randomized controlled clinical trial. *Health Econ* 1994;**3**(5):333–45.

40. Barber JA, Thompson SG. Analysis and interpretation of cost data in randomised controlled trials: review of published studies. *BMJ* 1998;**317**:1195–200.

41. Efron B, Tibshirani R. An introduction to the bootstrap. New York: Chapman and Hall; 1993.

42. Mooney CZ, Duval RD. Bootstrapping. A nonparametric approach to statistical inference. Newbury Park (CA): Sage; 1993.

43. Briggs A, Wonderling DE, Mooney CZ. Pulling cost-effectiveness analysis up by its bootstraps: a non-parametric approach to confidence interval estimation. *Health Econ* 1997;**6**(4):327–40.

44. Weinstein MC, Siegel JE, Gold MR, Kamlet MS. Recommendations of the panel on cost-effectiveness in health and medicine. *JAMA* 1996;**276**(15):1253–8.

45. Briggs A, Sculpher MJ, Buxton MJ. Uncertainty in the economic evaluation of health care technologies: the role of sensitivity analysis. *Health Econ* 1994;**3**(2):95–104.

46. Doubilet P, Begg CB, Weinstein MC, Braun P, McNeil BJ. Probabilistic sensitivity analysis using Monte Carlo simulation. *Med Decis Making* 1985;**5**(2):157–77.

47. Habbema JDF, Bossuyt PMM, Dippel DWJ. Analysing clinical decision analyses. *Stat Med* 1990;**9**:1229–42.

48. Lord J, Asante MA. Estimating uncertainty ranges for costs by the bootstrap procedure combined with probabilistic sensitivity analysis. *Health Econ* 1999;**8**(4):323–33.

49. Felli JC, Hazen GB. A Bayesian approach to sensitivity analysis. *Health Econ* 1999;**8**(3):263–8.

50. Gibson PG, Coughlan J, Wilson AJ, Hensley MJ, Abramson M, Bauman A, *et al.* The effects of limited (information only) patient education programs on the health outcomes of adults with asthma. Oxford: Cochrane Database of Systematic Reviews; 1997.

51. Riemsma RP, Kirwan JR, Taal E, Rasker JJ. Patient education for osteoarthritis (Protocol for a Cochrane Review). The Cochrane Library, Issue 4. Oxford: Update Software; 1999.

52. Kerry SM, Bland JM. Trials which randomize practices II: sample size. *Fam Pract* 1998;**15**(1):84–7.

53. Donner A, Klar N. Methods for comparing event rates in intervention studies when the unit of allocation is a cluster. *Am J Epidemiol* 1994;**140**(3):279–89.

54. Shaw WS, Cronan TA, Christie MD. Predictors of attrition in health intervention research among older subjects with osteoarthritis. *Health Psychol* 1994;**13**(5):421–31.

Appendix 1

Items included in the OAK study and economic evaluation

TABLE 14 *Items included in the OAK study and economic evaluation*

		Postal questionnaire				
	Baseline interview	**1 month**	**3 month**	**6 month**	**1 year**	**1 year interview**
Socio-economic status						
Age	YES					
Sex	YES					
Marital status	YES					YES
Lives alone	YES					YES
Number of people in household	YES					YES
Ethnic group	YES					
Is there someone to depend on if you are unwell and cannot get about?	YES					YES
Have any friends or relatives been to visit you in the last month?	YES					
Have you been to visit any friends or relatives in the last month?	YES					
Housing type	YES					
Home owner	YES					
Central heating	YES					
In the last year have you had any difficulties in keeping the house warm?	YES					
Inside WC and hot water	YES					
Employment status	YES					YES
Government benefits	YES					YES
Sources of income	YES					YES
School leaving age	YES					
Higher education	YES					
Qualifications	YES					
Clinical characteristics						
Smoking	YES					
Frequency of alcohol drinking	YES					
Body Mass Index	YES					
Physical activities	YES	YES	YES	YES	YES	
Arthritis in left, right or both knees	YES					YES
Duration of arthritis in the worst knee	YES					
OA in other joints	YES					YES
Has knee pain stopped you doing anything in the last month?	YES	YES	YES	YES	YES	
Has knee pain interfered with sleep in the last month?	YES					
Maximum walking distance	YES					
Use walking stick	YES					
Frequency of using walking stick	YES					
Long-term illness	YES					YES
Limiting long-term illness	YES					YES
Difficulty getting to toilet because of knee OA	YES					
Sexual problems due to knee OA	YES					

continued

TABLE 14 contd *Items included in the OAK study and economic evaluation*

	Baseline interview	Postal questionnaire: 1 month	3 month	6 month	1 year	1 year interview
Sources of information and satisfaction with GP						
Did GP explain side-effects of prescribed medications?	YES					
Has GP given you information about knee OA?	YES					
Read any leaflets about OA?	YES					
Has GP given advice on coping with knee pain?	YES					
Has GP given advice on managing your daily activities?	YES					
Satisfaction with GP over services and treatment for knee OA?	YES					
Would you recommend a friend with knee OA to go to your GP?	YES					
Outcome measures						
Knowledge of knee arthritis (10 true/false questions)	YES	YES	YES	YES	YES	
Pain (four items, two 5-point and two 6-point)	YES	YES	YES	YES	YES	
AHI	YES	YES	YES	YES	YES	
WOMAC pain score	YES	YES	YES	YES	YES	
WOMAC stiffness score	YES				YES	
WOMAC disability score	YES	YES	YES	YES	YES	
AIMS2, social activity	YES					
AIMS2, social support	YES					
SF-36 physical	YES	YES	YES	YES	YES	
SF-36 role physical	YES	YES	YES	YES	YES	
SF-36 role emotional	YES	YES	YES	YES	YES	
SF-36 social	YES	YES	YES	YES	YES	
SF-36 pain	YES	YES	YES	YES	YES	
SF-36 mental health	YES	YES	YES	YES	YES	
SF-36 vitality	YES	YES	YES	YES	YES	
SF-36 general health	YES	YES	YES	YES	YES	
GHQ	YES	YES	YES	YES	YES	
Impact of knee OA on employment						
Not working because of knee OA	YES					YES
Time off work over past month	YES					YES
Time off work over past month due to knee OA						YES
Worked shorter days over past month	YES					
Been less careful over work over past month	YES					
Had to change way work is done over past month	YES					
Hours worked per week						YES
Change in hours worked over past year due to OA						YES
Healthcare utilisation						
Medication						
Prescribed medication for knee OA	YES					
Medication frequency for knee OA	YES	YES	YES	YES	YES	
Prescribed medicines	YES					YES
Over-the-counter medicines	YES					YES
Complementary medicines	YES					YES

continued

TABLE 14 contd *Items included in the OAK study and economic evaluation*

		Postal questionnaire				
	Baseline interview	**1 month**	**3 month**	**6 month**	**1 year**	**1 year interview**
***Healthcare utilisation* contd**						
Inpatient						
Stays in last year	YES					YES
Days in last year	YES					YES
Day patient						
Days in last year	YES					YES
Outpatient						
Visits in last 3 months	YES					YES
Regular appointments per annum						YES
Accident and emergency						
Visits in last 3 months	YES					YES
Family health services						
Surgery visits in past 2 weeks	YES					YES
Home visits in past 2 weeks	YES					YES
Regular surgery visits						YES
Regular home visits						YES
Community services (frequency in last month)						
District nurse	YES					YES
Health visitor	YES					YES
Local authority home help/carer	YES					YES
Private domestic help	YES					YES
Meals on wheels	YES					YES
Social worker	YES					YES
Lunch club	YES					YES
Day centre for elderly	YES					YES
Helper from voluntary organisation	YES					YES
Paramedical services (frequency in last 3 months)						
Primary care nurse	YES					YES
Specialist nurse	YES					YES
Dentist	YES					
Optician	YES					
Chiropodist	YES					YES
Dietician	YES					YES
Physiotherapist	YES					YES
Occupational therapist	YES					YES
Speech therapist	YES					
Continence adviser	YES					YES
Day hospital	YES					YES
Complementary therapist	YES					YES
Aids and adaptations						
Aids bought/adaptations made	YES					YES
Aids/adaptations needed	YES					
Private costs						
Indirect						
Do you personally lose money if you have to take time off work?						YES
Does your employer have to pay somebody specially to cover for you?						YES

continued

TABLE 14 contd *Items included in the OAK study and economic evaluation*

	Baseline interview	Postal questionnaire				1 year interview
		1 month	3 month	6 month	1 year	
***Private costs* contd**						
Medication						
Do you pay prescription charges?						YES
Inpatient						
Time off paid work for last OA stay						YES
Accompanied for last OA stay						YES
Hours for companion for last OA stay						YES
Travel method for last OA stay						YES
Cost of fares for last OA stay						YES
Day patient						
Time off paid work for last OA-related day						YES
Accompanied for last OA-related day						YES
Hours off for companion for last OA-related day						YES
Travel method for last OA-related day						YES
Cost of fares for last OA-related day						YES
Outpatient						
Time off paid work for last OA-related visit						YES
Accompanied for last OA-related visit						YES
Time off for companion for last OA-related visit						YES
Travel method for last OA-related visit						YES
Cost of fares for last OA-related visit						YES
Accident and emergency						
Time off paid work for last visit						YES
Accompanied for last visit						YES
Time off for companion for last visit						YES
Travel method for last visit						YES
Cost of fares for last visit						YES
Family health services						
Time off paid work for last visit						YES
Hours off paid work for last visit						YES
Accompanied for last visit						YES
Time off for companion for last visit						YES
Hours off for companion for last visit						YES
Travel method for last visit						YES
Cost of fares for last visit						YES
Community services						
Private domestic help – cost per hour						YES
Meals on wheels – cost per meal						YES
Lunch club – cost per meal						YES
Paramedical services						
Chiropodist – cost per visit						YES
Complementary therapy – cost per visit						YES

Appendix 2

Unit costs for items included in the economic evaluation

TABLE 15 *Unit costs for items included in the economic evaluation*

Code	Resource	Units	Unit cost (1996/1997 UK£) NHS	Private	SSD	Source and comments
D00: Medications						
D00	Prescription unknown	–	8.74	–	–	PPA Annual Report, 1996[35]
D01	**BNF Chapter 1: gastrointestinal**					
D01.1.1.5.2	Asilone® liquid	500 ml	1.95	–	–	BNF (Sept 1997) price
D01.1.3.1.3A	Gaviscon® tablets	500 mg	0.04	0.10	–	BNF (Sept 1997) price
D01.1.3.1.3B	Gaviscon® liquid	500 ml	2.70	–	–	BNF (Sept 1997) price
D01.2.3	Hyoscine butylbromide (Buscopan®)	10 mg	0.05	–	–	BNF (Sept 1997) price
D01.3.1.1A	Cimetidine (np)	400 mg	0.12	–	–	BNF (Sept 1997) price
D01.3.1.1B	Cimetidine (np)	200 mg	0.09	–	–	BNF (Sept 1997) price
D01.3.1.2	Axid® (nizatidine)	150 mg	0.38	–	–	BNF (Sept 1997) price
D01.3.1.3A1	Ranitidine (np)	150 mg	0.46	–	–	BNF (Sept 1997) price
D01.3.1.3B1	Zantac®	150 mg	0.46	–	–	BNF (Sept 1997) price
D01.3.5.1A	Losec®	10 mg	0.71	–	–	BNF (Sept 1997) price
D01.3.5.1B	Losec®	20 mg	1.27	–	–	BNF (Sept 1997) price
D01.3.5.2A	Lansoprazole (Zoton®)	15 mg	0.68	–	–	BNF (Sept 1997) price
D01.3.5.2B	Lansoprazole (Zoton®)	30 mg	1.06	–	–	BNF (Sept 1997) price
D04	**BNF Chapter 4: central nervous system**					
D04.3.1.7A	Lofepramine (np)	70 mg	0.17	–	–	BNF (Sept 1997) price
D04.7.1.1A	Aspirin (np)	300 mg	0.00	–	–	BNF (Sept 1997) price
D04.7.1.1B	Aspirin dispersible (np)	75 mg	0.00	0.03	–	BNF (Sept 1997) price
D04.7.1.2.1.1A	Panadol®	Tablet	–	0.11	–	BNF (Sept 1997) price
D04.7.1.2.1A	Paracetamol (np)	500 mg	0.00	0.03	–	BNF (Sept 1997) price
D04.7.1.2.1B	Paracetamol soluble (np)	500 mg	0.04	0.08	–	BNF (Sept 1997) price
D04.7.1.2.2	Co-codamol (np tablet)	8 mg/500 mg	0.03	–	–	BNF (Sept 1997) price
D04.7.1.2.2B	Co-codamol dispersible (np)	8 mg/500 mg	0.03	–	–	BNF (Sept 1997) price
D04.7.1.2.3B1	Solpadol®	30 mg/500 mg	0.08	–	–	BNF (Sept 1997) price
D04.7.1.2.3B2	Solpadol® effervesent	30 mg/500 mg	0.09	–	–	BNF (Sept 1997) price
D04.7.1.2.3C	Tylex®	30 mg/500 mg	0.09	–	–	BNF (Sept 1997) price
D04.7.1.2.5	Co-dydramol (np tablet)	10 mg/500 mg	0.01	–	–	
D04.7.1.2.6C	Remediene Forte®	500 mg	0.13	–	–	BNF (Sept 1997) price
D04.7.1.2.7	Co-proxamol (np tablet)	32.5 mg/325 mg	0.01	–	–	BNF (Sept 1997) price
D04.7.1.3.1	Anadin Extra®	Tablet	–	0.12	–	BNF (Sept 1997) price
D04.7.1.3A	Disprin®	Tablet	–	0.08	–	BNF (Sept 1997) price
D04.7.1.3B	Solpadeine®	Tablet	0.11	0.11	–	BNF (Sept 1997) price
D04.7.2.15A	Tramadol®	50 mg	0.18	–	–	BNF (Sept 1997) price
D04.7.2.3	Dextromoramide (Palfium®)	5 mg	0.08	–	–	BNF (Sept 1997) price
D04.7.2.6A	Dihydocodeine	30 mg	0.03	–	–	BNF (Sept 1997) price
D04.7.2.6B	Dihydocodeine Continus®	60 mg	0.12	–	–	BNF (Sept 1997) price

BNF, British National Formulary (British Medical Association, Royal Pharmaceutical Society of Great Britain. London: British Medical Association; 1997)
np, nonproprietory
SSD, Local Authority Social Services Department

continued

TABLE 15 contd *Unit costs for items included in the economic evaluation*

Code	Resource	Units	Unit cost (1996/1997 UK£) NHS	Private	SSD	Source and comments
***D00: Medications* contd**						
D09	**BNF Chapter 9: nutrition and blood**					
D09.1.1.1.1A	Ferrous sulphate	200 mg	0.01	0.01	–	BNF (Sept 1997) price
D09.1.2.2A	Vitamin B_{12}	50 µg	0.05	–	–	BNF (Sept 1997) price
D09.5.1.1A	Calcium gluconate	600 mg	0.02	0.02	–	BNF (Sept 1997) price
D09.5.1.1B2	Sandocal-1000®	Tablet	0.22	–	–	BNF (Sept 1997) price
D09.6.2.3A	Vitamin B_6 (pyridoxine hydrochloride)	50 mg	0.02	0.03	–	BNF (Sept 1997) price
D09.6.2.5	Vitamin B compound	Tablet	0.00	0.07	–	BNF (Sept 1997) price
D09.6.3	Ascorbic acid (vitamin C)	500 mg	0.04	0.06	–	BNF (Sept 1997) price
D09.6.4	Vitamin D (with calcium), ergocalciferol	Tablet	0.01	0.04	–	BNF (Sept 1997) price
D09.6.5.1A	Vitamin E	Tablet	–	0.06	–	BNF (Sept 1997) price
D09.6.7B	Multivitamins (Ketovite®)	Capsule	0.04	0.04	–	BNF (Sept 1997) price
D10	**BNF Chapter 10: musculoskeletal and joint diseases**					
D10.1.1.11A1	Indomethacin (Indocid®), m/r	25 mg	0.01	–	–	BNF (Sept 1997) price
D10.1.1.11A2	Indomethacin (Indocid®), m/r	75 mg	0.17	–	–	BNF (Sept 1997) price
D10.1.1.13A	Mefenamic acid (np)	500 mg	0.03	–	–	BNF (Sept 1997) price
D10.1.1.14	Meloxicam (Mobic®)	7.5 mg	0.33	–	–	BNF (Sept 1997) price
D10.1.1.15	Nabumetone (Relifex®)	500 mg	0.32	–	–	BNF (Sept 1997) price
D10.1.1.16A1	Naproxen (np)	250 mg	0.09	–	–	BNF (Sept 1997) price
D10.1.1.16A2	Naproxen (np)	500 mg	0.18	–	–	BNF (Sept 1997) price
D10.1.1.16B1	Naproxen (Naprosyn EC®)	250 mg	0.12	–	–	BNF (Sept 1997) price
D10.1.1.16B2	Naproxen (Naprosyn EC®)	500 mg	0.24	–	–	BNF (Sept 1997) price
D10.1.1.18A	Piroxicam (np)	10 mg	0.07	–	–	BNF (Sept 1997) price
D10.1.1.1A1	Ibuprofen (np)	200 mg	0.01	0.08	–	BNF (Sept 1997) price
D10.1.1.1A2	Ibuprofen (np)	400 mg	0.01	–	–	BNF (Sept 1997) price
D10.1.1.1A3	Ibuprofen (np)	600 mg	0.03	–	–	BNF (Sept 1997) price
D10.1.1.1B1	Ibuprofen (Brufen®)	200 mg	0.03	–	–	BNF (Sept 1997) price
D10.1.1.1B2	Ibuprofen (Brufen®)	600 mg	0.09	–	–	BNF (Sept 1997) price
D10.1.1.1C	Ibuprofen (Brufen Retard®)	800 mg	0.21	–	–	BNF (Sept 1997) price
D10.1.1.21A	Surgam®	200 mg	0.19	–	–	BNF (Sept 1997) price
D10.1.1.21B	Surgam SA®	300 mg	0.28	–	–	BNF (Sept 1997) price
D10.1.1.4	Azapropazone (Rheumox®)	300 mg	0.14	–	–	BNF (Sept 1997) price
D10.1.1.5A1	Diclofenac sodium	25 mg	0.04	–	–	BNF (Sept 1997) price
D10.1.1.5A2	Diclofenac sodium	50 mg	0.08	–	–	BNF (Sept 1997) price
D10.1.1.5B	Diclofenac sodium (Voltarol®)	25 mg	0.09	–	–	BNF (Sept 1997) price
D10.1.1.5B2	Diclofenac sodium (Voltarol®)	50 mg	0.18	–	–	BNF (Sept 1997) price
D10.1.1.5C	Diclomax®	75 mg	0.23	–	–	BNF (Sept 1997) price
D10.1.1.5D	Diclomax Retard®	100 mg	0.33	–	–	BNF (Sept 1997) price
D10.1.1.5E	Diclofenac (Motifene®)	75 mg	0.27	–	–	BNF (Sept 1997) price
D10.1.1.5F	Diclofenac sodium (Voltarol SR®)	75 mg	0.31	–	–	BNF (Sept 1997) price
D10.1.1.5G	Diclofenac sodium (Voltarol Retard®)	100 mg	0.45	–	–	BNF (Sept 1997) price
D10.1.1.5H1	Arthrotec 50® (diclofenac sodium with misoprostol)	50 mg/200 µg	0.25	–	–	BNF (Sept 1997) price
D10.1.1.5H2	Arthrotec 75® (diclofenac sodium with misoprostol)	75 mg/200 µg	0.29	–	–	BNF (Sept 1997) price

BNF, British National Formulary (British Medical Association, Royal Pharmaceutical Society of Great Britain. London: British Medical Association; 1997)
np, nonproprietory
m/r, modified release

continued

TABLE 15 contd *Unit costs for items included in the economic evaluation*

Code	Resource	Units	Unit cost (1996/1997 UK£) NHS	Private	SSD	Source and comments
***D00: Medications* contd**						
D10	**BNF Chapter 10: musculoskeletal and joint diseases *contd***					
D10.1.2.2.3	Hydrocortisone injection (Hydrocortistab®)	1 ml ampoule	1.05	–	–	BNF (Sept 1997) price
D10.1.2.2.4	Depo-medrone® with/ without lignocaine	2 ml ampoule	4.87	–	–	BNF (Sept 1997) price
D10.1.2.2.4A	Depo-medrone® with/ without lignocaine	1 ml ampoule	2.70	–	–	BNF (Sept 1997) price
D10.1.2.2.9B	Lederspan® injection 20 mg/ml	1 ml vial	2.48	–	–	BNF (Sept 1997) price
D10.1.4.2B	Allopurinol (np)	100 mg	0.01	–	–	BNF (Sept 1997) price
D10.3.2C	Difflam® cream	100 g	7.00	–	–	BNF (Sept 1997) price
D10.3.2D1	Feldene® gel (piroxicam)	60 g	5.00	–	–	BNF (Sept 1997) price
D10.3.2D2	Feldene® gel (piroxicam)	112 g	7.84	–	–	BNF (Sept 1997) price
D10.3.2E	Ibuprofen gel (Ibugel®) 5%	100 g	6.53	–	–	BNF (Sept 1997) price
D10.3.2F	Ibuprofen spray (Ibuspray®) 5%	100 ml	6.95	–	–	BNF (Sept 1997) price
D10.3.2G	Intralgin® gel	50 g	0.49	–	–	BNF (Sept 1997) price
D10.3.2H	Movelat® gel	100 g	4.14	–	–	BNF (Sept 1997) price
D10.3.2I	Oruvail® gel	100 g	6.78	–	–	BNF (Sept 1997) price
D10.3.2L2	Transvasin® cream	80 g	1.51	–	–	BNF (Sept 1997) price
D10.3.2L3	Transvasin® spray	125 ml	1.46	–	–	BNF (Sept 1997) price
D10.3.2N	Voltarol Emulgel®	100 mg	7.00	–	–	BNF (Sept 1997) price
D15	**BNF Chapter 15: anaesthesia**					
D15.2.1A1	Lignocaine	1%, 2 ml ampoule	0.16	–	–	BNF (Sept 1997) price
D15.2.1A2	Lignocaine	2%, 5 ml ampoule	0.21	–	–	BNF (Sept 1997) price
D15.2.1C3	Xylocaine® 1% injection	20 ml vial	0.67	–	–	BNF (Sept 1997) price
DA9	**BNF appendix 9: wound management and elastic hosiery**					
DA9.13.1A	Elasticated tubular bandage	1 m x 12 cm	1.40	–	–	BNF (Sept 1997) price
DA9.23A	Graduated compression tights, Class 1	1 pair	0.57	–	–	BNF (Sept 1997) price
DA9.26A	Knee support, Class 2	1 pair	5.36	–	–	BNF (Sept 1997) price
DA9.5A	Tegaderm®	10 cm x 12 cm	1.21	–	–	BNF (Sept 1997) price
DA9.6A	Povidone–iodine fabric dressing (Inadine®)	5 cm x 5 cm	0.26	–	–	BNF (Sept 1997) price
DB1	**Over-the-counter and complementary preparations**					
DB1.01	Cod liver oil capsules	Tablet	–	0.05	–	Local retail price
DB1.04	Brewers yeast	Tablet	–	0.01	–	Local retail price
DB1.08	Cod liver oil and primrose oil	Tablet	–	0.08	–	Local retail price
DB1.11	Evening primrose oil	Tablet	–	0.09	–	Local retail price
DB1.13	Garlic capsules	Tablet	–	0.13	–	Local retail price
DB1.15	Magnesium	Tablet	–	0.07	–	Local retail price
DB1.19	Osteocare®	Tablet	–	0.10	–	Local retail price
DB1.22	Selenium od	Tablet	–	0.09	–	Local retail price
DB1.44	Ginseng	Tablet	–	0.15	–	Local retail price
DB1.45	Glucosamine sulphate	Tablet	–	0.33	–	Local retail price
DB1.49	Pro Plus 2® od	Tablet	–	0.27	–	Local retail price

BNF, British National Formulary (British Medical Association, Royal Pharmaceutical Society of Great Britain. London: British Medical Association; 1997)
np, nonproprietory
od, once daily

continued

TABLE 15 contd *Unit costs for items included in the economic evaluation*

Code	Resource	Units	Unit cost (1996/1997 UK£) NHS	Private	SSD	Source and comments
SO100: General practice						
S0101	Doctor at surgery	Consultation	10	–	–	Netten & Dennett, 1997[34] (p 72)*
S0102	Doctor home visit	Consultation	30	–	–	Netten & Dennett, 1997[34] (p 72)*
S0103	Doctor by telephone	Consultation	13	–	–	Netten & Dennett, 1997[34] (p 72)*
S0104	Nurse at surgery	Consultation	6	–	–	Netten & Dennett, 1997[34] (p 71)†
S0105	Doctor and nurse at surgery	Consultation	16	–	–	S0101 + S0104
S0106	Prescription only	Prescription	0	–	–	–
S02000: Outpatient						
S02100	General surgery	Attendance	48.60	–	–	CIPFA database 1995/1996[36]‡
S02110	Trauma and orthopaedics	Attendance	52.73	–	–	CIPFA database 1995/1996[36]‡
S02180	Accident and emergency	Attendance	43.43	–	–	CIPFA database 1995/1996[36]‡
S02300	General medicine	Attendance	65.14	–	–	CIPFA database 1995/1996[36]‡
S02301	Gastroenterology	Attendance	59.97	–	–	CIPFA database 1995/1996[36]‡
S02410	Rheumatology	Attendance	62.04	–	–	CIPFA database 1995/1996[36]‡
S02430	Geriatrics	Attendance	85.82	–	–	CIPFA database 1995/1996[36]‡
S03000: Inpatient						
S03100	General surgery	Day	246.09	–	–	CIPFA database 1995/1996[36]‡
S03110	Orthopaedics	Day	232.65	–	–	CIPFA database 1995/1996[36]‡
S04000: Day patient						
S04100	General surgery	Attendance	53.91	–	–	CIPFA database 1995/1996[36]‡
S0500: Community health and social services						
S0501	District nurse	Home visit	13	–	–	Netten & Dennett, 1997[34] (p 69) (includes nurse travel)
S0511	Chiropodist	Visit	8	16	–	Netten & Dennett, 1997[34] (p 65). Clinic visit. Private average: £13.50, £15.00, £15.50, £16.00, £17.00, £19.00
S0512	Dietician	Visit	10	–	–	Assume same as physiotherapist
S0513	Physiotherapist	Visit	10	–	–	Netten & Dennett, 1997[34] (p 64)
S0514	Occupational therapist	Home visit	–	–	22	Netten & Dennett, 1997[34] (p 63). Local Authority occupational therapist home visit including travel
S0600: Complementary therapists						
S0601	Acupuncturist	Session	–	25	–	Average: £25, £25
S0602	Chiropractor	Session	–	25	–	Assume same as acupuncturist
S0603	Homeopathic clinic	Session	52.37	–	–	Assume same as hospital outpatient
S0604	Osteopath	Session	–	25	–	Average: £25
T00: Tests						
T0210	X-ray	Test	13	–	–	ECR prices 1998: Band A, £14.50, £13.00 and £11.00
OAK intervention						
OAK1	OAK intervention	Participant	240	–	–	£240 (including full development costs)

* *Excluding cost of prescriptions and cost of practice nurses*
† *Cost for surgery consultation (excludes travel), and does not include London multiplier*
‡ *Uprated to 1996/1997 prices by the HCHS pay and price index, 3.4%*[34]

Appendix 3

Quantities of resources used

TABLE 16 *Quantities of resources used*

			Year before baseline		Year after baseline	
Code	**Resource**	**Units**	**Intervention**	**Control**	**Intervention**	**Control**
D00: Medications						
D00		Prescription	13	2	20	–
D01	**BNF Chapter 1: gastrointestinal**					
D01.1.1.5.2	Asilone® liquid	500 ml	5	–	–	–
D01.1.3.1.3A	Gaviscon® tablets	500 mg	–	–	60	260
D01.1.3.1.3B	Gaviscon® liquid	500 ml	23	8	13	9
D01.2.3	Hyoscine butylbromide (Buscopan®)	10 mg	90	–	–	–
D01.3.1.1A	Cimetidine (np)	400 mg	262	–	56	–
D01.3.1.1B	Cimetidine (np)	200 mg	–	–	120	–
D01.3.1.2	Axid® (nizatidine)	150 mg	30	–	60	30
D01.3.1.3A1	Ranitidine (np)	150 mg	–	30	228	536
D01.3.1.3B1	Zantac®	150 mg	–	–	30	–
D01.3.5.1A	Losec®	10 mg	114	30	28	–
D01.3.5.1B	Losec®	20 mg	–	56	–	–
D01.3.5.2A	Lansoprazole (Zoton®)	15 mg	–	14	–	–
D01.3.5.2B	Lansoprazole (Zoton®)	30 mg	224	–	–	–
D04	**BNF Chapter 4: central nervous system**					
D04.3.1.7A	Lofepramine (np)	70 mg	42	–	–	–
D04.7.1.1A	Aspirin (np)	300 mg	–	–	30	–
D04.7.1.1B	Aspirin dispersible (np)	75 mg	–	–	350	–
D04.7.1.2.1.1A	Panadol®	Tablet	–	–	115	–
D04.7.1.2.1A	Paracetamol (np)	500 mg	8175	1230	8987	1396
D04.7.1.2.1B	Paracetamol soluble (np)	500 mg	–	–	120	–
D04.7.1.2.2	Co-codamol (np tablet)	8 mg/500 mg	202	500	600	100
D04.7.1.2.2B	Co-codamol dispersible (np)	8 mg/500 mg	460	–	–	–
D04.7.1.2.3B1	Solpadol®	30 mg/500 mg	–	600	–	130
D04.7.1.2.3B2	Solpadol® effervesent	30 mg/500 mg	–	300	–	–
D04.7.1.2.3C	Tylex®	30 mg/500 mg	160	–	50	50
D04.7.1.2.5	Co-dydramol (np tablet)	10 mg/500 mg	1940	3648	2256	2108
D04.7.1.2.6C	Remediene Forte®	500 mg	–	60	–	500
D04.7.1.2.7	Co-proxamol (np tablet)	32.5 mg/325 mg	1380	5660	906	6906
D04.7.1.3.1	Anadin Extra®	Tablet	–	–	–	525
D04.7.1.3A	Disprin®	Tablet	–	–	56	–
D04.7.1.3B	Solpadeine®	Tablet	100	–	100	–
D04.7.2.15A	Tramadol®	50 mg	240	–	–	100
D04.7.2.3	Dextromoramide (Palfium®)	5 mg	–	20	–	–
D04.7.2.6A	Dihydocodeine	30 mg	270	900	720	900
D04.7.2.6B	Dihydocodeine Continus®	60 mg	–	–	–	224
D09	**BMF Chapter 9: nutrition and blood**					
D09.1.1.1.1A	Ferrous sulphate	200 mg	30	–	–	–
D09.1.2.2A	Vitamin B_{12}	50 µg	8	–	–	–
D09.5.1.1A	Calcium gluconate	600 mg	1050	–	30	–
D09.5.1.1B2	Sandocal-1000®	Tablet	–	–	–	60
D09.6.2.3A	Vitamin B_6 (pyridoxine hydrochloride)	50 mg	–	–	–	175

continued

TABLE 16 contd *Quantities of resources used*

Code	Resource	Units	Year before baseline		Year after baseline	
			Intervention	Control	Intervention	Control
***D00: Medications* contd**						
D09	**BNF Chapter 9: nutrition and blood *contd***					
D09.6.2.5	Vitamin B compound	Tablet	–	–	350	350
D09.6.3	Ascorbic acid (vitamin C)	500 mg	350	–	812	1050
D09.6.4	Vitamin D (with calcium), ergocalciferol	Tablet	–	350	–	–
D09.6.5.1A	Vitamin E	Tablet	–	–	350	1050
D09.6.7B	Multivitamins (Ketovite®)	Capsule	700	350	2440	1458
D10	**BNF Chapter 10: musculoskeletal and joint diseases**					
D10.1.1.11A1	Indomethacin (Indocid®), m/r	25 mg	170	–	60	–
D10.1.1.11A2	Indomethacin (Indocid®), m/r	75 mg	28	120	–	–
D10.1.1.13A	Mefenamic acid (np)	500 mg	100	–	–	–
D10.1.1.14	Meloxicam (Mobic®)	7.5 mg	330	–	–	–
D10.1.1.15	Nabumetone (Relifex®)	500 mg	336	–	224	–
D10.1.1.16A1	Naproxen (np)	250 mg	30	–	172	–
D10.1.1.16A2	Naproxen (np)	500 mg	180	60	180	–
D10.1.1.16B1	Naproxen (Naprosyn EC®)	250 mg	–	–	450	–
D10.1.1.16B2	Naproxen (Naprosyn EC®)	500 mg	30	60	202	–
D10.1.1.18A	Piroxicam (np)	10 mg	40	–	–	–
D10.1.1.1A1	Ibuprofen (np)	200 mg	950	838	1000	260
D10.1.1.1A2	Ibuprofen (np)	400 mg	1780	3090	3182	1528
D10.1.1.1A3	Ibuprofen (np)	600 mg	–	–	660	300
D10.1.1.1B1	Ibuprofen (Brufen®)	200 mg	–	–	30	60
D10.1.1.1B2	Ibuprofen (Brufen®)	600 mg	–	–	60	–
D10.1.1.1C	Ibuprofen (Brufen Retard®)	800 mg	840	560	740	888
D10.1.1.21A	Surgam®	200 mg	84	–	120	–
D10.1.1.21B	Surgam SA®	300 mg	448	–	448	–
D10.1.1.4	Azapropazone (Rheumox®)	300 mg	–	–	–	21
D10.1.1.5A1	Diclofenac sodium	25 mg	96	–	368	90
D10.1.1.5A2	Diclofenac sodium	50 mg	330	200	180	160
D10.1.1.5B	Diclofenac sodium (Voltarol®)	25 mg	–	–	90	–
D10.1.1.5B2	Diclofenac sodium (Voltarol®)	50 mg	–	–	28	–
D10.1.1.5C	Diclomax®	75 mg	284	364	314	396
D10.1.1.5D	Diclomax Retard®	100 mg	–	56	140	56
D10.1.1.5E	Diclofenac (Motifene®)	75 mg	112	–	112	–
D10.1.1.5F	Diclofenac sodium (Voltarol SR®)	75 mg	30	148	116	60
D10.1.1.5G	Diclofenac sodium (Voltarol Retard®)	100 mg	30	198	10	160
D10.1.1.5H1	Arthrotec 50® (diclofenac sodium with misoprostol)	50 mg/200 µg	1566	648	430	878
D10.1.1.5H2	Arthrotec 75® (diclofenac sodium with misoprostol)	75 mg/200 µg	86	60	–	–
D10.1.2.2.3	Hydrocortisone injection (Hydrocortistab®)	1 ml ampoule	–	–	1	0
D10.1.2.2.4	Depo-medrone® with/ without lignocaine	2 ml ampoule	–	6	4	7
D10.1.2.2.4A	Depo-medrone® with/ without lignocaine	1 ml ampoule	–	–	3	–
D10.1.2.2.9B	Lederspan® injection 20 mg/ml	1 ml vial	–	–	2	1

continued

TABLE 16 contd *Quantities of resources used*

Code	Resource	Units	Year before baseline		Year after baseline	
			Intervention	Control	Intervention	Control
***D00: Medications* contd**						
D10	**BNF Chapter 10: musculoskeletal and joint diseases *contd***					
D10.1.4.2B	Allopurinol (np)	100 mg	672	–	560	–
D10.3.2C	Difflam® cream	100 g	–	–	–	1
D10.3.2D1	Feldene® gel (piroxicam)	60 g	6	1	9	8
D10.3.2D2	Feldene® gel (piroxicam)	112 g	–	1	1	2
D10.3.2E	Ibuprofen gel (Ibugel®) 5%	100 g	2.3	8	6.6	16
D10.3.2F	Ibuprofen spray (Ibuspray®) 5%	100 ml	1	–	1	–
D10.3.2G	Intralgin® gel	50 g	1	–	–	–
D10.3.2H	Movelat® gel	100 g	11.5	10	7.5	15
D10.3.2I	Oruvail® gel	100 g	11	–	9.5	–
D10.3.2L2	Transvasin® cream	80 g	–	–	1	–
D10.3.2L3	Transvasin® spray	125 ml	–	–	1	–
D10.3.2N	Voltarol Emulgel®	100 mg	7	20	3	12
D15	**BNF Chapter 15: anaesthesia**					
D15.2.1A1	Lignocaine	1%, 2 ml ampoule	–	4	–	6
D15.2.1A2	Lignocaine	2%, 5 ml ampoule	–	–	1	–
D15.2.1C3	Xylocaine® 1% injection	20 ml vial	–	–	–	3
DA9	**BNF appendix 9: wound management and elastic hosiery**					
DA9.13.1A	Elasticated tubular bandage	1 m x 12 cm	3	1	22	–
DA9.23A	Graduated compression tights, Class 1	1 pair	–	–	2	2
DA9.26A	Knee support, Class 2	1 pair	2	–	5	–
DA9.5A	Tegaderm®	10 cm x 12 cm	–	1	–	–
DA9.6A	Povidone–iodine fabric dressing (Inadine®)	5 cm x 5 cm	–	1	–	–
DB1	**Over-the-counter and complementary preparations**					
DB1.01	Cod liver oil capsules	Tablet	5445	3150	4045	4025
DB1.04	Brewers yeast	Tablet	–	350	–	–
DB1.08	Cod liver oil and primrose oil	Tablet	700	–	350	–
DB1.11	Evening primrose oil	Tablet	350	700	1050	525
DB1.13	Garlic capsules	Tablet	350	–	350	1400
DB1.15	Magnesium	Tablet	–	–	–	350
DB1.19	Osteocare®	Tablet	–	–	–	350
DB1.22	Selenium od	Tablet	–	350	–	–
DB1.44	Ginseng	Tablet	–	–	14	350
DB1.45	Glucosamine sulphate	Tablet	350	–	350	50
DB1.49	Pro Plus 2® od	Tablet	700	–	700	–
SO100: General practice						
S0101	Doctor at surgery	Consultation	181	95	219	156
S0102	Doctor home visit	Consultation	2	–	1	1
S0103	Doctor by telephone	Consultation	–	1	–	–
S0104	Nurse at surgery	Consultation	12	13	14	1
S0105	Doctor and nurse at surgery	Consultation	17	7	24	7
S0106	Prescription only	Prescription	67	100	76	70
SO2000: Outpatient						
S02100	General surgery	Attendance	–	–	2	–
S02110	Trauma and orthopaedics	Attendance	15	8	18	4
S02180	Accident and emergency	Attendance	7	2	5	–
S02300	General medicine	Attendance	1	–	2	–
S02301	Gastroenterology	Attendance	–	1	–	–
S02410	Rheumatology	Attendance	14	–	6	7
S02430	Geriatrics	Attendance	–	3	–	–

continued

TABLE 16 contd *Quantities of resources used*

			Year before baseline		Year after baseline	
Code	**Resource**	**Units**	**Intervention**	**Control**	**Intervention**	**Control**
S03000: Inpatient		Day	7			
S03100	General surgery	Day	–	–	2	–
S03110	Orthopaedics	Day	–	8	5.9	–
S04000: Day patient		Attendance				
S04100	General surgery	Attendance	2	–	2	–
S0500: Community health and social services						
S0501	District nurse	Home visit	–	2	–	–
S0511	Chiropodist	Visit	31	21.5	26	14.5
S0512	Dietician	Visit	7	2	3	–
S0513	Physiotherapist	Visit	89.5	43.5	67	21
S0514	Occupational therapist	Home visit	–	2	–	–
S0600: Complementary therapists						
S0601	Acupuncturist	Session	7.5	7.5	15	–
S0602	Chiropractor	Session	1	–	1	–
S0603	Homeopathic clinic	Session	2	–	2	–
S0604	Osteopath	Session	–	–	7.5	–
T00: Tests						
T0210	X-ray	Test	9	6	65	48
OAK intervention						
OAK1	OAK intervention	Participant	–	–	87	–

Health Technology Assessment panel membership

This report was identified as a priority by the Primary and Community Care Panel.

Acute Sector Panel

Current members

Chair:
Professor Francis H Creed
University of Manchester

Professor Clifford Bailey
University of Leeds

Ms Tracy Bury
Chartered Society of Physiotherapy

Professor Collette Clifford
University of Birmingham

Dr Katherine Darton
M.I.N.D.

Mr John Dunning
Papworth Hospital, Cambridge

Mr Jonathan Earnshaw
Gloucester Royal Hospital

Mr Leonard Fenwick
Freeman Group of Hospitals, Newcastle-upon-Tyne

Professor David Field
Leicester Royal Infirmary

Ms Grace Gibbs
West Middlesex University Hospital NHS Trust

Dr Neville Goodman
Southmead Hospital Services Trust, Bristol

Professor Mark Haggard
MRC Institute of Hearing Research, University of Nottingham

Professor Robert Hawkins
University of Manchester

Dr Duncan Keeley
General Practitioner, Thame

Dr Rajan Madhok
East Riding Health Authority

Dr John Pounsford
Frenchay Hospital, Bristol

Dr Mark Sculpher
University of York

Dr Iqbal Sram
NHS Executive, North West Region

Mrs Joan Webster
Consumer member

Past members

Professor John Farndon*
University of Bristol

Professor Senga Bond
University of Newcastle-upon-Tyne

Professor Ian Cameron
Southeast Thames Regional Health Authority

Ms Lynne Clemence
Mid-Kent Health Care Trust

Professor Cam Donaldson
University of Aberdeen

Professor Richard Ellis
St James's University Hospital, Leeds

Mr Ian Hammond
Bedford & Shires Health & Care NHS Trust

Professor Adrian Harris
Churchill Hospital, Oxford

Dr Gwyneth Lewis
Department of Health

Mrs Wilma MacPherson
St Thomas's & Guy's Hospitals, London

Dr Chris McCall
General Practitioner, Dorset

Professor Alan McGregor
St Thomas's Hospital, London

Professor Jon Nicholl
University of Sheffield

Professor John Norman
University of Southampton

Professor Michael Sheppard
Queen Elizabeth Hospital, Birmingham

Professor Gordon Stirrat
St Michael's Hospital, Bristol

Dr William Tarnow-Mordi
University of Dundee

Professor Kenneth Taylor
Hammersmith Hospital, London

* Previous Chair

continued

continued

Diagnostics and Imaging Panel

Current members

Chair:
Professor Mike Smith
University of Leeds

Dr Philip J Ayres
Leeds Teaching Hospitals NHS Trust

Dr Paul Collinson
St George's Hospital, London

Dr Barry Cookson
Public Health Laboratory Service, Colindale

Professor David C Cumberland
University of Sheffield

Professor Adrian Dixon
University of Cambridge

Mr Steve Ebdon-Jackson
Department of Health

Mrs Maggie Fitchett
Association of Cytogeneticists, Oxford

Dr Peter Howlett
Portsmouth Hospitals NHS Trust

Professor Alistair McGuire
City University, London

Dr Andrew Moore
Editor, *Bandolier*

Dr Peter Moore
Science Writer, Ashtead

Professor Chris Price
London Hospital Medical School

Dr William Rosenberg
University of Southampton

Mr Tony Tester
South Bedfordshire Community Health Council

Dr Gillian Vivian
Royal Cornwall Hospitals Trust

Dr Greg Warner
General Practitioner, Hampshire

Past members

Professor Michael Maisey*
Guy's & St Thomas's Hospitals, London

Professor Andrew Adam
Guy's, King's & St Thomas's School of Medicine & Dentistry, London

Dr Pat Cooke
RDRD, Trent Regional Health Authority

Ms Julia Davison
St Bartholomew's Hospital, London

Professor MA Ferguson-Smith
University of Cambridge

Dr Mansel Haeney
University of Manchester

Professor Sean Hilton
St George's Hospital Medical School, London

Mr John Hutton
MEDTAP International Inc., London

Professor Donald Jeffries
St Bartholomew's Hospital, London

Dr Ian Reynolds
Nottingham Health Authority

Professor Colin Roberts
University of Wales College of Medicine

Miss Annette Sergeant
Chase Farm Hospital, Enfield

Professor John Stuart
University of Birmingham

Dr Ala Szczepura
University of Warwick

Mr Stephen Thornton
Cambridge & Huntingdon Health Commission

Dr Jo Walsworth-Bell
South Staffordshire Health Authority

Methodology Group

Current members

Chair:
Professor Martin Buxton
Health Economics Research Group, Brunel University

Professor Doug Altman
ICRF/NHS Centre for Statistics in Medicine, University of Oxford

Dr David Armstrong
Guy's, King's & St Thomas's School of Medicine & Dentistry, London

Professor Nicholas Black
London School of Hygiene & Tropical Medicine

Professor Ann Bowling
University College London Medical School

Dr Mike Clarke
UK Cochrane Centre, Oxford

Professor Paul Dieppe
MRC Health Services Research Collaboration, University of Bristol

Professor Mike Drummond
Centre for Health Economics, University of York

Dr Vikki Entwistle
University of Aberdeen

Professor Ewan Ferlie
Imperial College, London

Professor Ray Fitzpatrick
University of Oxford

Mrs Jenny Griffin
Department of Health

Professor Jeremy Grimshaw
University of Aberdeen

Dr Stephen Harrison
University of Leeds

Mr John Henderson
Department of Health

Professor Richard Lilford
R&D, West Midlands

Professor Theresa Marteau
Guy's, King's & St Thomas's School of Medicine & Dentistry, London

Dr Henry McQuay
University of Oxford

Dr Nick Payne
University of Sheffield

Professor Maggie Pearson
NHS Executive North West

Dr David Spiegelhalter
Institute of Public Health, Cambridge

Professor Joy Townsend
University of Hertfordshire

Ms Caroline Woodroffe
Standing Group on Consumers in NHS Research

Past members

Professor Anthony Culyer*
University of York

Professor Michael Baum
Royal Marsden Hospital

Dr Rory Collins
University of Oxford

Professor George Davey Smith
University of Bristol

Professor Stephen Frankel
University of Bristol

Mr Philip Hewitson
Leeds FHSA

Mr Nick Mays
King's Fund, London

Professor Ian Russell
University of York

Professor David Sackett
Centre for Evidence Based Medicine, Oxford

Dr Peter Sandercock
University of Edinburgh

Dr Maurice Slevin
St Bartholomew's Hospital, London

Professor Charles Warlow
Western General Hospital, Edinburgh

* Previous Chair

Pharmaceutical Panel

Current members

Chair:
Professor Tom Walley
University of Liverpool

Dr Felicity Gabbay
Transcrip Ltd

Dr Peter Golightly
Drug Information Services,
NHS Executive Trent

Dr Alastair Gray
Health Economics
Research Centre,
University of Oxford

Professor Rod Griffiths
NHS Executive
West Midlands

Mrs Jeanette Howe
Department of Health

Professor Trevor Jones
ABPI, London

Ms Sally Knight
Lister Hospital, Stevenage

Dr Andrew Mortimore
Southampton & SW Hants
Health Authority

Mr Nigel Offen
NHS Executive Eastern

Dr John Reynolds
The Oxford Radcliffe Hospital

Mrs Marianne Rigge
The College of Health,
London

Mr Simon Robbins
Camden & Islington
Health Authority, London

Dr Frances Rotblat
Medicines Control Agency

Dr Eamonn Sheridan
St James's University Hospital,
Leeds

Mrs Katrina Simister
National Prescribing Centre,
Liverpool

Dr Ross Taylor
University of Aberdeen

Past members

Professor Michael Rawlins*
University of Newcastle-
upon-Tyne

Dr Colin Bradley
University of Birmingham

Professor Alasdair
Breckenridge
RDRD, Northwest Regional
Health Authority

Ms Christine Clark
Hope Hospital, Salford

Mrs Julie Dent
Ealing, Hammersmith &
Hounslow Health Authority,
London

Mr Barrie Dowdeswell
Royal Victoria Infirmary,
Newcastle-upon-Tyne

Dr Tim Elliott
Department of Health

Dr Desmond Fitzgerald
Mere, Bucklow Hill, Cheshire

Professor Keith Gull
University of Manchester

Dr Keith Jones
Medicines Control Agency

Dr John Posnett
University of York

Dr Tim van Zwanenberg
Northern Regional
Health Authority

Dr Kent Woods
RDRD, Trent RO,
Sheffield

Population Screening Panel

Current members

Chair:
Professor Sir John
Grimley Evans
Radcliffe Infirmary, Oxford

Mrs Stella Burnside
Altnagelvin Hospitals Trust,
Londonderry

Mr John Cairns
University of Aberdeen

Professor Howard Cuckle
University of Leeds

Dr Carol Dezateux
Institute of Child Health,
London

Mrs Anne Dixon-Brown
NHS Executive Eastern

Professor Dian Donnai
St Mary's Hospital,
Manchester

Dr Tom Fahey
University of Bristol

Mrs Gillian Fletcher
National Childbirth Trust

Dr JA Muir Gray
National Screening Committee,
NHS Executive Oxford

Professor Alexander Markham
St James's University Hospital,
Leeds

Dr Ann McPherson
General Practitioner,
Oxford

Dr Susan Moss
Institute of Cancer Research

Mr John Nettleton
Consumer member

Mrs Julietta Patnick
NHS Cervical
Screening Programme,
Sheffield

Dr Sarah Stewart-Brown
Health Service Research Unit,
University of Oxford

Past members

Dr Sheila Adam*
Department of Health

Professor George Freeman
Charing Cross & Westminster
Medical School, London

Dr Mike Gill
Brent & Harrow
Health Authority

Dr Anne Ludbrook
University of Aberdeen

Professor Theresa Marteau
Guy's, King's &
St Thomas's School of
Medicine & Dentistry,
London

Professor Catherine Peckham
Institute of Child Health,
London

Dr Connie Smith
Parkside NHS Trust,
London

Ms Polly Toynbee
Journalist

Professor Nick Wald
University of London

Professor Ciaran Woodman
Centre for
Cancer Epidemiology,
Manchester

* Previous Chair

continued

continued

Primary and Community Care Panel

Current members

Chair:
Dr John Tripp
Royal Devon & Exeter Healthcare NHS Trust

Mr Kevin Barton
East London & City Health Authority

Professor John Bond
University of Newcastle-upon-Tyne

Dr John Brazier
University of Sheffield

Ms Judith Brodie
Cancer BACUP

Mr Shaun Brogan
Ridgeway Primary Care Group, Aylesbury

Mr Joe Corkill
National Association for Patient Participation

Dr Nicky Cullum
University of York

Professor Pam Enderby
University of Sheffield

Dr Andrew Farmer
Institute of Health Sciences, Oxford

Dr Jim Ford
Department of Health

Professor Richard Hobbs
University of Birmingham

Professor Allen Hutchinson
University of Sheffield

Dr Aidan MacFarlane
Independent Consultant

Professor David Mant
Institute of Health Sciences, Oxford

Dr Chris McCall
General Practitioner, Dorset

Dr Robert Peveler
University of Southampton

Professor Jennie Popay
University of Salford

Dr Ken Stein
North & East Devon Health Authority

Past members

Professor Angela Coulter*
King's Fund, London

Professor Martin Roland*
University of Manchester

Dr Simon Allison
University of Nottingham

Professor Shah Ebrahim
Royal Free Hospital, London

Ms Cathy Gritzner
King's Fund, London

Professor Andrew Haines
RDRD, North Thames Regional Health Authority

Dr Nicholas Hicks
Oxfordshire Health Authority

Mr Edward Jones
Rochdale FHSA

Professor Roger Jones
Guy's, King's & St Thomas's School of Medicine & Dentistry, London

Mr Lionel Joyce
Chief Executive, Newcastle City Health NHS Trust

Professor Martin Knapp
London School of Economics & Political Science

Dr Phillip Leech
Department of Health

Professor Karen Luker
University of Liverpool

Dr Fiona Moss
Thames Postgraduate Medical & Dental Education

Professor Dianne Newham
King's College London

Professor Gillian Parker
University of Leicester

Dr Mary Renfrew
University of Oxford

Ms Hilary Scott
Tower Hamlets Healthcare NHS Trust, London

* Previous Chair

National Coordinating Centre for Health Technology Assessment, Advisory Group

Current members

Chair:
Professor John Gabbay
Wessex Institute for Health Research & Development

Dr Sheila Adam
Department of Health

Professor Nicholas Black
London School of Hygiene and Tropical Medicine

Professor Martin Buxton
Health Economics Research Group, Brunel University

Mr Harry Cayton
Alzheimer's Disease Society

Professor Angela Coulter
The King's Fund, London

Professor Paul Dieppe
MRC Health Services Research Collaboration, University of Bristol

Professor Mike Drummond
Centre for Health Economics, University of York

Professor Shah Ebrahim
MRC Health Services Research Collaboration, University of Bristol

Ms Lynn Kerridge
Wessex Institute for Health Research & Development

Professor Jos Kleijnen
NHS Centre for Reviews and Dissemination, University of York

Dr Ruairidh Milne
Wessex Institute for Health Research & Development

Ms Kay Pattison
Research & Development Directorate, NHS Executive

Professor James Raftery
Health Economics Unit, University of Birmingham

Professor Ian Russell
Department of Health Sciences & Clinical Evaluation, University of York

Dr Ken Stein
North & East Devon Health Authority

Professor Andrew Stevens
Department of Public Health & Epidemiology, University of Birmingham

Professor Kent Woods
Department of Medicine & Therapeutics, University of Leicester

Past member

Dr Paul Roderick
Wessex Institute for Health Research & Development

HTA Commissioning Board

Current members

Chair:
Professor Shah Ebrahim
Professor of Epidemiology of Ageing, University of Bristol

Professor Doug Altman
Director, ICRF Medical Statistics Group, Centre for Statistics in Medicine, University of Oxford

Professor John Bond
Director, Centre for Health Services Research, University of Newcastle-upon-Tyne

Mr Peter Bower
General Manager and Independent Health Advisor, Thames Valley Primary Care Agency

Ms Christine Clark
Honorary Research Pharmacist, Hope Hospital, Salford

Professor Martin Eccles
Professor of Clinical Effectiveness, University of Newcastle-upon-Tyne

Dr Mike Gill
Regional Director of Public Health, NHS Executive South East

Dr Alastair Gray
Director, Health Economics Research Centre, University of Oxford

Professor Mark Haggard
Director, MRC Institute of Hearing Research, University of Nottingham

Dr Jenny Hewison
Senior Lecturer, Department of Psychology, University of Leeds

Professor Alison Kitson
Director, Royal College of Nursing Institute

Dr Donna Lamping
Senior Lecturer, Department of Public Health, London School of Hygiene & Tropical Medicine

Professor Alan Maynard
Joint Director, York Health Policy Group, University of York

Professor David Neal
Joint Director, York Health Policy Group, University of York

Professor Jon Nicholl
Director, Medical Care Research Unit, University of Sheffield

Professor Gillian Parker
Nuffield Professor of Community Care, University of Leicester

Dr Tim Peters
Reader in Medical Statistics, Department of Social Medicine, University of Bristol

Professor Martin Severs
Professor in Elderly Health Care, University of Portsmouth

Dr Sarah Stewart-Brown
Health Service Research Unit, University of Oxford

Professor Ala Szczepura
Director, Centre for Health Services Studies, University of Warwick

Dr Gillian Vivian
Consultant, Royal Cornwall Hospitals Trust

Professor Graham Watt
Department of General Practice, University of Glasgow

Professor Kent Woods
Professor of Therapeutics, University of Leicester

Dr Jeremy Wyatt
Senior Fellow, Health Knowledge Management Centre, University College London

Past members

Professor Ian Russell*
Department of Health Sciences & Clinical Evaluation, University of York

Professor Charles Florey*
Department of Epidemiology & Public Health, Ninewells Hospital & Medical School, University of Dundee

Professor David Cohen
Professor of Health Economics, University of Glamorgan

Mr Barrie Dowdeswell
Chief Executive, Royal Victoria Infirmary, Newcastle-upon-Tyne

Dr Michael Horlington
Head of Corporate Licensing, Smith & Nephew Group Research Centre

Professor Sir Miles Irving
Professor of Surgery, University of Manchester, Hope Hospital, Salford

Professor Martin Knapp
Director, Personal Social Services Research Unit, London School of Economics & Political Science

Professor Theresa Marteau
Director, Psychology & Genetics Research Group, Guy's, King's & St Thomas's School of Medicine & Dentistry, London

Professor Sally McIntyre
MRC Medical Sociology Unit, Glasgow

Professor David Sackett
Centre for Evidence Based Medicine, Oxford

Dr David Spiegelhalter
MRC Biostatistics Unit, Institute of Public Health, Cambridge

Professor David Williams
Department of Clinical Engineering, University of Liverpool

Dr Mark Williams
Public Health Physician, Bristol

* Previous Chair

Copies of this report can be obtained from:

The National Coordinating Centre for Health Technology Assessment,
Mailpoint 728, Boldrewood,
University of Southampton,
Southampton, SO16 7PX, UK.
Fax: +44 (0) 23 8059 5639 Email: hta@soton.ac.uk
http://www.hta.nhsweb.nhs.uk

ISSN 1366-5278