Improving the referral process for familial breast cancer genetic counselling: findings of three randomised controlled trials of two interventions

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Executive summary

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Executive summary

Background

Clinical genetics services need to find cost-effective ways of meeting increasing demand resulting from advances in knowledge of genetic contribution to risk of common diseases. GPs need both to provide first line genetic assessment and to identify patients who would benefit from referral to genetics clinics.

This project evaluated the effectiveness and cost-effectiveness of two complementary interventions, using familial breast cancer as a model condition. The primary care intervention consisted of providing computerised referral guidelines and related education to GPs. The nurse counsellor intervention evaluated genetic nurses as substitutes for specialist geneticists in the initial assessment and management of referred patients.

Primary care trial

Objectives

This study aimed to evaluate a computer support system for breast cancer genetics within a general practice setting and to examine the factors influencing its implementation.

Methods

The design was a pragmatic, cluster randomised controlled trial (RCT) with general practices randomised to intervention or control groups. The trial took place in general practices in the Grampian region of Scotland. Data were collected from GPs and patients they referred.

Intervention

A software system was developed with GPs. It presented cancer genetic referral guidelines in a checklist approach, along with other features designed to enhance its utility. The software was disseminated as a CD-ROM to intervention practices by information technology technicians, by the research team or by post, followed by a letter to each intervention GP individually. Intervention GPs were invited to postgraduate update education sessions, which included a hands-on demonstration of the software. Both intervention and control practices received paper-based guidelines when the Scottish Executive mailed these to all GPs in Scotland. The intervention period ran from November 2000 to June 2001.

Main outcome measures

The primary outcome was GPs' confidence in their management of patients with concerns about family history of breast cancer. Secondary outcomes were changes in referral patterns, patients' perceptions of risk and understanding of breast cancer risk factors. An economic evaluation was conducted in parallel with the main trial.

Results

Fifty-seven practices (230 GPs) were randomised to the intervention group and 29 (116 GPs) to the control group. Three postgraduate education sessions were attended by 27 (11.9%) GPs from 20 (35.1%) intervention practices.

No statistically significant differences were detected in GPs' confidence or any other outcomes. Fewer than half of the intervention GPs were aware of the software, and only 22 reported using it in practice. It was not possible to assess effects in just these 22 GPs. The estimated total cost was £3.12 per CD-ROM distributed (2001 prices), largely reflecting development costs. This estimate was sensitive to the number of copies produced and the timing of updates.

Conclusions

The trial had sufficient statistical power to detect a meaningful difference in the primary outcome. However, no improvement in GP confidence was observed and too few women were referred to allow clear conclusions on referral patterns or patient outcomes. The pragmatic approach to dissemination of the software did not lead to high levels of awareness or uptake of the intervention. It is not possible to conclude that the policy of developing the software package and disseminating it within a pragmatic strategy was effective in promoting GP confidence in their management of women concerned about the genetic risk of breast cancer.

Nurse counsellor trial

Objectives

This study aimed to test whether trained genetics nurse counsellors are as effective as current models of service for familial breast cancer counselling and to explore factors influencing cost-effectiveness.

Methods

Two concurrent RCTs were conducted in separate UK health service locations in 1998–2001, using predetermined definitions of equivalence. Trial 1 took place in a regional genetics clinic serving Grampian in north-east Scotland, and trial 2 in two health authorities in Wales served by a single genetics service. Both trials included women referred for the first time, aged 18 years or over, whose main concern was family history of breast cancer.

Interventions

In trial 1, a nurse counsellor, based in the regional cancer genetics clinic in Aberdeen, ran outpatient sessions with the same appointment length as the standard service offered by geneticists. She saw new patients at the first appointment and referred back to the GP or on to a clinical geneticist according to locally developed protocol, under the supervision of a consultant geneticist. The control intervention was the current service, which comprised an initial and a follow-up appointment with a clinical geneticist.

In trial 2, a nurse counsellor based in the regional genetics service in Cardiff ran outpatient sessions with the same appointment length as the new consultant-based cancer genetics service. She saw new patients at the first appointment and referred back to the GP or on to a clinical geneticist according to locally developed protocol, under the supervision of a consultant geneticist. The control intervention was a new service, and comprised collection of family history by telephone followed by a consultation with a clinical assistant or a specialist registrar, supervised by a consultant.

Main outcome measures

The primary outcome was patient anxiety, measured using the short form of the Spielberger State Trait Anxiety Inventory, the Hospital Anxiety and Depression Scale and the mental health and role emotional domains of the Short Form 36 health status instrument. Secondary outcomes were other aspects of health status, satisfaction, risk perceptions and understanding of breast cancer risk factors. Acceptability to GPs was also assessed and a concurrent economic evaluation conducted.

Results

In trial 1, 289 patients (193 intervention, 96 control) consented, were randomised, returned a baseline questionnaire and attended the clinic. Their mean age was 40.9 years and eventual clinic assessment placed 28% in the highest genetic risk category. The analysis suggested equivalence in all anxiety scores, and no statistically significant differences were detected in other outcomes. These findings were not altered by the per-protocol analysis. A cost-minimisation analysis suggested that the cost per counselling episode of £10.23 (95% confidence interval –£1.69 to 22.15) was lower in the intervention arm than in the control arm (2001 prices)

In trial 2, 297 patients (197 intervention and 100 control) consented, were randomised, returned a baseline questionnaire and attended the clinic. Their mean age was 39.5 years and eventual clinic assessment placed 30% in the highest genetic risk category. The analysis suggested equivalence in all anxiety scores, and no statistically significant differences were detected in other outcome in either trial. These findings were not altered by the per-protocol analysis. A cost-minimisation analysis suggested that the cost per counselling episode was £10.89 higher in the intervention arm than in the control arm (2001 prices).

Taking the trials together, the costs were sensitive to the grades of doctors and the time spent in consultant supervision of the nurse counsellor, but they were only slightly affected by the grade of nurse counsellor, the selected discount rate and the lifespan of equipment.

Conclusions

Genetics nurse counsellors could be considered equivalent across a range of outcomes to the current model of cancer genetic counselling in both trial locations, providing evidence of generalisability. This approach can be a cost-effective alternative to physician-led care for breast cancer genetic counselling, depending on the grade of doctor being substituted and the extent of consultant supervision.

Implications for healthcare

The primary care intervention described here cannot be recommended for widespread use without further evaluation. Computer-based systems must be tested in real practice settings, with realistic dissemination and implementation strategies. ▶

Genetic nurse counsellors may be a cost-effective alternative to assessment by doctors, when working within a defined protocol under supervision and under the same constraints. This trial does not provide definitive evidence that the general policy of employing genetics nurse counsellors is sound, as it was based on only three individuals.

Recommendations for research

Primary care trial

- Future evaluations of computer-based decision support systems for primary care must first address their efficacy under ideal conditions.
- In-depth studies are required to identify barriers to the use of such systems in practice.
- The growing adoption of handheld computers (personal digital assistants) for clinical and administrative tasks suggests that they may be more attractive to busy clinicians than desktop-based systems, but they require rigorous evaluation.
- Strategies for disseminating and implementing decision-support systems that have been shown to have efficacy in exploratory studies should be based on the best available evidence. Pragmatic trials are required to provide evidence of the impact of the policy of offering or installing such systems in routine practice.

Nurse counsellor trial

- This study should be replicated in other settings to provide reassurance of the generalisability of the intervention.
- Other models of nurse-based assessment, such as in outreach clinics, should be developed and evaluated.
- The design of future evaluations of professional substitution should address issues such as the effect of different levels of training and experience of nurse counsellors, and learning effects.

Publication

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Research suggestions are carefully considered by panels of independent experts (including consumers) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or designing a trial to produce new evidence where none currently exists.

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The research reported in this monograph was commissioned by the HTA Programme as project number 94/14/20. As funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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