



A randomised 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 randomised 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. © 2007 Published by Elsevier Inc.

Keywords: Randomised controlled trial; Distress; Psychological intervention; Uncertainty

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 of coping strategy reduces distress depends upon

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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 hypothesised 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 minimise 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.

Randomisation

Potential participants were prerandomised 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.

Randomisation sequences were generated by an independent statistician using computerised random number generators. Block randomisation was used to ensure equal numbers in each group. The lead researcher (C.P.) allocated randomisation codes to study packs for new referrals on a weekly basis. Clinical staff remained blind as to the group into which patients were randomised. 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 randomised 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 randomised to the intervention group, the

study pack also contained the leaflet in a separate sealed envelope. Participants were instructed not to open this envelope until the baseline questionnaire had been completed and returned.

The intervention

The two-page leaflet gave a short introduction to the principles of distraction and examples of distraction techniques and how to use them. It encouraged participants to plan what distraction strategies they would use and when. Finally, it suggested participants allow themselves a set period within the day to think about their concerns, should they choose. They were encouraged to use distraction at all other times when experiencing unwanted intrusive thoughts. The leaflet had a Flesch [15] readability statistic of 67.4, which is at the upper end of the range of ease of reading for documents and, according to Wikipedia, slightly above that of the Reader's Digest. The leaflet was positively received in preliminary focus groups [16].

Measures

Demographic data collected included age, marital status, education level and number of children. Data were also collected on method of referral and participants' prior knowledge of their family history of cancer.

The primary outcome was the Impact of Event Scale (IES) [17], which comprises two subscales that can be combined to provide a global distress score. The intrusion subscale (Cronbach's $\alpha=.90$) measured the frequency of intrusive thoughts concerning undergoing cancer genetic risk assessment. The avoidance subscale (Cronbach's $\alpha=.90$) measured the frequency of avoidance behaviours. A second measure involved a series of 10-point Likert scales measuring the degree to which 16 emotions, both positive and negative, were experienced when participants thought about their genetic assessment and its implications. Only six scales (hopeful, anxious, challenged, tranquil, relief, fear) achieved scores above 1 at baseline and are reported here.

Analysis

The IES scores were not normally distributed, with 17.8% ($n=28$) of participants scoring zero at baseline. To deal with this large floor effect, participants scoring zero at baseline were filtered out of the analysis. Raw IES scores for the remaining participants were then transformed to produce a more normal distribution, using logarithm transformations suitable for positively skewed data. Levels of global distress across study groups at follow-up were then compared using analysis of covariance (ANCOVA), with baseline scores as the covariate. A planned subgroup analysis was conducted on participants in each study group reporting high levels of distress upon referral. The cutoff

scores used to identify "high-distress" participants was that recommended by Horowitz [18]: 19 or over on the global IES scale and the equivalent scale scores for intrusion and avoidance. The scale scores of the emotions were significantly skewed and resisted transformation. Accordingly, these data were analysed by using Mann–Whitney U tests to compare change scores in the intervention and control groups.

Results

Participant flow and follow up

In total, 471 new referrals were invited to participate in the study over a 10-month period: 239 were randomised to receive the intervention and 232 received the standard information. Of these, 139 and 129 women entered CGSW by returning their completed FHQ. Amongst those who entered CGSW, 86 baseline questionnaires were returned from those allocated to receive the intervention, and 76 baseline questionnaires were returned from those receiving the standard information: a response rate among those expected to enter the study of 61.9% and 58.9%, respectively. Five participants in the intervention group (5.8%) and seven in the control group (9.2%) had a known

Table 1

Baseline comparison of follow-up completers and noncompleters

	Follow-up Completers [<i>n</i> (%)]	Follow-up completers [<i>n</i> (%)]	Noncompleters		
			χ^2	<i>df</i>	<i>P</i>
Study group					
Intervention group	51 (51.5)	33 (56.9)	.24	1	.63
Control group	48 (48.5)	25 (43.1)			
Age ^a (categorical)					
Under 40 years	35 (35.7)	27 (47.4)	1.58	1	.21
Over 40 years	63 (64.3)	30 (52.6)			
Marital status					
Married or cohabiting	71 (72.4)	41 (71.9)			
Separated/divorced	10 (10.2)	11 (19.3)	4.28	4	.37
Single	15 (15.3)	4 (7.0)			
Widowed	2 (2.0)	1 (1.8)			
Highest qualifications ^a					
O-level or equivalent	38 (38.8)	24 (42.1)			
A-level of equivalent	6 (6.1)	4 (7.0)			
Clerical/commercial	4 (4.1)	6 (10.5)	5.0	4	.29
None	18 (18.4)	12 (21.1)			
Other	4 (4.1)	2 (2.2)			
Children ^a					
At least 1 child	72 (72.7)	47 (81.0)	3.12	4	.54
No children	27 (27.3)	11 (19.0)			
Referral initiated by:					
General practitioner	34 (34.3)	23 (39.7)	.52	3	.91
Self	25 (25.3)	12 (22.4)			
Hospital doctor	23 (23.2)	12 (21.4)			
Other	17 (17.2)	10 (17.9)			

^a Cells collapsed as expected frequency is less than 5 in at least 20% of cells.

history of cancer upon referral. At follow-up, 53 participants in the intervention group and 51 in the control group returned their questionnaires: a follow-up response rate of 61.6% and 67.1%, respectively. Five protocol deviations, who were notified of their risk before returning their follow-up, were excluded from the analysis. For the main trial analysis, the number of eligible participants in the intervention group was therefore 51, with 48 in the control group.

Participation bias

As shown in Table 1, there was no differential dropout between those in the intervention and control groups and no significant differences between follow-up completers and noncompleters on demographic variables. Independent *t* tests on the transformed IES scores revealed significantly higher IES avoidance scores [$t(-2.05)$, $df=154$, $P=.04$] amongst women who did not return the follow-up questionnaire (mean=8.24) than those who remained in the study (mean=11.44).

Sample characteristics

There were no baseline differences between study groups on any of the demographic or psychological outcome measures used. The majority of participants ($n=63$) were over 40 years of age, married or cohabiting ($n=71$), educated to at least secondary level ($n=76$) and had at least one child ($n=70$). Sixty-five percent of women ($n=64$) had been referred by their general practitioner, and 25% ($n=25$) stated that they had initiated the referral. The small number of participants with a personal history of cancer across both groups (intervention=5, control=7) meant that it was not possible to analyse this variable.

The impact of the intervention

Over 95% of people in the intervention group reported reading the leaflet at least once; many reported reading it

Table 3
Emotion scores at baseline and follow-up

Emotions (score range 0–9)	Intervention ($n=51$)		Control ($n=48$)		Between-groups analysis of change scores	
	Time 1	Time 2	Time 1	Time 2	<i>Z</i>	<i>P</i>
	Median	Median	Median	Median		
	(IQR)	(IQR)	(IQR)	(IQR)		
Hope	6.0 (3)	6.5 (3)	5.0 (4)	5.0 (4.8)	-.02	.99
Anxiety	4.0 (5)	2.0 (4)	5.0 (5)	3.0 (5)	-.10	.92
Challenge	5.0 (6)	3.0 (4)	3.5 (5)	3.0 (4.5)	-.93	.36
Interest	6.0 (4)	6.0 (4)	6.0 (4)	5.0 (4)	-.38	.71
Tranquillity	3.0 (5)	5.0 (7)	2.0 (4)	4.0 (4.5)	-.71	.48
Relief	5.0 (5)	4.0 (5.3)	5.0 (5)	4.0 (5.5)	-.03	.97
Gratitude	5.0 (6)	5.0 (7.0)	6.0 (6)	5.0 (6.5)	-1.30	.20
Fear	3.0 (4)	1.0 (4.0)	4.0 (5.8)	3.0 (4)	-.35	.73
IQR, interquartile ratio.						

on more occasions. Significantly less participants reported using the strategies described in it. However, the meaning of this response is not clear. Although we intended to ask about the use of distraction strategies in general, it is possible that at least some respondents were referring to the specific strategies used as examples in the leaflet, did not use them, but did use *different* distraction strategies. We suggest this on the basis that a number of respondents denied using the distraction strategies described in the leaflet but, in a free text box, spontaneously reported the use of distraction techniques as one of the coping strategies used to help them cope with the waiting period.

Means and standard deviations for both the whole study and high-distress population are reported in Table 2. ANCOVA revealed that, for participants reporting at least some level of distress at baseline, there was no significant difference between study groups on follow-up global distress scores after adjusting for baseline global distress scores [$F(1,72)=1.20$, $P=.28$]. However, 16 participants in the intervention group and 19 participants in the control group (35.4% of the main trial sample) fell into the high-distress subgroup. Analyses on these data revealed a significant difference between the two groups on levels of global distress at follow-up, with participants in the intervention group having lower distress scores than those in the control group [$F(1,32)=6.10$, $P=.02$, partial eta squared=.16]. The equivalent analyses on the individual intrusion and avoidance subscales of the IES also revealed significant differences between levels of intrusive thoughts [$F(1,34)=5.86$, $P=.02$, partial eta squared=.15] and avoidance of these thoughts [$F(1,31)=5.07$, $P=.03$, partial eta squared=.14] between the intervention and control groups. Measures of emotional responses while thinking of the assessment process did not change differentially across groups or time (see Table 3).

Table 2
IES scores at baseline and follow-up for both the total and high distress subgroups

	Mean (S.D.)		Mean (S.D.)	
	Time 1	Time 2	Time 1	Time 2
Total scores				
IES, intrusion				
Intervention	7.00 (8.38)	4.50 (6.73)	16.38 (8.55)	9.19 (8.91)
Control	9.06 (9.68)	7.50 (8.55)	16.00 (8.94)	13.89 (8.90)
IES, avoidance				
Intervention	7.43 (9.18)	6.43 (7.77)	18.88 (6.96)	11.50 (7.61)
Control	9.10 (10.52)	8.42 (10.19)	17.89 (9.82)	17.05 (9.94)
IES, total				
Intervention	14.43 (16.21)	10.93 (13.01)	35.25 (11.90)	20.69 (14.86)
Control	18.17 (19.56)	15.92 (17.88)	33.89 (17.45)	30.94 (17.47)

314 **Discussion**

315 This low cost and easily implemented self-help inter-
 316 vention proved effective among women reporting high
 317 levels of distress following referral for cancer genetic risk
 318 assessment. Levels of distress among the cohort were
 319 similar to those reported in a previous cohort within the
 320 same service and in other similar cohorts [1,2,4]. Just over
 321 a third of women reported high levels of distress in the
 322 form of intrusive thoughts about undergoing cancer genetic
 323 risk assessment and avoidance of these thoughts. Subgroup
 324 analysis of this high-distress group showed the intervention
 325 to result in a significantly lower of intrusive thoughts and
 326 attempts to avoid such thoughts during the waiting period
 327 between referral and notification of risk. That said, the
 328 differentially high dropout from the study of women who
 329 were scoring high on the IES avoidance scale at baseline
 330 means that we cannot be sure that the intervention would
 331 be of value to individuals already using high (and perhaps
 332 excessive) levels of avoidance as a coping strategy. The
 333 finding that participants in the intervention group experi-
 334 enced both a reduction in levels of intrusive thoughts and
 335 in avoidance of such thoughts may appear counterintuitive.
 336 However, this was expected. We would expect an increase
 337 in avoidance in the early phases of the intervention, as
 338 participants actively attempt to distract from their worries.
 339 Once such worries have been effectively countered, then
 340 the effort required is reduced. Our expectations were,
 341 therefore, that effective implementation of the distraction
 342 would result in both a reduction in the frequency of
 343 worries and attempts at their avoidance by the time of the
 344 follow-up measure.

345 These findings suggest that the intervention is appro-
 346 priate for individuals who experience distress whilst waiting
 347 for potentially adverse personal health information. The
 348 failure of the coping leaflet to impact on the cohort as a
 349 whole is understandable when considering the overall low
 350 levels of reported distress. Individuals with low levels of
 351 distress are unlikely to benefit from or make use of an
 352 intervention designed to reduce distress. Of note also was
 353 that there was no difference between the groups on the
 354 emotion scores in response to thinking about the assessment
 355 process and its implications, either before or after the
 356 intervention. Accordingly, there was no evidence of any
 357 rebound anxiety effect as a consequence of successful
 358 avoidance of thinking about the assessment process. As
 359 noted in the introduction, for the intervention to be
 360 considered successful, participants in the intervention
 361 condition needed to both experience less intrusive worries
 362 about their cancer genetic risk assessment *and* to have no
 363 greater negative emotional response while thinking about
 364 the process than those in the control condition. These
 365 criteria seem to be met, at least in the short term. Longer-
 366 term follow-up is required to assess the impact of this
 367 process when individuals receive risk information. How-
 368 ever, it appears that the time-limited thinking about issues

and avoidance of unwanted worries may have provided an
 opportunity for participants to prepare and habituate to the
 implications of any adverse risk information, while at the
 same time minimising levels of unwanted worries and
 distress [19,20].

As in the present study, previous and ongoing research
 of women taking part in the CGSW [1,21] has also found
 that only participants who returned their FHQ and,
 therefore, participated in the risk assessment process, are
 willing to take part in research programmes. These
 individuals were therefore the focus of the analyses,
 limiting the generalisability of the findings to people who
 engage in the process of assessment and excluding those
 who disengage from the process. Of note also is that the
 cohort was not followed up after risk provision. There is a
 need for a fully-powered Phase III randomised control trial
 [22] to identify the active components of the intervention
 and to assess the impact of the intervention on longer-term
 psychological outcomes. Despite these provisos, the sig-
 nificant reduction in distress experienced by women in the
 high-distress group suggest the potential for this interven-
 tion to benefit women undergoing cancer genetic risk
 assessment, as well as individuals undergoing other periods
 of waiting and uncertainty, such as awaiting breast disease
 diagnosis [23] or recall for screening [24,25]. The benefit
 of the coping leaflet over existing interventions [6,7,8] is
 that it can be easily administered to all individuals waiting
 for potentially negative health information, with minimal
 cost and disruption.

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