

A randomized controlled trial of a brief self-help coping intervention designed to reduce distress when awaiting genetic risk information

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Abstract

Objective: The aim of this study was to evaluate the effectiveness of a distraction-based coping leaflet in reducing distress in women undergoing genetic risk assessment for breast/ovarian cancer. **Method:** One hundred sixty-two women participated in a randomized controlled trial, receiving either the intervention or standard information. Data were collected through a postal questionnaire at entry into a genetic risk assessment programme and 1 month later. **Result:** Analysis of covariance revealed a nonsignificant reduction in distress in all women, and a significant reduction

of distress among those with high baseline stress, who received the intervention. No gains were found among the control group. Measures of emotional response while thinking about cancer genetic assessment suggested these benefits were achieved in the absence of any rebound emotional response. **Conclusion:** The intervention offers a low-cost effective coping intervention, which could be integrated into existing services with minimal disruption and may also be appropriate for other periods of waiting and uncertainty.

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Introduction

Many medical procedures, such as prenatal screening, HIV testing, or genetic risk assessment result in the provision of potentially negative health information. While the receipt of such information can be emotionally challenging, waiting for it can be equally difficult. The frequency with which such procedures occur and the short duration of some waiting times, varying between hours and weeks, mean that any attempts to moderate distress at such times needs to be brief, focussed, and capable of delivery without direct therapeutic contact.

The present study investigated the effectiveness of an intervention designed to reduce distress during one such period of medical uncertainty: while waiting for the results of cancer genetic risk assessment. Services such as the Cancer Genetics Service for Wales (CGSW) provide information

about an individual's risk of developing familial cancer and appropriate advice about risk management options [1,2]. The process involves estimation of an individual's genetic risk of developing cancer, based on a detailed assessment of their family history of cancer and other risk factors. Obtaining and analysing this information can take several weeks. There is evidence to suggest that this "waiting period" may create distress for a significant minority of patients [1–4], who may benefit from some degree of psychological support at this time. One earlier study of the service reported here [1], for example, noted that 25% of women undergoing risk assessment experienced clinical levels of anxiety during the waiting period. Currently, no interventions have specifically targeted this period of waiting and uncertainty, prior to the receipt of genetic risk information. The few interventions that have been reported in this, or similar, populations have focused on attempts to reduce distress following identification of a genetic risk or in populations related to individuals diagnosed with cancer [5–8].

According to the transactional theory of stress and coping [9] and coping effectiveness training [10], how well any type

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of coping strategy reduces distress depends upon the “goodness of fit” between the chosen strategy and the demands of the situation. When faced with periods of uncertainty, strategies aimed at minimising any emotional distress are likely to be more effective than those aimed at changing the nature of the stressor. One simple strategy for achieving this, involving active distraction from unwanted distressing thoughts, has been found to significantly reduce physical and psychological distress in patient groups faced with short-term pain and health problems [11–13]. Wells and Matthews [14] have also found this approach to be of benefit in people with mental health problems. Accordingly, the intervention used in the present study comprised a short leaflet which encouraged individuals to limit any consideration of issues related to their risk assessment for clearly defined periods of time (e.g., 10–15 min) each day, should they choose to do so, and to actively distract from any intrusive thoughts at all other times. This approach was considered appropriate at this stage of risk assessment, as participants had no information on which to base more active coping strategies. Nevertheless, it did not prevent anticipatory planning or other relevant actions, should participants choose to do so.

The primary objective of the study was to compare levels of intrusive thoughts and attempts at their avoidance in women undergoing assessment of genetic risk for breast and/or ovarian cancer who did, and did not, receive the leaflet. It was hypothesized that those who received the leaflet would report lower levels of intrusive worries whilst waiting for genetic risk information than those who received standard information. A concern was that such avoidance may have one adverse effect. Thinking about an issue, while unpleasant, may allow the individual to habituate to the distress associated with those thoughts: a process denied those who avoid them. We attempted to minimize the risk of this process by suggesting that participants did think, to a limited extent, about issues related to their risk assessment process, should they wish to do so. However, we considered it important check that, if participants in the active intervention condition reported less frequent worries, they did not, paradoxically, experience more distress than those in the control group when they *did* think about issues related to their genetic risk assessment. For the intervention to be considered successful, participants in the intervention condition needed to both experience less intrusive worries about their cancer genetic risk assessment *and* to have no greater negative emotional response while thinking about the process and its implications than those in the control condition.

Method

The CGSW

Participants were women being assessed for genetic risk of breast and/or ovarian cancer in the CGSW. In this,

participants receive a letter explaining the nature of the service and a request to complete a detailed family history questionnaire (FHQ). The completed questionnaire is reviewed and the individual assigned a broad level of risk (high, moderate, population). After assessment, patients are informed of their risk level by telephone and letter, following which, they are offered a number of different outcomes depending on the level of risk assigned [1]. Completion, return, and assessment of the FHQ usually takes at least 6 weeks and can be several weeks longer than this.

Participants

Eligible participants were referred into the Cardiff area of the CGSW between February and December 2003 for assessment of genetic risk for breast and/or ovarian cancer.

Randomization

Potential participants were prerandomized to an intervention group (coping leaflet) or control group (standard care). This strategy was adopted for two key reasons: (i) the time frame between entry into the service, and preresult assessment (see below) was limited and would have been even shorter if participants had to respond to a request (and potentially a subsequent reminder) to take part in the study; (ii) we wanted participants to engage in the intervention as soon as they entered the genetic risk assessment process. This is what would occur were the intervention to be used routinely within the cancer genetics service and ensure that an effective intervention could prevent the establishment of high levels of worry in the early stages of waiting for risk information.

Randomization sequences were generated by an independent statistician using computerized random number generators. Block randomization was used to ensure equal numbers in each group. The lead researcher (C.P.) allocated randomization codes to study packs for new referrals on a weekly basis. Clinical staff remained blind as to the group into which patients were randomized. Participants with a personal history of cancer were stratified across study groups.

Procedure

Participants were asked to complete a postal questionnaire on two occasions: upon referral (baseline) and 4–6 weeks after referral (follow-up), while they were still waiting for familial risk information. Information about the study was distributed alongside standard information sent to new referrals. For both study groups, the information pack indicated to which group the individual had been randomized and included the baseline assessment questionnaire. Women who agreed to participate in the study were asked to return their completed consent form and questionnaire. For women randomized to the intervention group, the

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