|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **Current Review** | | | | | | |
| Albada et al., 2016125  NA | Risk perception | To report on a study of the counselees' expressed understanding as a response to the risk estimate and surveillance recommendation and whether they express surveillance intentions in the final consultation for breast cancer genetic counseling. | Before and after | Eligible: NR  Enrolled: Unclear, only reported for whole group, not unaffected women only  Analyzed: 89 | The Netherlands | Consecutive new counselees seen at the department of Medical Genetics of the University Medical Centre Utrecht (UMCU). |
| **2013 Review** | | | | | | |
| Armstrong et al., 2005126  Good | Cancer worry  Attitudes | To assess the association between race and use of genetic counseling for *BRCA1/2* testing among women at risk of carrying a *BRCA1/2* mutation and to evaluate the potential contributions of socioeconomic characteristics about genetic testing, and interactions with primary care physicians to this association. | Case-control | Eligible: NR Enrolled: NR Randomized: NR Analyzed: 408 (217 cases, 191 controls) | U.S. | Visit to University of Pennsylvania Health System **Cases:** women from reference population who presented for genetic counseling, mean age 42.5 years, 29% Jewish  **Controls:** random sample of women from reference population, mean age 53.1 years, 11% Jewish |

| **Author, year**  **Quality** | **Demographics** | I**nclusion and exclusion criteria** | **Risk level definition** |
| --- | --- | --- | --- |
| **Current Review** | | | |
| Albada et al., 2016125  NA | Only unaffected women  Mean age (years): 37.9 (SD 10.6) | Inclusion: Female counselees aged ≥18 years who were the first of their first degree family members to seek breast cancer genetic counseling.  Exclusion: Lack of internet or email access. | 39.3% population risk (<20% lifetime risk)  47.2% moderate risk (20-30% lifetime risk)  13.5% high risk (≥30% lifetime risk) |
| **2013 Review** | | | |
| Armstrong et al., 2005126  Good | **Cases vs. controls**  Mean age (years): 42.5 (range: 19 to 66) vs.53.1 (range: 20 to 89)  Race/ethnicity  Black: 7.4% vs. 29%  Asian American: 3.3% vs. 3.2%  White: 85% vs. 66%  Hispanic: 0% vs. 2.1%  Other: 4.6% vs. 0%  Religious heritage  Jewish: 29% vs. 11%  Christian: 52% vs. 60%  Other: 13% vs. 13%  NR: 5.9% vs. 16% | Inclusion: Women aged 18-80 years, seen a primary care physician within the University of Pennsylvania Health System in the 3 years prior to the start of the study, and with FDR or SDR with a breast or ovarian cancer diagnosis  Exclusion: Personal diagnosis of breast or ovarian cancer, identified as being unable to participate because of illness or mental incapacity by their primary care physician.  Controls: previously participated in *BRCA1/2* genetic counseling | FDR or SDR with a breast or ovarian cancer diagnosis |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Interventions** | **Measures** | **Duration of followup** |
| **Current Review** | | | |
| Albada et al., 2016125  NA | Dutch Breast Cancer guidelines, personal risk estimate (if enough data was available), no other information described | Risk perception alignment with counselor | 2008 to 2010  1 year |
| **2013 Review** | | | |
| Armstrong et al., 2005126  Good | A) Genetic counseling prior to testing, otherwise not described  B) Controls | None | 1999 to 2003  Not applicable |

| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| --- | --- | --- | --- |
| **Current Review** | | | |
| Albada et al., 2016125  NA | **Accurate vs. overestimation vs. underestimation**  Immediately after counseling (n=70): 48.6% vs. 38.6% vs. 12.9%  -Population-risk (n=28): 53.6% vs. 46.4% vs. 0  -Moderate-risk (n=32): 37.5% vs. 43.8% vs. 18.8%  -High-risk (n=8): 62.5% vs. 0 vs. 37.5%  1 year after counseling (n=78): 34.6% vs. 55.1% vs. 10.3%  -Population-risk (n=30): 26.7% vs. 73.3% vs. 0  -Moderate-risk (n=38): 36.8% vs. 55.3% vs. 7.9%  -High-risk (n=8): 50% vs. 0 vs. 50% | A large percentage of counselees overestimated their risk post counseling. Expressed understanding of risk estimate during counseling appointments was not associated with postcounseling risk perception alignment. Significant decrease in accurate risk perception in the year post counseling might indicate that counselees' perception of their risk drifts further away from the risk estimate given by the counselor. | Grant from the Dutch Cancer Society (Nivel 2010-4875) |
| **2013 Review** | | | |
| Armstrong et al., 2005126  Good | **Logistic regression model of association between race and use of genetic counseling: OR (95% CI)**  -Black (vs. White): 0.28 (0.09 to 0.89)  -Increased age: 0.97 (0.93 to 0.99)  -Increased probability of BRCA mutation: 1.25 (1.10 to 1.42)  -Increased risk perception for breast cancer: 2.88 (1.98 to 4.21)  -Increased risk perception for ovarian cancer: 1.56 (1.02 to 2.38)  -Increase ovarian cancer worry: 1.56 (1.02 to 2.38)  -Belief that testing leads to discrimination: 0.74 (0.57 to 0.96)  -Increased belief that testing provides reassurance: 1.60 (1.15 to 2.23)  -Gynecologist discussed BRCA testing: 1.79 (1.02 to 3.13)  -PCP discussed BRCA testing: 1.93 (1.00 to 3.74)  -NS associations: marital status, education, income, health insurance, increased breast cancer worry, belief that testing provides information, belief that testing creates anxiety, and number of visits to gynecologist or PCP | Blacks are less likely to undergo genetic counseling than Whites. Women who believe testing is likely to lead to discrimination were not likely to undergo genetic counseling. Older women were less likely to undergo genetic counseling than younger women. Women with an increased risk perception for either breast or ovarian cancer were likely to undergo genetic counseling. | The American Cancer Clinical Research Training Grant and the Robert Wood Johnson Generalist Physician Faculty Scholar Award |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **2013 Review** | | | | | | |
| Bennett et al., 2008127  NA | Psychological | To examine the relationship between measures of anxiety and depression and a number of variables identified to be associated with distress | Before and after | Eligible: 367  Enrolled: 319  Analyzed: 128 | U.K. | Women referred for genetic risk assessment to a large Cancer Genetics Service for Wales (CGSW) center |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Demographics** | **Inclusion and exclusion criteria** | **Risk level definition** |
| **2013 Review** | | | |
| Bennett et al., 2008127  NA | Mean age of 43.3 years | Inclusion: Women undergoing assessment for risk of breast/ovarian cancer at the CGSW and who completed followup questionnaires  Exclusion: Did not complete risk assessment process before the end of the study | 23% low-risk  45% moderate-risk  31% high-risk |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year Quality** | **Interventions** | **Measures** | **Duration of followup** |
| **2013 Review** | | | |
| Bennett et al., 2008127  NA | CGSW referral guidelines and BRCAPRO risk calculation model | DUKE Social Support Questionnaire (DUKE- SSQ, scale 1 to 5)  Hospital Anxiety and Depression Scale (HADS, subscales 0 to 21)  Perceived health Quality of Life  Impact of Events Scale (IES, subscales 0 to 28)  Medical Coping Modes Questionnaire (MCMQ, scale NR) | Years: NR  1 week following risk notification |

| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| --- | --- | --- | --- |
| **2013 Review** | | | |
| Bennett et al., 2008127  NA | **Baseline vs. followup after risk assessment**  Mean scores (SE)  HADS-D: 4.44 (3.77) vs. 4.05 (3.85); NS  HADS-A: 8.02 (4.56) vs. 7.03 (4.41); NS  IES-I: 13.17 (10.57) vs. 7.76 (8.95); p<0.001  IES-A: 12.19 (10.78) vs. 8.45 (9.61); p<0.01  Perceived health, quality of life (scale 0 to 100): 76.74 (20.10) vs. 77.96 (17.68); p<0.05  DUKE-SSQ (scale not described): 27.15 (11.93) vs. 24.97 (11.02); p<0.01  **Correlations between key independent variables and HADS-A vs. HADS-D**  Age, level or risk assigned, and MCMQ-confrontation were not significant  IES-I: 0.703 (p<0.01) vs. 0.448 (p<0.01)  IES-A: 0.636 (p<0.01) vs. 0.365 (p<0.01)  DUKE-SSQ-confidant: 0.364 (p<0.01) vs. 0.493 (p<0.01)  DUKE-SSQ-affective: 0.375 (p<0.001) vs. 0.411 (p<0.01  Perceived health: -0.493 (p<0.01) vs. -0.664 (p<0.01)  Hopeless about getting cancer: 0.389 (p<0.01) vs. 0.366 (p<0.01)  Hopeless about health: 0.374 (p<0.01) vs. 0.197 (p<0.05)  Control over getting cancer: -0.372 (p<0.01) vs. 0.175 (NS)  MCMQ-avoidance: 0.429 (p<0.001) vs. 0.271 (p<0.01)  MCMQ-acceptance-resignation: 0.383 (p<0.01) vs. 0.206 (p<0.05)  Neuroticism: 0.265 (p<0.01) vs. 0.193 (p<0.05) | Following risk status disclosure women did not have changes in their level of anxiety or depressed, as measured by the HADS, their intrusive thoughts and avoidance of intrusive thoughts declined after notification, while their perceived quality life of health and satisfaction increased. This indicates the level or risk disclosed does not negatively impact women's psychological well being. | Not reported |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **2013 Review** |  |  |  |  |  |  |
| Bennett et al., 2009128  NA | Cancer worry  Psychological | To explore the relationship between a number of factors hypothesized to be associated with the frequency of intrusive worries close to the time women were informed of their genetic risk for developing breast and/or ovarian cancer | Before and after | Eligible: 221  Enrolled: 221  Analyzed: 128 | U.K. | Women referred for genetic risk assessment to a large Cancer Genetics Service for Wales (CGSW) center |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Demographics** | **Inclusion and exclusion criteria** | **Risk level definition** |
| **2013 Review** |  |  |  |
| Bennett et al., 2009128  NA | Mean age of 44.3 years (SD 10.81; range: 18 to 76) | Inclusion: Women undergoing assessment for risk of breast/ovarian cancer at the CGSW and who completed followup questionnaires  Exclusion: Did not complete risk assessment process before the end of the study | 30/128 (23.4%) at population-risk  61/128 (47.7%) at moderate-risk  37/128 (28.9%) at high-risk |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Interventions** | **Measures** | **Duration of followup** |
| **2013 Review** |  |  |  |
| Bennett et al., 2009128  NA | CGSW referral guidelines and BRCAPRO risk calculation model | DUKE Social Support Questionnaire (DUKE- SSQ, scale 1 to 5)  Impact of Events Scale (IES, subscales 0 to 28)  Medical Coping Modes Questionnaire (MCMQ, scale NR) | Years: NR  Approximately 5 to 7 weeks |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| **2013 Review** |  |  |  |
| Bennett et al., 2009128  NA | **Baseline vs. followup after risk assessment**  IES-I (estimated from graph)  High-risk: 12.5 vs. 7.8 (p<0.001)  Moderate-risk: 12.5 vs. 7.9 (p<0.001)  Low-risk: 11.8 vs. 8.2 (p<0.001)  Between group differences were not significant (p=0.694)  IES-A (estimated from graph)  High-risk: 13.1 vs. 8.3 (p<0.05)  Moderate-risk: 10.6 vs. 8.9 (p<0.05)  Low-risk: 10 vs. 11.3 (p<0.05)  Between group differences for low risk vs. moderate and high-risk was significant (p<0.05)  **Key variables associated with IES intrusion scores**  Cognitive response  Control over risk for cancer: -0.279 (p<0.001)  Hopelessness about developing cancer: 0.412 (p<0.001)  Emotional response to risk information  Hopeful: -0.331 (p<0.001)  Relieved: -0.278 (p<0.001)  Calm: -0.506 (p<0.001)  Anxious: 0.438 (p<0.001)  Social support  Confidant support: 0.232 (p<0.01)  Affective support: 0.208 (p<0.05)  Coping  Confrontation: 0.284 (p<0.001)  Avoidance: 0.442 (p<0.001)  Acceptance-resignation: 0.391 (p<0.001)  Variables not associated with IES intrusion scores: age, risk status, and surprised emotional response to risk information  Similar results were found for IES avoidance scores. | Levels of worry fell among all women following risk assessment, regardless of risk status assignment. Only women with low (population) risk had high frequencies of avoidance after risk assessment. Intrusive worries were associated with a lack of confidant support and a confrontive coping response. | Not reported |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **2013 Review** |  |  |  |  |  |  |
| Bloom et al., 2006129  Poor | Risk perception  Cancer worry  Health behaviors | To compare women in a telephone counseling intervention to controls and determine whether perceived risk would be more consistent with objective risk; and whether there would be reduction in breast cancer worries, improvement in health protective behaviors, and an increase in breast cancer screening. | RCT | Eligible: NR  Enrolled: 163  Randomized: 163 (80 in intervention, 83 in control) Analyzed: 149 (71 in intervention, 78 in control) | U.S. | Sisters of women diagnosed with breast cancer at age ≤50. Predominantly Euro-American, well-educated, and substantial majority receive regular breast cancer screening. |
| Bowen et al., 200266  Fair  Same population as Bowen et al., 200471 | Interest in genetic testing | To test the effects of breast cancer risk on interest in genetic testing in women who have a family history of breast cancer. | RCT | Eligible: 561  Enrolled: 357  Randomized: 357 (120 to genetic counseling, 114 to psychosocial group, 123 to delayed counseling) Analyzed: 317 (105 to genetic counseling, 103 to psychosocial, 109 to delayed counseling) | U.S. | Women recruited from the Seattle area-- see Bowen et al, 1999. All volunteered after seeing a notice, hearing about the study from a network or through a relative with cancer. |

| **Author, year**  **Quality** | **Demographics** | **Inclusion and exclusion criteria** | **Risk level definition** |
| --- | --- | --- | --- |
| **2013 Review** |  |  |  |
| Bloom et al., 2006129  Poor | Mean age of 47.4 years (SD 7.2)  77% Euro-American  6.1% Black  9.2% Latina  8.0% Asian/Other | Inclusion: Not reported  Exclusion: Prior breast cancer | All had ≥1 FDR (sister) with breast cancer diagnosis ≤ age 50 |
| Bowen et al., 200266  Fair  Same population as Bowen et al., 200471 | Psychological counseling arm:  Mean age of 41.9 years (SD 11.3)  90% White, non Hispanic  3.5 % White, Hispanic 0.9% Black  2.6% Asian or Pacific Islander  1.8% Native American  0.9% Multiracial  Genetic counseling arm:  Mean age of 42.8 years (SD 11.8)  94% White, non Hispanic  0.0% White, Hispanic  0.8% Black  1.7% Asian or Pacific Islander  1.7% Native American  1.7% Multiracial  Control arm:  Mean age of 42.4 years (SD 11.5)  93% White, non Hispanic  0.0% White, Hispanic  2.5% Black  3.3% Asian or Pacific Islander  0.0% Native American  0.8% Multiracial | Inclusion: Women aged 18 to 74, lived within 60 miles of research center, agreed to participate in counseling & complete questionnaires, and had ≥1 relative affected by breast cancer  Exclusion: Lack of family history of breast cancer, age outside the 18 to 74 range, more than one close relative affected by breast cancer, living outside the catchment area and lack of interest in completing the study | **Family history:** Close relatives affected by breast cancer included grandmothers, mothers, sisters, and aunts  **Risk level:** Gail and Claus scores, along with population data |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author, year**  **Quality** | **Interventions** | **Measures** | | **Duration of followup** | |
| **2013 Review** |  | |  | |  |
| Bloom et al., 2006129  Poor | 1. Telephone counseling from a master's level counselor within 2 weeks; breast cancer worries measured by 4-point Likert scale; perceived risk measured on 5-point scale; rating chances of diagnosis (0 to 100%). Telephone counseling session included: establishment of rapport and determination of special concerns, emotional readiness; risk notification by providing modified Gail model lifetime risk estimate and discussing in terms of her pre-test self-assessment of risk; de-escalation of tension regarding breast cancer checkup; evaluation of coping skills, reinforcement of problem solving and coping skills; information on health protective behaviors; early detection through American Cancer Society screening; and information on genetic testing when requested. 2. Delayed telephone counseling following the post-test | NSI: 3-item measure of breast cancer worry: perceived risk of breast cancer, health behaviors, and breast cancer screening | | 1999 to 2002  6 months | |
| Bowen et al., 200266  Fair  Same population as Bowen et al., 200471 | 1. IGC: Phone call to review pedigree information followed by a single 2-hour counseling session. Subject given information on her own risk for breast cancer using Gail and Claus scores along with population data. Information given on genetic testing, current knowledge about nonhereditary risk factors, and current screening techniques. Summary letter provided. 2. PGC: Four, 2-hour group meetings with 4 to 6 women led by a health counselor. Included: risk assessment and perception, education, stress management, problem-solving and social support. Personal risk for breast cancer, interpretation and appropriate screening provided privately to subjects. 3. CG: Offered choice of counseling modality after the final followup. | NSI: 3-item questionnaire to assess awareness, candidacy, and interest in genetic testing  Tolerance for ambiguity assessed using a questionnaire derived from previous research  5-point response scale to beliefs about genetic testing | | Years: NR  6 months | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| **2013 Review** |  |  |  |
| Bloom et al., 2006129  Poor | Women overestimated their risk of breast cancer by an average of 25 percentage points; proportion of women underestimating risk was larger in women with perceived lower risk (40%) than those who perceived it as the same (16%) or higher (10%) or much higher (5%) than the risk of other women (p=0.009)  Women reduced their overestimation more if the initial overestimate was higher (p<0.0001); and intervention effect was significant only in women aged 50 years and over (p=0.004) | Telephone counseling appears to reduce risk overestimates in women with higher than average risk and to promote healthy behaviors in sisters of women with breast cancer. | Grant 4EB-5800 from the California Breast Cancer Research Program |
| Bowen et al., 200266  Fair  Same population as Bowen et al., 200471 | Counseling on risk slightly changed levels of interest in genetic testing in women with a family history. Those who participated in counseling were less interested in genetic testing and less likely to view themselves as good candidates. Stigma and access beliefs about genetic testing were related to the effect of counseling on whether women thought they should participate in testing. As women gained more information, they were slightly less likely to want to participate in testing. | Individual counseling was more predictive of women's increased awareness than psychosocial group counseling. | The National Cancer Institute and the National Human Genome Institute (HG01190) |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **2013 Review** |  |  |  |  |  |  |
| Bowen et al., 200471  Fair  Same population as Bowen et al., 200266 | Cancer worry Psychological factors  Risk perception | To test the effects of two types of breast cancer risk counseling (group psychosocial or individual genetic) on perceived risk, negative affect, and worry about breast cancer | RCT | Eligible: 561  Enrolled: 354  Randomized: 354 (118 genetic counseling arm, 114 psychosocial counseling arm, 122 delayed intervention arm)  Analyzed: 348 (117 genetic counseling arm, 110 psychosocial counseling arm, 121 delayed intervention arm) | U.S. | Recruitment from among family members with breast cancer and through notices in local electronic and print outlets.  Recruitment completed in 8 months. Women with a range of actual breast cancer risk levels were included. |
| Bowen et al., 2006130  Fair | Risk perception  Cancer worry  Interest in genetic testing | To test the efficacy of 2 counseling methods in Ashkenazi Jewish women with average or moderately increased risk of breast cancer. | RCT | Eligible: 347  Enrolled: 221  Randomized: 221 (68 to psychosocial counseling, 77 to genetic counseling, 75 to control)  Analyzed: 96% followup rate | U.S. | Ashkenazi Jewish women from the greater Seattle, Washington area |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Demographics** | **Inclusion and exclusion criteria** | **Risk level definition** |
| **2013 Review** |  |  |  |
| Bowen et al., 200471  Fair  Same population as Bowen et al., 200266 | Mean age, years (SD)  Genetic counseling: 42.6 (11.8)  Psychosocial counseling: 42.1 (11.4)  Delayed intervention: 42.5 (11.5) | Inclusion: Women aged 18 to 74 with≥1 relative with breast cancer, no personal history of breast or ovarian cancer, no family history consistent with a BRCA mutation for breast cancer risk, living within 60 mile radius of research center, willingness to complete research activities and completed and returned baseline questionnaire  Exclusion: Not Reported | **Family history:** Self-report of any family history of breast cancer  **Risk level:** Calculated by use of Gail and Claus models, along with population data |
| Bowen et al., 2006130  Fair | Mean age of 47 years  100% Ashkenazi Jewish | Inclusion: Women aged 18 to 74 years with ≥1 Ashkenazi Jewish ancestor, who lived within 60 miles of Seattle  Exclusion: Personal history of breast or ovarian cancer, family history consistent with an autosomal dominant inheritance of breast cancer predisposition | ≥1 Ashkenazi Jewish ancestor |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Interventions** | **Measures** | **Duration of followup** |
| **2013 Review** |  |  |  |
| Bowen et al., 200471  Fair  Same population as Bowen et al., 200266 | Telephone screening survey to determine eligibility, followed by mailed baseline survey. Those who returned completed surveys were randomized to individual genetic counseling (IGC), group psychosocial counseling (PC), or a delayed intervention control group (CG).   1. IGC: Telephone contact with genetic counselor to review pedigree information. One 2-hour session following protocol based on standard genetic practice. Letter sent to participant within 2 weeks summarizing the session. 2. PC: Group of 4-6 participants met for four, 2-hour sessions with trained health counselor. Each participant received her own risk assessment sheet, personalizing the group discussion to her own risk status. Main topics: risk assessment and perception, screening, stress management and problem solving, and social support. 3. CG: Offered counseling following study completion   For ICG and PC, brief survey on reactions to counseling within 4 weeks of last counseling contact. Mailed 2nd assessment 6 months after randomization, with a reminder call and offer of phone completion to those who did not return survey after 2 weeks. | NSI: 4-item questionnaire to assess risk perception  Survey to assess reactions to counseling | Years: NR  6 months |
| Bowen et al., 2006130  Fair | 1. Group psychosocial counseling: psychologist led 4 2-hour, weekly sessions of 5-6 women per group. Each session included 20-min group cohesion activities followed by 1 of 4 major intervention components: risk assessment and perception, education, stress management, and problem solving and social support. 2. Individual genetic counseling: genetic counselor provided 1-hour counseling sessions, individually. Sessions covered several topics, including participant's family background, breast cancer risk assessment, *BRCA1* and *BRCA2* mutations in the Ashkenazi Jewish population, nongenetic risk factors for breast cancer, and breast screening. 3. Delayed counseling: no counseling, served as control. | BSI: 53-item self-reported psychological symptom scale  NSI: Continuous scale of 0 to 100 to assess risk perception | Years: NR  6 months |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| **2013 Review** |  |  |  |
| Bowen et al., 200471  Fair  Same population as Bowen et al., 200266 | Women's perceived risk for breast cancer decreased by 50% for the two counseling groups relative to control (p<0.01). Cancer worry decreased in both counseling groups by one scale point (p<0.05). There were no differential effects of counseling type on perceived risk or cancer worry. Women in psychosocial counseling experienced more anxiety change than those in the other groups.  Depression was not impacted by study group. | Some women reported high levels of attendance, and satisfaction with counselors and counseling; women in the genetic counseling arm reported more frequently talking about concerns than did women in psychosocial groups. Perceived risk and worry can be reduced with both types of short- term interventions. | The National Human Genome Institute, the National Cancer Institute,  and the National Office for Research on Women’s Health (HG/CA01190) |
| Bowen et al., 2006130  Fair | **A vs. B vs. C (results at followup)**  Perceived risk (scale 0 to 100%): 18 (SD 16) vs. 18 (SD 16) vs. 32 (SD 23); p<0.001 both counseling groups vs. control  Cancer worry (scale 4 to 16): 5.2 (SD 1.5) vs. 4.9 (SD 1.1) vs. 6.1 (SD 1.9); p<0.001 both counseling groups vs. control  Awareness of genetic testing (range from 1=almost nothing to 4=a lot): 2.6 (SD 0.7) vs. 2.6 (SD 0.7) vs. 2.2 (SD 0.7); p<0.001 both counseling groups vs. control  Interest in having genetic testing (range from 1=definitely not to 4=definitely yes): 2.4 (SD 0.9) vs. 2.4 (SD 0.9) vs. 2.8 (SD 0.8); p<0.01 both counseling groups vs. control  Candidacy judgment (range from 1=definitely not to 4=definitely yes): 2.0 (SD 0.8) vs. 2.0 (SD 0.8) vs. 2.6 (SD 0.8); p<0.05 both counseling groups vs. control  Fear of stigma (scale range unclear, higher score indicates higher fear of stigma): 3.4 (SD 1.1) vs. 3.4 (SD 1.1) vs. 3.3 (SD 1.2); no significant difference between groups  Access to genetic testing (scale range unclear, higher score indicates more unrestricted access): 3.8 (SD 1.4) vs. 3.9 (SD 1.4) vs. 4.3 (SD 1.4); p<0.05 both counseling groups vs. control  Information flow (scale range unclear, higher score indicates more restrictions on information flow): 2.0 (SD 1.1) vs. 2.1 (SD 1.0) vs. 1.9 (SD 0.9); p<0.05 both counseling groups vs. control | Counseling, either group or individual, reduced cancer worry, lowered inflated risk perceptions, and decreased interest in genetic testing.  Included in Smerecnik, 2009 review. | National Human Genome Research Institute grant HG01190 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **2013 Review** |  |  |  |  |  |  |
| Brain et al., 2002131  Good | Psychological factors | To compare the psychological impact of a multidisciplinary specialist genetics service with surgical provision in women at high risk and lower risk of familial breast cancer | RCT | Eligible: 1,000  Enrolled: 740  Randomized: 735 (369 control, 366 trial)  Analyzed: 653 (315 control, 338 trial) | Wales | Welsh women with family history of breast cancer referred to breast cancer clinic by doctor in 18 month trial period (1996 to 1997).  Randomized to trial (n=366) or control group (n=369). |
| Brain et al., 2011132  NA  Moderate-risk group from Brain et al., 2002137 | Cancer worry | To provide 6 year followup on women in TRACE study, and the predictors of long- term cancer worry, perceived risk, and health behaviors. | Before and after | Eligible: 545  Enrolled: 384  Analyzed: 263 | U.K. | Women who took part in the TRACE study |
| Braithwaite et al., 2005133  Fair | Risk perception | To examine the acceptability of the GRACE prototype to women with a family history of breast cancer and test the hypothesis that GRACE would perform as well as the nurse counselor at improving women's risk perceptions without causing adverse emotional reactions. | RCT | Eligible: 89  Enrolled: 72  Randomized: 72 (38 to GRACE, 34 to clinical nurse specialist)  Analyzed: 58 | U.K. | Women with a family history of breast cancer recruited through newspaper ads and posters |

| **Author, year**  **Quality** | **Demographics** | **Inclusion and exclusion criteria** | **Risk level definition** |
| --- | --- | --- | --- |
| **2013 Review** |  |  |  |
| Brain et al., 2002131  Good | **Mean age, years (SD), low vs. moderate vs. high risk**  Control group: 48.6 (10.25) vs. 40.5 (9.13) vs. 39.2 (7.33)  Trial group: 52.9 (7.75) vs. 41.6 (8.52) vs. 33.7 (8.19) | Inclusion: Women with a first-degree female relative diagnosed with breast cancer before age 50 or with bilateral breast cancer diagnosed at any age, ≥2 FDRs with breast cancer, or a FDR and SDR with breast cancer  Exclusion: Personal history of breast cancer, previously received genetic counseling, or were not a resident of Wales | **Family history risk definition:** First degree female relative diagnosed with breast cancer before age 50; first degree female relative with bilateral breast cancer at any age; ≥2 FDRs with breast cancer; or a FDR and SDR with breast cancer.  **Risk definition:** In trial group, risk was assessed on detailed pedigree data collected and analyzed by geneticist using Claus model.  In control group, surgical assessment of risk was based on info collected on age, reproductive history, and minimal family history. |
| Brain et al., 2011132  NA  Moderate-risk group from Brain et al., 2002137 | Mean age of 42.3 years (SD 8.22) | Inclusion: Women who took part in TRACE study, identified as moderate-risk, and were approved by their physician to be contacted  Exclusion: Not reported | Moderate risk not otherwise described |
| Braithwaite et al., 2005133  Fair | **GRACE (n=37) vs. counseling (n=34)**  18-34 years: 62.2% vs. 67.6%  35-49 years: 27% vs. 20.6%  ≥50 years: 10.8% vs. 11.8%  White: 91.9% vs. 94.1%  Other race: 8.1% vs. 5.8% | Inclusion: Having ≥1 FDR or SDR with breast cancer  Exclusion: Personal history of breast cancer | All had ≥1 FDR or SDR with breast cancer |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Interventions** | **Measures** | **Duration of followup** |
| **2013 Review** |  |  |  |
| Brain et al., 2002131  Good | 1. Control group: 1) Breast cancer surveillance; 2) surgical assessment of individual breast cancer risk; 3) option to enter U.K. Tamoxifen Prevention Trial; and 40 annual surgical followup with surveillance and advice. 2. Trial group: components 1, 3, and 4 of control group with genetic risk assessment and counseling. | NSI: 3-item scale to assess interest in genetic testing  STAI: Measures an individual’s current anxiety feelings | Years: NR  Immediately |
| Brain et al., 2011132  NA  Moderate-risk group from Brain et al., 2002137 | 1. Claus model 2. Generalized risk level based on age, reproductive history, and minimal family history | Cancer Worry Scale-Revised (CWS-R, scale 6 to 24)  Perceived risk (single item scale 1 to 5) | Years: NR  6 years |
| Braithwaite et al., 2005133  Fair | Both interventions were 1 session  Cognitive outcomes assessed at baseline, postclinic, and at 3 months   1. Risk counseling arm: Clinical nurse specialist undertook counseling sessions and drew pedigree with information from family history and assessed risk as low, moderate, or high based on GRACE guidelines. Participants were mailed letters summarizing content afterward. 2. GRACE: Participants completed their pedigrees in GRACE and assessed their risk, learning their risk assessment and how to manage their risk. They received a numerical estimate of lifetime risk; a visual display of cumulative risk with general population as comparator; and a qualitative description. Clinical nurse specialists then offered to book mammography and arrange meetings with geneticists, where appropriate. | HADS: 14-item self-report scale for the detection of depression and anxiety in hospitalized patients  NSI: Measured attitude, perceived benefit, risk perception, and satisfaction and risk communication on a Likert scale  STAI: Measures an individual’s current anxiety feelings | Years: NR  3 months |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year Quality** | **Results** | **Conclusions** | **Funding source** |
| **2013 Review** |  |  |  |
| Brain et al., 2002131  Good | State anxiety: Significant main effect of time, with decreased anxiety from baseline to followup (p=0.03).  Breast cancer worry: Significant overall reduction from baseline to followup. Significant interaction between risk information and time. Decline in women at low risk (t(106)=5.92,p<0.001) and moderate risk (t(443)=12.13, p<0.001), but not at high risk.  Satisfaction: Significantly lower in high-risk group (p<0.001).  Perception of risk: Marginally significant trend to increased perceived risk in high- risk women in the trial group.  Interest in genetic testing: Effect of risk information not significant. | Specialists other than geneticists might provide assessment of breast cancer risk, reassuring those at reduced risk and targeting high-risk women for specialist genetic counseling and testing services.  Low-risk women: Anxiety and cancer concerns were reduced with personal risk information. High levels of satisfaction, whether or not information based on detailed genetic analysis.  High-risk women: Risk information, even unfavorable, does not appear to create significant anxiety. Concerns about breast cancer risk remained and they were less satisfied with consultation in either group. Implication: breast cancer worry may impact quality of life for women who recognize they are at high risk. | The Medical Research Council, National Assembly for Wales, NHS R&D (Wales), and Imperial Cancer Research Fund Dr. Gray is supported by Tenovus, the cancer charity |
| Brain et al., 2011132  NA  Moderate-risk group from Brain et al., 2002137 | **A vs. B**  Mean perceived risk post risk assessment: 3.83 (SD 0.51) vs. 3.97 (SD 0.38), p=0.01  All other outcomes were NS between groups | Women's cancer worry decreased over time regardless of intervention group, though there was a significant affect immediately after risk assessment this affect was gone by 9 months followup. | Wales Office for Research and Development in Health and Social Care |
| Braithwaite et al., 2005133  Fair | **A vs. B**  Mean baseline cancer worry (scale of 1 to 4): 1.92 vs. 1.81  Mean baseline STAI-state anxiety (scale of 20 to 80): 35.73 vs. 40.00 (p<0.01)  Perceptions of risk information  Participants were positive about risk information from both interventions on credibility, trustworthiness, accuracy, clarity, and helpfulness.  Nurse counseling scored significantly higher than GRACE for all; significant differences in participants' satisfaction with risk information  Clinical nurse specialist arm was 'very satisfied' with risk information (p<0.01) | No significant differences between GRACE and nurse counseling in risk perception or cancer worry.  Nurse counseling was superior to GRACE on patient attitudes and satisfaction indicators. | Cancer Research U.K. (CUK), grant no. C1345/A169 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **2013 Review** |  |  |  |  |  |  |
| Burke et al., 200067  Fair | Cancer worry  Risk perception | To assess whether modified traditional genetic counseling causes women with an intermediate risk of breast cancer to have a more realistic view of their risk, of genetic testing, and to decrease breast cancer worry | RCT | Eligible: 793  Enrolled: 356  Randomized: 243 (120 to genetic counseling, 123 to control group)  Analyzed: 237 (116 to genetic counseling, 121 to control group) | U.S. | Sources for solicitation include women who live within 60 miles of Seattle: 2 studies at Fred Hutchinson Cancer Research Center, an oncologist's practice at University of Washington, mass media announcements. |
| Cull et al., 199868  Good | Psychological factors  Risk perception | To evaluate use of video for education on the genetic basis of breast cancer and on strategies for breast cancer risk management in a breast cancer family clinic | RCT | Eligible: 159  Enrolled: 144  Randomized: 128 (66 to video before group, 62 to video after)  Analyzed: 95 (53 to video before group, 42 to video after group) | U.K. | A consecutive series of women newly referred to the breast cancer family clinic were invited by mail to participate. 24% of the video before (VB) and 30% of the video after (VA) group were referred by another hospital clinic. One subject in each group had been referred from another genetic clinic. The remaining were referred by general practitioners. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Demographics** | **Inclusion and exclusion criteria** | **Risk level definition** |
| **2013 Review** |  |  |  |
| Burke et al., 200067  Fair | **Genetic counseling vs. control**  Average age (years) 43 (SD 12) vs. 42 (SD 12)  White: 94% vs. 93% | Inclusion: Women aged 18 to 74, lived within 60 miles of Seattle, and had ≥1 biological relative who has been diagnosed with breast cancer  Exclusion: A personal history of breast or ovarian cancer and a family history indicative of autosomal dominant inheritance of breast cancer | Intermediate family history of breast cancer: 1 or more biological relative(s) with breast cancer but whose pedigree suggests a low likelihood of autosomal dominant transmission.  Family history indicative of autosomal dominant inheritance of breast cancer: ≥2 first degree or 1 first degree and 1 second degree relative with either breast cancer before age 50 or ovarian cancer at any age, or ≥2 paternal second degree relatives with either breast cancer before age 50 or ovarian cancer at any age. The Claus model showed that these women would have ≥20% breast cancer risk by age 79. |
| Cull et al., 199868  Good | Mean age of 39 years (SD 8) | NR | NR |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Interventions** | **Measures** | **Duration of followup** |
| **2013 Review** |  |  |  |
| Burke et al., 200067  Fair | Random assignment to 3 groups: individual genetic counseling (120 women), psychosocial group counseling (113 women, reported elsewhere, Bowen 1999), control (123 women).   1. Adapted genetic counseling protocol for women with intermediate risk included precounseling telephone call, baseline questionnaire, individual genetic counseling session, immediate followup questionnaire, 6-month followup questionnaire, mailed summary letter 2. Control group was offered group counseling following completion of the study | NSI: Questionnaire to assess breast cancer worry, opinions on genetic testing, and risk perception | Years: NR  6 months |
| Cull et al., 199868  Good | 1. Subjects sent information about study with initial clinic appointment 4 weeks before the appointment. They were asked to return baseline questionnaire and forms within 2 weeks if wanting to participate. Those who did so were randomized either to the VB (Video Before) group, and were sent a copy of the educational video about 10 days before the clinic consultation, or to the VA (Video After) group, taking the video home after the postclinic assessment. 2. Clinic consultation: individual meeting with geneticist to discuss individual risk and with breast surgeon to discuss risk management. Clinicians noted session length and rated assessment of it. Post clinic assessment included completion of instruments. Followup assessment by mail 4 weeks later. | GHQ: 30-item questionnaire to screen individuals for psychiatric disorders  NSI: 12 response category assessment of risk perception  4-point scale to assess genetic risk Multiple choice questionnaire to assess objective risk  STAI: Measures an individual’s current anxiety feelings | Years: NR  1 month following clinic consultation |

| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| --- | --- | --- | --- |
| **2013 Review** |  |  |  |
| Burke et al., 200067  Fair | Significant differences between counseling and control groups in mean perceived risk of breast cancer (F=27.9, p<0.009).  Significant differences over time in perceived risk for the counseling group (F=65.9, p<0.001).  Interaction between group and time for perceived risk was significant (F=50.6, p<0.001).  Low overestimators of breast cancer risk reduced risk estimates by an average of 19 percentage points after counseling, compared with high overestimators who reduced risk estimates by an average of 36 percentage points (F=13.41,p<0.00001).  After counseling, those who perceived themselves as candidates for testing decreased from 82% to 60%; interest in testing was reduced from 91% to 60%.  70% (82) liked the counseling very much, 56% (65) found the counseling very useful, and 22% (26) found it moderately useful.  After receiving risk estimates, 33% (39) were a lot less worried and 32% (37) were a little less worried. | Most participants saw a benefit to counseling and afterward had a more accurate understanding of their risk. Counseling reduced interested in genetic testing. | The National Institutes of Health (HGO1190) |
| Cull et al., 199868  Good | Duration of Consultation: VB group spent less time with surgeon (mean 11.8 min vs. 14.6, p<0.05), but their time with geneticist was not significantly shorter.  Risk Assessment: No significant difference between VB or VA in accuracy of estimate at baseline. VB retained accuracy from clinic to followup. VA were more likely to underestimate at followup (p<0.05).  Understanding of Risk Information: Subjective: At baseline and at followup, no significant difference.  Objective: VB had higher scores (p<0.01) and a higher proportion of correct responses to more items. Followup: no significant differences after adjusting for education level (t =0.34).  Emotional Distress: No significant difference in groups in anxiety or distress levels.  Use of Video and Family Discussion: VB: 94% watched video at least 1 time from start to finish. 76% reported it offered new information. VA: 41/42 who gave followup data watched the video at least once and 41% of them said it gave new information. In both VA and VB, most (66% and 65%, respectively) watched it alone and most discussed it with a partner. | Women who saw the video before their clinic visit were not deterred from attending. Compliance with the study and satisfaction with the clinic visit were higher among those who viewed the video beforehand. | The NHS R&D (Cancer) Programme and the Imperial Cancer Research Fund |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **2013 Review** |  |  |  |  |  |  |
| Fry et al., 2003134  Fair | Perceived risk  Cancer worry | To compare the psychological outcomes of two models of breast cancer genetics services. | RCT | Eligible: 574  Enrolled: 373  Analyzed: 244 | Scotland | Women referred by GP for breast cancer genetic risk counseling |
| Gurmankin et al., 2005135  NA | Risk perception | To examine the risk perception derived from a risk communication with a health care provider during genetic counseling for breast cancer and *BRCA1/2* mutation risks. | Before and after | Eligible: NR  Enrolled: 58  Analyzed: NR | U.S. | New patients at university cancer evaluation program |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Demographics** | **Inclusion and exclusion criteria** | **Risk level definition** |
| **2013 Review** |  |  |  |
| Fry et al., 2003134  Fair | Mean age (SD)  Standard service: 37.3 (9.4)  Novel service: 39.1 (9.6) | Inclusion: Women who lived in the region and were able to give informed consent, and complete a baseline questionnaire.  Exclusion: Women who were symptomatic or diagnosed with breast and/or ovarian cancer, or women who had previously consulted with another clinic about their family history of cancer. | Criteria for significantly increased risk: Having a FDR with breast cancer diagnosis before age 40; having 2 FDRs or SDRs on the same side of the family with breast cancer diagnosis before age 60, or with ovarian cancer; having 3 FDRs or SDRs on the same side of the family with breast or ovarian cancer; having a FDR with breast cancer in both breasts; and having a male relative with breast cancer. |
| Gurmankin et al., 2005135  NA | Mean age of 45.9 years (SD 10.5)  88% White  10% Black  2% Other  42% Ashkenazi Jewish | Inclusion: Females only  Exclusion: Health care provider indicated they were too ill to participate | NR |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Interventions** | **Measures** | **Duration of followup** |
| **2013 Review** |  |  |  |
| Fry et al., 2003134  Fair | 1. Standard (regional) service: Self-report family history and baseline questionnaire; genetics consultant and genetics nurse specialist assigned categorical risk via Cancer Research Campaign. Women at low risk receive informative letter; women at moderate/high risk offered appointment at familial breast cancer clinic where a genetics consultant discusses risk status and breast surgeon discusses risk management. Where appropriate, clinical exams and mammography included. Patients' GPs receive summary data, and patients receive followup questionnaires 4 weeks and 6 months later. 2. Novel (Community-based) service: Women sent an appointment for a community-based clinic near their residence. Meetings run by genetics nurse specialist where family history collected and compared to published criteria (Cancer Research Campaign) to determine risk. Women at low risk offered information, reassurance, and discharged. Women at moderate/high risk offered appointment at a regional center with a geneticist and genetics nurse specialist, and asked to complete followup questionnaires at 4 weeks and 6 months. | Cancer Worry Scale (scale 5 to 24)  GHQ-30 | Years: NR  6 months |
| Gurmankin et al., 2005135  NA | 1. Precounseling interview assessed patient's breast cancer risk perception, *BRCA1/2* mutation risk perception, worry about breast cancer, family history of cancer, breast cancer risk reduction behaviors, and demographic information 2. Postcounseling interview assessed patient's breast cancer risk, *BRCA1/2* mutation risk, recall of actual risk information, worry about breast cancer, completion of the Spielberger Trait Anxiety Inventory (20 to 80 score range) and the Life Orientation Test-Revised (0 to 32 measure of optimism) | NSI: Scale of 0 to 100 to assess risk perception scale of 1 to 7 to asses cancer worry  STAI: Measures an individual’s current anxiety feelings | October 2002 to February 2004  1 week |

| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| --- | --- | --- | --- |
| **2013 Review** |  |  |  |
| Fry et al., 2003134  Fair | **A vs. B**  Cancer worry  Baseline: 11.5 (3.2) vs. 11.3 (3.0)  4 weeks: 10.3 (2.4) vs. 10.2 (2.7)  6 months: 9.9 (2.5) vs. 9.7 (2.7)  GHQ-30 Total score: median (IQR)  Baseline: 2(9) vs. 2(7.3)  4 weeks: 1(8) vs. 2(8.5)  6 months: 0(4) vs. 0(5)  GHQ-30 Case-level distress: % (n)  Baseline: 36 (66) vs. 31 (58)  4 weeks: 21 (32) vs. 22 (27)  6 months: 21 (29) vs. 23 (28) | All women experienced a significant reduction in CWS scores, with greatest reductions from baseline to 4 weeks (p<0.000), and a smaller, but still significant reduction from 4 weeks to 6 months (p=0.003).  Women experienced a significant drop in case level distress from baseline to four weeks (p=0.004), but there were no other significant differences in numbers of women with case level distress between trial arms, or time points. | Chief Scientist's Office and cancer Research U.K. |
| Gurmankin et al., 2005135  NA | Mean breast cancer risk perception: 44%  Risk perception change from baseline: +17%, (p<0.001)  Accuracy of recall  Risk information patients recalled was higher than risk communicated to them (+6%, p=0.02 vs. 8%, p=0.001)  Patients' belief in recall was positive for breast cancer, showing postcounseling risk perceptions higher than risk information they recalled being told (+9%, p=0.001) | Patients' breast cancer risk perceptions following risk communication were higher than corresponding actual risk communicated to them (+19%, p<0.001)  Inaccurate risk perception (high or low) can lead patients to make different medical decisions than they would with accurate risk perception.  They could engage in interventions or experience unnecessary stress if perceived risks are inaccurately high. | The American Cancer Society and a Robert Wood Johnson Faculty Scholar Award |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **2013 Review** |  |  |  |  |  |  |
| Helmes et al., 2006136  Fair | Cancer worry  Risk perception | To assess whether women participating in either in-person or telephone counseling sessions would have a more accurate perception of their personal breast cancer risk, increase their intentions for breast screening, have reduced levels of cancer worry, and have less interest in genetic testing | RCT | Eligible: 898  Enrolled: 340  Randomized: 340 (104 to the in-person arm, 121 to the telephone arm, 115 to control)  Analyzed: 335 (102 in the in-person arm, 119 in the telephone arm, 114 control arm) | U.S. | Physicians network in Washington state |
| Hopwood et al., 2004138  NA | Cancer worry  Psychological factors | To assess changes in risk perception, psychological distress, health care behaviors, and use of health care resources, to assess satisfaction with services, to describe regional variations in outcomes | Before and after | Eligible: 271  Enrolled: 256  Analyzed: 234 (1 month), 202 (12 months), 192 (precounsel, 1 month and 12 months) | U.K. | Cancer genetic services centers |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Demographics** | **Inclusion and exclusion criteria** | **Risk level definition** |
| **2013 Review** |  |  |  |
| Helmes et al., 2006136  Fair | **Mean age (years)**  In-person counseling: 39.9 (SD 9.2)  Telephone counseling: 40.4 (SD 9.7)  Delayed counseling: 41.8 (SD 10.1) | Inclusion: Women aged 18-64 years, within 60 miles of research institute, planning to live in area for 1 year, spoke English, telephone in home, covered by commercial health insurance plan  Exclusion: Women with personal history of breast/ovarian cancer, personal history of genetic counseling or testing for cancer risk | 14.7% had family history of breast cancer |
| Hopwood et al., 2004138  NA | Average across all five cancer genetics services:  Mean age of 41 years (range: 22 to 72)  94% Female  2% Ethnic minority | Inclusion: Women seen at a cancer genetics services center  Exclusion: Women who had been diagnosed with cancer, under 18 years | NR |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Interventions** | **Measures** | **Duration of followup** |
| **2013 Review** |  |  |  |
| Helmes et al., 2006136  Fair | 1. In-person counseling: board certified genetic counselor conducted counseling consisting of a review of family history, discussion of breast cancer risk, and education about breast cancer genes. Also discussed genetic testing considerations, including implications of results, testing strategies, potential risks and benefits of test, cost of test, and psychological effects of test. Information packet was provided that contained personal risk information comparing the woman's risk with average-woman's risk; personal computer- drawn 3-generation pedigree; brochures on self-breast exams, pap-smear, and mammography; genetics visual aids; list of community resources; and cover letter. 2. Telephone counseling: information packet was sent in the mail with instructions to open at the beginning of the telephone counseling which was identical in content and structure to in person counseling. 3. Control group did not receive counseling. | NSI: Scale of 0 to 100 to assess risk perception  Scale of 1 to 4 to measure intention to obtain breast cancer screening  4-item questionnaire to assess interest in genetic testing | Years: NR  3 months |
| Hopwood et al., 2004138  NA | Genetic counseling, otherwise not described | GHQ: 60-item questionnaire to screen individuals for psychiatric disorders  NSI: 5-response category assessment of perceived cancer risk | Years: NR  At 1 month and 1 year following precounseling |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| **2013 Review** |  |  |  |
| Helmes et al., 2006136  Fair | **A vs. B vs. C (change from baseline to followup)**  Mean risk perception (scale of 0 to 100): -10.29 vs. -8.65 vs. +1.14 (p<0.001)  Mean cancer worry (scale of 4 to 16): -0.9 vs. -0.82 vs. -0.38 (p=0.002)  Breast health intentions (score of 1 to 4): 0 vs. +0.01 vs. +0.02 (NS)  Interest in genetic testing (score of 1 to 4): -0.61 vs. -0.52 vs. +0.51 (p<0.001) | There were no differences between in-person and telephone counseling, however both intervention groups decreased risk perception, cancer worry, and interest in genetic testing compared to the group that did not receive counseling. Counseling and no counseling had no effect on breast health intentions. | National Human Genome Research Institute grant HG01190 |
| Hopwood et al., 2004138  NA | **Precounseling vs. 1 month followup vs. 12 months followup**  Underestimated risk: 30% (49/162) vs. 23% (37/162) vs. 22% (36/162)  Mean GHQ (scale 0 to 28): 3.4 vs. 3.0 vs. 3.4 (NS)  Mean CWS (scale 1 to 16): 11.6 vs. 10.9 vs. 10.8 (p<0.001) | Cancer distress decreased after counseling and continued to be low 1 year later. | NHS Research and Development Directorate, Programme for Cancer; Project NCP/B42 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **2013 Review** |  |  |  |  |  |  |
| Hopwood et al., 1998137  Fair | Psychological factors | To understand psychological support needs for women at high genetic risk for breast cancer | Cohort | Eligible: 176  Enrolled: 174  Analyzed: 158 | U.K. | All were consecutive first-time attendees at the Family History Clinics (Manchester, U.K.). |
| Kelly et al., 2008139  NA | Risk perception | To examine change in subjective risk of ovarian cancer over time in response to genetic counseling and testing in the short- and long-term; and the discrepancy between subjective and objective estimates of ovarian cancer risk; and new methods for conceptualizing subjective risk derived from the Common Sense Model. | Before and after | Eligible: 78  Enrolled: 78 (40 to no personal history of breast cancer, 38 to personal history)  Analyzed: NR | U.S. | Women were recruited from the community |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Demographics** | **Inclusion and exclusion criteria** | **Risk level definition** |
| **2013 Review** |  |  |  |
| Hopwood et al., 1998137  Fair | Mean age of 36.19 years (range: 22.63 to 46.35) | Inclusion: Women aged 18 to 45 living within a 25-mile radius of the FHC with risk ≥2 fold greater than the population for breast cancer  Exclusion: Not reported | Risk was ≥2 fold greater than the population for breast cancer (i.e., 1:6 lifetime risk or greater as assessed using the Claus model). |
| Kelly et al., 2008139  NA | Mean age of 48.64 years (SD 12.69)  100% Ashkenazi Jewish women | Inclusion: Ashkenazi Jewish women with personal or family histories suggestive of an inherited predisposition to breast and/or ovarian cancer  Exclusion: Prior history of ovarian cancer, men, women having prophylactic oophorectomies | ≥1 Ashkenazi Jewish grandparent |

| **Author, year**  **Quality** | **Interventions** | **Measures** | **Duration of followup** |
| --- | --- | --- | --- |
| **2013 Review** |  |  |  |
| Hopwood et al., 1998137  Fair | 1. Postal questionnaire prior to counseling 2. At attendance for risk counseling, women were asked to complete GHQ together with several other self-report measures 3. Questionnaires completed again at 3, 6, 9, and 12 months later 4. Three months after Family History Consultation, home visit conducted with research interviews, including administration of the Psychiatric Assessment Schedule. Additional structured questions assessed attitude to risk information, reaction and concerns about cancer. | GHQ: 60-item questionnaire to screen individuals for psychiatric disorders  NSI: 5-item questionnaire to assess risk perception  PAS: Semi-structured clinical interview designed for use with respondents who have learning disability | Years: NR  3, 6, 9 and 12 months following genetic counseling |
| Kelly et al., 2008139  NA | Genetic counseling included review of family cancer history, personal risk factors for breast and ovarian cancer, mechanisms of cancer inheritance, meaning of a positive and negative test result, and risks and benefits associated with testing. | CWS: 3-item questionnaire to measure how frequently an individual worries about getting breast cancer | Years: NR  6 months |

| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| --- | --- | --- | --- |
| **2013 Review** |  |  |  |
| Hopwood et al., 1998137  Fair | GHQ scores: Compliance at baseline was 85% (n=34), and 94% at 3 months (n=148). Prevalence of psychological distress, with a cut-off score >5, was 31% at baseline and 26% at 3 months. An examination of the 4 subscales of GHQ showed that 9.7% scored ≥5 on the somatic scale, 14% on the anxiety subscale and 3% each on the depression and suicidal ideation subscales at baseline. At 3 months, proportions were 12%, 15%, 6.8%, and 3.4%, respectively. When analysis was restricted to 105 women with evaluable assessments on all occasions, prevalence was 31% and 25% respectively. Baseline scores compared with pre-counseling risk estimates showed no significant difference (p=0.087). Significant difference between psychological distress and perceived risk postcounseling (p=0.0053).  Women with accurate risk knowledge postcounseling had significantly lower scores than those who underestimated (p=0.0034) or who overestimated (p=0.0447).  Psychiatric Assessment Schedule: Psychiatric disorder was confirmed in 21 (13.3%) of the study participants at 3 months. Most women had multiple concerns, but none reported risk counseling as a precipitant for their distress.  Estimation of risk: Prior to risk counseling, 10% accurately estimated risk of breast cancer, while 50% accurately estimated after (p=0.0000). More women continued to overestimate (17%) than underestimate (11%). In general, giving women an accurate estimate of their probability of breast cancer when they perceived it to be much lower did not appear to trigger clinical anxiety or depression. | Prevalence rate for psychological distress when measured by a self-report questionnaire was double that ascertained by psychiatric interview, which is regarded as the gold standard.  Interview data suggests that psychiatric morbidity was not apparently caused by the genetic counseling. This suggests that routine genetic risk consultations do not facilitate disclosure of distress or unresolved grief, and the use of a screening instrument together with a second-stage assessment interview should be explored further. | The Cancer Research Campaign |
| Kelly et al., 2008139  NA | **Precounseling vs. postcounseling (ovarian cancer)**  Accuracy of risk perception (estimated from graph): 1 vs. -5  Mean risk assessment (0 to 100%): 30.81 (SD 3.84) vs. 25.45 (SD 3.45)  **Postcounseling vs. postresult vs. 6-month followup**  Mean risk assessment (0 to 100%)  Those with positive result (n=7): 27.86 (SD 8.01) vs. 31.43 (SD 7.46) vs. 22.14 (SD  7.23)  Those with informative negative result (n=5): 27.00 (SD 6.63) vs. 11.00 (SD 2.45)  vs. 15.00 (SD 5.00)  Those with uninformative negative result (n=28): 24.50 (SD 4.48) vs. 19.76 (SD 4.29) vs. 17.82 (SD 3.20) | All women underestimated their risk of developing ovarian cancer. | The New Jersey Commission on Cancer Research and the Mid- Atlantic Region Human Genetics Network |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **2013 Review** |  |  |  |  |  |  |
| Lerman et al., 1996140  Fair | Cancer worry  Risk perception | To study effect of individualized breast cancer risk counseling | RCT | Eligible: 438  Enrolled: 227  Randomized: 227 (group randomization NR)  Analyzed: 200 (90 to risk counseling, 110 to control group) | U.S. | Subjects identified by relatives under treatment for breast cancer at either Fox Chase Cancer Center or Duke Comprehensive Cancer Center. |
| Lerman et al., 199969  Fair | Cancer worry  Interest in genetic testing | To investigate racial differences in response to two alternate pretest education strategies for *BRCA1* genetic testing: a standard education model and an education plus counseling model | RCT | Eligible: 581  Enrolled: 364  Randomized: 364 (group randomization NR)  Analyzed: 298 (157 to education only, 141 to education plus counseling) | U.S. | Subjects were recruited from two cancer centers (Georgetown University Medical Center or Washington Hospital Center). |
| Lobb et al., 2004141  Good | Psychological factors | To examine the effect of different consultant communication styles on a variety of outcomes | Longitudinal cohort | Eligible: NR for unaffected group  Enrolled: NR for unaffected group  Analyzed: 89 | Australia | Women from high-risk breast cancer families attending their first consultation before genetic testing |

| **Author, year**  **Quality** | **Demographics** | **Inclusion and exclusion criteria** | **Risk level definition** |
| --- | --- | --- | --- |
| **2013 Review** |  |  |  |
| Lerman et al., 1996140  Fair | Aged 35 to 40 years: 18%  Aged 41 to 49 years: 41%  Aged ≥50 years: 42%  White: 90%  Black: 10% | Inclusion: Women aged 35 and older and a family history of breast cancer  Exclusion: A personal history of cancer and younger than 35 | ≥1 FDR with breast cancer  Breast cancer risk estimates for individual women were calculated using subject's Gail model variables and estimated the lifetime probability of developing breast cancer, the 95% CIs, and the estimated lifetime risk for a woman of the same age with the lowest risk of disease. |
| Lerman et al., 199969  Fair | Black: 24%  -<40 years of age: 34%  -≥40 years of age: 66%  White: 76%  -<40 years of age: 41%  -≥40 years of age: 59% | Inclusion: White and Black women with a family history of breast cancer or ovarian cancer  Exclusion: Personal history of cancer (except basal cell or squamous cell skin cancers) | ≥1 FDR affected with breast cancer and/or ovarian cancer |
| Lobb et al., 2004141  Good | Mean age of 38.7 years (range: 19 to 60) | Inclusion: Women attending their first consultation before genetic testing with no prior testing for or carrier of *BRCA1* or *BRCA2*  Exclusion: Unable to give informed consent, under the age of 18, showed evidence of severe mental illness, and non-fluent in English | NR |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Interventions** | **Measures** | **Duration of followup** |
| **2013 Review** |  |  |  |
| Lerman et al., 1996140  Fair | A) Study group: 1) discussion of individual factors contributing to elevated risk, 2) presentation of individualized risk data, 3) recommendations for annual mammography and clinical breast exams, 4) instruction in breast self-exam  B) Control group: 1) interview assessment of current health practices, 2) age-specific recommendations for variety of cancer screening tests, 3) encouragement to quit smoking, 4) suggestions for reducing dietary fat to 30% or less, 5) recommendations for regular aerobic exercise | IES: 17-item questionnaire to measure an individual’s level of distress in relation to a specific event or condition | Years: NR  3 months |
| Lerman et al., 199969  Fair | 1. Education only: topics discussed included individual risk factors for breast cancer and ovarian cancer and patterns of inheritance for breast and ovarian cancer susceptibility. Subjects given qualitative estimates of their risk of developing breast cancer and ovarian cancer. Pedigrees were reviewed. Potential benefits, limitations, and risks of genetic testing for inherited breast cancer and ovarian cancer susceptibility also reviewed. 2. Education plus counseling: provided the same education and materials described above. Subjects guided through a set of questions that explored personal issues related to cancer and genetic testing. Subjects discussed the emotional impact of having a family history of cancer, psychosocial implications of genetic testing for inherited breast cancer and ovarian cancer susceptibility, anticipated reactions to a positive and negative test result, and intentions to communicate test results to family members and friends. | IES: 17-item questionnaire to measure an individual’s level of distress in relation to a specific event or condition | Years: NR  1 month |
| Lobb et al., 2004141  Good | 1. Self-administered questionnaires were mailed 2 weeks before and 4 weeks after their genetic consultation. Consultations were taped and retained for analysis. Questionnaires included Breast Cancer Genetics Knowledge, Expectations, Perceived Risk, IES, HADS, and Satisfaction with Genetic Counseling Scale. 2. Women came to the center for their genetic consultation. The consultation was recorded, analyzed, and coded to capture 10 aspects of genetic counseling. Not all counselors incorporated all aspects and this was the basis for the study. | HADS: 14-item self-report scale for the detection of depression and anxiety in hospitalized patients  IES: 15-item scale measuring intrusion and avoidance responses in relation to a specific stressor  NSI: Scale of 0 to 7 to assess genetic clinic expectations  Scale of 0 to 9 to assess information sought Scale of 0 to 100 to assess risk perception | Years: NR  4 weeks |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| **2013 Review** |  |  |  |
| Lerman et al., 1996140  Fair | Breast cancer preoccupation: IES average score on measure of breast cancer preoccupation was 6.9+ 0.71 (means +SE).  No significant baseline difference in risk comprehension between groups; however, significant change in risk comprehension at 3-month followup due to movement in risk-counseling group from overestimation to accurate or underestimation. | Among women with less formal education, counseling led to significant reductions in distress by the 3-month followup, suggesting a possible increased adherence to mammography. | Public Health Service grants ROICA57767 and K07CAOI604 from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services |
| Lerman et al., 199969  Fair | Genetic testing intention: Family history and baseline genetic testing intentions both made significant independent contributions to 1-month genetic testing intentions. Women with stronger family history of cancer had greater increases in intentions. Only in Black, education plus counseling led to greater increases in intentions than education only (p=0.003).  IES scores: All groups evidenced a reduction in distress from baseline to 1 month. However, this decrease, although not a significant difference, was smallest among Black women who received education plus counseling. | Overall: Black women were found to differ significantly from White women in the effects of the interventions on testing intentions and provision of a blood sample. Effects were independent of socioeconomic status and referral mechanism. | The National Institutes of Mental Health and National Human Genome Research Institute grant MH/HG54435 |
| Lobb et al., 2004141  Good | Anxiety: Women who had more aspects of genetic testing discussed had a decrease in anxiety after 4 weeks (p=0.03). Women receiving a letter summarizing their consultation had lower anxiety (p=0.012) and a trend toward less anxiety about breast cancer (p=0.089). Women who received four or more supportive communications were more anxious about breast cancer (p=0.000).  Depression: Women whose consultants facilitated understanding more had a decrease in depression (p=0.052).  Risk Accuracy: Women receiving a letter summarizing their consultation had increased risk accuracy (p=0.023). | Women who understand what is being presented to them have decreased depression. This can imply that women may feel overwhelmed with the amount of information they receive and may feel worse if they are not helped to understand it. Providing a written summary of the consultation helped with accurate risk perception. | The University of Sydney Cancer Research Fund |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **2013 Review** |  |  |  |  |  |  |
| Matloff et al., 2006142  Fair | Risk perception | To examine if a personalized risk assessment and genetic counseling intervention would affect knowledge, risk perception, and decision making in a group of women who had 1 FDR with breast cancer compared with a control group | RCT | Eligible: NR  Enrolled: NR  Randomized: 64 (32 in each group)  Analyzed: 54 completed 1 month followup (28 control and 26 intervention), 48 completed 6 month followup (25 control and 23 intervention) | U.S. | Women recruited through advertisements in New Haven. |
| Mikkelsen et al., 2007143  Fair  Same population as Mikkelsen et al., 2009144 | Risk perception | To explore the impact of genetic counseling on perceived personal lifetime risk of breast cancer, the accuracy of risk perception, and possible predictors of inaccurate risk perception 1 year following counseling | Prospective cohort | Eligible: 3257 (568 in counseling group, 689 in reference group 1, 2000 in reference group 2)  Enrolled: 1971 (319 in counseling group, 381 in comparison group 1, and 1271 in group 2)  Analyzed: 1602 (213 in counseling group, 319 in comparison group 1, and 1070 in group 2) | Denmark | Danish women at risk of hereditary breast and ovarian cancer |
| Mikkelsen et al., 2009144  Fair  Same population as Mikkelsen et al., 2007143 | Psychological factors  Cancer worry  Quality of life changes | To clarify the psychosocial impact of genetic counseling for hereditary breast and ovarian cancer. | Prospective cohort | Eligible: 3257 (568 in counseling group, 689 in reference group 1, 2000 in reference group 2)  Enrolled: 1971 (319 in counseling group, 381 in comparison group 1, and 1271 in group 2)  Analyzed: 1602 (213 in counseling group, 319 in comparison group 1, and 1070 in group 2) | Denmark | Danish women at risk of hereditary breast and ovarian cancer |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Demographics** | **Inclusion and exclusion criteria** | **Risk level definition** |
| **2013 Review** |  |  |  |
| Matloff et al., 2006142  Fair | Mean age of 49 years (range: 41 to 55) 21% Ashkenazi Jewish | Inclusion: Women ≥40 years with ≥1 FDR with breast cancer, had gone through natural menopause  Exclusion: Taking menopausal therapy, having had cancer, atypical hyperplasia, or LCIS, being a known carrier of a *BRCA1/2* mutation, having heart disease, women with family history that placed them at >10% risk of carrying a mutation | ≥1 FDR with breast cancer |
| Mikkelsen et al., 2007143  Fair  Same population as Mikkelsen et al., 2009144 | Median age (years): Counseling: 39 (range: 18 to 72)  Group 1: 56 (range: 28 to 76)  Group 2: 45 (range: 18 to 75) | Inclusion: Women aged ≥18 years who attended an initial genetic counseling session for breast or ovarian cancer  Exclusion: Women affected with breast or ovarian cancer at baseline or who developed cancer during the followup period | NR |
| Mikkelsen et al., 2009144  Fair  Same population as Mikkelsen et al., 2007143 | Median age (years): Counseling: 39 (range: 18 to 72)  Group 1: 56 (range: 28 to 76)  Group 2: 45 (range: 18 to 75) | Inclusion: Women aged ≥18 years who attended an initial genetic counseling session for breast or ovarian cancer  Exclusion: Women affected with breast or ovarian cancer at baseline or who developed cancer during the followup period | NR |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Interventions** | **Measures** | **Duration of followup** |
| **2013 Review** |  |  |  |
| Matloff et al., 2006142  Fair | 1. Counseling session with personalized letter summarizing patient data 2. Controls who received no counseling | NSI: Reviewed detailed information about menopause, the risks and benefits of each menopause therapy option and a disease risk factor assessment | August 2002 to January 2004  6 months |
| Mikkelsen et al., 2007143  Fair  Same population as Mikkelsen et al., 2009144 | 1. Genetic counseling: information on incidence of sporadic breast cancer, genetics, inheritance patterns, and estimated personal lifetime risk of inherited cancer 2. Comparison group 1: women referred for mammography 3. Comparison group 2: random sample of women | IES: 17-item questionnaire to measure an individual’s level of distress in relation to a specific event or condition | 2003 to 2004  1 year |
| Mikkelsen et al., 2009144  Fair  Same population as Mikkelsen et al., 2007143 | 1. Genetic counseling: information on incidence of sporadic breast cancer, genetics, inheritance patterns, and estimated personal lifetime risk of inherited cancer 2. Comparison group 1: women referred for mammography 3. Comparison group 2: random sample of women | HADS: 14-item self-report scale for the detection of depression and anxiety in hospitalized patients | 2003 to 2004  1 year |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| **2013 Review** |  |  |  |
| Matloff et al., 2006142  Fair | **A vs. B**  Mean discrepancy between perceived risk for self and average woman  Baseline: 16.3 (SD 17.9) vs. 22.3 (SD 24.3)  1 month: 0.8 (SD 22.3) vs. 21.1 (SD 25.4)  6 months: 3.6 (SD 20.1) vs. 18.3 (SD 23.0)  **A only**  Mean discrepancy between perceived risk for self and actual risk  Baseline: 36.9 (SD 20.4)  1 month: 18.9 (SD 28.6)  6 months: 17.1 (SD 25.9) | After counseling accuracy of perceived risk of breast cancer increased. | Susan G. Komen Foundation |
| Mikkelsen et al., 2007143  Fair  Same population as Mikkelsen et al., 2009144 | **A vs. B vs. C**  Perceived absolute lifetime risk of breast cancer (%)  Mean within group changes from baseline to 1 year followup: -6.6 (95% CI -3.0 to -10.2) vs. 1.6 (95% CI 3.6 to -0.5) vs. 1.1 (95% CI 2.2 to 0.0)  Mean between group changes: -8.2 (95% CI -12.2 to -4.1) counseling vs. group 1; -7.7 (95% CI -11.4 to -4.0) counseling vs. group 2  Change in risk accuracy of perceived lifetime risk of breast cancer (%) overestimate: -12 vs. 5 vs. 2  Accurate at 1 year followup: 16 vs. -5 vs. -2 (p=0.03 A vs. B and p=0.07 A vs. C) | Genetic counseling helped to increase risk accuracy even 1 year after counseling. | Danish Cancer Society, Grant Number PP 02 010, the Center of Innovation and Development in Nursing Education in the County of Aarhus and Aarhus University Research Foundation |
| Mikkelsen et al., 2009144  Fair  Same population as Mikkelsen et al., 2007143 | **A vs. B vs. C**  HADS-A score decreased from baseline to 1 year: 4.7% (95% CI -3.5 to 12.8) vs. 2.5% (95% CI -4.5 to 9.5) vs. 1.1% (95% CI -2.3 to 4.7); decrease in anxiety in group 1 was in women in nonsystematic screening (7.0%, 95% CI: -4.1 to 18.1) with a slight increase in women in systematic screening (1.1%; 95% CI -7.5 to 9.8)  Baseline vs. 2 weeks followup vs. 6 months followup vs. 12 months followup  Cancer specific distress: 52% vs. 50% vs. 41% vs. 41%  Comparing women referred for mammography vs. no genetic counseling: (41% to 35%), or to a random sample from the general population (from 32% to 30%) with no counseling.  More women with genetic counseling experienced decrease in cancer-specific distress; difference statistically significant when compared to general population (p=0.006), and subgroup of women with mammography screening (p=0.05) | A 11% (95% CI 1.4 to 20.8) decrease in cancer-specific distress in genetic counseling group from baseline to 1 year followup exceeded decrease in groups 1 and 2 with significance in group 2 (p=0.006) and in subgroup of group 1 in systematic screening (p=0.05). | Danish Cancer Society, Grant Number PP 02 010, the Center of Innovation and Development in Nursing Education in the County of Aarhus and Aarhus University Research Foundation, and the Danish Nurses' Organization |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **2013 Review** |  |  |  |  |  |  |
| Pieterse et al., 2011145  NA | Risk perception accuracy, correct knowledge, perceived personal control  Generalized state anxiety  Cancer- related distress. | To assess changes in cognitions (accurate risk perception, correct knowledge, perceived personal control) and distress (state anxiety, cancer-related stress reactions) from before to immediately and six months after concluding breast cancer genetic counseling in female counselees, and whether changes in cognitions and distress were similar in affected versus unaffected women. | Before and after | Eligible: 204  Enrolled: 77  Randomized: N/A  Analyzed: 77 | The Netherlands | Women seeking counseling for hereditary cancer, University Medical Center in The Netherlands, surveys exchanged through the mail |
| Roshanai et al., 2009146  Fair | Risk perception  Psychological factors | To investigate the effect of an informational intervention on counselees' knowledge, risk perception, communication of information to at-risk relatives and satisfaction with the service. | RCT | Eligible: 210  Randomized: 163 (85 in intervention, 78 in control group)  Analyzed: 147 at precounseling (73 in intervention, 74 in control); 144 for risk perception (71 in intervention, 73 in control); 147 two weeks postcounseling (73 in intervention, 74 in control); 139 at eight months postcounseling (68 in intervention, 71 in control) | Sweden | Swedish women visiting a university cancer genetic clinic, mainly referred due to breast cancer or family history of breast, ovarian or colorectal cancer (groups separated for analysis) |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Demographics** | **Inclusion and exclusion criteria** | **Risk level definition** |
| **2013 Review** |  |  |  |
| Pieterse et al., 2011145  NA | 18 years or older | Inclusion: Patients sought counseling for hereditary cancer; were first among their first and second degree relatives to request counseling; were first time attendees; and age >18 years.  Exclusion: Not reported | Seeking counseling for hereditary cancer |
| Roshanai et al., 2009146  Fair | Female: 90.5% (n=133)  Male: 9.5% (n=14)  Median age, females (years): 56 (range: 23 to 84) | Inclusion: Women aged ≥18 years; able to read, write, and speak Swedish  Exclusion: Suffered from any mental illness | Risk estimated by geneticist:  Intervention % (n) vs. control % (n)  ≤20%: 15 (5) vs. 23 (3)  21 to 40%: 72.5 (29) vs. 77 (37)  >40%: 9 (3) vs. 4 (1) |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Interventions** | **Measures** | **Duration of followup** |
| **2013 Review** |  |  |  |
| Pieterse et al., 2011145  NA | A) First session topics included family's occurrence of breast and other cancers, inheritance, and criteria on probability of inherited breast cancer. Likelihood of hereditary breast cancer running in family was estimated. Genetic testing was offered to counselees or affected relatives when they have an a priori chance (≥10%) of carrying BRCA gene. Counselees eligible for testing informed of medical consequences and options.  Periodic surveillance recommended to all counselees at increased risk (>20%). Counselees and referring physician receive summary letter about genetic and risk information.  Counselors distributed postcounseling questionnaire after last session and asked participants to complete it within a day.  Six months later, counselees were sent a followup questionnaire. All three of these questionnaires assessed cognitions and distress. Counselors completed a questionnaire after counselee's last visit.  Counseling spanned 1 to 4 visits over 6 to 24 months; STAI, IES, and VAS were used to measure anxiety levels | IES: 17-item questionnaire to measure an individual’s level of distress in relation to a specific event or condition  NSI: Scale of 0 to 100 to assess risk perception; Scale of 0 to 7 to assess hereditary breast cancer knowledge  PPC: Construct reflecting the degree to which a person believes that a situation is under their control  STAI: Measures an individual’s current anxiety feelings  VAS: Any of a number of pain self-assessment tools where subjects indicate their level of pain in response to a continuous visual scale | Years: NR  24 months (6 months after last counseling session) |
| Roshanai et al., 2009146  Fair | 1. Genetic counseling from specialist nurse: pedigree explanation; Buckman's Breaking Bad News model to inform at-risk relatives; pamphlet, videotape, copies of pedigree and medical records 2. Control group received standard care given at the clinic: genetic counseling from a specialist nurse, no additional information, and no help in identify at-risk relatives | HADS: 14-item self-report scale for the detection of depression and anxiety in hospitalized patients  SPIKES: A 6-step protocol for delivering bad news | 2003 to 2005  At 2 weeks and at 8 months postcounseling |

| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| --- | --- | --- | --- |
| **2013 Review** |  |  |  |
| Pieterse et al., 2011145  NA | **Risk perception accuracy: % (n), Precounseling vs. immediately postcounseling vs. 6 months post-counseling**  Underestimation: 3 (1) vs. 16 (5) vs. 24 (8)  Correct estimation: (-) (0) vs. 32 (10) vs. 18 (6)  Overestimation: 97 (29) vs. 52 (16) vs. 57 (19)  Total number of counselees: 3 (unaffected group) | Counseling educates women on lifetime breast cancer risk; correct knowledge on breast cancer genetics decreased over time.  Benefits gained immediately after counseling seem to remain over time. | Dutch Cancer Society supported original study (Grant number NIVEL 1999-2090); author supported by a postdoctoral fellowship from the Dutch Cancer Society. |
| Roshanai et al., 2009146  Fair | The only significant difference between intervention and control was immediately after counseling, and at 2 weeks, when controls showed more accurate estimation of risk; groups showed the same results at 8-month followup.  No significant difference for anxiety or depression between control and intervention at any time point both groups significantly decreased over time (p<0.01). | At 8 month followup, 74% of counselees in control and intervention groups had informed relatives; 96% of relatives of intervention counselees and 89% of relatives of controls reported being informed.  The majority (75% of intervention relatives and 67% of controls) reported receiving sufficient information. | The Swedish Cancer Society |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **2013 Review** |  |  |  |  |  |  |
| Watson et al., 1998148  Good | Cancer worry  Psychological factors  Risk perception | To look at recall of risk information after genetic counseling, and to determine impact of receiving an audiotape of the genetic consultation on level of recall, cancer-related worry, and uptake of risk management methods | RCT | Eligible: 135  Enrolled: 115  Randomized: 115 (60  cases, 55 controls)  Analyzed: 107 (56 cases,  51 controls) | U.K. | First time attendees at the cancer family clinics of 2 London hospitals--Royal Marsden, Sutton and London, and St. George's Hospitals. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Demographics** | **Inclusion and exclusion criteria** | **Risk level definition** |
| **2013 Review** |  |  |  |
| Watson et al., 1998148  Good | -Median age of 37 years (range: 28 to 56) for participants from the Royal Marsden Hospital  -Median age of 41 years (range: 23 to 71) for participants from St. George's Hospital | Inclusion: Women with a family history of breast cancer, first visit to genetic clinic, never having been clinically affected with cancer, no known mental illness and aged ≥18 years  Exclusion: Not reported | Not reported |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Interventions** | **Measures** | **Duration of followup** |
| **2013 Review** |  |  |  |
| Watson et al., 1998148  Good | All subjects were referred for genetic counseling with a clinical geneticist who provided a consultation (randomized at clinic immediately after consultation to minimize bias), including pedigree based on risk calculation and information regarding management options based on risk level. All were as part of consultation.   1. Consultation plus audiotape group offered instructions on self-exam and clinical exam and received an audiotape of the consultation 2. Consultation only group offered instructions on self-exam and clinical exam | CWS: 3-item questionnaire to measure how frequently an individual worries about getting breast cancer  GHQ-12: 12-item questionnaire to screen individuals for psychiatric disorders  VAS: Any of a number of pain self-assessment tools where subjects indicate their level of pain in response to a continuous visual scale | Years: NR  6 months |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Results** | **Conclusions** | **Funding source** |
| **2013 Review** |  |  |  |
| Watson et al., 1998148  Good | CWS scores: For both groups, median score was 11 (range 6 to 22). 95% CI 10 to12 for cases and 95% CI 10 to11 for controls; mean 11.14 (SD 3.23) for cases and mean 11.39 (SD 3.37) for controls. Scores fell in subjects given a tape of consultation from median 11 at baseline to 10 at 1 month, then 9 at 6 months.  Relative risk scores: At 1-month followup 41% accurately recalled their risk of developing cancer, 25% overestimated, 11% underestimated, 23% didn't know/didn't remember. Results suggest that risk figure, regardless of accuracy, doesn't reflect more general view about risk compared with average women.  Risk figure given as odds ratio compared with other formats (percentage or descriptive terms): odds ratio--71% were accurate in recall compared with 25% when given in other formats.  Risk questionnaire scores: Usefulness of information rated on a visual analog scale. Average ratings were high, ranging from 8.5 (population risk) to 9.1 (risk of gene in family). Risk of gene in family, lifetime risk, and risk < age 50 were rated significantly more useful than population risk, risk of no cancer by age 50, and risk of disease over next 5 years.  Medical management uptake: No significant correlation between cancer worry change scores and either level of breast clinical exam (p=0.8) or mammography (p=0.8), no difference between cases and controls for rate of self-exam, doctor exam, or mammography at 6-month followup, no difference between groups for other health behaviors unaffected by whether consultation tape was received or not. | Overall: GHQ-12 scores: For combined groups, median score was 1 (range 0 to 11). 36 subjects had a score indicative of psychological morbidity (>3) at baseline and 31 at 1-month and 6-month followup. | Not reported |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, year**  **Quality** | **Sub-category** | **Purpose** | **Study type** | **N** | **Country** | **Population and setting** |
| **2013 Review** |  |  |  |  |  |  |
| Watson et al., 1999149  Good | Psychological factors | To investigate perception of genetic risk and the psychological effects of genetic counseling in women with a family history of breast cancer | Prospective cohort | Eligible: 303  Enrolled: 282  Analyzed: 282 | England | First time genetic clinic attendees recruited from four South London genetic counseling centers (Royal Marsden NHS Trust Hospital [2 separate clinics], Mayday University Hospital, and St. Georges' Hospital) |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Demographics** | **Inclusion and exclusion criteria** | **Risk level definition** |
| **2013 Review** |  |  |  |
| Watson et al., 1999149  Good | Median age of 37 years (range: 19 to 76) | Inclusion: Women with a family history of breast cancer, never clinically affected by cancer, no known serious mental illness, age 18 or older, and able to complete a questionnaire  Exclusion: Not reported | Breast cancer risk calculated using CASH model based on the number of breast cancer cases in first and second degree relatives, age of family members at disease onset, and age of woman presenting for genetic counseling. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Author, year**  **Quality** | **Interventions** | **Measures** | **Duration of followup** |
| **2013 Review** |  |  |  |
| Watson et al., 1999149  Good | Self-administered questionnaires given at genetic clinic immediately, pre-, and postgenetic consultation, and by postal survey at 1-, 6-, and 12-month followup | GHQ: 12-item questionnaire to screen individuals for psychiatric disorders  IES: 17-item questionnaire to measure an individual’s level of distress in relation to a specific event or condition  NSI: Lifetime risk perception assess as a 1 in x odds ratio  Relative risk assessed on a 5-point scale Breast cancer incidence assessed as 1 in x STAI: Measures an individual’s current anxiety feelings | Years: NR  12 months |

| **Author, year Quality** | **Results** | **Conclusions** | **Funding source** |
| --- | --- | --- | --- |
| **2013 Review** |  |  |  |
| Watson et al., 1999149  Good | GHQ: One-third had notable levels of distress. There was no statistically significant change in general mental health at each followup compared with pre-counseling level.  Cancer Anxiety and Helplessness / IES: No statistically significant changes in levels of cancer-specific distress. Followup assessment revealed that 13% (35/268) had received some psychological intervention during the 12 months since attending the clinic. Of these, 7% (n=19) had received psychotropic medication, 4% (n=10) had engaged in psychological counseling, and 2% (n=6) had received both forms of intervention.  Levels of state anxiety: Anxiety levels at precounseling were at similar levels to those reported in healthy women attending for breast cancer screening (mean 38.7), with a significant downward shift immediately postcounseling (mean 35.2, p<0.001).  Perception of risk: Specific figures about risk, provided within genetic counseling, tend not to be remembered. Continual overestimators may be worrying unnecessarily and excessively about breast cancer risk and under-estimators appear undisturbed by the information that their risk is greater than they thought. Underestimators were not significantly different from the rest of the sample in terms of their scores for intrusive and avoidant thoughts about breast cancer risk when assessed precounseling. However, at 12 months, their scores were significantly lower than the rest on each of the scales (avoidance p=0.02; intrusion p=0.006), indicating that in the long-term they are less likely to report having intrusive thoughts about breast cancer risk. High levels of cancer-specific distress were found in pregenetic counseling, with 28% reporting that they worried about breast cancer "frequently or constantly" and 18% that worry about breast cancer as a "severe or definite" problem. Following genetic counseling, levels of cancer- specific distress were unchanged. General mental health remained unchanged over time (33% psychiatric cases were detected pregenetic counseling, and 27% 12 months after genetic counseling). | High levels of cancer-related worry compare unfavorably to previously gathered data on general population risk samples. Genetic counseling does not alleviate cancer-specific distress in a substantial minority of women; this contradicts previous U.S. findings.  A single counseling session may not shift worries in some women.  General levels of psychological morbidity unaffected by genetic counseling.  Substantial minority of women who do not benefit from counseling and continue to overestimate risk, and worry was unrelieved. Study highlights problems with genetic counseling, e.g. some women continue to overestimate risk despite being told otherwise. Anxiety is not alleviated by genetic counseling, and women who continue to overestimate their risk and worry about breast cancer are likely to go on seeking unnecessary screening. | The Cancer Research Campaign  (CRC project CP1026) |

**Abbreviations:** aOR=adjusted odds ratio; BRCA=breast cancer susceptibility gene; BRCAPRO= breast cancer susceptibility gene prediction model; BCSC=Breast Cancer Surveillance Consortium; BSI=Brief Symptom Inventory; CASH=Cancer and Steroid Hormone Study; CG=control group; CGSW=Cancer Genetics Service for Wales; CI=confidence interval; CUK=Cancer Research UK; CWS=Cancer Worry Scale; CWS-R=Cancer Worry Scale-Revised; DUKE-SSQ=DUKE Social Support Questionnaire; FDR=first-degree relative; FHC=family history clinic; GHQ=General Health Questionnaire; GHQ-30=General Health Questionnaire 30; GP=general practitioner; GRACE=Genetic Risk Assessment in the Clinical Environment; HADS=Hospital Anxiety and Depression Scale; HADS-Anxiety=Hospital Anxiety and Depression Scale-Anxiety; HADS-D=Hospital Anxiety and Depression Scale-Depression; IES=Impact of Events Scale; IES-A=Impact of Events Scale-Avoidance; IES-I=Impact of Events Scale-Intrusion; IGC=Individual genetic counseling; IQR=interquartile range; LCIS=lobular carcinoma in situ; MCMQ=Medical Coping Modes Questionnaire; NA=not applicable; NHS=National Health Service; NR=not reported; NS=not significant; NSI=Neuropsychological Symptom Inventory; PAS=Psychiatric Assessment Schedule; PC=psychosocial counseling; PCP=primary care provider; PGC=psychological group counseling; PPC=Perceived personal control; R&D=research and development; RCT=randomized control trial; RST=referral screening tool; SD=standard deviation; SDR=second-degree relative; SD=standard deviation; SPIKES=Setting up, Perception, Invitation, Knowledge, Emotions- Protocol for delivering bad news; STAI=State/Spielberger Trait Anxiety Index; TRACE=trial of genetic assessment in breast cancer; U.K.=United Kingdom; U.S.=United States; VA=video after; VAS=Visual Analogue Scale; VB=video before