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Interventions to Improve Patient Education Regarding Multifactorial Genetic Conditions: A Systematic Review

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Abstract

The careful education of patients with complex genetic disease is essential. However, healthcare providers often have limited time to spend providing thorough genetic education. Furthermore, the number of healthcare professionals possessing strong genetics training may be inadequate to meet increasing patient demands. Due to such constraints, several interventions have been investigated over the past decade to identify potential resources for the facilitation of this specific type of patient education. This systematic literature review of these interventions for patient education attempts to elucidate the answer to the question: is there sufficient evidence for best practice for delivering genetic information to patients with multifactorial conditions? The various interventions (CD-ROM, group counseling, video/decision aid, and miscellaneous) were analyzed in terms of quality criteria and achievement of specific outcomes and were rated according to the Stetler model for evidence based practice.

Seven main outcomes were evaluated: 1. objective and subjective knowledge assessment 2. psychological measures (general anxiety, depression, stress, cancer worry) 3. satisfaction/effectiveness of intervention 4. time spent in counseling (time spent on basic genetic information vs. specific concerns) 5. decision making/intent to undergo genetic testing 6. treatment choice and value of that choice, and, finally 7. risk perception. Overall, the computer interventions resulted in more significant findings that were beneficial than any other category followed by the video category, although the group and miscellaneous categories did not measure all of the outcomes reported by the other two categories. Nevertheless, while these groups had neutral or negative findings in some of the outcomes, the computer intervention group showed significant improvement in genetics knowledge, psychological measures, satisfaction/effectiveness, time spent with counselor, and decision/intent to undergo testing.

Keywords

genetic counseling; patient education; multifactorial; interventions

INTRODUCTION

When faced with the implications of having or developing a genetic disease and making decisions about genetic testing, patients need to be thoroughly informed. Otherwise, they may not have a well established idea of either testing benefits (early detection, understanding risk, treatment options, prognosis) or risks (stigmatization, loss of

insurability, altered self-image) [Green & Fost, 1997]. Meanwhile, geneticists, genetic counselors, and genetics nurses who provide genetic education to patients find themselves limited in number and time. And, the successful sequencing of the human genome continually leads to researchers discovering more genetic diagnoses for patients. Many genetic disorders being investigated are no longer the result of a single gene mutation but rather are multifactorial conditions, involving several genes as well as environmental factors. In light of the importance of empowering patients to make informed decisions about genetic testing in the midst of these changes and challenges, we searched the literature on experimental studies of educational interventions for multifactorial conditions in order to establish an evidence base for best practice. Although educational materials can in no way substitute fully for sessions with a genetics health professional, they have many potential benefits, such as reinforcement of information, increased time for counseling personal issues, provision of multiple viewpoints, decreasing counselor fatigue, and the ability to share information with other family members [Axillbund, et al., 2005].

In this review, we attempt to answer the question: is there sufficient evidence for best practice for genetic education of patients with multifactorial conditions using specific interventions? The 13 studies we located comprising the evidence base to date generally compared individualized genetic counseling to an educational intervention such as a CD ROM, video, feedback checklist, audiotape, or group counseling.

Theoretical Framework

Constructivist learning theories state that creating meaning is based on prior knowledge, beliefs, and personal experience [Mayer, 1996]. Indeed, prior individual understandings combined with new information form the basis for individual and familial decision-making and coping. For patients with genetic disease, both decision making and coping are of extreme import. Usually genetic education, which includes information about inheritance patterns, risks to other family members, genetic testing options, symptoms, treatment, and prognosis, is delivered by geneticists, genetic counselors, and/or nurses trained in genetics via face to face counseling with patients who have referred to tertiary care settings. However minimal time with patients and relatively scarce genetics personnel pose limitations for the requisite thorough counseling of patients. Supplemental forms of genetic information, especially once processed with a genetics health professional, may increase desired outcomes such as knowledge gain, risk perception, coping with stress/anxiety, and making informed decisions (Axillbund et al., 2005). In turn, these will ideally lead to improved genetic services and an ultimate reduction of the medical, emotional, and psychological burden of genetic disease

DATA SEARCH

The following databases containing articles dating back to the years 1949, 1982, 1987, and 1996, respectively, were searched: PubMed, CINAHL, PsycINFO, and Cochrane. Search terms used included patient education, genetics, genetic information, genetic counseling, communication, and risk perception. We initially retrieved from PubMed 256 articles, from CINAHL 22, from PsycINFO 11, and from Cochrane 2. Studies cited in the relevant papers and authors of these papers were searched to obtain additional references. All experimental and quasi-experimental trials including multifactorial conditions that compared one or more patient education interventions involving genetic information were incorporated. Studies of single gene disorders were excluded since multifactorial conditions require comprehensive patient education which may be more involved, including genetic as well as other factors. Because genetic counseling for prenatal conditions is highly specific, literature involving prenatal counseling was also excluded. Thirteen studies were identified of which twelve compared interventions for providing genetic education for ovarian and/or breast cancer and

1 for cleft lip and palate. The study purposes, designs, sample characteristics, interventions, outcomes, and quality criteria (reliability and validity) were noted. A rating was assigned to each study according to the Stetler model for evidence based practice (See Tables I–IV) [Stetler et al., 1998].

Our search identified 13 studies addressing twelve trials of one or more genetic educational interventions meeting the inclusion criteria. Of these, five investigated the use of a computer program (CD-ROM, decision aid (DA), or computer kiosk) as a tool for genetic education. Two studies used a video, and of these one was a DA (video and brochure), to test their efficacy as genetic educational methods. Other strategies used to provide genetic education included; group counseling (3 studies), a feedback checklist completed by the subject for the genetic counselor (same study as one CD-ROM study), an audiotaped session (1 study), a cognitive-behavioral strategy using problem solving training (1 study) and a breast cancer genetics educational session (1 study). The interventions were then categorized into four groups: CD-ROM, video, group counseling and miscellaneous (feedback checklist, audiotapes, problem solving training, educational session). Seven main outcomes were evaluated in the twelve studies. These outcomes included: 1) an objective and subjective genetic knowledge assessment (baseline, post intervention, follow up/retention) 2) psychological measures (general anxiety, depression, stress, cancer worry) 3) satisfaction/effectiveness of intervention 4) time spent in counseling (time spent on basic genetic information versus specific concerns) 5) decision making/intent to undergo genetic testing 6) treatment choice and value of that choice, and, finally 7) risk perception (baseline, post intervention, and follow up). We noted that no one study assessed all seven outcomes, but these were found to be the major categories tested in the trials. Nearly all studies compared these interventions to the use of genetic counseling alone, the process by which trained individuals assist patients to understand and adapt to the numerous implications of having a genetic disease [Resta et al., 2006]. Validity was considered greater for studies using instruments reputed to be reliable and valid and those published in peer reviewed journals. Findings were evaluated based on whether or not interventions achieved significant changes in outcomes. Table V depicts the statistically significant differences in outcomes per intervention type.

Genetic Knowledge

For the first outcome (genetic knowledge) computer interventions had the greatest impact, followed by the feedback checklist. Mixed findings for video interventions were observed in regard to genetic knowledge. Two randomized control trials of women with a personal or family history of breast cancer using computer interventions demonstrated greater improvement in basic genetic understanding among subjects who viewed the CD-ROM prior to counseling than those individuals who viewed it following counseling [Green et al. 2001; Green et al. 2004] (Tables I and V). In one of these trials, counselors found subjects who self-administered the CD-ROM had a better understanding of breast cancer heredity during the counseling session than those who had not [Green et al. 2005]. Wang, et al. [2005] reported a significant knowledge improvement for women at risk for breast or ovarian cancer who completed a feedback checklist and gave it to the counselor prior to the counseling session, enabling the counselor to tailor the time to meet specific needs of the subjects. In three studies of subjects at risk for breast/ovarian cancer and parents of children with cleft lip and palate, no difference in knowledge was noted when comparing standard genetic counseling to an educational session, group counseling or video interventions [Lerman et al., 1997; Calzone et al., 2005; Young et al., 1986]. However, Cull and colleagues [1998] observed that the group that viewed a video prior to standard counseling had a higher objective score of knowledge, albeit no change in subjective score. In another study the group reviewing the video and brochure DA felt more knowledgeable and better

informed, regardless whether the DA was applied before or after counseling [Van Roosmalen, 2004]. Both of these studies were also performed in women at risk for breast and ovarian cancer.

Psychological Measures

Several investigators assessed if particular educational interventions resulted in subjects' improvements in such psychological outcomes as general anxiety, stress, depression and cancer worry when compared to genetic counseling alone and/or no counseling. Indeed, psychological outcomes of subjects after a genetics consult improved following exposure to computer interventions, group psychosocial counseling, problem solving training, and audiotaped sessions. Women who initially had low anxiety scores at baseline demonstrated increased worry scores unless they viewed the CD-ROM [Wang et al., 2005]. In a another study of women at risk for breast cancer, individual counseling and group psychosocial counseling reduced cancer worry when compared to those who had no counseling. Group psychosocial counseling alone also resulted in decreased general anxiety [Bowen et al., 2004]. Psychosocial counseling differed from most group counseling sessions because it addressed stress management and problem solving techniques, which was not a part of the other group counseling in group intervention trials. Therefore, this form of counseling may have similar aspects to the problem solving training, after which the Center for Epidemiologic Studies Depression Scale (CESD) score decreased for those who received this miscellaneous intervention [McInerney et al., 2004]. The intervention of audiotaping counseling sessions and then providing the tapes to subjects at risk for breast cancer afterwards also decreased anxiety and depression scores [Lobb et al, 2002].

Satisfaction/Effectiveness

Video interventions had the greatest impact on the satisfaction/effectiveness outcome. Cull and colleagues [1998] reported that the group who viewed the video prior to, rather than after, counseling was more satisfied with information about genetics, breast cancer, and access to screening. Van Roosmalen and colleagues [2004] demonstrated that the DA improved satisfaction with information quality compared to the group that did not receive the DA. The subjects receiving computer interventions showed no difference in satisfaction when compared to untreated control groups. It is of interest that both were highly effective when rated by counselees and counselors, with mean score ratings for counselors slightly lower than for counselees [Green et al. 2005]. Similarly, group counseling and audiotape interventions revealed no difference in satisfaction between standard genetic counseling and the intervention [Calzone et al., 2005; Lobb et al. 2002]. Nevertheless, Bowen and colleagues [2004] commented that individuals were more likely to openly share concerns in individual counseling than in group sessions. Regardless of this observation, Bowen's group found no difference in attendance, appeal of the sessions, or sense of supportiveness of counseling between individual or group counseling.

Time Spent with Counselor

All four categories of interventions reduced time during ensuing individual counseling sessions. Green et al. [2005] and Wang et al. [2005] reported subjects needed less individual counseling after viewing a CD-ROM, however Green and colleagues noted this only among low risk BRCA1/2 subjects. Calzone et al. [2005] likewise found individual counseling sessions to take less time after the group counseling intervention. Video intervention prior to individual counseling resulted in less time in turn with the breast surgeon, but not in less time with the geneticist [Cull et al., 1998]. Of the miscellaneous interventions, the feedback checklist, given to the genetic counselor who saw the patient prior to the oncologist, showed a decrease in time needed with the oncologist [Wang et al., 2005].

Decision/Intent to Undergo Testing

In three of the four intervention categories, the outcome of decision-making/intent to undergo genetic testing was measured. The video intervention and the education session (miscellaneous) failed to show differences between the intervention group and the standard counseling group in decision uncertainty, decision-making preference [Van Roosmalen et al., 2004], or intent to undergo testing [Lerman et al., 1997]. However, Wang and colleagues [2005] did find a decreased intent to undergo testing after viewing the CD. Initially, Green and colleagues [2001] noted this same decreased intent to undergo genetic testing for both groups receiving counseling alone and those receiving the computer intervention. Yet further studies revealed decreased intent to undergo testing only among low risk participants [Green et al., 2004]. However, this follow-up study demonstrated that the women in the counselor group, but not the CD-ROM group, experienced less decision conflict and, if also low risk, more satisfaction with their decision [Green et al., 2004].

Treatment Option

The decision to undergo treatment was only measured by the video intervention category. Van Roosmalen and associates [2004] found that the DA group was more likely to choose prophylactic mastectomy or oophorectomy. In addition, they valued the option of prophylactic surgery more than cancer screening. The strength of this preference did not vary between groups, and the timing of the DA administration (before or after counseling) did not play a role in treatment choice.

Risk Perception

Finally, in every category, risk perception was measured. In two studies no difference was found among standard genetic counseling and group counseling or CD-ROM. Rather, all three of these interventions decreased excess perception of risk of breast cancer among subjects [Green et al., 2004; Bowen et al., 2004]. Furthermore, the educational session failed to reduce risk perception unless it was accompanied by genetic counseling [Lerman et al., 1997]. Van Roosmalen and colleagues [2004] found that the group exposed to the video DA was more accurate in three out of eight risk assessment items than the control group. In addition, Cull and colleagues [1998] found individuals who watched the video before counseling were more accurate at assessing their risk one month after counseling than those who viewed the video after counseling. Those who used a computer kiosk in the lobby or waiting room of a cancer center to enter family history of cancer and received a follow up letter of personal risk assessment were likely to remember their risk status, but unlikely to change behavior or follow up with a health care provider. This finding was not compared to a control group receiving standard care. [Westman, et al., 2000].

DISCUSSION

Is there sufficient evidence for best practice for delivering complex genetic information to patients? Our review suggests that certain educational interventions do in fact improve various outcomes related to patient education regarding multifactorial genetic disease. These interventions may become increasingly helpful to clinicians and counselors who see many patients and have limited time and/or genetics training.

Computer/Video Interventions

In particular, computer-assisted methods, followed by video methods, appear to be the most beneficial interventions to assist in providing such genetic education (see Tables I and III). However, the studies involving group counseling and miscellaneous interventions did not examine as many outcomes as the computer and video categories, making comparisons

between all of the interventions difficult. While these latter groups had neutral or negative findings for some of the outcomes, the computer and video intervention groups exhibited improvement in genetics knowledge, satisfaction/effectiveness of intervention, and time spent with counselor. In addition, the computer group had better outcomes for psychological measures and decision/intent to undergo testing. While the video intervention category was the only category to measure all outcomes, it did not change the outcomes of psychological measures or decision/intent to undergo testing. Only Van Roosmalen and colleagues measured preference for prophylactic surgery vs. cancer screening or undecided. Prophylactic surgery was consistently preferred and valued as a better option if the DA had been viewed [Van Roosmalen et al., 2004]. Yet, with only one trial studying this, further research of various interventions' effect on treatment outcome is recommended. Instruments used to assess knowledge by Wang et al. [2005] and anxiety by Green et al. [2004] were previously validated, but the reliability of the knowledge scaled us by Green et al. [2004,2001] and decision aid used by Roosmalen et al. [2004], although used previously, were not discussed.

Group Counseling

Findings for the remaining interventions were varied. For example, the group counseling intervention category (Table II) revealed mixed results. Less time was spent in individual counseling sessions following group sessions, but the utility of this in practice is debatable. One psychological measure improved, namely anxiety. Yet other psychological measures showed no differences when compared to individual counseling, nor did genetics knowledge, accuracy of risk perception, or satisfaction/effectiveness. Furthermore, subjects preferred sharing concerns in an individual counseling setting. Both Calzone et al. [2005] and Bowen et al. [2005] discussed the adequate reliability of scales used for knowledge and psychological distress, however, Young et al. [1986] did not mention the reliability of their scales.

Miscellaneous

Although miscellaneous interventions (Table IV) offered some improvement in outcomes, such as time spent with counselor, knowledge improvement, and decrease in depression and anxiety, no one miscellaneous intervention changed all three of these outcomes. The feedback checklist, noteworthy for its practicality, improved both knowledge and amount of time spent in individual counseling. Problem solving training was very effective for reduction of depression, but might be best incorporated into individual counseling rather than as a separate intervention. Finally, audiotapes of sessions showed little promise as an effective intervention. Audiotapes affected only the outcomes of anxiety and depression, which are also impacted by other, more robust interventions such as CD-ROM and video. Despite being exposed to audiotapes of counseling sessions, subjects did not always listen to them [Lobb et al., 2002].. McInerney-Leo et al. [2004],Lobb et al. [2002], and Lerman [1997] et al. used scales with adequate reliability for use self-esteem, psychological distress, satisfaction, but depression and expectations scales showed internal consistency of less than 0.7. In general, further research is necessary to address the outcome measurement gaps among these less well-researched interventions.

As the understanding of multifactorial disorders increases, patients may be able to know their risk for multifactorial genetic conditions, which involve several genes and environmental factors. Published experimental trials of such interventions were reviewed, including CD-ROM/decision aid, group counseling, informative video, feedback checklist, audio recording of session, problem solving training, and educational session. Of these, computer interventions, followed by videos, positively impacted most of the seven main outcomes evaluated across the studies. These findings are similar to educational

interventions (Video, DA) given to patients with prostate cancer, which has an unknown cause to date. Those with prostate cancer who viewed a video, booklet, or decision aid increased in knowledge, decreased in decisional conflict, improved in risk perception, decreased in testing intention, and had no change in satisfaction with the screening decision. No difference in anxiety was noted between video, internet and written education interventions [Ilic et al., 2008; Taylor et al., 2006; Gattellari and Ward, 2003; Watson et al., 2006].

Comprehensive genetic education for patients about multifactorial conditions is needed, but time and personnel are limited. The evidence thus argues for the integration of these interventions into the practice of genetics education for patients with multifactorial conditions. However, due to the lack of studies in various disorders, the generalizability of this application may be limited to breast and ovarian cancer and cleft lip and palate. Other limitations of the studies included the lack of the investigation into the ultimate outcomes of genetic education such as the reduction of the medical, emotional, and psychological burden of genetic disease. For example, Van Roosmalen and colleagues [2004] found that subjects who were administered the DA overwhelmingly chose prophylactic surgery as a treatment option. Further research is needed to elaborate whether patient education increases uptake of cancer screening or prophylactic surgery, in turn leading to a reduction in cancer risk. The impact of anxiety on knowledge retention is also an important question for future research.

In addition to pursuing research for areas which have not been fully investigated by all of the above interventions, standardizing the CD-ROM and video interventions for regular use may be a helpful next step toward their implementation. Ideally, materials would be created that are appropriate and unbiased, with short, organized sections based on learning theory. Barriers such as lack of space or equipment and the inability of clients to ask question also need to be considered. [Axillbund et al, 2005]. Nevertheless, according to the evidence in these trials, having such tools readily available for counselors and clinicians may reduce the time needed to explain to patients their condition and its implications. According to the evidence to date, these tools may improve patient care in regard to comprehension of their condition, decreased anxiety and depression, improved risk perception and decision making, and greater satisfaction with visits. Even more importantly, these in turn may help reduce the medical, emotional, psychological, and social burden of genetic disease and improve delivery of medical genetic services, two ultimate goals of genetics health care.

In summary we determined that the investigations do substantiate the integration of computer interventions such as CD ROM into patient education for multifactorial conditions due to improved outcomes in genetics knowledge, psychological measures, satisfaction/effectiveness, time spent with counselor, and decision/intent to undergo testing. Further research is needed to evaluate whether these outcomes ultimately improve genetic services and increase patient screening uptake in such a way as to reduce genetic disease risk and burden.

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Table 1

Computer interventions

Primary author, year	Design	Intervention	Control group	Major Findings	QR*	Outcomes measured
Green et al., 2005	RCT English speaking women 18 or older, majority Caucasian N=211	Computer based DA (CD Rom) prior to GC, N=106	Yes	Participants rated both sessions as highly effective (6.6/7) as did counselors, but less so (P=0.001); Lower risk for BRCAl/2 mutation needed sign less counseling after CD Rom (P=0.027), no sign difference in time for counseling between high risk gps (P=0.39); also counselors rated computer group as having sign better underst. of heredity (P=0.03) and most couns. able to tailor to needs of pt more quickly regardless of risk.	II	<ul style="list-style-type: none"> Time with counselor Effectiveness of counseling session, 12 specific attributes of counseling session, Counselors' impressions
Green et al., 2004	Same as above	Same as above	Yes	Knowledge increased in both groups regardless of risk (P<0.001), improved knowledge more sign in CD group among low risk women (P=0.03), intent to test decreased sign after CD intervention in low risk but not high risk women, lower decisional conflict for counselor group (P=0.04), higher satisfaction of decision in counselor group among low risk women (P=0.001), anxiety decreased by counseling but within normal for all groups at baseline	II	<ul style="list-style-type: none"> Knowledge Risk Intention to be tested Decisional conflict and satisfaction with decision Anxiety Evaluation of computer intervention and GC
Green et al., 2001	Descriptive and qualitative, part of larger RCT Educated, English speaking women, 18 or older with first degree relative with breast ca. mostly Caucasian N=72	Interactive computer program prior to counseling N=29	No	In general, 66% preferred GC over computer. Preferred GC for addressing concerns and discussing options (93%); being sensitive to emotional concerns, helping with decisions and listening (86%), assuring understanding (76%), telling them what they needed to know (62%), setting relaxed tone and putting them at ease (55%). Preferred or neutral about computer program for learning at own pace and avoiding embarrassment (81%), making good use of time and explaining genetics of breast ca (62%), treating pt as adult (59%), perception of risk decreased after either intervention among all participants (P<0.007)	IV	<ul style="list-style-type: none"> Preferences of computer vs. GC Subjects' assessment of computer program as educational and counseling tool Four open-ended qual questions about likes and dislikes for education/ counseling sessions
Green et al., 2001	Same as above	Same as above	Yes	Knowledge/% of questions correct control gp 74%, Counselor gp 92%, computer gp 96% (p<.0001), intent to undergo testing pretest all gps 66%, post intervention gps only 44% (P<.0002, OR=2.8, 95% CI 1.7-4.9)	II	<ul style="list-style-type: none"> Knowledge Intent to undergo genetic testing
Wang et al., 2005	RCT Mostly Caucasian, married women N=197	Cd=50 Feed=49 CD+feed=50	Yes	If viewed CD women took sign. less time with counselor (F (1, 189) = 6.35, P=0.01), less time with oncol if feedback to GC (F (1, 188) = 5.42, P<0.05), knowledge improved in all gps but mean was sign. higher for feedback gp (P<0.05), worry declined overall, but more with CD Rom viewing (P=0.06), of women who scored low for worry at baseline, if they did not view CD ROM, their worry increased whereas those who viewed stayed low,	II	<ul style="list-style-type: none"> Face-to-face time with genetics team (GC and oncologist) Knowledge

Primary author, year	Design	Intervention	Control group	Major Findings	QR*	Outcomes measured
Westman et al., 2000	Quasi-experimental individual with hereditary ca and their family members N=1440	Computer kiosk to enter family hx data followed by personal risk of ca letter	No	Majority of people (89%) provided sufficient info into kiosk to receive a personal risk assessment by a genetics professional in the form of a letter; the majority of those who received letters and did follow up telephone interview remembered receiving them (93%) and what their level of risk was (72%). 95% felt comfortable using computer kiosk. 42% felt their risk perception changed. 80% did not change behavior as a result of risk assessment.	III	<ul style="list-style-type: none"> Changes in worry in regard to being positive for mutation Genetic testing decision Risk perception

* Quality Rating: Stetler model for evidence based practice (Stetler, 1998). I=Meta-analysis II= Individual experimental study; III=Quasi-experimental study IV=Non-experimental study. V=Case Report VI=Expert opinion.

Table II

Group Counseling Interventions

Primary author, year	Design	Intervention	Control group	Major Findings	QR*	Outcomes measured
Calzone et al., 2005	RCT English speaking women and men at high risk for BRCA, mostly Caucasian N=142	Group counseling done by genetics NP followed by brief indiv couns with genetics NP, N=71	Yes	No difference in knowledge level; Impact of Events Scales higher in pts with positive results but IES returned to baseline by 12 months; group session took sign. less time P<0.0001; satisfaction equal in both groups, no stat. sign. difference (0.12-0.45); preferred method equal (P=0.82 McNemar's test)	II	<ul style="list-style-type: none"> Knowledge and psych. distress measured at baseline, after education and counseling, and at 1 week and at 3, 6, 12 months Satisfaction with educ. and counseling after session, preferred method solicited at 3 months Secondary analysis of time per pt
Bowen et al., 2004	RCT General public and relatives of women with breast ca N=227	Group psychosocial counseling with 4-6 other participants for four 2hr sessions, n=110; genetic counseling (one 2 hr session and phone call) n=117	Yes	In both interv. gps women reported high levels of attendance, liking and support from their counseling in both gps; however more likely to share concerns in genet couns session than gp session (P<0.05), both interv. gps reported lower perceived risk at follow up than control gp (P<0.01); both interv decrease worry vs. ctrl gp (P<0.01), however anxiety decreased sign only with gp psychosocial counseling (P<0.01)	II	<ul style="list-style-type: none"> Perceived risk Emotional reactions Cancer worry Reactions to counseling General anxiety and depression
Young et al., 1986	Quasi-experimental Parents of children with isolated (multifactorial) CL/P N=61	Videotape (21), group counseling (18), individual/couple (19) counseling	No	No sign. difference b/w gps for mean percent knowledge scores at any of the 3 time points; Genetic counseling is underprovided, (89% of the families had not had any), video and gp counseling are generally accepted w/o loss of efficacy, video could enhance basic genetic teaching for CL/P or other disorders, no preferred method of counseling	II	<ul style="list-style-type: none"> Preference of method, Knowledge baseline, after counseling, after 6 months Attitudes

* Quality Rating: Stetler model for evidence based practice (Stetler, 1998). I=Meta-analysis II= Individual experimental study III=Quasi-experimental study IV=Non-experimental study. V=Case Report VI=Expert opinion.

Video Interventions

Table III

Primary author, year	Design	Intervention	Control group	Major Findings	QR*	Outcomes measured
Cull et al., 1998	RCT newly referred women to breast ca clinic N=128	Video with basic info about breast ca gen. and risk assessment before vs. after counseling	Yes	Video before spent sign. less time with breast surgeon (P<0.05) but same amount with geneticist, risk assessment sign. more accurate by video before gp one month follow up (P<0.05) (otherwise same before, and immediately after), video before gp also had sign better obj but not subj assessment of breast ca genetics (P<0.001), anxiety levels same, GHQ-30 same/no increased distress with video shown, video before gp sign more satisfied with clinic visit in terms of info on genetics, BRCA, and screening (P<0.05)	II	<ul style="list-style-type: none"> • Time with geneticist and breast surgeon • Self eval of lifetime risk of breast ca • Subj and obj understanding of breast ca genetics • Anxiety • Presence of clinically sign. psych disorder • Use of video • Satisfaction with clinic
Van Roosmalen et al., 2004	RCT Dutch speaking, no previous cancer treatment N=372	Decision aid (DA) given 2 weeks after blood testing, (brochure and video given) N=184, before test result available; N=47 for women given DA prior and positive BRCA1/2 test result	Yes	No sign difference between 2 gps for anxiety, depression, ca related distress, and general health; DA prior gp more likely to choose prophyl surg over genetic screening and gave higher value for prophyl surg option (p= 0.04, p=0.00); no differences for strength of tx preference, decision uncertainty, or preference for decision-making; women in DA gp felt more knowledgeable, better informed, also more satisfied with info quality (p=0.00, p=0.00, p=0.00); DA prior gp made more accurate risk assessments for 3/8 items (p<0.05), timing of DA did not matter for well-being, decision, info related outcomes, and tx choice except for 1/8 items on risk perception (p<0.05)	II	<ul style="list-style-type: none"> • Anxiety • Depression • Cancer related distress • Rating of general health state • Tx choice for breasts and ovaries • Decision uncertainty • Preference for decision-making • Subj knowledge • Amount of info received • Satisfaction with info • Risk perception

* Quality Rating: Stetler model for evidence based practice (Stetler, 1998). I=Meta-analysis II= Individual experimental study IV=Non-experimental study V=Case Report VI=Expert opinion.

Table IV

Miscellaneous Interventions

Primary author, year	Design	Intervention	Control group	Major Findings	QR*	Outcomes measured
McInerney-Leo et al., 2004	RCT Extended relatives of people with hereditary breast and ovarian cancer N=212	Problem solving training (PST), a cognitive behavioral intervention which teaches effective coping strategies for given	Yes	Testers decreased in worry sign, compared to non-testers (p=0.015); indiv with HBOC had greater increase in breast ca worries than those without HBOC regardless of decision to test or test results, (p<0.001) PST reduced depr sympt at follow up more than GC regardless of whether or not tested for mutation (p=0.052) and also decreased CESD sign more (p=0.021), pts who were tested decreased sign in breast and ovarian ca worries (p=0.008, 0.007) while others did not, maintains psych health, may enhance decision making for genetic testing	II	<ul style="list-style-type: none"> Psychological Well-being self esteem cancer related symptoms Breast Ca Worries Ovarian Ca Worries
Lobb et al., 2002	RCT English literate women attending any of 10 cancer clinics in 4 Australian states N=160	N=98 or 82? (unclear) received tape (of these, 51% listened)	Yes	more likely to listen if affected (p=0.03), anxious (p=0.01), depressed (p=0.06), or low BRCA genetics knowledge (p=0.07); unaffected women who received tape were less likely to be accurate in risk perception (p=0.05), however when only those inaccurate at baseline were included, tape had no effect (p=0.21); Audiotape did not improve satisfaction, knowledge, information received, or expectations met, however, for those who listened to it, audiotape did improve anxiety (p=0.02) and depr scores (p=0.01), only 20% of women found tape satisfactory and 35% extremely helpful to increase risk understanding	II	<ul style="list-style-type: none"> Expectations (pre/post intervention); BRCA knowledge Psych measures Risk perception Obj risk Satisfaction with GC Satisfaction with audiotape
Lerman et al., 1997	RCT Women with at least one first degree relative with breast and/or ovarian cancer N=400	educational info about BRCA 1 (N=128), genetic counseling in addition to educational info (N=132)	Yes	Increase in knowledge in E and E+C groups (both P<0.001), decrease in WLC group; only E+C group showed increase in perceived limitations and risks (P<0.01) and decrease in perceived benefits (P<0.05); no difference in testing intentions in E or E+C (no difference in percent of individuals with initial intentions to test and actually providing blood sample)	II	<ul style="list-style-type: none"> Knowledge Perceived risk Perception of benefits, limits, risks of BRCA 1 testing Intention to be tested Provision of blood sample as surrogate for testing decision

* Quality Rating: Stetler model for evidence based practice (Stetler, 1998). I=Meta-analysis II= Individual experimental study; III=Quasi-experimental study IV=Non-experimental study. V=Case Report VI=Expert opinion.

Table V

Statistically significant differences in outcomes per intervention category.

	Genetic Knowledge	Psychological Measures	Satisfaction/Effectiveness	Time Spent with counselor	Decision/Intent to undergo testing	Tx option	Risk perception
Computer	Counselors rated CD viewers as having higher understanding of heredity $P=0.39$ (Green, 2005). Knowledge increased in both computer and counseling group. $P<0.001$ but greater in computer group, $P<0.03$ (Green, 2004). knowledge for counselor group 92%, computer group 96%, control group 74% $p<0.0001$ (Green, 2001)	Worry declined statistically significantly overall, but more with CD rom $P=0.06$ and women who scored low at baseline for worry but did not see CD increased worry whereas CD viewers did not, $P<0.005$ (Wang, 2005)	Subjects rated both CD rom and standard counseling sessions as highly effective, as did counselors, but less so, $P<0.001$ comparing both mean score assessments (Green, 2005)	Lower risk BRCA1/2 subjects needed less individual counseling time p CD rom, $P=0.027$ (Green, 2005) CD rom group significantly less time with counselor, $P=0.01$ (Wang, 2005)	Intent to undergo testing 66% all groups, post intervention groups counseling or computer only 44%, $P<0.002$, OR=2.8, 95% CI 1.7–4.9 (Green, 2001). Intent to test decr. after either interv. for low but not high risk women, less decision conflict for couns interv. $P=0.04$, and higher decision satisf. for low risk in couns gp, $P=0.001$ (Green, 2004). Less likely to undergo testing if viewed CD $P<0.01$ (Wang, 2005)	DA group likely to choose prophyl. surg $p=0.04$, gave high value for prophyl surg option, DA group more accurate for 3/8 risk item, $p<0.05$ (van Roosmalen, 2004)	Perception of risk of BRCA decreased after either intervention (Green, 2004). Level of risk retained months later, but not followed by behavior change or health care appointment (Westman, 2000)
Video/Decision Aid	No difference in knowledge precounseling, post counseling, 6 month follow up among video, individual or group counseling (Young, 1986). Video before gp had better objective but not subjective assessment of BRCA genetics $P<0.001$ (Cull, 1998). DA group felt more knowledgeable, $p=0.00$, and better informed, $p=0.00$, than standard counseling, timing of DA did not matter (van Roosmalen, 2004)	No difference in anxiety or GHQ-30 scale for distress (Cull, 1998). No difference between DA group and standard counseling group for anxiety, depression, ca related distress, and general health, timing of DA did not affect well-being (van Roosmalen, 2004)	Video before group more satisfied with information about genetics, $P<0.05$, breast cancer, $P<0.05$, and access to screening $P<0.05$, than video after consultation group (Cull, 1998). DA group felt more satisfied with info quality, $p=0.00$, timing of DA did not matter (van Roosmalen, 2004)	Video prior to consultation group spend statistically significantly less time than video post with breast surgeon, $P<0.05$, but same amount with geneticist (Cull, 1998)	No difference for decision uncertainty or preference for decision-making between DA group and standard counseling, also timing of DA did not impact decision (van Roosmalen, 2004)	DA group likely to choose prophyl. surg $p=0.04$, gave high value for prophyl surg option, DA group more accurate for 3/8 risk item, $p<0.05$ (van Roosmalen, 2004)	Risk assess. stat sign. more accurate by video before gp after one month ($P<0.05$) (otherwise same before, and immediately after) (Cull, 1998). DA group more accurate for 3/8 risk item, $p<0.05$ (van Roosmalen, 2004)

Group	Genetic Knowledge	Psychological Measures	Satisfaction/Effectiveness	Time Spent with counselor	Decision/Intent to undergo testing	Tx option	Risk perception
	No difference in knowledge level between individual and group counseling subjects (Calzone, 2005) No difference in knowledge precounseling, or 6 month follow up among video, individual, or group counseling (Young, 1986)	IES higher in subjects with positive results but returned to baseline by 12 months (Calzone, 2005). Group and individual counseling decrease cancer worry compared to no counseling, P<0.01, however general anxiety decreased significantly only with group psychosocial counseling, P<0.01 (Bowen, 2004)	No difference in satisfaction between group and individual counseling and methods equally preferred (Calzone, 2005) More likely to share concerns in individual than group session P<0.05, but no difference in attendance, liking of session and support from counseling (Bowen, 2004)	Subjects took significantly less time after group session in individual counseling P<0.0001 (Calzone, 2005)			Lower perceived risk at follow up for group and individual counseling compared to no counseling P<0.01 (Bowen, 2004)
Miscellan.	Knowledge improvement for feedback group significant, P<0.05 (Wang, 2005) AT listeners showed no change in knowledge or amount of info received (Lobb, 2002), E and E+C both increased knowledge (both P<0.001) (Lerman, 1997)	PST reduced CESD score, p=0.021 (McInemey-Leo, 2004) AT improved anxiety p=0.02 and depression scores p=0.01 (Lobb, 2002)	AT revealed no change in satisfaction or expectations being met (Lobb, 2002)	Less time with oncologist if feedback list given to GC P<0.05 (Wang, 2005)	Neither E nor E+C changed decision to undergo testing (Lerman 1997)		Only E+C improved risk and limitations perception (P<0.01), but not E alone (Lerman, 1997)

TABLES KEY

AT = Audiotape

BRCA = breast cancer

Ca=cancer

CD = Compact Disk

CESD = Center for Epidemiologic Studies Depression Scale

CI = Confidence Interval

Comp=computer

Couns = counseling

DA = Decision Aid

Deccr = decreased

Depr=depression

E=education session

E+C=education with genetic counseling

GHQ-30 = Goldberg and Williams screen for clinically significant psychological disorder

- Edu=education
- Eval=evaluation
- Feed=feedback checklist
- GC=Genetic counselor
- Gp(s) = group(s)
- HBOC=Hereditary Breast and Ovarian Cancer
- Hx=history
- IES = Impact of Events Scale
- Indiv=individual
- Interv = intervention
- Knowl=knowledge
- NP=nurse practitioner
- Obj=objective
- Oncol=oncologist
- OR = Odds Ratio
- Prophyl Surg = prophylactic surgery
- PST = Problem solving training
- Psych=psychological
- Pt=patient
- RCT=Randomized controlled trial
- Sign=significant
- Subj=subjective
- Qual=qualitative
- Tx=treatment
- Tx pref = treatment preference
- Underst=understanding
- Vs=versus
- WLC=waiting-list control