

Primary care

Randomised controlled trial of an interactive multimedia decision aid on hormone replacement therapy in primary care

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Abstract

Objective To determine whether a decision aid on hormone replacement therapy influences decision making and health outcomes.

Design Randomised controlled trial.

Setting 26 general practices in the United Kingdom.

Participants 205 women considering hormone replacement therapy.

Intervention Patients' decision aid consisting of an interactive multimedia programme with booklet and printed summary.

Outcome measures Patients' and general practitioners' perceptions of who made the decision, decisional conflict, treatment choice, menopausal symptoms, costs, anxiety, and general health status.

Results Both patients and general practitioners found the decision aid acceptable. At three months, mean scores for decisional conflict were significantly lower in the intervention group than in the control group (2.5 *v* 2.8; mean difference -0.3, 95% confidence interval -0.5 to -0.2); this difference was maintained during follow up. A higher proportion of general practitioners perceived that treatment decisions had been made "mainly or only" by the patient in the intervention group than in the control group (55% *v* 31%; 24%, 8% to 40%). At three months a lower proportion of women in the intervention group than in the control group were undecided about treatment (14% *v* 26%; -12%, -23% to -0.4%), and a higher proportion had decided against hormone replacement therapy (46% *v* 32%; 14%, 1% to 28%); these differences were no longer apparent by nine months. No differences were found between the groups for anxiety, use of health service resources, general health status, or utility. The higher costs of the intervention were largely due to the video disc technology used.

Conclusions An interactive multimedia decision aid in the NHS would be popular with patients, reduce decisional conflict, and enable patients to play a more active part in decision making without increasing anxiety. The use of web based technology would reduce the cost of the intervention.

Introduction

Decision aids to assist patients in deciding about health care have been welcomed as one solution for improving doctor-patient communication, providing information for patients, and addressing the shortcomings in much of the information available.¹⁻⁵ Both patient outcomes and the rational use of health service resources may be improved by better provision of information.⁶⁻⁹

Decision aids for patients differ from simple information packages. They often contain exercises to help patients clarify their own health needs, and they emphasise that different patients reach different decisions.¹⁰ Decision aids aim to promote shared decision making,¹¹ where the clinician and patient jointly negotiate and agree on a treatment decision, taking into account both the probability of a range of clinical outcomes and the relative weight the patient places on these outcomes.

A recent systematic review of decision aids determined that they improve patients' knowledge of their condition and treatment options.¹² They seem to help with decision making in that "decisional conflict scores" (a measure of patients' internal perceptions of ability to make a decision and satisfaction with the decision made) tend to be lower in groups that have used a decision aid than in control groups.¹³ There are, however, several unanswered questions,¹⁴ in particular the impact of decision aids on choice of treatment, satisfaction, health status, and persistence with treatment. Additionally, there is little evidence on the use of decision aids in primary care. Few data are available on clinicians' perceptions of decision aids or their cost effectiveness. We address these questions here and in the accompanying paper on patients with benign prostatic hypertrophy.¹⁵ The two trials were designed to complement each other by examining qualitatively different decisions in different populations. In this paper we aimed to determine whether an interactive multimedia decision aid promoted greater patient involvement in decision making and what influence this had on the uptake of hormone replacement therapy, health status, and anxiety. We also aimed to determine the acceptability of such a system and to undertake an economic analysis.

Participants and methods

We invited general practitioners in two urban (Oxford and London) areas and one suburban (Harrow) and one semirural (Thame and the Chilterns) area to participate in our study. We asked participating general practitioners to recruit perimenopausal or menopausal women who were facing a decision about whether to start, stop, or continue with hormone replacement therapy.

Intervention

The intervention, developed by the Foundation for Informed Medical Decision Making, comprised an interactive multimedia programme, with booklet and printed summary.¹⁶ Information comprised quantified probabilities of the risks and benefits of hormone replacement therapy taken from systematic reviews and other published data available in 1996 and updated in 1998. Topics discussed were menopausal symptoms, mood changes, skin changes, changes in energy, vaginal dryness, changes in libido, heart disease, osteoporosis, breast cancer, and endometrial cancer. After viewing the programme the patients were given a summary of the information; a copy was also sent to their general practitioners.

As the programme used interactive video disc technology, we imported specialised hardware from the United States. This limited the number of machines available for patients to use. Patients travelled to one of five sites, chosen for ease of access from referring practices, to view the programme in a private room. All the patients saw the core programme, lasting about one hour; viewing optional sections for further information took up to 30 minutes more.

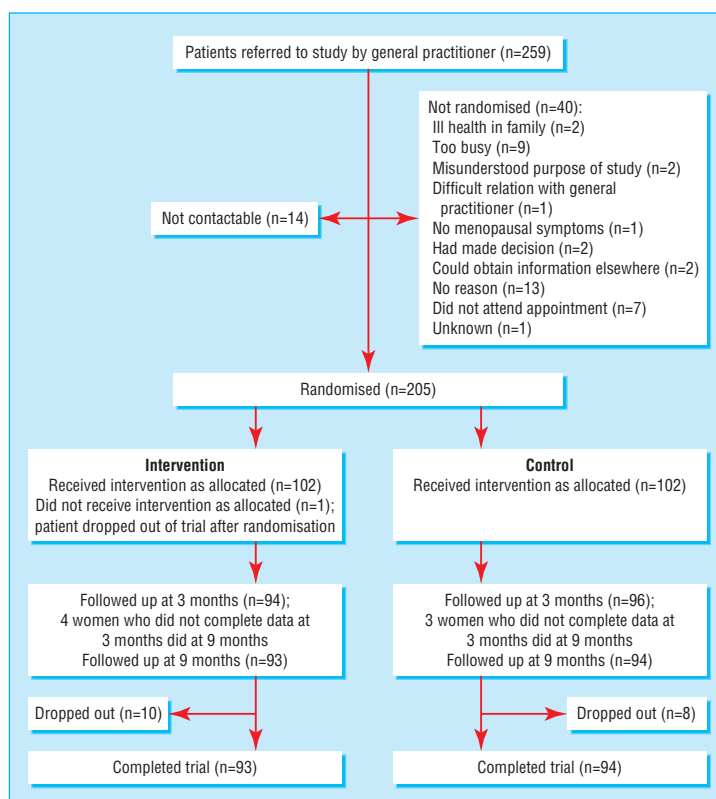
Randomisation and data collection

Patients randomised to the control group received normal clinical care. The randomisation schedule was generated by computer. Allocations were sealed in opaque numbered envelopes, opened by the study nurse after collection of the baseline data.

We collected data from the patients at baseline and at three and nine months after randomisation. Data included personal details, decisional conflict scores, patients' and general practitioners' perceptions of who made the decision, treatment preference, persistence with treatment, anxiety,¹⁷ health status and limitations in physical functioning (SF-36),¹⁸ health states and valuation of health states (EQ-5D),¹⁹ and menopausal symptoms (MenQol).²⁰ Patients in the intervention group completed a questionnaire immediately after viewing the programme.

Economic evaluation

We recorded the resources used by each patient over the trial period. The unit costs were attached to resource volumes to obtain a total cost per patient. As the technology we used was superseded by CD Rom, personal computer, and internet technology by the time our trial was completed, we also present some estimates of the costs of an alternative delivery system. Utility was measured with the EQ-5D at baseline and at three and nine months. Valuations of health states were taken from the UK population tariff.²¹ We conducted our economic evaluation from the perspective of the healthcare system. All costs are in pounds sterling at 1999 prices.



Progress of patients through trial

Sample size

Allowing for a 30% dropout rate, 120 women in each arm (84 women completing the trial) would give our study an 80% power of detecting a 15% point difference in use of hormone replacement therapy (between 8% and 23%)²² in the two arms at the 5% significance level.

Table 1 Baseline characteristics of participants. Values are numbers (percentages) of women unless stated otherwise

Characteristic	Intervention group (n=103)	Control group (n=102)
Mean age (years)	50.75	50.11
Ethnicity (white)	95 (92)	93 (93)
Educational attainment:		
Up to secondary education	40 (39)	24 (24)
Beyond secondary education	63 (61)	78 (77)
Treatment choice for hormone replacement therapy:		
To take	31 (30)	27 (27)
Not to take	21 (20)	18 (18)
Let doctor decide	4 (4)	5 (5)
Unsure	47 (46)	51 (51)
Mean (SD) MenQol score:		
Vasomotor	2.71 (1.73)	3.02 (2.0)
Psychosocial	3.55 (1.82)	3.65 (1.81)
Physical	3.42 (1.33)	3.47 (1.35)
Sexual	2.85 (2.16)	2.34 (1.62)
Mean (SD) decisional conflict score:		
Uncertainty	3.61 (0.73)	3.69 (0.87)
Factors contributing to uncertainty	2.70 (0.45)	2.65 (0.46)
Mean (SD) score on Spielberger state trait anxiety inventory	38.87 (12.34)	38.73 (13.18)

Table 2 Treatment preferences for hormone replacement therapy at three and nine months' follow up. Values are numbers (percentages) of patients unless stated otherwise

Treatment preference	Intervention group	Control group	% difference (95% CI)
Three months' follow up*:			
Therapy	36 (40)	40 (42)	-2.1 (-16 to 12)
No therapy	41 (46)	30 (32)	14 (1 to 28)
Undecided	13 (14)	25 (26)	-11.9 (-23 to -0.4)
Nine months' follow up†:			
Therapy	36 (41)	31 (36)	5.8 (-9 to 20)
No therapy	46 (53)	44 (51)	2.3 (-13 to 17)
Undecided	5 (6)	12 (14)	-8.1 (-17 to 1)

Data are missing for some participants.
 Confidence intervals are based on *t* tests assuming unequal variances between study groups.
 * $\chi^2=5.573$, df=2, P=0.06.
 † $\chi^2=3.30$, df=2, P=0.2.

Table 3 Decisional conflict scores at three months. Values are means (SDs) unless stated otherwise

	Intervention group	Control group	Mean difference (95% CI)
Uncertainty	3.1 (1.0)	3.4 (1.1)	-0.3 (-0.7 to -0.04)*
Factors contributing to uncertainty	2.4 (0.5)	2.8 (0.6)	-0.4 (-0.5 to -0.2)**
Perceived effective decision making	2.2 (0.6)	2.5 (0.7)	-0.3 (-0.5 to -0.2)**
Total decisional conflict score	2.5 (0.5)	2.8 (0.6)	-0.3 (-0.5 to -0.2)**

*P<0.05, **P<0.01.
 The decisional conflict scale contains three subscales that elicit uncertainty about choosing between alternatives, awareness of modifiable factors contributing to uncertainty, and perceived effectiveness of decision making process. Higher scores indicate increased uncertainty in each subscale. Subscales can be combined to give a total decisional conflict score.

Table 4 Resource use and costs in pounds sterling (at 1999 prices) per patient, by allocation. Values are means (SDs) unless stated otherwise

	Intervention (n=85)	Control (n=84)	Mean difference (95% CI)
Cost of video technology	216	0	216
Duration of initial consultation (minutes)	13.4 (5.9)	13.9 (5.8)	-0.5 (-2.5 to 1.6)
No of appointments to see doctor over 9 months	3.4 (1.2)	3.6 (1.5)	-0.2 (-0.6 to 0.2)
Cost of appointments over 9 months	64.6 (23.6)	66.5 (24.6)	-1.9 (-9.2 to 5.5)
No of specialist referrals over 9 months	0.03 (0.17)	0.03 (0.18)	0.00 (-0.06 to 0.06)
Cost of specialist referrals over 9 months	1.7 (10.1)	1.9 (10.6)	-0.19 (-3.75 to 3.37)
Cost of hormone replacement therapy over 9 months	24.3 (28.3)	23.0 (27.2)	1.3 (-7.1 to 9.7)
Total cost	306.5 (42.8)	90.9 (39.2)	215.5 (203.1 to 228.0)***

***P<0.001.

Analysis

We present the results for the patients who completed the nine months' assessment, as the intention to treat analysis did not alter the results.

Results

Overall, 26 general practices agreed to participate, and between October 1996 and August 1998, 205 women were recruited (figure).

Baseline characteristics

The intervention and control groups were comparable at baseline (table 1), except for educational achievement, which was higher in the control group.

Reactions to decision aid

Patients reacted positively to the decision aid. Women in the intervention group seemed to make a more definite choice about treatment than those in the control group, with fewer women being "undecided" and more women deciding not to take hormone replacement therapy at three months; by nine months, however, this difference was no longer significant (table 2).

Decisional conflict scores were lower in the intervention group than in the control group at three months (table 3); the significant differences persisted at nine months. General practitioners perceived the decision to have been made "mainly or only [by the] patient" in a significantly higher proportion of patients in the intervention group than in the control group, although there were no differences in patients' perceptions of who should make the decision.

Economic analysis

No significant differences were detected when the cost of the trial technology was excluded (table 4). When the cost of the video intervention was included, the cost per patient was £306 in the intervention group and £91 in the control group over nine months (P<0.001).

Discussion

The decision aid for hormone replacement therapy was acceptable to both the patients and their general practitioners. It enhanced the women's understanding of the effects of hormone replacement therapy and seemed to reduce decisional conflict for the duration of follow up. These findings are compatible with the recent systematic review of decision aids⁵ and provide new information on the acceptability of such decision aids to clinicians and patients in primary care and the impact on costs to the NHS.

Implications for the NHS

Public demand for improved access to quality sources of information is high and likely to increase. Decision aids have the potential to alter the use of healthcare resources in line with patients' preferences and, through the influence of patient choice on clinicians, may help to promote evidence based practice.²³

Delivering programmes to standard personal computers through the internet would reduce the cost per session from about £177 to £5 (excluding the cost of software). This assumes equipment costs of £1500 over three years, with a fairly low utilisation rate (two users per weekday) and lower space and staff costs commensurate with the programme.

What is already known on this topic

- Patients want more information about their conditions and treatment options, and many want to play an active part in decision making
- Decision aids improve patients' knowledge of their conditions and treatment options

What this study adds

- The decision aid was acceptable to both the patients and their general practitioners
- Decisional conflict was reduced in the intervention group
- Patients who viewed the programme played a more active part in the decision making process and were no more anxious than control patients
- Such aids could be introduced throughout the NHS at relatively low cost by using the internet

surate with a less dedicated technology. Thus this type of interactive decision aid, which provides a realistic and practical solution to the problem of achieving informed patient choice at low cost, could easily be incorporated into multiple access points for information such as those envisaged for NHS Direct Online.

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- 1 General Medical Council. *Seeking patients' consent: the ethical considerations*. London: GMC, 1998.
- 2 Department of Health. *Saving lives: our healthier nation*. London: Stationery Office, 1999.
- 3 Jones R, Pearson J, McGregor S, Cawsey AJ, Barret A, Craig N, et al. Randomised trial of personalised computer based information for cancer patients. *BMJ* 1999;319:1241-7.
- 4 Meredith C, Symonds P, Webster L, Lamont D, Pyper E, Gillis CR, et al. Information needs of cancer patients in west Scotland: cross sectional survey of patients' views. *BMJ* 1996;313:724-6.
- 5 Coulter A, Entwistle V, Gilbert D. Sharing decisions with patients: is the information good enough? *BMJ* 1999;318:318-22.
- 6 Legg England S, Evans J. Patients' choices and perceptions after an invitation to participate in treatment decisions. *Soc Sci Med* 1992;34:1217-25.
- 7 Kaplan SH, Greenfield S, Ware JE. Assessing the effects of physician-patient interactions on the outcomes of chronic disease. *Med Care* 1989;27:110-27S. [Published erratum appears in *Med Care* 1989;27:679.]
- 8 Flood AB, Wennberg JE, Nease RFJ, Fowler FJJ, Ding J, Hynes LM. The importance of patient preference in the decision to screen for prostate cancer. *J Gen Intern Med* 1996;11:342-9.
- 9 Wolf AM, Nasser JF, Schorling JB. The impact of informed consent on patient interest in prostate-specific antigen screening. *Arch Intern Med* 1996;156:1333-6.

- 10 Llewellyn TH. Patients' health-care decision making: a framework for descriptive and experimental investigations. *Med Decis Making* 1995;15:101-6.
- 11 Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (Or it takes at least two to tango). *Soc Sci Med* 1997;44:681-92.
- 12 O'Connor AM, Rostom A, Fiset V, Tetroe J, Entwistle V, Llewellyn TH, et al. Decision aids for patients facing health treatment or screening decisions: systematic review. *BMJ* 1999;319:731-4.
- 13 O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making* 1995;15:25-30.
- 14 Molenaar S, Sprangers MA, Postma-Schuit FC, Rutgers EJ, Noorlander J, Hendriks J, et al. Feasibility and effects of decision aids. *Med Decis Making* 2000;20:112-27.
- 15 Murray E, Davis H, See Tai S, Coulter A, Gray A, Haines A. Randomised controlled trial of an interactive multimedia decision aid on benign prostatic hypertrophy in primary care. *BMJ* 2001;323:493-6.
- 16 Foundation for Informed Medical Decision Making. *Hormone replacement therapy: a shared decision making program. Clinician's guide*. Boston, MS: FIMDM, 1996.
- 17 Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the Spielberger state-trait anxiety inventory (STAI). *Br J Clin Psychol* 1992;31:301-6.
- 18 Brazier JE, Harper R, Jones NM, O'Cathain A, Thomas KJ, Usherwood T, et al. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. *BMJ* 1992;305:160-4.
- 19 EuroQol Group. EuroQol: a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16:199-208.
- 20 Hilditch JR, Lewis J, Peter A, van-Maris B, Ross A, Franssen E, et al. A menopause-specific quality of life questionnaire: development and psychometric properties. *Maturitas* 1996;24:161-75. [Published erratum appears in *Maturitas* 1996;25:231.]
- 21 Dolan P, Gudex C, Kind P, Williams A. The time trade-off method: results from a general population study. *Health Econ* 1996;5:141-54.
- 22 Townsend J. Hormone replacement therapy: assessment of present use, costs, and trends. *Br J Gen Pract* 1998;48:955-8.
- 23 Entwistle VA, Sheldon TA, Sowden A, Watt IS. Evidence-informed patient choice. Practical issues of involving patients in decisions about health care technologies. *Int J Technol Assess Health Care* 1998;14:212-25.

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Abstract

Objective To determine whether a decision aid on benign prostatic hypertrophy influences decision making, health outcomes, and resource use.

Design Randomised controlled trial.

Setting 33 general practices in the United Kingdom.

Participants 112 men with benign prostatic hypertrophy.

Intervention Patients' decision aid consisting of an interactive multimedia programme with booklet and printed summary.

Outcome measures Patients' and general practitioners' perceptions of who made the decision, conflict over decisions, treatment choice and prostatectomy rate, American Urological Association symptom scale, costs, anxiety, utility, and general health status.

Results Both patients and general practitioners found the decision aid acceptable. A higher proportion of patients (32% v 4%; mean difference 28%, 95% confidence interval 14% to 40%) and their general practitioners (46% v 25%; 21%, 3% to 40%) perceived that treatment decisions had been made mainly or only by patients in the intervention group compared

with the control group. Patients in the intervention group had significantly lower decisional conflict scores than those in the control group at 3 and 9 months (2.3 v 2.6; -0.3, -0.5 to -0.1, $P < 0.01$ at 3 months). No differences were found between the groups for anxiety, general health status, prostatic symptoms, utility, or costs (excluding costs associated with the video disc equipment).

Conclusions The decision aid reduced decisional conflict in men with benign prostatic hypertrophy, and the patients played a more active part in decision making. Such programmes could be delivered cheaply over the internet, and there are good arguments for coordinated investment in them, particularly for conditions in which patient utilities are important.

Introduction

The rationale for decision aids is addressed in the accompanying paper.¹ Unlike hormone replacement therapy, prostate surgery is a "Rubicon" procedure—that is, once undertaken it cannot be reversed. In the United States, a pilot study on the impact of a programme to aid in decisions about benign prostatic hyperplasia showed a 40% decrease in surgery rates.²

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