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| Title | Improving the Referral Process for Familial Breast Cancer Genetic Counseling: Findings of Three Randomized Controlled Trials of Two Interventions |
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Aim

To evaluate two interventions (a primary care trial and a clinical trial) designed to improve management of women concerned about familial breast cancer risk.

Conclusions and results

The primary care trial compared the effects of an active, computer-supported educational strategy versus passively disseminated national guidelines, on general practitioner (GP) confidence in key skills. The trial randomized 57 practices (230 GPs) to intervention and 29 (116 GPs) to control groups. Twenty-seven (11.9%) intervention GPs from 20 (35.1%) of the practices attended one of the postgraduate education sessions. No effect of the intervention was detected on primary or secondary outcomes. Fewer than half of intervention GPs were aware of the software, and only 22 reported using it in practice, too few for meaningful analysis.

The clinic trial determined whether substituting medical geneticist assessment by nurse counselor assessment for newly referred patients was equivalent in terms of patient anxiety and a range of other outcomes. The cost effectiveness of both interventions was also examined. The participants, 289 Grampian patients (193 intervention, 96 control) and 297 Wales patients (197 intervention, 100 control) consented, were randomized, returned a baseline questionnaire, and attended the clinic. Primary analysis in both trials suggested “equivalence” in all anxiety scores, and no statistically significant differences in a range of other outcomes. “Per protocol” analysis did not alter the findings. Cost minimization analysis suggested similar costs per counseling episode. Costs were sensitive to grades of doctors substituted for and consultant time required for nurse counselor supervision, but insensitive to grade of nurse counselor, selected discount rate, or lifespan of equipment.

Recommendations

Primary care trial: No effect on GP confidence was detected. The pragmatic approach to software dissemination did not lead to high levels of awareness or uptake

of the intervention. It is not possible to tell whether the lack of effect was due to the computer system itself, or because too few GPs used it.

Clinic trial: Nurse counselor intervention appeared “equivalent” to conventional cancer genetic counseling across the range of outcomes and both trial locations, suggesting some generalizability. It might be a cost-effective option for breast cancer genetic counseling, depending on the grade of doctor replaced and consultant supervision required.

Methods

Primary care trial: Cluster randomized controlled trial, with eligible general practices stratified by prior referral rate and randomized 2:1 to intervention or control groups. The intervention system was developed with GPs and disseminated using passive and active strategies. Baseline and followup outcome data were collected from GPs and patients. Concurrent economic evaluation was conducted. Analysis was by intention to treat.

Clinic trial: Two independent randomized controlled equivalence trials in different UK health service locations. Eligible, newly referred patients were randomized 2:1 to intervention (nurse counselor) or control (clinical geneticist). Patient outcome data were collected at baseline, immediately following, and 6 months after the referral episode. Data were collected from referring GPs. Primary equivalence analysis was by intention to treat, with sensitivity analysis by treatment received (per protocol). Concurrent economic evaluation was conducted.

Further research/reviews required

Primary care trial: Future evaluations must identify and address barriers to using computer based systems and clarify the relative importance of the system characteristics themselves, their integration into practice routines, and implementation strategies.

Clinic trial: Replication in other settings would provide reassurance of generalizability. Other models of nurse-based assessment, eg, in outreach clinics, should be evaluated.