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| **Author, year****Quality** | **Sub-category** | **Purpose** | **Study type** | **N** |
| **Current Review** |  |  |  |  |
| Andrews et al., 2004150Fair | Psychological | Explore characteristics of those who choose to receive their testing results. | Prospective cohort | Eligible: 65Enrolled: 60 |
| Godard et al., 2007157Good | Psychological | To determine why people decline genetic testing. | Prospective cohort | 364 who withdrew before or after genetic testing |

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| **Author, year****Quality** | **Country** | **Population and setting** | **Demographics** | **Inclusion and exclusion criteria** |
| **Current Review** |  |  |  |  |
| Andrews et al., 2004150Fair | Australia | Women of Ashkenazi Jewish ancestry, who underwent genetic testing, at a hospital clinic in Sydney | Mean age (years): 50.9 | Inclusion: Ashkenazi Jewish women ages ≥20 years with and without prior breast/ovarian cancer who agreed to provide information about post-test anxiety; study evaluated anxiety in those who received testing results and those who did not. |
| Godard et al., 2007157Good | Canada | Individuals from high risk breast and ovarian cancer families who declined genetic testing | Mean age: not reported -Age <40 years: 16.9% -Age 40 to 59 years: 43.3% -Age ≥60 years: 39.8%Female: 85.9% Male:14.1% | 1,220 individuals from 385 high-risk families; 886 received results and 364 withdrew either before or after genetic testing. 234 of these voluntarily explained their withdrawal. |

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| **Author, year****Quality** | **Risk level definition** | **Population/mutation status** | **Measures** | **Duration of** **followup** |
| **Current Review** |  |  |  |  |
| Andrews et al., 2004150Fair | **Using the National Guidelines on Familial Aspects of Breast Cancer**Average risk (lifetime risk of 1:8 to 1:12): 45%High risk (lifetime risk of 1:2 to 1:4 or higher): 22%**Using BRCA PRO:** Score < 10%: 29Score > 10%: 31 | BRCA carriers and noncarriers | Impact of Event Scale (15-item) State Component of the State-Trait Anxiety Inventory (STAI-State) Beck Depression Inventory (BDI) Satisfaction with the Decision to Undergo Testing (pleasure, unsure or regretted having had the test at 12 months after result disclosure) | Years: NR12 months |
| Godard et al., 2007157Good | Individuals were recruited if family met one of the following characteristics: 1) >4 individuals with breast and/or ovarian cancer diagnosed in 1st or 2nd degree relatives; 2) families with 3 individuals with breast and/or ovarian cancer in 1st degree relatives; and 3) families with an identified *BRCA1/2* mutation. | BRCA mutation carriers and noncarriers. Of those who withdrew after testing: 45.8% (87/190) had no mutation and 54.2% (103/190) had a mutation. | Those who declined to receive results voluntarily submit reasons for withdrawal; recorded in notes and comments received from the research subjects or taken by genetic counselors and genetic nurses. | Years: NRThrough completion of genetic counseling and testing. |

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| **Author, year****Quality** | **Results** | **Conclusions** | **Funding source** |
| **Current Review** |  |  |  |
| Andrews et al., 2004150Fair | **Baseline vs. 4 months vs. 12 months, among those without prior breast cancer (n=50)**Carriers (n=4) Breast cancer worry: 23.0 vs. 12.8 vs. 11.5Anxiety: 42.7 vs. 33.5 vs. 35.5Depression 7.3 to 5.0 to 7.0Noncarriers (n=28)Breast cancer worry: 11.5 vs. 7.6 vs. 6.3Anxiety: 39.7 vs. 45 vs. 39.6Carriers and noncarriers combinedBreast cancer worry for all non affected women: p=0.018 for 4 months vs. baseline and p=0.002 for 12 months vs. baselineAnxiety and depression scores were not significantly different from baselineDecline to be tesed: 34% (17/50)**Baseline vs. 4 months vs. 12 months, among those with prior breast cancer (n=10)**Carriers (n=3) Breast cancer worry: 21.7 vs. 15.5 vs. 10.5 Anxiety: 25.1 vs. 31.5 vs. 26.5Depression: 9.3 vs. 10.0 vs. 7.0Noncarriers (n=6)Breast cancer worry: 23.3 vs. 17.3 vs. 16.8 Anxiety: 34.1 vs.40.9 vs. 33.3Depression: 6.3 vs. 6.6 vs. 4.8 | Breast cancer anxiety declined significantly for both the carrier and noncarrier groups. No significant change from baseline in generalized anxiety or depression. No significance testing done on the affected women because of small numbers. | NIH |
| Godard et al., 2007157Good | **Prior to 1st counseling session vs. after 1st counseling session vs. after 1st blood draw**Timing of withdrawal: 48.8% (163/334) vs. 37.4% (125/334) vs. 12.8% (46/334)Concerns/reasons for withdrawal prior to 1st counseling sessionExpected psychological impact: 19 vs. 66 Saw no advantage to genetic counseling: 11 vs. 23Did not want to discuss cancer or preferred testing in clinical setting: 19 vs. NR Concern about insurance: 3 vs. 11Logistical constraints: NR vs. 14 Relative's refusal to participate or difficulty contacting family: NR vs. 20 | Anxiety was the most common reason for withdrawing from genetic testing. Confidentiality did not come up as a concern. Cost was not an issue in this study because testing was provided as part of the study (no charge). | Canada Institutes of health for the INHERITS BRCAs research program. |

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| **Author, year****Quality** | **Sub-category** | **Purpose** | **Study type** | **N** |
| **Current Review** |  |  |  |  |
| Lieberman et al., 2017161Good | Testing approaches | To compare streamlined BRCA screening via proactive recruitment in medical settings with self-referral. | Prospective cohort | Eligible: NREnrolled: 1771 (1027 recruiter enrolled vs. 744 self-referred) Analyzed: 845 1 week after testing prior to result disclosure, 623 6 months after testing, after receiving results |

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| **Author, year****Quality** | **Country** | **Population and setting** | **Demographics** | **Inclusion and exclusion criteria** |
| **Current Review** |  |  |  |  |
| Lieberman et al., 2017161Good | Israel | Unclear, recruiter enrolled patients recruited from mammography center, ambulatory clinics, and an executive screening clinic | Mean age (years): 52 (SD 13); 54 recruiter enrollees vs. 48 self- referred enrollees, p<0.001 79% female | Inclusion: Ashkenazi Jewish, age ≥25 years, previously unaffected with cancer, and without a known familial BRCA mutation.Exclusion: Not reported |

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| **Author, year****Quality** | **Risk level definition** | **Population/mutation status** | **Measures** | **Duration of** **followup** |
| **Current Review** |  |  |  |  |
| Lieberman et al., 2017161Good | Ashkenazi Jewish, self-defined as 4 grandparents of Ashkenazi Jewish origin | BRCA carriers and noncarriers | General satisfaction with participation and testing (scale 1 to 5, very dissatisfied to extremely satisfied) Impact of Events Scale (IES, scale 0 to 75)Knowledge of breast cancer genetics and genetic testing (scale 0 to 10) Perceived Personal Control (PPC, scale 0 to 2)Satisfaction with Health Decision scale (SWD, scale 6 to 30)State-Trait Anxiety Inventory (STAI, scale 6 to 24) | Years: NR 6 months |

| **Author, year****Quality** | **Results** | **Conclusions** | **Funding source** |
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| **Current Review** |  |  |  |
| Lieberman et al., 2017161Good | **Recruiter enrolled vs. self-referred***Mean on psychological scale*IES before result disclosure: 5.4 vs. 6.2, p=0.02IES after result disclosure, non carriers only: 4.8 vs. 5.6, p=NSIES score >30 (indicating high post-event distress): 0.7% vs. 2.7% , p=0.02 PPC before result disclosure: 1.00 vs. 1.10, p<0.001PPC after result disclosure, non carriers only: 1.18 vs. 1.28, p=0.006 STAI before result disclosure: 9.8 vs. 10.2, p=NSSTAI after result disclosure: 9.8 vs. 10.2, p=NS Knowledge before result disclosure: 6.8 vs. 7.4, p<0.001 Knowledge after result disclosure: 6.8 vs. 7.5, p<0.001 SWD before result disclosure: 25.2 vs. 26.3, p<0.001 SWD after result disclosure: 26.2 vs. 26.8, p=0.01Very satisfied before result disclosure: 40% vs. 55%, p<0.001 Satisfied before result disclosure: 48% vs. 40%Very satisfied after result disclosure: 53% vs. 61%, p=0.02 Satisfied after result disclosure: 37% vs. 35%**Carriers vs. noncarriers** *Mean on psychological scale* IES: 19.9 vs. 4.9, p<0.001PPC: 1.43 vs. 1.23, p=NSSTAI: 12.6 vs. 9.9, p=0.016Knowledge: 8.7 vs. 7.1, p<0.001SWD: 25.3 vs. 26.5, p=NSVery satisfied: 63% vs. 57%, p=NSSatisfied: 26% vs. 36% | Overall 90% of participants reported being satisfied or very satisfied both 1 week and 6 months after testing, with increased satisfaction over time. Most participants (71%) and 40% of carriers did not have relevant family history. | Breast Cancer Research Foundation |

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| **Author, year****Quality** | **Sub-category** | **Purpose** | **Study type** | **N** |
| **Current Review** |  |  |  |  |
| Lumish et al., 2017163Fair | Psychological | To describe patient understanding, psychological outcomes and utilization of genetic information among patients with a personal or family history of breast or ovarian cancer who were offered panel gene testing.  | Cohort | Eligible: 367Enrolled: 232Analyzed:103 without prior personal history of cancer |
| Manchanda et al., 2015164Good | Testing approaches | To assess the benefits/disadvantages of a population-based approach to genetic testing for high penetrance- dominant gene mutations compared with the conventional family history- based approach. | RCT | Eligible: NR Enrolled: 1042Randomization: 1034 (530 population screening, 504 family-history based)Analyzed: 1017 (520 population screening, 497 family-history based) |
| Smith et al., 1999170Good | Psychological | To compare psychological distress among individuals tested for *BRCA1* based on siblings' test results | Cohort | Eligible/Invited: 759Enrolled 87 males and 125 females who completed baseline interview (n=408) and were tested for *BRCA1*, received results in person from genetic counselor (n=230) and completed a follow- up interview 1-2 weeks after the receipt of their test results (n=212) and had completed data on all variables |

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| **Author, year****Quality** | **Country** | **Population and setting** | **Demographics** | **Inclusion and exclusion criteria** |
| **Current Review** |  |  |  |  |
| Lumish et al., 2017163Fair | U.S. | Patients with family history of breast or ovarian cancerColumbia University Cancer Genetics Clinic | Mean age: 41.6 years (SD 13.0)Female: 93.2% (96/103) | Inclusion: All patients referred to the clinic for counseling for hereditary breast and ovarian cancer between June 2013 and May 2015.Exlusion: Non-English, deceased, no current contact information, no personal or fam history of breast or ovarian cancer or did not undergo genetic testing at the time of consultation. |
| Manchanda et al., 2015164Good | U.K. | North-London Jewish community | Mean age (years): 54.30 (SD: 14) 66.8% female | Inclusion: Age >18 years and Ashkenazi Jewish ethnicityExclusion: Known BRCA mutation, first-degree relatives of a BRCA carrier or previous BRCA testing |
| Smith et al., 1999170Good | U.S. | Participants are all part of larger main study of Kindred 2082, the largest known kindred identified with a *BRCA1* mutation (750 living members); all were invited to participate including those affected with breast and ovarian cancer | Mean age: men 46 years; women 46 years Men, n = 87Women, n=125 | Inclusion: All members of Kindred 2082; Utah and Idaho; all members of the Church of Jesus Christ of Latter-day Saints, primarily White and of northern European descent.Exclusion: Unable to consent to participate or unable to attend two in-person genetic counseling sessions at the University of Utah. |

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| **Author, year****Quality** | **Risk level definition** | **Population/mutation status** | **Measures** | **Duration of** **followup** |
| **Current Review** |  |  |  |  |
| Lumish et al., 2017163Fair | Any family history of breast or ovarian cancer | 13.5% (14/103) *BRCA1/2* positive66.9% (69/103) negative19.4% (20/103) VUS | IES (event related distress) Multidimensional Impact of Cancer Risk Assessment (MICRA, scale)SWD (Satisfaction with Decision Instrument) | June to December 2015Mean of 12.5 months after genetic testing (range 3 to 27 months |
| Manchanda et al., 2015164Good | Ashkenazi Jewish, self-defined as 4 grandparents of Ashkenazi Jewish origin | BRCA carriers and noncarriers | Health Anxiety Inventory (HAI, scale) Hospital Anxiety and Depression Scale (HADS, scale)Short Form 12-item (SF-12, both MSC [Mental Health Component] and PCS [Physical Health Component Scale] subscales)Multidimensional Impact of Cancer Risk Assessment (MICRA, scale) | 2008 to 2010 |
| Smith et al., 1999170Good | All members of known *BRCA1* mutation carrier kindred. | Known and unknown mutation status but all at risk for *BRCA1*Mutation carrier status: Men 33%; Women 38%. | Baseline State Anxiety Scale Test-related Distress:IES (event related distress) Carrier/noncarrier and sibling status (all siblings test positive; all siblings tested including both positive and negative; all siblings tested negative; no other siblings with results yet) | 1 to 2 weeks after testing result |

| **Author, year****Quality** | **Results** | **Conclusions** | **Funding source** |
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| **Current Review** |  |  |  |
| Lumish et al., 2017163Fair | **Positive vs. negative vs. VUS**Mean IES total score: 18.1 (SD 12) vs. 8.8 (SD 11) vs. 6.7 (SD 11), p<0.05 for positive vs. othersMean IES-I score: 1 (SD 0.8) vs. 0.4 (SD 0.5) vs. 0.3 (SD 0.5), p=0.006 for positive vs. others and p=0.008 for VUS vs. negativeMean IES-A score: 1 (SD 0.6) vs. 0.5 (SD 0.6) vs. 0.4 (SD 0.7), p=NSMean IES-H score: 0.5 (SD 0.7) vs. 0.2 (SD 0.4) vs. 0.2 (SD 0.4), p=NSMean MICRA total score: 29.6 (SD 14.0) vs. 19.0 (SD 10.8) vs. 12. 4 (SD 8.6), p=0.002 for positive vs. negative and p=0.001 for VUS vs. negativeMean MICRA-distress score: 10.9 (SD 5.7) vs. 3.3 (SD 5.8) vs. 1.5 (SD 3.1), p<0.05 for positive vs. othersMean MICRA-uncertainty score: 9.6 (SD 7.7) vs. 6.0 (SD 7.3) vs. 4.3 (SD 5.3), p=NSMean MICRA-positive experience score: 9.1 (SD 4.6) vs. 9.7 (SD 7.1) vs. 6.6 (SD 7.3), p=0.04 for positive vs. negative and p=0.01 for VUS vs. negativeMean SWD score: 21.7 (SD 3.3) vs. 23.1 (SD 2.2) vs. 22.2 (SD 4.2), p=NS | Patients without personal history of breast or ovarian cancer, who tested positive for a mutation tended to have higher levels of post-testing distress and some intermediate levels of distress among those receiveing a VUS. | NIA Grant T35 AG 044303 |
| Manchanda et al., 2015164Good | 13 carriers were detected in teh PS arm, and of these only 3 had a clinically significant FH.9 carriers were detected in the FH arm5 more carriers were detected among FH-negative FH-arm participants following study completion.Overall decrease in anxiety, distress and uncertainty with time. The overall *BRCA1/2* prevalence detected was 2.45%.Of the 1034 participants, 12.4% (128) were FH positive.The most decrease in anxiety was baseline to 7 days (-0.64) compared to 7 days to 3 mo (-0.24).Positive experience scores increased by QOL and health anxiety did not change with time (after testing).For 27 BRCA carriers in the population, the sensitivity of FH-based approach is 44.4% (95% CI=26.4 to 63.9); positive likelihood ratio is 3.86 (95% CI=2.2 to 5.81) and negative-likelihood ratio is 0.63 (95% CI = 0.41 to 0.84).No signficant short-term differences between FH and population-based approaches with respect to levels of anxiety, depression, health anxiety, physical/mental well-being, distress, and uncertainty linked to genetic testing. | Overall anxiety decreases in both groups.No difference between groups in terms of psychological outcomes.FH-strategy failed to detect some mutation carreiers who had negative FH. | Cancer Charity The Eve Appeal |
| Smith et al., 1999170Good | Relative to noncarriers, men who tested positive and who were the first sibling tested experienced more distress than those who tested positive when all of their siblings were negative.Noncarrier males whose siblings all tested positive also experienced distress. For women, distress was greatest among those who learned they were carriers. Carrier women whose siblings were negative or mixed had attenuated levels of elevated distress. | Siblings’ reaction to testing results varies by whether siblings have been tested and what their results were. | NCI |

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| **Author, year****Quality** | **Sub-category** | **Purpose** | **Study type** | **N** |
| **2013 Review** |  |  |  |  |
| Arver et al., 2004151NA | Psychological | To prospectively evaluate the psychological consequences during the 1st year following pre-symptomatic testing with respect to anxiety, depression, and QOL in self-referred individuals tested for breast/ovarian or colon cancer genes known in their families. | Before and after | Eligible: NR Enrolled: 66Analyzed: 63 at week 1 and 2 months, 61 at 6 months, 59 at 12 months |
| Dagan and Shochat, 2009152FairSame population as Shochat and Dagan, 2010169 | PsychologicalCancer worry | To investigate the association between *BRCA1/2* status and HR-QOL in Ashkenazi asymptomatic women. | Case-control | Eligible: 152 (39 carriers, 77 noncarriers, 36 controls)Enrolled: 73 (17 carriers, 20 noncarriers, 36 controls)Analyzed: 73 (17 carriers, 20 noncarriers, 36 controls) |
| Ertmanski et al., 2009153NA | Psychological | To predict which women might suffer from abnormally high levels of anxiety and depression after receiving a positive genetic test result. | Before and after | Eligible: NR Analyzed: 56 |

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| **Author, year****Quality** | **Country** | **Population and setting** | **Demographics** | **Inclusion and exclusion criteria** |
| **2013 Review** |  |  |  |  |
| Arver et al., 2004151NA | Sweden | Clinical Genetic Unit, Karolinska University Hospital, Stockholm | Mean age of 40.5 years (SD 11.1) | Inclusion: Healthy females belonging to a family with a known mutation in 1 of the genes *(BRCA1, BRCA2, MLH1* , or *MSH2* ), wishing for genetic testing, aged ≥18 years, Swedish speakingExclusion: Individuals with cancer and men |
| Dagan and Shochat, 2009152FairSame population as Shochat and Dagan, 2010169 | Israel | Rambam Health Care Campus oncogenetic clinic | Mean age of 51.5 years (SD 8.9)Carriers: 51.4 years (SD 9.1)Noncarriers: 54.5 years (SD 9.4)Controls: 50.0 years (SD 8.3) | Inclusion: Asymptomatic *BRCA1/2* carriers and noncarriers who had undergone genetic testing at Rambam Health Care Campus click*Control:* Age-matched low-risk community control, with no family history of breast/ovarian cancer and not tested for *BRCA1/2* mutationsExclusion: Major chronic illnesses, pregnancy, aged ≤1 year |
| Ertmanski et al., 2009153NA | Poland | Women seeking genetic testing at cancer genetics center in Poland. Women who tested positive for BRCA were included in analysis. | NR for women without breast cancer | Inclusion: Women who tested positive for BRCA mutation and completed both baseline and followup measuresExclusion: Not reported |

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| **Author, year****Quality** | **Risk level definition** | **Population/mutation status** | **Measures** | **Duration of** **followup** |
| **2013 Review** |  |  |  |  |
| Arver et al., 2004151NA | Women with a 50% or 25% risk of being gene carriers | BRCA carriers and non- carriers | Hospital Anxiety and Depression Scale (HADS, each subscale 0 to 21) Swedish SF-36 Health Survey (SF-36, scale NR) | 1995 to 1999At 1 week, 2, 6, and 12 months |
| Dagan and Shochat, 2009152FairSame population as Shochat and Dagan, 2010169 | FDR and/or SDR with breast or ovarian cancer and/or relative with other cancer | BRCA carriers and noncarriers | The Brief Symptom Inventory (BSI, scale NR)Cancer Related Worry (CRW, scale NR)Health-Related Quality of Life (HR-QOL, scale NR) | January 2006 to November 2007Mean followup of 8.0 years (SD 1.9) |
| Ertmanski et al., 2009153NA | Positive family history of early onset breast or ovarian cancer | BRCA positive | Impact of Events Scale (IES, scale 0 to 75)State-Trait Anxiety Inventory (STAI, scale 1 to 10) | January 2005 to December 2007At 1 month and 1 year |

| **Author, year****Quality** | **Results** | **Conclusions** | **Funding source** |
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| **2013 Review** |  |  |  |
| Arver et al., 2004151NA | **Pretest vs. 1 week posttest vs. 2 months posttest vs. 6 months posttest vs. 1 year post-test**Mean on psychological scaleHADS-A (estimated from graph): 5.6 vs. 4.6 vs. 4.0 vs. 4.0 vs. 4.2; p<0.001 over time, only pretest is above normal valueHAD-D (estimated from graph): 2.4 vs. 2.4 vs. 2.4 vs. 2.4 vs. 2.6; p=NSSF-36 general health: 78.7 (SD 19.2) vs. 78.8 (18.1) vs. 79.6 (20.2) vs. 81.0 (20.1) vs. 81.0 (20.3); p=NSSF-36 vitality: 67.0 (21.9) vs. 66.4 (19.8) vs. 71.9 (21.8) vs. 68.2 (25.4) vs. 69.3 (23.4); p=NSSF-36 social function: 87.3 (15.6) vs. 86.5 (20.0) vs. 91.1 (17.5) vs. 89.1 (19.4) vs. 89.0 (18.2); p=NSSF-36 role emotional: 83.8 (30.5) vs. 82.5 (34.8) vs. 79.2 (38.6) vs. 88.0 (29.2) vs. 86.2 (33.1)SF-36 mental health: 77.4 (18.7) vs. 74.9 (20.0) vs. 80.1 (19.5) vs. 78.6 (17.9) vs. 78.3 (19.6); p=NS | Anxiety went down over time, however depression and QOL were not affected. The results were not separated out by carriers and noncarriers though. | King Gustav V's Jubilee Fund and the Swedish Cancer Society |
| Dagan and Shochat, 2009152FairSame population as Shochat and Dagan, 2010169 | **Carriers (n=17) vs. noncarriers (n=20) vs. controls (n=36)**Mean on psychological scale (SD)CRW: 0.75 (0.5) vs. 0.67 (0.5) vs. 0.45 (0.4); p=NSBSI total: 0.66 (0.7) vs. 0.35 (0.4) vs. 0.50 (0.4); p=NSHR-QOL total: 74.4 (19.2) vs. 80.3 (13.7) vs. 83.0 (10.2); p=NSHR-QOL role limitation due to emotional problems subscale: 74.5 (36.4) vs. 91.7 (21.3) vs. 97.2 (9.3); p<0.01HR-QOL role limitation due to physical problems subscale 79.4 (30.9) vs. 85.0 (28.6) vs. 95.1 (13.1); p=0.05 | Carriers had higher QOL distress regarding role limitation due to emotional problems and physical problems compared to noncarriers and controls. | NR |
| Ertmanski et al., 2009153NA | **Pretest vs. 1 month posttest vs. 1 year posttest**Mean STAI-Anxiety: 6.6 vs. 6.5 vs. 6.5At 1 month posttest, IES mean score was 23.8, this is considered a low level of negative psychological reaction | For women not affected by breast cancer themselves, testing positive for the BRCA mutation did not increase anxiety and did not have a negative psychological impact. | Polish Ministry of Science and Higher Education grant number 2 PO5 D 12929 |

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| **Author, year****Quality** | **Sub-category** | **Purpose** | **Study type** | **N** |
| **2013 Review** |  |  |  |  |
| Foster et al., 2007154Fair | Cancer worry | To assess long-term impact of genetic testing for breast/ovarian cancer predisposition in a clinical cohort. | Prospective cohort | Eligible: NR Analyzed: 154 |
| Geirdal et al., 2005156GoodSame population as Geirdal and Dahl, 2008155 | Psychological | To explore psychological distress in women at risk of FBOC and HNPCC cancers and without access to genetic testing, and to compare them with mutation carriers and with healthy women from the general population. | Prospective cohort | Eligible: 10,321 (253 FBOC, 10,000 normal controls, 68 *BRCA1* mutation carriers) Enrolled: 10,244 (176 FBOC, 10,000 normal controls, 68 *BRCA1* mutation carriers) Analyzed: 10,244 (176 FBOC, 10,000 normal controls, 68 *BRCA1* mutation carriers) |
| Geirdal and Dahl, 2008155GoodSame population as Geirdal et al., 2005156 | Psychological | To examine how coping strategies used by women with FBOC were associated with caseness of anxiety disorder and to explore if a similar pattern of associations were observed in the carrier group. | Prospective cohort | Eligible: 333 (253 FBOC, 80 *BRCA1* mutation carriers)Enrolled: 242 (174 FBOC, 68 *BRCA1* mutation carriers) Analyzed: 242 (174 FBOC, 68 *BRCA1* mutation carriers) |

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| **Author, year****Quality** | **Country** | **Population and setting** | **Demographics** | **Inclusion and exclusion criteria** |
| **2013 Review** |  |  |  |  |
| Foster et al., 2007154Fair | U.K. | Recruited from 9 U.K. centers between 1997 to 2000 | Median age: 42 years (range: 23 to 72) | Inclusion: Unaffected by cancer and from families with a *BRCA1/2* mutation identified in an affected blood relativeExclusion: Not reported |
| Geirdal et al., 2005156GoodSame population as Geirdal and Dahl, 2008155 | Norway | Section for Genetic Counseling, Department of Cancer Genetics, The Norwegian Radium Hospital | **Mean age (years)**FBOC: 40.5 (SD 9.7)*BRCA1* carriers: 42.0 (SD 10.6)Controls: 42.5 (SD 10.9) | Inclusion: Self-referred or referred from doctors to Section for Genetic Counseling, at risk for FBOC or BRCA positiveControls: random sample of age-matched women completing same questionnaires Exclusion: Not reported |
| Geirdal and Dahl, 2008155GoodSame population as Geirdal et al., 2005156 | Norway | Section for Genetic Counseling, Department of Cancer Genetics, The Norwegian Radium Hospital | **Mean age (years)**FBOC: 40.5 (SD 9.7)*BRCA1* carriers: 42.0 (SD 10.6) | Inclusion: FBOC: Women aged ≥18 years, had been to genetic counseling at Section for Genetic Counseling*BRCA1* positive: Women aged ≥18 years, had been to genetic counseling and testing at Section for Genetic Counseling, carried a demonstrable mutationExclusion: FBOC: Any identifiable mutation in family, diagnosed with breast or ovarian cancer *BRCA1* positive: Diagnosed with breast or ovarian cancer |

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| **Author, year****Quality** | **Risk level definition** | **Population/mutation status** | **Measures** | **Duration of** **followup** |
| **2013 Review** |  |  |  |  |
| Foster et al., 2007154Fair | 50% risk of inheriting a *BRCA1/2* mutation, this was lower if an intervening relative had died | BRCA carriers and non- carriers | Cancer worry scale-revised (CWS-R, scale 6 to 24)General Health Questionnaire (GHQ- 28, scale 0 to 28) | 1997 to 20003 years |
| Geirdal et al., 2005156GoodSame population as Geirdal and Dahl, 2008155 | Family history of ≥2 FDR (or SDR though males) with early onset (<50 years) breast cancer and/or multiple cases of breast cancers in the same lineage compatible with dominant inheritance in the family and/or a combination of early onset breast cancer and ovarian cancer in the family | BRCA positiveFBOC, mutation status unknown | Beck Hopelessness Scale (BHS, scale 0 to 20)General Health Questionnaire (GHQ- 28, scale 0 to 84)Hospital Anxiety and Depression Scale (HADS, each subscale 0 to 21)Impact of Event Scale (IES, IES-I subscale 0 to 35 and IES-A subscale 0 to 40) | January 2000 to December 2001 |
| Geirdal and Dahl, 2008155GoodSame population as Geirdal et al., 2005156 | Family history of ≥2 FDRs (or SDRs though males) with early onset (<50 years) breast cancer and/or multiple cases of breast cancers in the same lineage compatible with dominant inheritance in the family and/or a combination of early onset breast cancer and ovarian cancer in the family | BRCA positiveFBOC, mutation status unknown | Coping Orientation to Problems Experienced Scale (COPE, scale varied for each coping strategy) Hospital Anxiety and Depression Scale (HADS, anxiety subscale 0 to 21) | January 2000 to December 2001 |

| **Author, year****Quality** | **Results** | **Conclusions** | **Funding source** |
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| **2013 Review** |  |  |  |
| Foster et al., 2007154Fair | **Carriers (n=53) vs. noncarriers (n=101)**Mean on psychological scales (SD)GHQ at baseline: 2.7 (4.6) vs. 2.6 (3.8); p=NSGHQ at 3 year posttest: 4.5 (6.3) vs. 3.7 (5.3); p=0.03 for carriers baseline vs. posttest; p=NS for between groups differencesCWS-R at baseline: 11.7 (3.1) vs. 11.5 (3.4); p=NSCWS-R at 3 year posttest: 10.4 (3.6) vs. 9.3 (2.1); p=0.03 for carriers baseline vs. post-test; p=NS for between groups differences | Overtime cancer worry decreased for both carriers and noncarriers, while general distress increased for both groups, with 18% of carriers and 17% of noncarriers identified as cases using the GHQ-28 at 3 year followup. | Award C1226/A137 from Cancer Research U.K. |
| Geirdal et al., 2005156GoodSame population as Geirdal and Dahl, 2008155 | **FBOC (n=176) vs. carriers (n=68) vs. controls (n=10,000)**Mean differences on psychological scales (SD)HADS-D: 2.4 (2.9) vs. 1.7 (2.4) vs. 3.2 (2.9); p<0.05 FBOC vs. carriersHADS-A: 5.2 (3.8) vs. 4.2 (3.6) vs. 4.5 (3.5); p<0.05 FBOC vs. carriersGHQ-28: 3.3 (5.4) vs. 2.3 (4.0) vs. NR; p<0.05 FBOC vs. carriersIES-I: 10.2 (8.7) vs. 9.8 (7.6) vs. NR; p=NSIES-A: 8.3 (7.9) vs. 8.4 (7.6) vs. NR; p=NSBHS: 3.7 (2.5) vs. 3.8 (2.6) vs. NR; p=NS | Women in FBOC group, but who had not undergone genetic testing were more anxious, more depressed, and higher general distress than women who were known to be BRCA mutation carriers. | The Norwegian Foundation for Health and Rehabilitation, the National Council for Mental Health, Norway, and a donation from Edith Kongshe, Oslo |
| Geirdal and Dahl, 2008155GoodSame population as Geirdal et al., 2005156 | **FBOC (n=174) vs. carriers (n=68)**Mean HADS-A: 5.3 (SD 3.9) vs. 4.2 (SD 3.6); p=0.04Prevalence of HADS-defined anxiety: 24% vs. 24%; p=NSMean (SD) on subscales of COPE with significant differences, higher scores=strategy used more oftenActive coping: 10.2 (3.2) vs. 8.7 (3.2); p=0.002Planning: 9.1 (3.5) vs. 7.9 (3.7); p=0.01Suppression of competing activities: 6.7 (2.7) vs. 5.2 (2.3); p<0.001Focus on and venting of emotions: 8.1 (3.6) vs. 6.2 (2.7); p<0.001Seeking instrumental support: 10.2 (3.6) vs. 7.4 (3.1); p<0.001Seeking emotional support: 9.4 (3.3) vs. 7.9 (2.7); p=0.003Acceptance: 12.4 (3.1) vs. 13.3 (2.9); p=0.01Mental disengagement: 6.7 (2.8) vs. 6.0 (2.2); p=0.03NS COPE subscales: positive reinterpretation and growth, restraint coping, denial, behavioral disengagement, turning to religion, and use of humor | Women in FBOC group, but who had not undergone genetic testing were more anxious than *BRCA1* mutation carriers.FBOC groups used many more coping strategies compared with *BRCA1* mutations carriers, however mutation carriers were more accepting of their breast cancer risk than those in the FBOC group and therefore may not have used other coping strategies. | The Norwegian Foundation for Health and Rehabilitation, the National Council for Mental Health, Norway, and a donation from Edith Kongshe, Oslo |

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| **Author, year****Quality** | **Sub-category** | **Purpose** | **Study type** | **N** |
| **2013 Review** |  |  |  |  |
| Graves et al., 2012158NA | Psychological | To examine long-term psychosocial outcomes in a large U.S. sample | Case-series | Eligible: 655Enrolled: 464Analyzed: 107 (unaffected) |
| Julian-Reynier et al., 2011159Good | Risk perception | To describe the sequences of preventive decisions made by women up to 5 years after disclosure of their test results and the surveillance/surgical options chosen by various age groups. | Prospective cohort | Eligible: 331Analyzed: 246 |
| Kinney et al., 2005160Poor | Psychological | To evaluate the effect of receiving genetic test results on general and cancer-specific psychological distress among African Americans at high-risk for carrying a deleterious *BRCA1* mutation. | Prospective cohort | Eligible: NR Analyzed: 52 |

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| **Author, year****Quality** | **Country** | **Population and setting** | **Demographics** | **Inclusion and exclusion criteria** |
| **2013 Review** |  |  |  |  |
| Graves et al., 2012158NA | U.S. | Women at the Lombardi Comprehensive Cancer Center Familial Cancer Registry | NR for women without breast cancer | Inclusion: Women ages 25 to 75 years, received *BRCA1/2* test results, and were at least 3 years post disclosure at the time of the studyExclusion: Not reported |
| Julian-Reynier et al., 2011159Good | France | French Cancer Genetic Network | **Mean age (years)**Carriers: 37.2Noncarriers: 41.7 | Inclusion: *BRCA1/2* mutation carriers and non- carriers in the same familiesExclusion: Not reported |
| Kinney et al., 2005160Poor | U.S. | Members of a high-risk African American kindred that was identified previously with the *BRCA1* mutation | NR for women without breast cancer | Inclusion: Women aged ≥18 years and members of the family identified in the genetic linkage study as having *BRCA1* mutation Exclusion: Not reported |

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| **Author, year****Quality** | **Risk level definition** | **Population/mutation status** | **Measures** | **Duration of** **followup** |
| **2013 Review** |  |  |  |  |
| Graves et al., 2012158NA | Not reported | 43.9% (47/107) BRCA positive56.1% (60/107) BRCA true negative | Impact of Events Scale (IES, scale 0 to 75)State-Trait Anxiety Inventory (STAI, scale 20 to 80) | Years: NRMedian of 5 years posttest |
| Julian-Reynier et al., 2011159Good | *BRCA 1/2* mutation carriers or members of families where a mutation was identified | 41% (101/246) *BRCA 1/2* | Perception of personal risk of cancer (6- point Likert scale)Preventive health behaviors | 2000-20065 years |
| Kinney et al., 2005160Poor | All women from *BRCA1* mutation positive family | *BRCA 1* carriers and noncarriers | Center for Epidemiologic Studies- Depression (CES-D, scale NR)Impact of Events Scale (IES, scale 0 to 75)State-Trait Anxiety Inventory (STAI, scale 1 to 10) | Years: NR 4 months |

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| **Author, year****Quality** | **Results** | **Conclusions** | **Funding source** |
| **2013 Review** |  |  |  |
| Graves et al., 2012158NA | **Logistic regression bivariate analysis (statistically significant associations)**Positive genetic test with genetic testing distress: p=0.03 Negative genetic test with positive experiences: p=0.008**Multiple regression analysis (statistically significant associations)**Genetic testing distressModel 1 adjusting for marital status, pretest cancer distress, and receipt of RRM accounted for 13% of variance in genetic testing distress; p=0.003Model 2 adjusting for model 1 and genetic test result (positive or true negative) accounted for an additional 12% of variance in genetic testing distress; p=0.00001 Positive experiencesModel 1 adjusting for income and pretest cancer distress accounted for 8% of variance in positive; p=0.04Model 2 adjusting for model 1 and genetic test result (positive or true negative) accounted for an additional 6% of variance in positive experiences; p=0.008 | Among unaffected women, *BRCA1/2* carriers reported higher genetic testing distress and lower positive experiences compared with *BRCA1/2* true negatives. | Department of Defense grant DAMD BC021733, Jess and Mildred Fisher Center for Familial Cancer Research, and Lombardi Comprehensive Cancer Center's Familial Cancer Registry and Clinical and Molecular Epidemiology Shared Resources |
| Julian-Reynier et al., 2011159Good | **Carriers (n=101) vs. noncarriers (n=145)**Change from before test result to after test result of those who perceived personal risk as highBreast cancer risk: +18% vs. -47%; p=0.016 for carriers change and p<0.001 for noncarriers changeOvarian cancer risk: +20% vs. -27%; p=0.007 for carriers change and p<0.001 for noncarriers change | Carriers’ perception of risk increased after receiving genetic test results, while noncarriers perception of risk decreased. | Institute National du Cancer |
| Kinney et al., 2005160Poor | Noncarriers unaffected with breast cancer decreased anxiety from baseline to 1 month followup; p=0.001, data not shown | Noncarriers’ anxiety went down after receiving genetic test results. | National Human Genome Research Institute, National Institute of Nursing Research and the National Cancer Institute |

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| **Author, year****Quality** | **Sub-category** | **Purpose** | **Study type** | **N** |
| **2013 Review** |  |  |  |  |
| Low et al., 2008162Fair | Psychological | To examine the relationship between mutation carrier status, personal cancer history, and the potential positive impact of genetic testing. | Prospective cohort | Eligible: NR Analyzed: 47 |
| Meiser et al., 2002165Good | Psychological | To study the psychological adjustment of women who have undergone testing for *BRCA1/2* breast and ovarian cancer susceptibility | Prospective cohort | Eligible: NREnrolled: 143 (30 carriers, 60 noncarriers, and 53 controls) Analyzed: 140 (30 carriers, 59 noncarriers, and 51 controls) |

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| **Author, year****Quality** | **Country** | **Population and setting** | **Demographics** | **Inclusion and exclusion criteria** |
| **2013 Review** |  |  |  |  |
| Low et al., 2008162Fair | U.S. | UCLA Familial Cancer Registry and Genetic Evaluation Program | NR for women without breast cancer | Inclusion: Aged ≥18 years with family history of breast, ovarian, or other cancer consistent with *BRCA1/2* heredity and/or 10% prior probability of carrying a *BRCA1/2* mutation based on published risk assessment dataExclusion: Did not complete followup data |
| Meiser et al., 2002165Good | Australia | Women in outreach clinics who had *BRCA1/2* testing, were healthy with a family history of breast or ovarian cancer, and approached 1 of 14 familial cancer clinics (FCC) and 6 associated clinics | Mean age of 40 years (SD 11.1) | Inclusion: Eligible for genetic testing and at risk for developing hereditary breast cancer with an affected living relative to provide blood sample Exclusion: History of breast or ovarian cancer, limited English literacy, and being tested for founder mutations only |

| **Author, year****Quality** | **Risk level definition** | **Population/mutation status** | **Measures** | **Duration of** **followup** |
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| **2013 Review** |  |  |  |  |
| Low et al., 2008162Fair | Personal and/or family history consistent with *BRCA1/2* heredity and/or 10% prior probability of carrying a *BRCA1/2* mutation | BRCA positive and negative Variant of uncertain significance was grouped with negative results | Brief COPE (scale NR)Emotional Approach Coping Scale (scale NR)Impact of Events Scale-Revised (IES- R, scale NR)Post-Traumatic Growth Inventory (PTGI, scale 0 to 105) | September 1998 to Fall 2003Average of 20.9 months |
| Meiser et al., 2002165Good | 25% mutation (*BRCA1/2* ) carrier risk: Subjects from high-risk family with closest affected relative or relative with a *BRCA* mutation is 2nd degree50% risk: Subjects from high-risk family who has either a 1st degree affected relative or unaffected relative with a known pathogenic *BRCA1/2* mutation | BRCA carriers and non- carriers | Beck Depression Inventory (BDI, scale 0 to 63)Impact of Events Scale (IES, scale 0 to 75)Miller Behavioural Style Scale (scale NR)State-Trait Anxiety Inventory (STAI, scale 20 to 80) | November 1996 to October 200012 months |

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| **Author, year****Quality** | **Results** | **Conclusions** | **Funding source** |
| **2013 Review** |  |  |  |
| Low et al., 2008162Fair | **Carriers (n=7) vs. noncarriers (n=40)**Mean on psychological scale (SE)PTGI total score (estimated from graph): 14 vs. 22; p=NR IES-R at 1-month posttest: 5.83 (2.47) vs. 1.37 (0.10); p<0.05Approach coping score: 2.32 (0.18) vs. 2.37 (0.14); p=NS | Women with BRCA positive mutations reported greater distress after testing than non- carriers, but did not report differences in positive life changes. | STOP CANCERResearch Career Development Award |
| Meiser et al., 2002165Good | **Carriers (n=30) vs. noncarriers (n=59) vs. controls (n=51)**Baseline mean scores (SD); p=NS for allBreast cancer worry: 13.1 (13.1) vs. 13.4 (14.6) vs. 16.0 (14.8)STAI: 36.1 (11.2) vs. 33.6 (12.1) vs. 33.6 (10.7)BDI: 5.5 (5.7) vs. 6.3 (6.7) vs. 5.9 (5.6)7-10 day followup mean scores (SD)Breast cancer worry: 21.2 (14.4) vs. 13.9 (16.1) vs. 14.9 (12.3); p=0.005 carriers vs. controls, p=NR carriers vs. noncarriersSTAI: 38.5 (13.8) vs. 31.6 (11.1) vs. 36.8 (12.1); p=0.024 noncarriers vs. othersBDI: 5.3 (6.2) vs. 5.7 (7.0) vs. 7.2 (6.8); p=NS4 month followup mean scores (SD)Breast cancer worry: 17.7 (18.6) vs. 8.1 (13.5) vs. 13.1 (13.5); p=NS carriers vs. controls; p=NR carriers vs. noncarriersSTAI: 36.8 (15.3) vs. 32.2 (10.8) vs. 36.3 (14.2); p=NSBDI: 6.2 (8.7) vs. 3.6 (5.4) vs. 6.4 (6.3); p=0.024 noncarriers vs. others 12 month followup mean scores (SD)Breast cancer worry: 16.1 (14.9) vs. 8.2 (14.2) vs. 12.3 (14.8); p=0.045 carriers vs. controls, p=NR carriers vs. noncarriersSTAI: 31.7 (10.5) vs. 36.2 (12.9) vs. 39.0 (12.2); p=0.007 noncarriers vs. controlBDI: 4.0 (5.1) vs. 5.4 (6.4) vs. 6.9 (7.00); p=NS | Those without deleterious BRCA mutations derive psychological benefits from genetic testing. Those who test positive for deleterious BRCA mutations may anticipate a sustained increase in breast cancer distress following disclosure, although no other adverse effects were found in this group | Project Grants Nos. 970929 and 113877 from National Health and Medical Research Council of Australia |

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| **Author, year****Quality** | **Sub-category** | **Purpose** | **Study type** | **N** |
| **2013 Review** |  |  |  |  |
| Metcalfe et al., 2012166NA | Psychological | To report on cancer-related distress levels, uptake of cancer risk reduction options, and the resulting breast and ovarian cancer risk in Jewish women 2 years after receiving a postive BRCA mutation result | Before and after | Eligible: 22Enrolled: 19Analyzed: 17 |
| Reichelt et al., 2004167Good | Psychological | To examine the short-term psychological impact of receiving definite results concerning *BRCA1* mutation status in a clinical setting. | Prospective cohort | Eligible: 301Enrolled: 244Analyzed: 209 |
| Reichelt et al., 2008168NA | Psychological | To examine the levels of psychological and cancer-specific distress at 18 months after getting genetic test results in women with demonstrated *BRCA1* mutations and to explore associations with baseline characteristics. | Before and after | Eligible: NR Analyzed: 181 |

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| **Author, year****Quality** | **Country** | **Population and setting** | **Demographics** | **Inclusion and exclusion criteria** |
| **2013 Review** |  |  |  |  |
| Metcalfe et al., 2012166NA | Canada | Jewish women responding to a newspaper ad | Mean age: 46 years (range: 28-67) | Inclusion: Women self-identified as Jewish, ages 25 to 70 years, residing in Ontario, and positive for a BRCA mutationExclusion: Not reported |
| Reichelt et al., 2004167Good | Norway | Unit of Medical Genetics, The Norwegian Radium Hospital | **Mean age (years)**Tested: 43.9 (SD 11.7)Not tested: 33.0 (SD 11.7) | Inclusion: Aged ≥18 years and risk based on clinical criteriaExclusion: None |
| Reichelt et al., 2008168NA | Norway | Section for Hereditary Cancer, Department of Medical Genetics, Rikshospitalet-Radiumhospitalet Medical Center, Oslo, Norway | NR for women without breast cancer | Inclusion: Women aged ≥18 years, with a known *BRCA1* mutation in a close relative Exclusion: None |

| **Author, year****Quality** | **Risk level definition** | **Population/mutation status** | **Measures** | **Duration of followup** |
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| **2013 Review** |  |  |  |  |
| Metcalfe et al., 2012166NA | All were positive for BRCA mutation | 42% (8/19) *BRCA1*58% (11/19) *BRCA2* | Impact of Events Scale (IES, scale 0 to 75, IES-I subscale 0 to 35, IES-A subscale 0 to 40) | Years: NR 2 years |
| Reichelt et al., 2004167Good | 50% risk for FDRs to carriers25% risk for SDRs through males to carriers | BRCA carriers and noncarriersUnknown status, for those who refused testing | Beck Hopelessness Scale (BHS, scale 0 to 20)General Health Questionnaire (GHQ- 28, scale 0 to 84)Hospital Anxiety and Depression Scale (HADS, each subscale 0 to 21)Impact of Event Scale (IES, IES-I subscale 0 to 35 and IES-A subscale 0to 40) | September 1997 to October 19996 weeks |
| Reichelt et al., 2008168NA | Known *BRCA1* mutation in close relative | BRCA positive and negative | Hospital Anxiety and Depression Scale (HADS, scale 0 to 42)Impact of Events Scale-Intrusive subscale (IES-I, scale 0 to 35) | September 1997 to October 1999At 6 weeks and 8 months |

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| **Author, year****Quality** | **Results** | **Conclusions** | **Funding source** |
| **2013 Review** |  |  |  |
| Metcalfe et al., 2012166NA | **Pretest vs. 1 year posttest vs. 2 years posttest**Mean IES-I (SD): 1.1 (1.9) vs. 10.9 (8.6) vs. 6.9 (6.2); p=0.02Mean IES-A (SD): 4.1 (8.7) vs. 12.9 (8.2) vs. 10.4 (9.4); NSMean IES-total (SD): 5.2 (10.5) vs. 23.8 (14.5) vs. 17.2 (14.5); p=0.05**2 years posttest clinical distress levels**11% (2/19) severe distress (score ≥44)21% (4/19) moderate distress (score 26-43)37% (7/19) mild distress (score 9-25)32% (6/19) subclinical distress (score <9) | Intrusive behaviors increased 1 year posttest but decreased by 2 years, with most women (69%) scoring in the mild or subclinical distress level at 2 years | Not reported |
| Reichelt et al., 2004167Good | **Carriers (n=141) vs. noncarriers (n=68)**Mean on psychological scales (SD) at followup; all p=NS IES-I: 9.8 (7.6) vs. 9.3 (8.0)IES-A: 8.4 (7.6) vs. 7.6 (7.4)HADS-A: 4.2 (3.6) vs. 4.1 (3.9)HADS-D: 1.7 (2.4) vs. 2.3 (2.7)GHQ-28: 2.3 (4.0) vs. 2.4 (4.5)BHS: 3.8 (2.6) vs. 4.0 (2.8)**Tested (n=244) vs. not tested (n=57)**Mean on psychological scales (SD) at baselineIES-I (subscale 0 to 35): 8.8 (7.5) vs. 8.9 (7.3); p=NSIES-A (subscale 0 to 40): 8.0 (7.1) vs. 7.7 (7.3); p=NSHADS-A (subscale 0 to 21): 4.4 (3.8) vs. 4.1 (3.2); p=NSHADS-D (subscale 0 to 21): 2.0 (2.6) vs. 1.3 (1.8); p<0.05GHQ (scale 0 to 84): 2.5 (4.2) vs. 2.0 (3.2); p=NSBHS (scale 0 to 20): 4.0 (2.7) vs. 3.7 (2.1); p=NS | Women who chose to get tested had higher baseline depression than those who decided not to get tested. There were no differences at followup between women who were tested and found to be mutation carriers and those who were not mutation carriers. | A grant from the Norwegian Research Council |
| Reichelt et al., 2008168NA | **Pretest vs. 6 weeks posttest vs. 18 months posttest**Mean psychological scales (SD)HADS: 6.6 (6.1) vs. 6.2 (6.1) vs. 6.9 (6.9); p=NSIES-I: 9.3 (7.8) vs. 9.0 (7.8) vs. 8.7 (7.9); p=NS | This study did not separate out women without cancer by carrier status. The results show no differences in distress before testing or up to 18 months after testing. | Norwegian Research Council grant number 115586/320 |

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| **Author, year****Quality** | **Sub-category** | **Purpose** | **Study type** | **N** |
| **2013 Review** |  |  |  |  |
| Shochat and Dagan, 2010169FairSame population as Dagan and Schochat, 2009152 | Insomnia | To investigate the association between positive genetic diagnosis for *BRCA1/2* founder mutations and symptoms of insomnia in Ashkenazi asymptomatic women. | Case-control | Eligible: 152 (39 carriers, 77 noncarriers, 36 controls)Enrolled: 73 (17 carriers, 20 noncarriers, 36 controls)Analyzed: 73 (17 carriers, 20 noncarriers, 36 controls) |

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| **Author, year****Quality** | **Country** | **Population and setting** | **Demographics** | **Inclusion and exclusion criteria** |
| **2013 Review** |  |  |  |  |
| Shochat and Dagan, 2010169FairSame population as Dagan and Schochat, 2009152 | Israel | Rambam Health Care Campus oncogenetic clinic between 1996 to 2006 | Mean age: 51.5 years (SD 8.9) -Carriers: 51.4 years (SD 9.1) -Noncarriers: 54.5 years (SD 9.4) -Controls: 50.0 years (SD 8.3) | Inclusion: Asymptomatic *BRCA1/2* carriers and noncarriers who had undergone genetic testing at Rambam Health Care Campus click*Control:* Age-matched low-risk community control, with no family history of breast/ovarian cancer and not tested for *BRCA1/2* mutationsExclusion: Major chronic illnesses, pregnancy, aged ≤1 year |

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| **Author, year****Quality** | **Risk level definition** | **Population/mutation status** | **Measures** | **Duration of** **followup** |
| **2013 Review** |  |  |  |  |
| Shochat and Dagan, 2010169FairSame population as Dagan and Schochat, 2009152 | FDR and/or SDR with breast or ovarian cancer and/or relative with other cancer | BRCA carriers and noncarriers | The Brief Symptom Inventory (BSI, scale NR)Cancer Related Worry (CRW, scale NR)Daily sleep logMultidimensional Fatigue SymptomInventory-Short Form (MFSI-SF, scale 0 to 120)Pittsburgh Sleep Quality Index (PSQI, each subscale 4-point Likert)Wrist activity monitors | January 2006 to November 2007Mean followup of 8.0 years (SD 1.9) |

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| **Author, year****Quality** | **Results** | **Conclusions** | **Funding source** |
| **2013 Review** |  |  |  |
| Shochat and Dagan, 2010169FairSame population as Dagan and Schochat, 2009152 | **Carriers (n=17) vs. noncarriers (n=20) vs. controls (n=36)**Reported sleep problems (PSQI >5): 53% vs. 20% vs. 28%; p=0.03 for carriers vs. other groupsMean on sleep measures (SD)PSQI total: 7.29 (4.34) vs. 3.94 (2.49) vs. 4.21 (2.80); p=0.013 for carriers vs. noncarriersSleep latency (minutes, recorded by wrist monitor): 12.23 (14.36) vs. 5.41 (5.93) vs. 9.44 (8.05); p=NSSleep duration (minutes, recorded by wrist monitor): 435.96 (47.68) vs. 407.46 (55.56) vs. 434.40 (52.19); p=NSSleep efficiency (%, recorded by wrist monitor): 94.46 (10.65) vs. 96.80 (2.43) vs. 97.26 (2.85); p=NSWake after sleep onset (minutes, recorded by wrist monitor): 18.08 (23.90) vs. 12.82 (10.64) vs. 11.51 (10.03); p=NSCorrelations between PSQI total score and other measuresCRW: 0.417 vs. 0.125 vs. 0.029; p=NSBSI: 0.437 vs. 0.546 vs. 0.057; p=0.013 for noncarriersMFSI-SF: 0.418 vs. 0.315 vs. 0.430; p=0.009 for controlsLinear regression model predictors of PSQI total score (poor sleep quality)Menopausal symptoms and lower level of education combined accounted for 12.6% of the variance; p=0.019Menopausal symptoms, lower level of education, and fatigue combined accounted for 23.0% of the variance; p=0.001Menopausal symptoms, lower level of education, fatigue, and carrier status combined accounted for 28% of the variance; p<0.001 | Carriers reported more sleep problems compared to noncarriers and healthy controls. However, actual sleep duration, latency and wakefulness after sleep onset were not significantly different between groups. | Not reported  |

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| **Author, year****Quality** | **Sub-category** | **Purpose** | **Study type** | **N** |
| **2013 Review** |  |  |  |  |
| van Dijk et al., 2006171Good | Cancer worry | To assess whether the pedigree-based familial risk estimation and the personal cancer history can explain cancer worry and distress among women who receive an uninformative DNA test result. | Prospective cohort | Eligible: NR Enrolled: 133Analyzed: 132 |

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| **Author, year****Quality** | **Country** | **Population and setting** | **Demographics** | **Inclusion and exclusion criteria** |
| **2013 Review** |  |  |  |  |
| van Dijk et al., 2006171Good | The Netherlands | Department of Clinical Genetics in Leiden or RotterdamThe Netherlands between 1995 to 2002, in families where a BRCA mutation was already detected | NR for women without breast cancer | Inclusion: Women from a family with a previously detected BRCA mutation, aged ≥18 years, and had not previously received genetic counseling elsewhereExclusion: Not reported |

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| **Author, year****Quality** | **Risk level definition** | **Population/mutation status** | **Measures** | **Duration of** **followup** |
| **2013 Review** |  |  |  |  |
| van Dijk et al., 2006171Good | BRCA mutation previously detected in family and individuals with a probability of mutation detection of ≥10%Women with an uninformative result were separated into 2 risk groups, 1) <30% personal risk estimate for low-risk and 2) ≥30% personal risk estimate for high-risk | BRCA positive, true negative, and uninformative results | Breast cancer worry question of "During the last 2 weeks, how often did you worry about developing breast cancer?" (Likert scale ranging from 1=almost never to 4=almost all the time)Impact of Events Scale (IES, scale 0 to 75) | 1998 to 2002At 1 and 7 months |

| **Author, year****Quality** | **Results** | **Conclusions** | **Funding source** |
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| **2013 Review** |  |  |  |
| van Dijk et al., 2006171Good | **Positive (n=22) vs. true negative (n=41) vs. uninformative low risk (n=35) vs. uninformative high-risk (n=34)**Mean on psychological scales (SD)IES at pretest: 21.55 (14.70) vs. 14.85 (11.99) vs. 13.54 (11.97) vs. 22.53 (14.22); p<0.05 for uninformative low risk group vs. positive and true negative groupsIES at 1 month following test result: 24.14 (13.21) vs. 10.85 (13.62) vs. 7.40 (8.57) vs. 14.38 (12.41); p<0.05 for positive group vs. other groupsIES at 7 months following test result: 24.09 (15.57) vs. 8.32 (13.30) vs. 6.31 (8.44) vs. 14.00 (14.51); p<0.05 for positive group vs. other groups and p<0.05 for uninformative high-risk group vs. uninformative low risk groupBreast cancer worry at pretest: 2.41 (0.73) vs. 1.88 (0.87) vs. 1.94 (0.73) vs. 2.21 (0.81); p<0.05 positive group vs. true negative and uninformative low risk groups Breast cancer worry at 1 month following test result: 2.64 (1.00) vs. 1.29 (0.75) vs. 1.51 (0.66) vs. 1.68 (0.81); p<0.05 for positive group vs. other groupsBreast cancer worry at 7 months following test result: 2.18 (0.96) vs. 1.24 (0.70) vs. 1.37 (0.55) vs. 1.59 (0.66); p<0.05 for positive group vs. other groups | Women unaffected with breast cancer but with a positive mutation had higher levels of distress and cancer worry. However, at times they were similar in their level of distress and cancer worry as those who received an uninformative test result but were at high-risk. | The Dutch Cancer Society Grant number UL 98-1740 |

**Abbreviations:** BDI=Beck Depression Inventory; BHS=Beck Hopelessness Scale; BRCA=breast cancer susceptibility gene; BRCAPRO=breast cancer susceptibility gene prediction model; BSI=Brief Symptom Inventory; CES-D=Center for Epidemiologic Studies-Depression Scale; COPE=Emotional Approach Coping Scale; CRW=Cancer-Related Worry; CWS-R=Cancer Worry Scale-Revised; DNA=deoxyribonucleic acid; FBOC=familial breast ovarian cancer; FCC=family cancer clinic; FDR=first degree relative; GHQ=General Health Questionnaire; HADS= Hospital Anxiety and Depression Scale; HADS-A=Hospital Anxiety and Depression Scale- Anxiety; HADS-D=Hospital Anxiety and Depression Scale- Depression; HAI=Health Anxiety Inventory; HNPCC=hereditary non-polyposis colorectal cancer; HR-QOL=Health Related-Quality of Life; IES=Impact of Events Scale; INHERITS BRCA=Interdisciplinary Health Research International Team on Breast Cancer susceptibility; MCS=Mental Health Component Scale; MFSI-SF=Multidimensional Fatigue Symptom Inventory-Short Form; MICRA=Multidimensional Impact of Cancer Risk Assessment; NCI=National Cancer Institute; NIH=National Health Institute; NR=not reported; NS=not significant; PCS=Physical Component Summary; PPC=Perceived Personal Control; PSQI=Pittsburgh Sleep Quality Index; PTGI=Post-Traumatic Growth Inventory; QOL=quality of life; RCT=randomized control trial; SD=standard deviation; SDR=second degree relative; SF-36=Swedish SF-36 Health Survey; STAI=State-Trait Anxiety Inventory; SWD=Satisfaction With Decision Instrument; UCLA=University of California, Los Angeles; U.K.=United Kingdom; U.S.=United State