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A Randomized Trial of A Computerized Versus An Audio-Booklet Decision Aid for Women Considering Post-Menopausal Hormone Replacement Therapy

By

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Abstract:

Background: Decision support interventions (DSIs) are interventions used by patients and their practitioners to help make difficult shared healthcare decisions. The efficacy of these interventions is well established. However, there are no formal comparisons of the efficacy of different delivery methods. Interactive computerized delivery methods have the advantage of allowing patients to control the flow of information and to receive feedback on their comprehension.

Objective: To compare the efficacy of an interactive computerized DSI for women considering long term hormone replacement therapy (HRT), to that of a validated audio-booklet-based version of the same intervention.

Study Design: Fifty-one peri- and post-menopausal women aged 40-70 who were literate in English, and who showed no evidence of cognitive impairment, were randomized to use either the computerized or the standard audio-booklet version of the DSI. The patients were interviewed with a pre- and post-intervention questionnaire.

Interventions:

1) Standard audio-booklet-based decision aid: A 40-minute audio tape guided participants through an illustrated booklet describing the risks and benefits of post-menopausal HRT.

2) Interactive computer based decision aid: The computerized version of the DSI presents identical information as synchronized text/audio/animation. Animation and icons were used to illustrate the data, while movement foreword or backward through the DSI was controlled by the user. Participants could bypass or review information as needed. Programmed instructional feedback modules were presented throughout the aid to reinforce the participants understanding.

Outcomes: 1) realistic expectations (RE); 2) knowledge (Kn); 3) decisional conflict (DC); and 4) satisfaction with, and ease of use of the aid, were assessed through the participant's responses to a pre- and post-intervention questionnaire.

Results: The computerized DSI was superior to the standard decision aid at improving RE, and Kn. Over baseline, the computerized DSI was associated with a 52.7% improvement in RE, while the audio-booklet showed a 27.6% improvement ($p=0.015$). Knowledge scores improved over baseline by 17.5% and 8.4% for the computer and standard DSI groups , respectively ($p=0.019$). No statistically significant differences were observed for DC or satisfaction between the two interventions. However, 43.1% of participants felt that a booklet, with or without audio, would be the best format to present this data to women of this age group.

Conclusion: The use of a computerized DSI with automated self-assessment and feedback significantly improves realistic expectations and knowledge, compared to a standard DSI. For this particular age group, the use of a computer-based format may present an operational barrier, but this may be less important with time as more individuals have access to computers, or if the hardware is provided to the patients in the health-care setting. The results of this study have implications for other areas where patient knowledge and understanding are important, such as in the setting of informed consent.

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1 Introduction

Hormone replacement therapy is currently recommended by both the American College of Physicians, and the Canadian Menopause Consensus Conference, for all post-menopausal women who do not have contraindications to its use. HRT reduces a woman's risk of heart disease and osteoporosis. However, since HRT may increase the risks of breast and endometrial cancer, women have to weigh their own risks and benefits associated with the use of HRT before arriving at a decision to use this long-term therapy. The task of disseminating knowledge of the risks and benefits of HRT to peri-menopausal women is daunting and makes this women's health issue an ideal candidate for a decision support intervention that primary care practitioners can utilize to meet this goal.[1,2]

Patient-based decision support interventions (DSIs) are increasingly being developed and disseminated to help patients make decisions regarding various aspects of their health care.[3] DSIs have been promoted under various names, such as decision aids, decision support aids and, less accurately, as information or educational pamphlets. These interventions are intended to help patients gain a greater understanding of their particular disease, their medical choices, alternative treatment options, as well as the risks and benefits of these alternatives.[1-5] However, DSIs differ from general educational interventions by helping patients consider the benefits and risks of the specific options. The underlying theme of these interventions is to empower patients to actively participate in a shared decision-making process with their practitioner. DSIs also aim to reduce feelings of uncertainty or decisional conflict regarding difficult decisions, and to promote "value congruent" choices.[1,2,4,5]

Decisional conflict regarding a health decision stems in part from being uninformed regarding the illness in question, the treatment options and the expected outcomes.[1,6-8] DSIs attempt to improve a patient's knowledge of these areas, thereby allowing the patient to weigh their own risks and benefits of the various options against the backdrop of their own values and beliefs. The efficacy of DSIs at improving a patient's knowledge and expectations of benefits and risks is now well established.[5] However, O'Connor et al. have found that despite improvements in expectations, a significant proportion of those using DSIs still have expectations of outcomes that are inconsistent with the estimates from the best available evidence for their clinical risk category.[1,2] Therefore, to address this issue, we suggest that modification of a standard decision aid—to incorporate a programmed test and feedback system derived from the principles of behavioral learning theory—could improve on the gains in knowledge, and expectations obtained with previous DSIs. A test and feedback system would also have the added benefit of allowing a health care provider to determine whether an individual patient has grasped, at the very least, the crucial aspects of the risks and benefits of the options under consideration.

2 Purpose

The purpose of this investigation was to compare a computerized DSI (including a programmed test-feedback system) to a previously validated, factually identical audio-booklet based DSI for peri-menopausal women considering HRT on four main outcomes measures: 1) realistic expectations; 2) knowledge; 3) decisional conflict; and 4) satisfaction with the tool, and operational barriers to its widespread use.

3 Background

3.1 Decision aid theory

DSIs provide a framework for patients and practitioners to make treatment choices. They provide information on particular medical problems, treatment options, and risks and benefits—using probabilities researched from the literature—that are tailored to the patient's individual clinical profile.[1-4,9-11] DSIs present descriptions of what it is like to live with the consequences of each choice; some also provide explicit values clarification exercises, in which the patient considers the personal importance of the risks and benefits among the presented alternatives.[1,2] These types of interventions are most useful under certain clinical circumstances wherein the decision requires careful deliberation because of the uncertain or value-sensitive nature of the benefits and risks, and where more effort is required during the deliberation stage of the decision as opposed to the implementation stage.[1,10,12]

DSIs can take on a variety of forms, from simple printed pamphlets (fixed or computer generated) to computer-based platforms. As well, these tools differ with respect to their emphasis on either education or on decision making, their level of interactivity, and the degree to which they can be tailored to an individual patient.[3]

Developers of DSIs have different conceptual frameworks of decision support,[1,3,13-18] but most are based on decision theories from economics and cognitive psychology[18-20] that structure decisions according to options, outcomes, and probabilities of outcomes so that individuals are better able to judge the value of the benefits versus the risks. Many frameworks broaden this predominantly cognitive perspective by including emotional,

social, or environmental dimensions.[21-25] For example, the Ottawa decision support framework[1] identifies several determinants of health care decisions that may be sub-optimal and are potentially modifiable by DSIs. Patients may have problems with: a) perceptions of the decision (e.g. inadequate knowledge, unrealistic risk perceptions, unclear values, high uncertainty or decisional conflict); b) perceptions of others (e.g. biased perceptions of the variation in others' opinions, social pressures, inadequate support); and c) personal and external resources to make the decision (e.g. limited skills in shared decision making, finances). DSIs are designed to address these problems by providing accurate, balanced, and tailored information on options, outcomes, and probabilities, by clarifying patients' values, and by augmenting skills in shared decision making. For example, knowledge may be improved with DSIs by providing information on options and outcomes. Unrealistic risk perceptions may be re-aligned by presenting probabilities of outcomes that are tailored to the patient's clinical risk and by describing outcomes so that they are easy to imagine and identify with.[19] Unclear values are addressed by describing outcomes in familiar, simple, and experiential terms so as to better judge their value[20] and by providing the opportunity to weigh the benefits versus the risks. Biased perceptions of the variation in others' opinions may be corrected by presenting all options and, in some cases, by providing examples of others' choices and statistics on variation in choices. Shared decision making may be improved by providing structure, guidance or coaching in deliberating about the personal issues involved in the choice and in communicating preferences.[25-33] As a consequence of these interventions, patients presenting with uncertainty or decisional conflict caused by these problems may become

more certain about what to choose and may be more likely to implement these choices.[1,3,8,13,15-21]

Based on the Ottawa decision support framework,[1] one can hypothesize that decision aids will improve the determinants of choice so that decisions are more likely to be: 1) informed (i.e. based on better knowledge and realistic risk perceptions); 2) consistent with personal values; and 3) implemented. As well, patients' comfort with the decision-making process (decisional conflict, satisfaction with decision making) may be improved. Based on the results of other educational interventions[26-34] designed to promote realistic expectations of outcomes and informed active involvement in one's care, it is also reasonable to hypothesize that patients may be more likely to persist with decisions and to report less distress with the consequences of health-related quality of life.

Figure 1: Ottawa Decision Support Framework (adapted from O'Connor et al.)[1]

Determinants of Decisions/Needs	Decision Support Interventions	Evaluation
Perceptions of the Decision knowledge of options and outcomes expectations (perceived probabilities) of outcomes values for outcomes decisional conflict (uncertainty) choice predisposition stage of decision making **Perceptions of Important Others Involved in Decision** perceptions of others' opinions and practices pressure from others support for decision making decision participation preferences **Resources to Make Decision** ***Personal*** previous experience self-confidence and skill in decision making ***External*** availability and access to options support from outside social networks, support groups, and agencies **Demographic and Clinical Characteristics** *patient:* age, gender, marital status, education, occupation, culture, religion, locale, medical diagnosis and duration, health status (physical, emotional, cognitive, social) *practitioner:* age, gender, education, specialty, culture, practice locale, experience, counseling style	**Prepare Patient** • general information on health condition, options, outcomes • personal worksheet to identify personal benefits, risks; clarify personal values, list questions, identify preferences for participation, indicate leaning toward options **Prepare Practitioner** • information on decision; efficacy of decision aid; timing and use in practice. **Structure Follow-up Counseling** • clinician/patient review of completed worksheet to discuss: benefits/risks; values; questions; choice; next steps	**Decision making** • informed (knows options and outcomes, realistic expectations of outcomes, realistic perception of variation in opinions and practices) • consistent with personal values (aware of personal values; agreement between values and choice) • implemented (acts on choice) • expresses satisfaction with decision making **Outcomes of Decision** persistence with choice improved quality of life reduced distress reduced regret informed use of resources

The evaluation of the efficacy of DSIs must take into consideration the ultimate goal of a DSI, which is to "improve" decision making. However, decision making is complex, and involves various components, as discussed above. Therefore, one must break down the process of decision making into components, based on a logical framework such as the one defined by O'Connor et al., and thereafter assess the impact of an intervention on the modifiable components of this framework (see Figure 1). [1] The reasons for this added complexity in evaluating DSIs becomes clear when one considers some illustrative factors. It is clear that a good decision can be associated with a "bad" outcome, and vice versa. For example, a person with a heart attack may correctly choose, based on overwhelming evidence, to take a clot breaking agent to unclog a heart artery, but after doing so suffer massive bleeding in the brain, and death. Ironically, had this same individual made what most would consider a bad decision—to not take this treatment—he may have survived. Therefore, clinical outcome alone cannot be used as a true measure of improved decision making. Furthermore, in less dramatic circumstances, the decision made may be completely appropriate for one individual while inappropriate for another. For example, one peri-menopausal woman may appropriately choose to take hormones, while another with a personal history of breast cancer may also appropriately decide not to take hormones. Therefore, except for special circumstances, the actual decision made may be a meaningless measure. Changes in decision, or becoming more sure of a choice, however, could yield more valuable information. Therefore, surrogates of improved decision making based on an appropriate decision support framework represents the most logical means of assessing DSI efficacy.[1] To this end, outcome measures exist to assess specific

components of decision making (as illustrated in Figure 1), and generally fall into the realms of: 1) knowledge and expectations; 2) decisional conflict, anxiety, and quality of life; 3) satisfaction with the decision, the decision-making process, increased participation in the decision-making process, and persistence with the choice.

3.2 From theory to practice: Evidence of efficacy

The value of DSIs in the aid of patient-based health decision making is now well established. We have recently completed a Cochrane Collaboration systematic review of the efficacy of DSIs.[5] Using the methods of the Cochrane collaboration,[35] electronic data bases (MEDLINE (1966-April 98); EMBASE (1980?Nov 98); PsycINFO (1979-March 98); CINAHL (1983-Feb 98); Aidsline (1980-98); CancerLit (1983-April 98); and the Cochrane Controlled Trials Register (1998, Issue 4)), and the table of contents of relevant journals (Health Expectations (1998), Medical Decision Making (Jan-March 1986-Jan-March 1998), and Patient Education and Counseling (Jan1995-Feb 1998)) were searched by two independent reviewers (AR, JT) using published methods.[36,37] All potentially relevant articles obtained from these sources and from the personal files of the investigators were assessed for inclusion by two independent reviewers. Randomized controlled trials comparing a DSI to standard care or to another intervention were included if the DSIs were defined as interventions designed to help people make specific and deliberative choices among available options. Outcome data from the included studies were extracted by two independent reviewers using a tested data extraction form. Study

quality was assessed using the Jadad quality score.[38] Any disagreement regarding the inclusion or exclusion or data extraction was resolved by consensus.

Seventeen randomized controlled trials fulfilled the inclusion criteria.[2,28,39-53] The studies examined DSIs in a variety of clinical conditions, ranging from cancer screening to choosing between minimally invasive and more extensive surgery. As discussed above, the choice of the ideal outcome measure to assess improvement in decision making is difficult. This was well demonstrated in this review by the fact that different investigators concentrated on different outcome measures. Additionally we found it uniformly difficult to determine the exact nature of the various DSIs based on the published reports. Therefore, a need exists for the adoption of standardized methods for the conduct and reporting of DSI trials.

Eight studies assessing improvement in knowledge of the disease process and of the available treatment options showed a clear benefit of DSI.[2,39,40,45,47,48,50,51] Only one study assessed the impact of DSIs on realistic expectations of the potential benefits and risks of treatment or screening options.[2] This study showed a clear benefit of a DSI over a printed pamphlet at realigning expectations. Other, non-randomized before/after studies have demonstrated clear improvements in expectation over baseline measures.[54,55] DSIs reduce decisional conflict as assessed in four studies.[2,28,48,50] Three studies assessed satisfaction with the decision-making process and with the actual decision made.[39,40,48] The pooled estimates from these studies failed to show a statistically significant benefit of DSIs on these two outcomes, though a type II error is likely. Fourteen studies assessed the impact of a DSI on the actual decision made.[2,28,39-41,43-46,48,49,51-53] In trials focused on decisions

regarding major surgery, DSIs appeared to reduce the preferences for the more intensive treatment, while in other types of decisions no clear effect was seen. Two studies, suggested an amelioration of the decline in quality of life after treatment for prostate cancer, and ischemic heart disease,[39,40] but no clear reduction in state anxiety scores were seen based on the results of four studies.[28,42,47,52] DSI showed a consistent but not statistically significant increase in the proportion of participants assuming a more active role in decision making compared to usual care controls.[28,42,48]

This review did not turn up any comparisons of a computerized vs. a standard DSI, an observation support by a recent review by the Agency for Health Care Policy and Research.[3] Among the screened articles, however, several studies were found that used a computer to provide information or to act as a DSI but with no non-computerized intervention for comparison.[39,56-61]

3.3 Computerized decision aids

Computerized decision aids (CDAs) offer several potential advantages over standard dissemination formats such as pamphlets, booklets or audio-booklets.[39,60] A CDA can self-tailor to any given patient much more accurately and precisely, without any extra effort or skill on the part of a patient, when compared with a paper-format aid. It is interactive and can allow patients to review past information easily or to seek more detailed information if desired. A CDA focuses attention through synchronized audio-visual presentation, and can easily test understanding and loop back if a certain level of knowledge is not reached. Patient inputs and interactions with the decision aid can be recorded, summarized and

stored for research purposes. Interactivity can occur through a variety of means from mouse input, standard keyboard input, simplified keyboard devices, touch screen or simple voice recognition. The same computer format can be disseminated in a variety of ways: by CDROM, Internet, local hospital Intranet or local area networks. Patients can take home a CDROM, or access a hospital/university web page from home or use the tool in a clinic setting. As well, video tape versions can be easily made from the computerized version, though clearly with some loss of interactivity. On a practical level, the use of a computer-based technology allows the authors to produce a DSI product and to distribute and disseminate it unchanged or minimally altered through electronic means, and the intermediate steps of publishing and marketing current DSIs is eliminated. Furthermore, from an evidenced-based perspective, updating and modifying these DSIs becomes extremely simple when this schema is used. For example if a DSI is maintained on a university or hospital server, only one "copy" exists, therefore only one copy needs modification. Additionally, there is no wastage resulting from the disposal of outdated hard copy. This flexible production paradigm is planned for all common computer applications. It is probable that in the near future one will not buy "wordprocessor" software, but will instead "rent" it off the Internet. Major software companies lose tremendous amounts of money on software packaging, distribution, piracy, and updates. These problems can be mitigated through centralized maintenance of a program coupled with remote access by the end user. (As an illustration, the reader can "visit" the *Corel WordPerfect* web site and use an online, Java-based version of the popular wordprocessing software.)

The biggest hurdle faced by CDAs is one which is quickly becoming less important, namely, the issue of access to and comfort with computers and the Internet. Currently, the advances in computer technology, both on the hardware and software sides, allow individuals to interact with computer programs in natural and intuitive ways, with little need for classical computer knowledge. Computer and Internet users are no longer the stereotypical young single white male professional. In fact, although these were the demographics of the early users, a recent extensive study by the United States Internet Council (USIC) Report published in 1999, has shattered these assumptions.[62] The USIC *(www.usic.org)* is an American, nonpartisan organization composed of federal and state legislators who, with the aid of industry representatives, are tasked with the creation of policies and laws governing various aspects of the Internet.

Worldwide, there were 61 million Internet users in 1996, and it is estimated that there are currently over 320 million users today. In 1998, 37 million Americans were using the Internet from home on a daily basis, and this number is projected to rise to 133 million in the next year. In the last year alone, the number of e-mails sent through America Online nearly doubled from 28 million to 51 million per day. In 1995, 76% of all Internet users were males. However, this proportion dropped to 54% in early1999, and projections estimate that by now use has equalized. In fact, in a recent survey of the top medical sites online, by Jupiter Communications[63], 68% of all users were women, with the authors suggesting women's traditional role as care-givers as the explanation. The USIC also found a drastic drop in the level of education, and yearly income of Internet users towards a more typical American cross-section. But perhaps the most striking finding was the

comparison of the time in years it has taken common household technologies to penetrate 30% of the American population. For example, it took the telephone 38 years to reach 30% of Americans, the television took 17 years, and home computers achieved this level in 13 years. The Internet, on the other hand, has reached this landmark in only 7 years.[62] Concerns over Internet bandwidth and speed abound, particularly given the explosion of new users; however, the backbone of Internet servers itself currently doubles every 100 days, and more and more Internet service providers are offering "high speed" access.

Clearly, barriers to computer and Internet use in some ways have already fallen. Therefore, it makes sense to pursue this technology further in Medicine.

3.4 Status of computer technology in patient-based decision support

Over the last several years there has been a dramatic increase in the use of various informatics tools in the field of medicine. Of particular importance has been the increasing use of computer technology at various levels of medical decision making based on the assumption that the use of such technology would have a positive impact on the quality, efficiency, costs and outcomes of health care delivery.[3,64] Additionally, patients on their own are increasingly using information technology on the Internet to research their medical conditions, treatment options, and often to verify information given them by their healthcare providers[65,66]

There are now mounting examples of the efficacy of such informatics tools in the aid of day-to-day decision making by health care providers.[67-81] Similarly such technology has been applied to aid patient-based decision making as discussed above, and to aid patients

in controlling their disease, such as in the case of diabetes.[82-84] Typically, patient-based decision support is most valuable under circumstances of shared healthcare decisions involving difficult treatment or screening options, but it is also valuable in the aid of informed consent.

Although several available decision aids utilized computer technology, we were unable to identify any studies that compared a computerized to a standard DSI, either currently, or in our recent Cochrane systematic review.[5] Two other, independent investigators came to the same conclusion. A recent extensive review of the published and unpublished data on informatics tools and patient-based decision aids by the Agency for Health Care Policy and Research (AHCPR) found no published comparisons of computerized versus non-computerized informatics tools, and there have been no assessments of the determinants of tool use from the patient's perspective[3]. It is known that the use of these tools by eligible patients can be variable, and can be limited by a variety of operational variables. Recently, in the related area of patient informed consent interventions, Bekker et al. found a paucity of well-designed theory driven interventions, and found no evaluations of computerized patient-based DSI vs. standard interventions for informed consent[85].

Clearly, computer technology has an immense potential for the aid of patient-based decision support, which as of yet has been under-utilized and untested.

3.5 Rationale for the feedback system

As indicated above, the efficacy of DSIs are well established. However, for certain outcomes, room exists for further improvement and refinement of how these DSIs are

implemented. Of particular interest, O'Connor et al. have found that, despite improvements in patients' perception of the probabilities of benefits and risks associated with the respective medical options, a significant proportion (30-50%) of patients were still outside the correct quartile containing their estimated probabilities of lifetime risks[1,2]. To address this concern, the computerized DSI was designed to improve patients' perceptions of their risks and benefits. To this end we drew upon the principles of basic learning theory, both to augment the effectiveness of the standard decision aid and to leverage the capabilities of a computerized system towards this goal.

A great deal of research in the psychology and education fields has focused on adult learning, and there are many theories of learning itself,.[86,87] and still more theories on memory;[88] discussion of them is far beyond the scope of this thesis. However, all the current learning theories have their basis in either behavioural or cognitive psychology. Behavioral theories emphasize the principles of stimulus-response interactions, drive reduction and the value of reinforcement, while cognitive theories emphasize expectations, and past experience.[86,87,89,90] There are strong and outspoken proponents of each view, but clearly a place exists for both views depending on the goal to be achieved.[86,87,90] Basic memory theory suggests that new information, once registered, is stored in short term memory. This memory imprint has a finite life and begins to fade, unless the information is repeated either internally through a conscious effort on the part of the learner, or externally through the re-presentation of the information.[86,88,90,91] This timed repetition is important for the transfer of information from short-term to long-term memory.[88,92] (Interestingly, repetition if overdone can also lead to learning fatigue, and diminished

retention of new knowledge.[88,90]) Multiple associations during the learning process facilitate both the learning and the retrieval of information, in particular if the associations involve various senses.[87,88,90]

Programmed instruction, a technique developed by the behavioral psychologist B.F. Skinner in the 1960's and later modified, is familiar to most individuals.[86,89,90,93,94] This technique involves the breakup of the instructional material into small, easily "digested" pieces. Once the information is presented, the learner is then presented with a "programmed test" wherein a question or series of questions are asked regarding the previously presented information. Typically, these questions are designed to closely reflect the presented material. Following a response, the learner receives immediate feedback and the correct responses, if required. In this way, several psychological learning principles are met, such as timed repetition, and reinforcement.[90]

An automated self-assessment system based on programmed instruction that would "test" patients about the information they were presented with, and correct any misunderstandings, may improve patient's expectations and knowledge over levels achieved with standard DSIs. Therefore, for the DSI in this study, this simple behavioral learning technique was used to build upon the more cognitively based learning theories already employed to strengthen a patient's retention of knowledge and risk data relating to their medical disorder and its treatments. The goal was to test the assumption that the behaviorally based programmed instruction would be most suited to enhance the patient's retention of what must be, to the patient, relatively foreign, lifetime risk data. Although, there are no examples of computerized programmed instruction in the field of patient-

based decision support, Wise et al., in a study of diabetic patients, have shown that the addition of "prescriptive" feedback to a knowledge-assessment program results in greater improvements in knowledge over the same program without feedback.[84]

The computerized DSI, therefore, uses a multi-sensory automated, programmed instruction module with a single timed repetition. This system uses synchronized aurally and visually presented information, and provides positive reinforcement and feedback at intervals during the presentation.

4 Methods

4.1 Study design

After agreeing to participate, and giving informed consent (Appendix 1), eligible peri-menopausal women were randomized to use either the standard audio-booklet DSI or the computerized DSI. Randomization was performed using a table of random numbers that assigned the consecutive patient number to an intervention group. Allocation concealment was maintained through the use of consecutively numbered sealed envelopes.

Once randomized, participants completed a pre-intervention questionnaire designed to test their baseline knowledge, expectations, decisional conflict and favored treatment decision (Appendix 1). Participants then used their assigned DSI, which was followed up by a post-study questionnaire designed to test the same outcomes with the addition of perceived acceptability of the intervention, and by demographics questionnaires (Appendix 1). All data was collected within a single contact with the participant and all randomized participants completed the study.

The participants could not be blinded to the intervention; however, potential bias was minimized by not telling the participants the format of the other intervention. The participants were simply told that two educational techniques were being compared, and that they could view the other intervention, if they so desired, after the completion of the study. The investigator also could not be blinded to the intervention; however, special measures were taken to ensure that participants were not biased by the interviewer/investigator when questionnaires and interventions were used by the participants. Namely, the principal investigator remained silent after the initial introduction

and explanation of the study, questionnaires and the interventions, and spoke only to answer a participant's question.

4.2 Study Participants

Participants were recruited from various medical clinics of the Ottawa Hospitals and among companions of patients undergoing day surgery or endoscopy at the Ottawa Civic Hospital Day surgery and Gastroenterology clinics. Additionally, subjects were recruited through the personal networking of staff in the division of Gastroenterology.

Fifty-one women, aged 40-70, in the peri- and post-menopausal period met the following entry criteria: participants were fully fluent in spoken and written English, and showed no evidence of cognitive impairment or overt psychiatric illness. Previous or current use of HRT, and evidence of osteoporosis or coronary artery disease (CAD) were not considered exclusion criteria. The inclusion criteria were set broadly to improve patient enrollment. These participants were not necessarily at the point of decision making, since decision was not a primary outcome. However, the participants still represented a broad spectrum of peri-menopausal women for whom the decision was, or soon would be, relevant.

4.3 Interventions

4.3.1 The HRT audio-booklet decision aid

The HRT audio-booklet decision aid[1,2] is a self-administered, self-paced, 40-minute audio tape that guides women through a 32-page illustrated booklet (Appendix 2). The

DSI provides information on a variety of areas of concern to women considering HRT. Briefly, the decision aid gives detailed information about coronary artery disease, osteoporosis, endometrial and breast cancer, as well as information about the major risk factors for, and the emotional and social impact of, these disorders. The risks and benefits of HRT are presented along with the probabilities of disease both with and without HRT, tailored to the individual's risk of disease and hysterectomy status. The development and evaluation of this DSI, was based on the decision support framework discussed previously.[1] The HRT decision aid, therefore, addresses each of the components of the decision support framework, and its efficacy has been documented in a before/after study,[1] as well as in an RCT comparing the decision aid to the American College of Physicians (ACP) pamphlet on HRT.[2]

The HRT decision aid has been shown to improve realistic expectations of the occurrence of heart disease, hip fractures, and breast cancer, both with and without HRT. In the before/after study of 94 menopausal women, realistic expectations improved from 32% at baseline to 55% (p=0.001).[1] The greatest improvements in expectations were seen for the impact of HRT on disease occurrence. This intervention also decreased decisional conflict, with the greatest reduction seen in the uninformed sub-scale. The before/after study demonstrated a significant improvement in the general knowledge score, from 54% to 75% (p=0.001). In the RCT comparing the audio-booklet HRT DSI to the ACP pamphlet, 165 menopausal women, were randomized to each intervention, and a single post-intervention assessment was undertaken. In that study, the audio-booklet DSI was superior to the pamphlet at improving realistic expectations (72% vs. 46%, p=0.001), and

reducing decisional conflict (2.1 vs. 2.3, p=0.04). However, general knowledge was comparable between the two groups; and no clear differences were observed for actual decision or changes in decision.[2]

The HRT decision aid was chosen for evaluation as a delivery method because the intervention was already fully evaluated. Therefore, there was a basis for comparison of the results of this study with those of the previously published evaluations. Additionally, since only a small aspect of the validated intervention was altered, the observed effects were more likely to be the result of the additions (as described below), rather than a flaw in the decision aid itself.

4.3.2 The computerized HRT decision aid

The present CDA was developed by the A. Rostom and is based entirely on the previously validated HRT audio-booklet decision aid developed by O'Connor et al.[2] Prior to the development of this CDA, the feasibility of such an undertaking was tested in two pilot studies. The first evaluated the availability of computer hardware and software resources to develop an interactive computerized educational tool for medical residents studying the evaluation and management of gastrointestinal (GI) hemorrhage (Rostom & Bormanis). Through the development of this educational tool, this study allowed the identification of the appropriate computer platform and authoring environments for future studies, and demonstrated the feasibility of such an undertaking under the constraints of limited resources. The second study fully computerized a decision aid, developed by Laupacis et al., for anticoagulation therapy in patients with atrial fibrillation.[54]

4.3.2.1 Development of a computerized endoscopy teaching program

The goal of this project was to accumulate endoscopic photographs and videos relating to GI endoscopy, and GI hemorrhage, and to present them as a computerized index atlas. Additionally, the program was to have two educational components that guided students through the assessment and management of upper and lower GI hemorrhage. This project was undertaken while the author was a Fellow in the Gastroenterology training program at the University of Ottawa. At that time (1995-1996), several programming packages were available, though they were considerably less elaborate than current ones, and had little or no Internet connectivity. Therefore, for reasons of ease of dissemination the use of HTML(hypertext markup language)-based web technology was considered, but it offered limited animation, audio and video capabilities, and audio and video web streaming technologies were not yet "mainstream." Therefore, the decision was made to use *Macromedia Director*®, a programming application that combines multimedia manipulation with a true embedded programming language. Unfortunately, Director did not have excellent database capabilities, and it was necessary to use lists and strings to manipulate data and image indexes.

Microsoft Visual Basic® is a true visual, object-oriented, programming language, and is advertized as being used by more programmers worldwide than all other languages combined. This language allows the production of native *Windows*® applications, and has the advantage of seamlessly embedded *Microsoft Jet*® database connectivity. Therefore, complex database applications can be built easily with visual basic, and these database

records are not limited to holding text and numbers, but can also easily index images, video or sound files. The GI teaching aid was, however, programmed fully in *Macromedia*. It became clear that, for future projects, the best course would be to combine the individual strengths of each of these applications. Another technological development that occurred during this period was the improvement of Internet streaming technology—the ability to "play" a file as parts of it are being downloaded, as opposed to waiting for the whole file to arrive before "playback." This technology makes possible two major developments: 1) the use of large audio and video files over wide area networks and the Internet; and; 2) the ability to program once and distribute a product multiple ways—for example by CD and by the Internet. This second development lets a *Macromedia*-developed application, which would otherwise be too large to download, to be streamed over the Internet and run a little at a time as it is being downloaded. The obvious benefits of this technology are evidenced by its ubiquitous use on the Internet today.

4.3.2.2 Development of a computerized atrial fibrillation decision aid

The computerization of a DSI involves two major phases: preparation, and programming. In the initial preparation phase, all materials, graphics, and media were converted to a computer-based format. For example, all text needed to be in a simple *DOS* text format, and all icons and graphic images had to be produced digitally scanned or otherwise obtained. Depending on the length of the text and the complexity of the graphic images, this may be a long process. All text was organized using *WordPerfect*®, and

subsequently saved in a simple text format. Icons and graphic images were obtained from commercial image libraries, hand-drawn, or scanned. All image modification required extensive knowledge of a graphics package, *Corel Draw®*. Backgrounds, iconic buttons, and textures were made using *Corel Draw®*, *Corel 3D®*, and *Corel Texture®*. The audio tape was digitized by running the cassette through a standard computer audio-card and converting the sound to a *Microsoft Wave®* format. Once the entire tape was digitized, the sound was edited and spliced into 450 individual small segments that corresponded to the bulleted text of the decision aid booklet. All sound editing and splicing was performed with *Goldwave®* sound editing software. The splicing of the sound source was relatively straight forward, but extremely time consuming. With all the building blocks in place, the project was subsequently programmed using a combination of *Macromedia Director®*, and *Microsoft Visual Basic®*. *Macromedia Director* is extremely well suited to the manipulation of graphic objects and multimedia elements, which allows a programmer to concentrate on the logic and flow of a program, and the coding of user inputs. *Director* possesses a full featured, visual, object oriented programing language dubbed "Lingo"® by *Macromedia*. *Lingo* is very similar to *Visual Basic*, and most of the programming was accomplished using it. However, *Visual Basic* is better suited to variable, string manipulations, and mathematical and database operations, and was therefore used in some circumstances. The synchronization capabilities of *Director* allowed straight-forward linking of graphic, text, and sound transitions.

4.3.2.3 Development of the computerized HRT decision aid

The HRT CDA was developed to run in a native *Windows 95/98/NT* 32-bit operating system from an autorun CDROM, as well as through the Internet/Hospital intranet in a graphics-simplified format. The CDA was developed by A. Rostom using two widely available programming applications (*Microsoft Visual Basic 6.0®* and *Macromedia Director 6.0®*) and standard computer programming techniques, in a manner identical to that indicated above for the atrial fibrillation DSI. The CDA was designed to present the validated HRT decision aid in a format that is intuitive and appealing to patients, while maintaining the exact factual content and visual "feel" of the original audio-booklet (Appendix 2). After an introduction and explanation, the application begins by presenting some general information about heart disease, breast cancer and osteoporosis. The patient is introduced to the general benefits and risks of HRT. An enhanced self-tailoring module was developed that calculates tailored, individual risk/benefit data for heart disease, osteoporosis, and breast cancer, both with and without HRT, based on the patient's responses to a short series of simple yes/no or multiple-choice questions (HRT Risk Calculator, developed by A. Rostom). Regression formulas to model this data were determined by curve-fitting an extensive data list published by N. Col et al.[95,96] Based on the risk stratification, the patient is presented with a personalized, tailored decision aid wherein the patient has full control to advance, review or pause and ask for help. The factual data is identical to that presented in the audio-booklet. The exact text appears synchronized with the exact audio obtained from the original digital master. Additionally, through the real-time calculation of the patient's risk profile and expected risks and

benefits with and without HRT, the computerized version provides a greater degree of tailoring, and which is not dependant on the patient's ability to decide for themselves what risk group they fall into. They are simply presented with their risk/benefit data based on the best estimates from the literature.

The computer is used to focus attention on the text and audio through the use of various animation, graphic, and transition techniques. At the completion of each module of the CDA, a brief computer-driven, "user friendly" programmed instruction module is presented. If the response to these questions is incorrect, the program either loops back to re-present the appropriate section of the CDA, or presents a simplified summary of the correct responses with appropriate reinforcement and feedback. Since the entire patient contact occurred in one sitting, the feedback loop was limited to the presenting of a summary of the correct responses and why some responses were incorrect. Since the patient encounter was already long, a shorter summary was deemed to be more tolerable than would have been a re-presentation of the previous section.

The feedback module was programmed using *Macromedia Director*. After each segment of the decision aid a call was made to this module, which subsequently presented a series of multiple-choice questions. Movement through the questions was controlled by the participant through the use of navigation buttons. Error trapping was used to ensure all questions were answered and that the participant did not select more than one response. The participant was free to change her response, but once she moved on to the answer segment her previous answer could not be changed. The answers given, and the number of tries, were recorded in a variable array. The correct responses were stored in

another variable array. The arrays were compared after each question and a third variable was used to give the response during feedback to that question based on the initial comparison. In responses that required the recollection of a lifetime risk, the computer asked the participant to select a range, out of the list that included her lifetime risk (as was done in the pre/post questionnaires; see Appendix 1). In these situations the computer held in memory the participant's true lifetime risk as calculated in the Risk Calculator Module (see below). The patient's estimated lifetime risk was presented to her during the feedback to the question.

The feedback module was designed to be fully modifiable, and capable of being introduced at any point in the decision aid. The questions used to test participant knowledge and expectations in the programmed instruction module were the same as those asked in the pre/post questionnaire (Appendix 1).

4.3.2.4 Development of the real time risk calculator

Col et al. have developed risk stratification models for peri-menopausal women considering HRT based on decision analytical techniques.[95,96] These models were designed for use by both clinicians, and consumers. The model assigns a risk point score for the three major health areas (heart, osteoporosis, and breast cancer) based on responses to a simple questionnaire (Appendix 3). The risk points are then converted to a lifetime risk for the given health issue through the use of a calculated formula and a "look-up" table. This modeled data is ideal for computerization, since it is very difficult to calculate by hand, and it could benefit the HRT DSI by providing patients with tightly tailored risk data. An

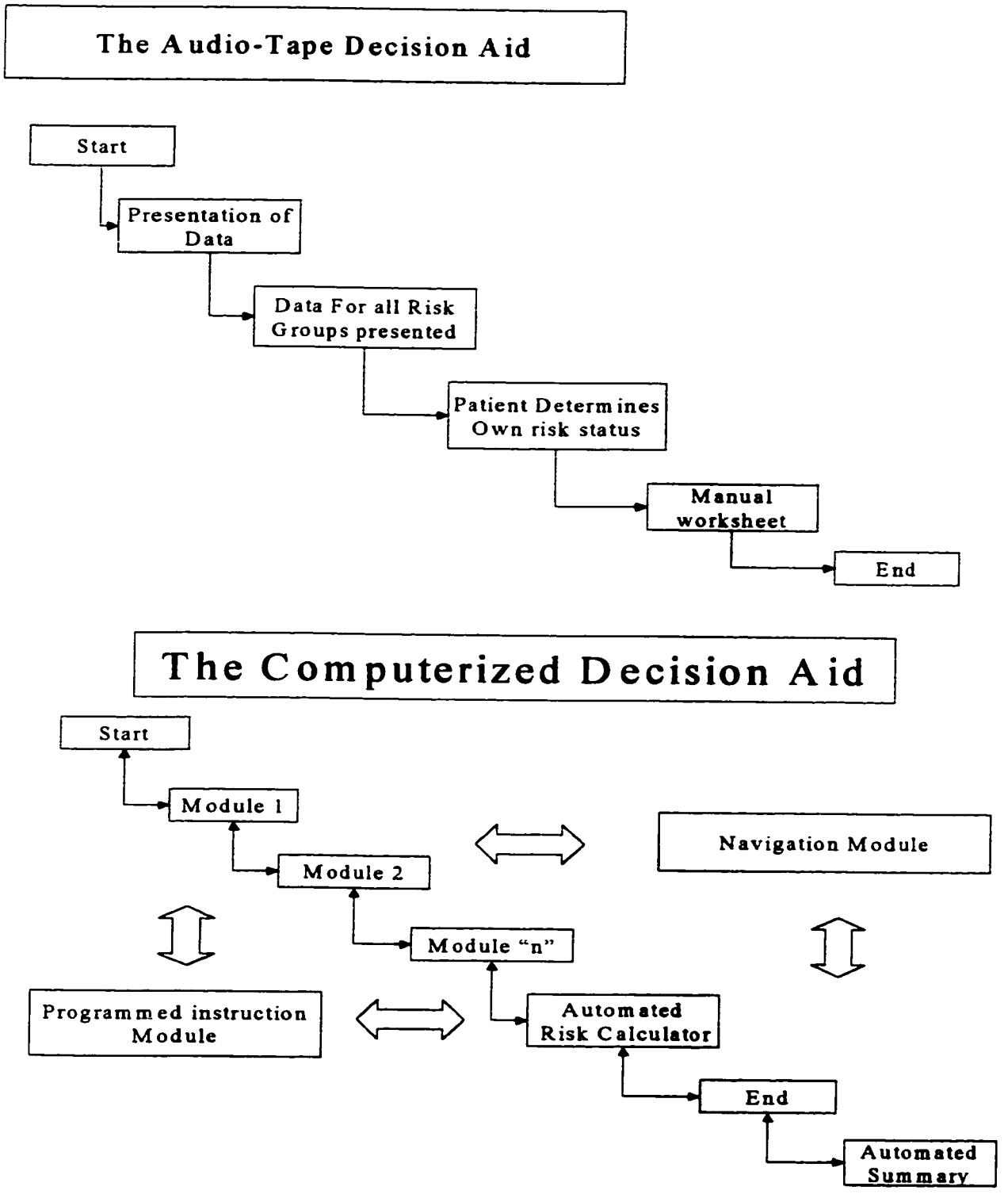
interactive, computerized version of this questionnaire was produced by A. Rostom which automatically calculated the participant's risk point, without error and without need of any calculations on the part of the participant.

This module required the development of a computerized questionnaire using a combination of *Visual Basic* and *Director Lingo* programming. The Questionnaire allows the user to read the question, and point and click to select the desired response out of the multiple-choice list. The module has extensive error trapping functionality such that the user could not select two or more responses (unless specifically allowed for that question), and the user could not bypass a question without answering. The user could navigate forward and backward through the questions and change answers at will, since this was not a test. The answers were stored in a variable array indexed by question number. A second indexed array was used to hold Col's point score system for each response. After all the questions were answered, a tabulated and 100-figure lifetime probability of outcomes was displayed by variable array comparison, calculation of the total point system, and subsequently using a formula to model Col's risk data. The curve fitting function of *SPSS®* was then used to assign a mathematical formula to the look-up tables for each health issue, both with and without HRT. The best curve was identified by an R value closest to 1.0, and by visually verifying that the curve predicted by the formula matched the actual data points over the range of interest. (The formulas and original tables are presented in Appendix 3.) The Risk calculator was extensively tested by A. Rostom and J. Tetroe to ensure that it produced accurate risk data as presented in Col's look-up tables.

4.3.2.5 Summary of similarities and differences between the computerized and audio-booklet DSIs

The computerized DSI presents the exact text and sound narration of the audio-booklet DSI. The look and feel of the DSIs are identical. However, the computer automates and synchronizes the sound text and graphics, and adds animation transitions to focus attention on the points being emphasized. The audio-booklet DSI runs a cassette tape that beeps for the user to turn the page of the booklet. The computerized DSI is fully synchronized, with fully linked sound and visually presented material. Navigation is accomplished by pushing a forward or back button, or through the use of a table of contents. As Figure 2 graphically illustrates, the audio-booklet is linear, while the computer allows random access to the DSI. The computerized DSI further adds two segments, the programmed instruction module discussed above, and the automated risk calculator that provides fully tailored personalized risk data. The added segments increased the length of the computerized intervention by less than 10 minutes.

Figure 2: Schema of the audio-booklet and computerized decision aids



4.4 Outcome variables and statistical analysis

4.4.1 Baseline characteristics

The following baseline characteristics were recorded for each participant and were summarized by group for comparative purposes:

- Age
- Education
- < High school diploma
- High school diploma
- Some post-secondary education
- University degree
- Menopausal status
- Previous HRT discussion with physician
- Previous use of HRT
- Own or have access to a home computer
- Access to Internet

Risk factors for heart disease, osteoporosis, and breast cancer were assessed using a risk stratification questionnaire developed by Col et al.[95]

4.4.2 Main outcome variables

The optimal choice of outcome measures for DSIs is not straight-forward, for a variety of reasons. It is clear that there is a dissociation between what would be considered a "good" decision, and a "good" health-related outcome. Specifically, it is possible for an

individual to choose a specific treatment or course of action that most reasonable individuals under the same circumstance would also choose, and have that decision result in a bad outcome. In retrospect, it would be easy to label such a decision a "bad" decision that led to a poor outcome. However, by the nature of health-related decisions, which are the subjects of DSIs, each option is "conflicted," as discussed previously. Therefore the measurement of pure health outcomes, such as survival or death, resulting from a decision and thus as a measure of a decision aid's efficacy is not appropriate. Clearly, one has to accept that a "good" decision can result in a poor outcome. Similarly, one cannot always depend on the actual choice made between various options as a reliable measure of appropriate decision making, since again, given the nature of the decisions addressed by decision aids, each option may be equally appropriate under different circumstances.

Researchers in this field have chosen multiple other surrogate outcomes of appropriate decision making, as detailed in the recent systematic review.[5] One can measure components of the decision support framework variables which are known to be essential for proper decision making. Examples of these would include knowledge of the disease entity, the choices and the risks and benefits of each option, and realistic expectations of the expected benefits and risks of the various outcomes. Alternatively, one can measure surrogates of the psychological impact of the decision and the decision-making process on the patient. Examples of theses would include more psychologically based outcomes such as decisional conflict, anxiety questionnaires, quality of life, and satisfaction with the decision-making process and the decision itself, and persistence with the decision.

The outcome variables used in this study are detailed below. Realistic expectations of the benefits and risks of the use or non-use of HRT on heart disease, hip fractures, and breast cancer was chosen as the major endpoint. As described previously, accurate understanding of the risks and benefits of treatment options and their expected outcomes are a foundation of proper informed decision making. Additionally, it has been documented previously that room exists for improving patients "realistic expectations" of the various outcomes.

4.4.2.1 Realistic expectation

Realistic expectations (RE) were determined by having patients indicate their specific lifetime risks of menopause and HRT-related consequences on a 0-100% probability scale divided in intervals of 5%. The specific questions address issues of risk of heart disease, bone fractures and breast cancer with and without HRT. Realistic was defined as a response within 15% of the model estimated lifetime risk. The estimated risk was defined as the risk that the patient was presented with during the DSI. The realistic expectation score was calculated as the mean proportion of those within 15% of their true risk over the six risk categories (heart disease, hip fracture, breast cancer, each with and without HRT). This outcome measure was developed by O'Connor et al., and was used in previous studies assessing DSIs. This variable has an approximately normal distribution.

4.4.2.2 Knowledge

Knowledge (Kn) was assessed by an 11-item multiple-choice questionnaire designed to determine the patient's understanding of the symptoms and risks of menopause and the risks and benefits of HRT. The items of this questionnaire were developed for this study and were purposefully made more challenging than previously used questionnaires since it was hypothesized that the previous failure to show a benefit of the HRT DSI over a basic pamphlet was related to the possibility that the Kn questions were too easy. The Kn score is an approximately normal variable, and was expressed as the percent of correct responses.

4.4.2.3 Decisional conflict

The decisional conflict scale is a validated measure of a patient's uncertainty in making a treatment decision.[7,8] We used the uncertainty and the uninformed sub-scales of the decisional conflict scale. These sub-scales were chosen because they have been previously shown to be most responsive to change, and since our primary emphasis was on improving expectations and knowledge with the computerized DSI. Each question in this instrument is a five-point Likert scale. The decisional conflict (DC) score is subsequently determined by dividing the total scores by the number of questions, giving a value in the range of 1 (low DC) to 5 (high DC). The DC score has an approximately normal distribution.

4.4.3 Secondary outcome variables

4.4.3.1 Satisfaction with the decision aid and barriers to use

A multiple-choice questionnaire was used to measure participants' satisfaction with the decision aids. Participants were asked to specify the strength of their agreement or disagreement with each item (see Appendix 1). Four questions assessed the participants enjoyment of the intervention overall, while two asked specifically about the programmed instruction feedback system. Since the audio-booklet group did not receive feedback during their intervention, they were asked to hypothetically consider if they felt feedback would be helpful. Two questions asked about participant comfort with computers and the Internet, and two asked what decision-aid formats participants think would be best, and which they actually could use at home (see Appendix 1, post-questionnaire).

4.4.3.2 Realistic risk group selection

Each participant was asked to rate her personal risks of heart disease, hip fracture, and breast cancer as low, medium or high at baseline and post-intervention. All participants also filled out a risk profile questionnaire (see Appendix 3, risk calculator). The data from this questionnaire was used to determine a participants estimated risk group (for the purpose of this study) for each of the three disease states based on the risk stratification scheme proposed by Col et al. The mean proportion of correct risk group selection was calculated analogously to O'Connor's RE score.

4.4.3.3 Impact on the decision made

Participants were asked to indicate whether they would choose to take HRT, or not, on a 15-point scale ranging from: +7 yes hormones to -7 no hormones. Zero in the middle, with a range of -1 to 1, was used to indicate that the participants was unsure. Participants were considered to be strongly leaning if they indicated scores of |Decision|> 4, and weakly leaning for |Decision| scores between 2 and 4. These divisions were chosen arbitrarily, such that a range of three points existed for each category. The impact of the interventions on the decision made was not a primary outcome of this study, and therefore was explored simply by presenting the percentages of participants in each group who were strongly leaning, weakly leaning or unsure regarding the decision. As well, the percent of individuals who changed from unsure or weakly leaning to strongly leaning and extreme changers from no HRT to yes, or vice versa, were recorded.

4.4.4 Data analysis and assessment of normality

Hypothesis testing was performed for the main outcome variables only and, as also detailed in the thesis proposal, no subgroup analyses were attempted given the small sample size of this study. Group differences in mean changes from baseline for the outcome variables (RE, Kn, DC) were tested using an independent sample t-test with a two-tailed alpha of 0.05. Ninety-five percent confidence intervals were presented for the baseline characteristics, and for pre- and post- estimates of these variables. For variables expressed as proportions (decision made, and the preference questions) estimates of the

variability of the measure were made by providing 95% confidence intervals (see Appendix 4 for formula).[97-99]

The above reference to the normal distribution of outcome variables is based on the demonstration of the normality of these variables in previous studies, the application of the central limit theorem, and through the testing of normality through the use of histograms, P-P plots (a plot of a variable's cumulative proportions against the cumulative proportions of Normal test distributions).[97,98] Based on the central limit theory, outcome variables that are of questionable normality will approach an approximate normal distribution, if the sample size is large enough. This required sample size increases with increasingly non-normal variables, but typically lies in the range of 20-30 subjects which is close to the group sizes studied.[97] Also, the Mann-Whitney test was also used to test significance.

4.5 Sample size estimation

Sample size estimates were derived from data obtained from previous studies by O'Connor et al. that have used similar outcome variables in a nearly identical patient population.[1,2] The estimates are based on expectations that the computerized decision aid will be superior to the standard decision aid, rather than on an assumption of equivalency. The primary outcome of this study is the realistic expectation score. Based on a single post-intervention comparison in RE given observed standard deviations of 25 (range 19-28) in previous studies, it was estimated that a sample of 50 patients (2N) would be required to have an 80% power to detect a difference of 20% in RE score between groups. A 20% difference in RE was felt to be a clinically important and meaningful

difference to detect. The formula for the sample size calculation is presented in Appendix 4. The sample size for the comparison of the pre/post change in RE would be estimated to be fewer based on the observed standard deviation for the mean difference of 22 in a previous study.[1]

4.6 Ethics approval

This conduct of this study was approved by the ethics committee of the Ottawa Hospital (Approval No. 1998147-01H).

5 Results

5.1 Baseline characteristics

Fifty-one participants fulfilled the inclusion criteria, and were randomized to either the computerized DSI (n=25) or the audio-booklet DSI (n=26). Fifty-five percent of the participants were recruited through hospital networking by colleagues (n=29), 29% through the Gastroenterology or Osteoporosis Clinics (n=15), while the remaining 14% (n=7) were recruited from out-of-hospital sources (Figure 3). A complete data set was available for all randomized patients with no loss to follow-up. The baseline characteristics for the included patients are presented in Table 1. The groups were similar except that, on average, participants in the computer group were more likely to be still having menses, and therefore not taking HRT. Overall, 74.5% of the participants had a college or university degree. At the time of this study, only 27% of the participants were contemplating the decision to take HRT.

Figure 3: Study outline

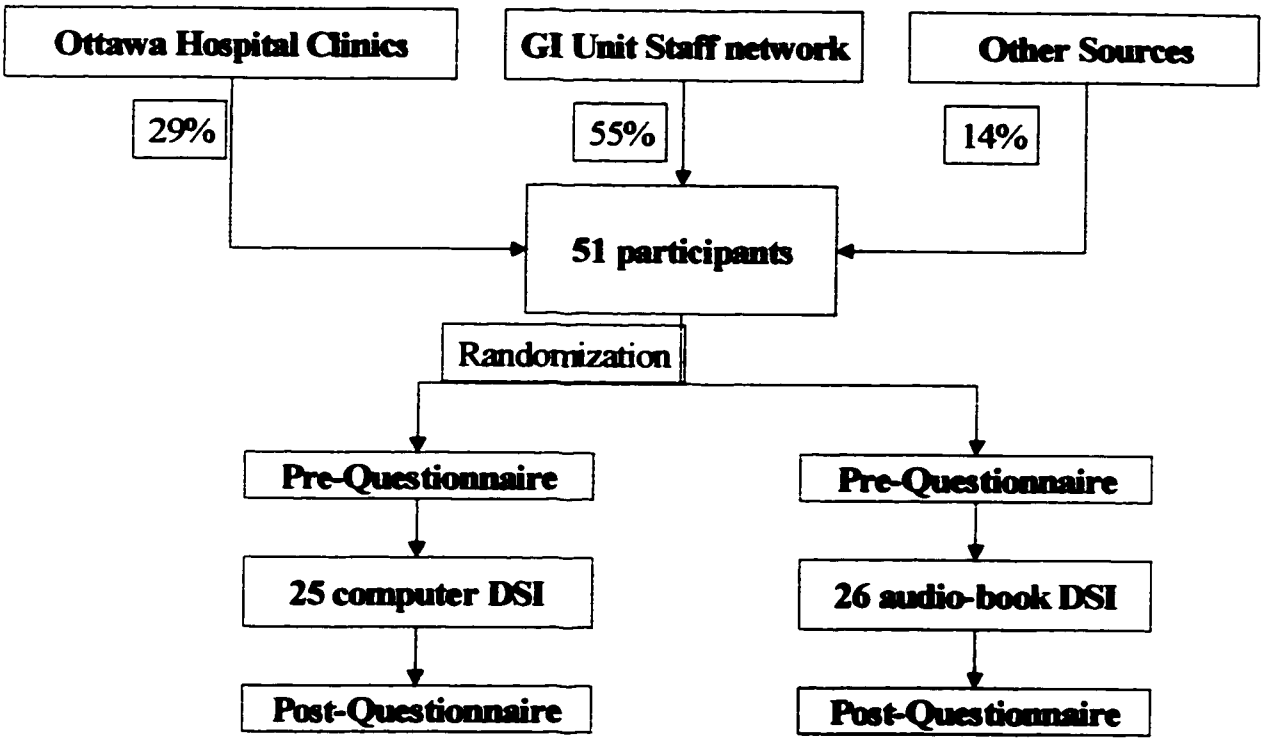


Table 1 - Baseline Characteristics:

Baseline Characteristics	Computer (n=25)			Audio-Booklet (n=26)		
			95% CI			95% CI
Age (SD)	50.6	(7.67)	(47.6, 53.6)	53.8	(8.13)	(50.0, 56.9)
High School Degree	6	(24.0 %)	(7.3, 40.7)	7	(26.9 %)	(9.5, 43.9)
University or College	19	(74.0 %)	(56.8, 91.2)	19	(73.1 %)	(56.1, 90.1)
Currently Not Using HRT	19	(76.0 %)	(59.3, 92.7)	13	(50.0 %)	(30.8, 69.2)
Menses	16	(64.0 %)	(45.2, 82.8)	7	(26.9 %)	(9.9, 43.9)
Contemplating the Decision	8	(32.0 %)	(13.7, 50.3)	6	(23.1 %)	(6.9, 39.3)
Strongly Leaning	16	(64.0 %)	(45.2, 82.8)	18	(69.2 %)	(51.5, 86.9)

5.2 Realistic expectations

The primary endpoint of this study, the realistic expectation (RE) score, is the proportion of participants who had realistic perceptions of their lifetime risks for six measures (heart disease, hip fracture, and breast cancer, each without and with HRT). Realistic was defined as within 15% of the risk presented to then in the DSI. (See Table 2 for a summary of the results.)

At baseline, 32% (95% CI: 0.20-0.44) of those in the computerized DSI and 37% (95% CI: 0.27-0.47) of those in the audio-booklet DSI had realistic expectations. After the interventions, this proportion rose to 84.7% (95% CI: 0.746-0.948), and 64.7% (95% CI: 0.544-0.750), respectively. The computerized DSI was associated with a significantly greater improvement in RE over baseline (52.7%), than the audio-booklet group (27.6%) (p=0.015) (Table 2).

Also explored was the tendency of participants to over- or under-estimate their lifetime risks. Therefore, participants were divided into three groups: realistic (within 15%); over-estimators (>15% above true risk); or under-estimators (>15% below true risk). As can be seen in Figure 4, the majority of participants at baseline were over-estimators (58.2%) , 34.6% were realistic, and 7.2% were under-estimators. Following the interventions, the large group of over-estimators declined to be replaced by realistic estimators (Figure 5), with the improvement being most pronounced in the computerized DSI group. The proportions in the computer and audio-booklet groups, respectively, who were over- (11.3% vs. 26.3%) and under-estimators (4.0% vs. 9.0%) favoured the computerized DSI. When this data was grouped by the three disease states (Figure 6), with or without HRT,

participants over all tended to over-estimate their risks of disease. This was most evident for breast cancer, where 70% over-estimated and no one under-estimated their lifetime risk. After the interventions, the group as a whole become much more realistic, with 74.5% within 15% of their risk, 19.0% over-estimators, and 6.5% under-estimators (Figure 4).

Table 2 - Realistic Expectations

Realistic	Computer			Audio-Booklet		
	Mean proportion	**SD**	**95% CI**	**Mean Proportion**	**SD**	**95% CI**
Pre	**32.0**	30.4	(19.5, 44.5)	**37.2**	25.5	(26.9, 47.5)
Post	**84.7**	25.9	(74.0, 95.3)	**64.7**	26.8	(53.9, 75.6)
Difference[1, 2]	**52.7**	37.5	(37.2, 68.1)	**27.6**	33.3	(14.1, 41.0)

[1]- p=0.015, t=2.530, MD=0.25, 95% CI of MD: 0.0517-0.4504

[2]- p=0.023, Mann-Whitney U=205, Z= -2.282.

Figure 4: Realistic expectations - overall risk perception

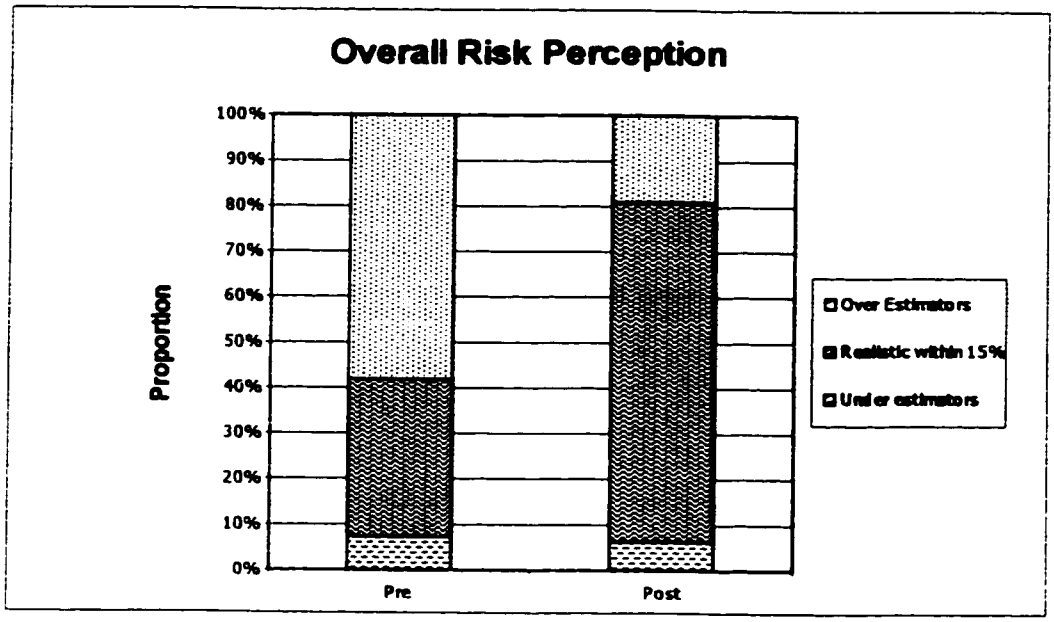


Figure 5: Realistic expectations—risk perception by group

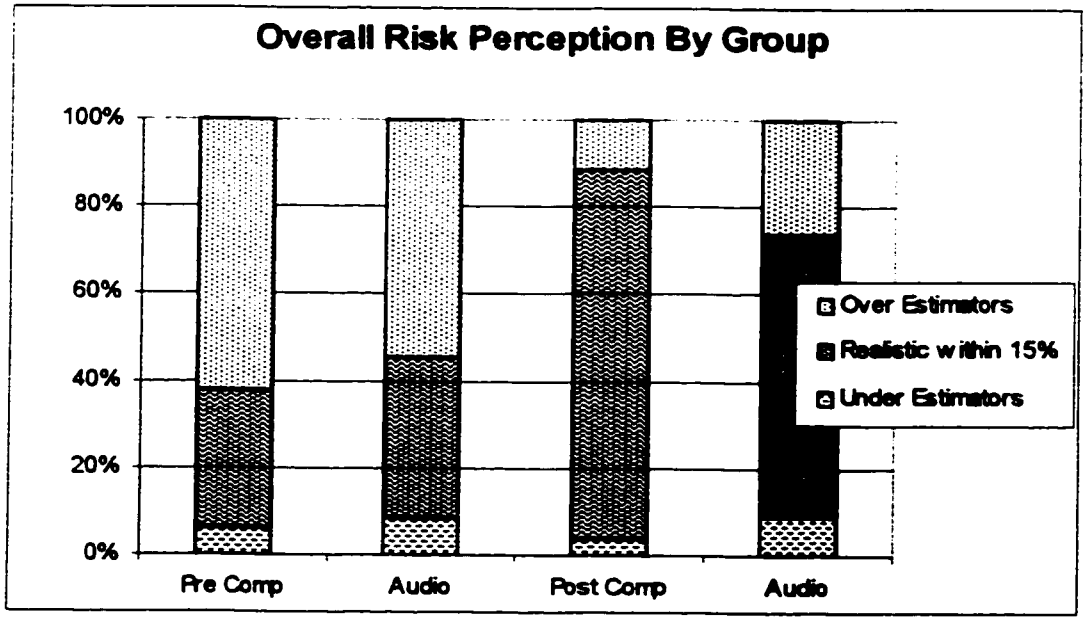


Figure 6: Realistic expectations—pre-intervention

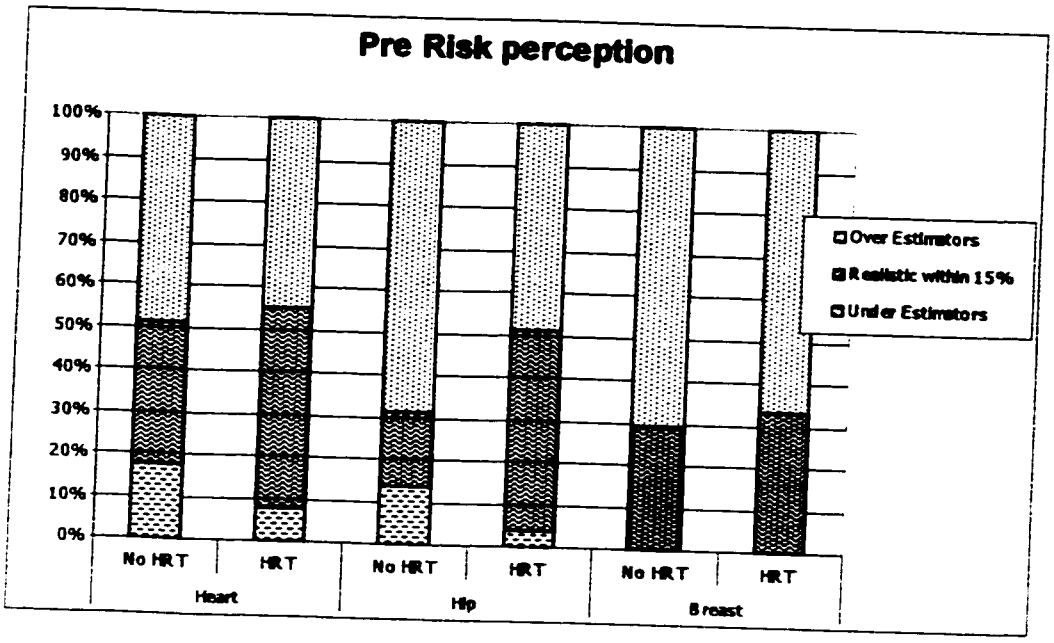
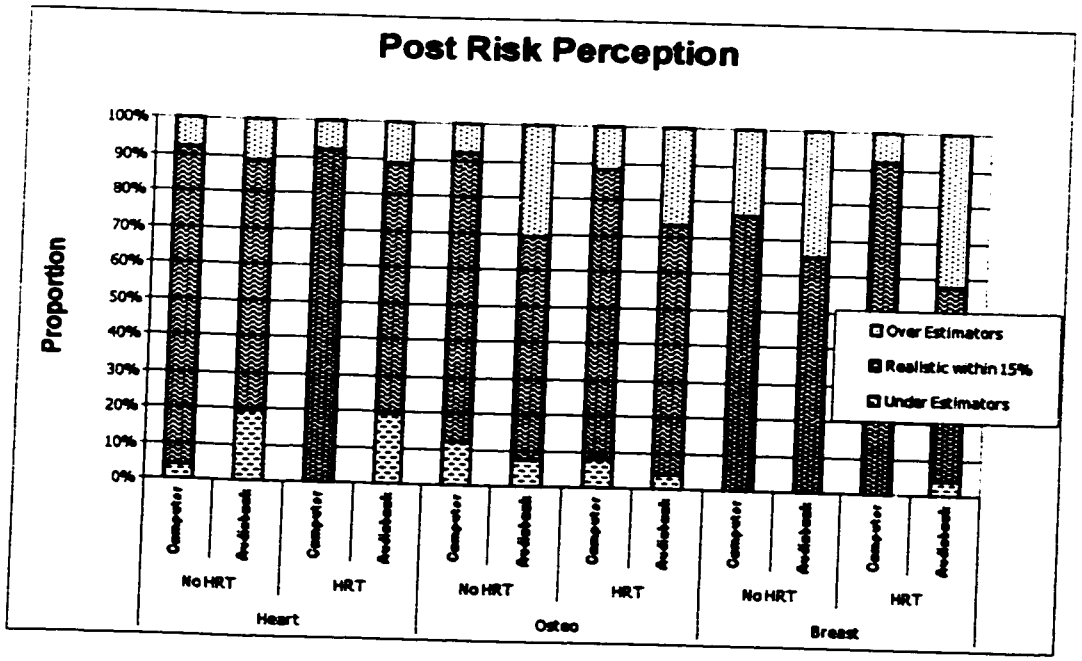


Figure 7: Realistic expectations—post-intervention



5.3 Knowledge

Knowledge score results are presented in Table 3. At baseline, the computer group scored a mean of 76.4% (95% CI: 70.2, 82.5) on the knowledge questionnaire compared to a mean of 78.7% (95% CI: 72.0, 85.4) in the audio-booklet group. Post-intervention, the mean percent correct scores improved to 93.8% and 87.1% for the computer and audio-booklet groups , respectively. The computerized DSI was associated with a greater improvement in knowledge score over baseline: 17.5% vs. 8.4% (p=0.019).

Table 3 - Knowledge

Knowledge	Computer			Audio-Booklet		
	Mean	**SD**	**95% CI**	**Mean**	**SD**	**95% CI**
Pre	**76.4**	14.9	(70.2, 82.5)	**78.7**	16.7	(72.0, 85.4)
Post	**93.8**	9	(90.1, 97.5)	**87.1**	11.8	(82.3, 91.8)
Difference [1, 2]	**17.5**	13.4	(11.9, 23.0)	**8.4**	13.3	(3.0, 13.8)

[1] - p=0.019, t=2.423, MD=0.0906, 95% CI of MD: 0.0155-0.1658

[2]- p=0.017, Mann-Whitney U=201, Z= -2.397.

5.4 Decisional conflict

Decisional conflict was evaluated using the uncertainty and the uninformed sub-scales of the decisional conflict scale (appendix). This scale gives values from 1(low DC) to 5 (high DC). The mean decisional conflict scores and the respective 95% confidence intervals are presented in Table 4. There was a trend towards greater reduction from

baseline in the uninformed (0.87 vs. 0.42) and total decision (0.53 vs. 0.38) conflict scores with the computerized DSI compared to the audio-booklet, but these did not reach statistical significance ($p>0.05$). Although with the Mann-Whitney test the change in the uninformed sub-scale appeared significant, the groups were somewhat uneven at baseline.

Table 4 - Decisional Conflict

Decisional Conflict		Computer			Audio-Booklet		
		Mean	**SD**	**95% CI**	**Mean**	**SD**	**95% CI**
Feeling Uncertain	**Pre**	**2.4**	1.0	(2.0, 2.9)	**2.5**	1.2	(2.0, 2.9)
	Post	**2.2**	0.9	(1.9, 2.6)	**2.1**	0.9	(1.7, 2.5)
	Difference	**0.2**	0.6	(-0.1, 0.5)	**0.3**	0.8	(0.0 0.7)
Feeling Uninformed	**Pre**	**2.7**	1.1	(2.2, 3.1)	**2.1**	1	(1.7, 2.5)
	Post	**1.8**	0.5	(1.6, 2.0)	**1.7**	0.5	(1.5, 1.9)
	Difference[1,2]	**0.9**	1.0	(0.5, 1.3)	**0.4**	0.8	(0.1, 0.8)
Total	**Pre**	**2.6**	0.9	(2.2, 2.9)	**2.3**	1.0	(1.9, 2.7)
	Post	**2.0**	0.7	(1.7, 2.3)	**1.9**	0.7	(1.7, 2.2)
	Difference[3, 4]	**0.5**	0.6	(0.3, 0.8)	**0.4**	0.7	(0.1, 0.7)

[1] - $p=0.087$, $t=1.745$, MD=0.082, 95% CI of MD: -0.0672, 0.9544

[2] - $p=0.025$, Mann-Whitney $U=210$, $Z=-2.234$.

[3] - $p=0.42$, $t=0.811$, MD= 0.148, 95% CI of MD: -0.2197, 0.5171

[4] - $p=0.166$, Mann-Whitney $U=252$, $Z=-1.384$.

5.5 Secondary outcomes

5.5.1 Satisfaction with the DSI

The acceptability of, and the satisfaction with, the DSI was assessed using a multiple-choice questionnaire given after the DSI (Appendix 1). Ninety-two percent of participants (95% CI: 72.5, 98.6) in the computer group and 88.5% (95% CI: 68.8, 97.0) of those in the audio-booklet group agreed or strongly agreed that the intervention was enjoyable. Similarly, 96.0% (95% CI: 77.7, 99.8) and 96.2% (95% CI: 78.5, 99.8) of participants in each group, respectively, agreed or strongly agreed that the intervention helped them to learn more about menopause and HRT, and 88% (95% CI: 67.7, 96.9) and 92% (95% CI: 73.1, 95.5) of participants, respectively, would recommend the intervention to a friend or relative.

Eighty-four percent of participants (95% CI: 63.1, 94.8) in the computerized DSI group agreed or strongly agreed that the computerized self-testing of their knowledge during the intervention was helpful. However, when participants in the audio-booklet group were asked hypothetically if self-testing would be helpful, only 61.5% (95% CI: 40.7, 79.1) agreed or strongly agreed. Similarly, only one person (4.0%) (95% CI: 0.002, 22.3) in the computer group did not like self-testing during the intervention, while 42% (n=11) (95% CI: 23.7, 62.5) of those in the audio-booklet group would not like self-testing when asked this question hypothetically (p=0.01, Chi-square=10.395).

5.5.2 Barriers to computerized decision aid use

Seventy-two percent (95% CI: 57.5, 83.2) of participants agreed or strongly agreed with the statement: "I feel comfortable using computers." The mean age of those who were comfortable vs. those who were uncomfortable with computers was 51.4 (95% CI:48.81, 54.00) and 54.4 (95% CI:49.49, 59.22), respectively. Seventy-eight percent (95% CI: 63.8, 87.9) of those who were comfortable with computers had a university or college degree compared to 64.3% (95% CI: 49.6, 76.9) of those who were uncomfortable with computers.

When asked what format the participant felt would be best suited to inform women about menopause and HRT, 43.1% (95% CI: 29.5, 57.6) felt that a booklet with or without audio would be best. One quarter of patients (95% CI: 14.4, 39.4) felt that a video tape format would be best, while 23.5% (95% CI: 13.2, 37.8) felt a computer or Internet format would be best. The remaining 7.8% (95% CI: 2.5, 19.7) felt that a computer, audio-booklet or video format would be equally effective. Participants cited the convenience and accessibility of the booklet format as the most common reasons for their choice.

5.5.3 Realistic risk group selection

The risk group selection score was calculated analogously to the realistic expectation score by determining those who identified their correct risk group (low, medium or high risk) for each of the three health outcomes (heart disease, hip fracture, and breast cancer). At baseline only 49% of the computer group and 39% of the audio-booklet group had

realistic risk group selection (Table 5). This increased in both groups, to 62.7% and 45.3%, respectively. The computerized DSI demonstrated a trend toward greater improvement in the realistic risk group selection above baseline (13.3% vs. 6.7%) but this did not reach statistical significance ($p>0.05$).

Table 5 - Realistic Risk Group Selection

Realistic Group	Computer			Audio-Booklet		
	Mean	**SD**	**95% CI**	**Mean**	**SD**	**95% CI**
Pre	**49.3**	32.1	(36.1, 62.6)	**38.7**	20.8	(30.1, 47.3)
Post	**62.7**	24.2	(52.7, 72.7)	**45.3**	27.0	(34.2, 56.5)
Difference [1, 2]	**13.3**	33.3	(-0.4, 27.1)	**6.7**	27.2	(-4.6, 17.9)

[1] - p=0.442, t=0.775, MD=0.667, 95% CI of MD: -0.1064, 0.2397

[2] - p=0.448, Mann-Whitney U=287, Z= -0.758.

5.5.4 Impact on decision made

This study was not designed to assess the impact of the intervention of the decision made by participants (whether to take HRT or not). Only 27% of the participants were contemplating the decision to take HRT at the time of this study. At baseline, 14 participants (56.0%) in the computer group, and 17 (65.4%) in the audio-booklet group had a strong leaning towards taking or not taking HRT, and all remained strongly leaning in the same direction at study's end. Fourteen participants (27.5 %) were unsure, and 6 (11.8 %) were weakly leaning towards a choice at baseline. Of the 14 individuals who

were initially unsure, 9 (64.3 %) moved to a more sure category, while 5 remained unsure. Eleven participants became more sure after the interventions, even if still undecided (5 and 6, in the computer and audio-booklet groups, respectively). Two (8.0%) and 3 (11.5%) participants moved from unsure or weakly leaning to strongly leaning, respectively. Only one individual in the audio-booklet group moved to a less sure category (Table 6).

Table 6 - Influence on Decision Made

			Post			
			Unsure	Weakly leaning	Strongly leaning	Total
Pre	Computer	Unsure	5	3	1	9 (36.0 %)
		Weakly	0	1	1	2 (8.0 %)
		Strongly	0	0	14	14 (56.0
		Total	5 (20.0%)	4 (16.0%)	16 (64.0%)	25
	Audio-booklet	Unsure	0	3	2	5 (19.2 %)
		Weakly	1	2	1	4 (15.4 %)
		Strongly	0	0	17	17 (65.4
		Total	1 (3.8%)	5 (19.2%)	20 (76.9%)	26

This table represents a cross-tabulation of each individual's leaning category pre-intervention with their leaning category post-intervention. For example, in the computer group 9 individuals were unsure at onset. Five remained unsure, 3 became weakly leaning, and 1 strongly leaning.

6 Discussion

The results of this study demonstrate that the addition of an interactive programmed self assessment and feedback module to an otherwise factually identical DSI can significantly improve realistic expectation and knowledge scores over levels obtained with a standard DSI. In particular, the increase in the RE score with the computerized DSI is greater than previously reported with other DSI formats.[1,2]

This study is the first trial comparing a computerized decision aid with a standard decision aid in the setting of patient health-related decision support. Unlike most studies of DSIs, which tend to compare a DSI to usual care or a simple information pamphlet, the present study compares two factually identical interventions with similar visual style, with the only difference being the presentation of one intervention by computer, and the addition of a self-testing module. As a result, it is reasonable to conclude that the observed differences in outcomes are due to the method of information presentation.

The use of new decision support technologies does not alter the basic mechanism of knowledge acquisition. Therefore, the adoption of a new technology must have some basis in evidence or relate to accepted learning theories. As such, one would not expect that the presentation of a DSI by video tape, laser disc or computer to influence any important research outcomes, unless the particular strengths of that technology are employed in the implementation of tested and effective techniques of learning theory. The computerized DSI incorporates several accepted instructional techniques from various learning theories, such as timed repetition, programmed instruction, self-evaluation, reinforcement, multi-

sensory association, and self-directed instruction to reach the goal of improved knowledge acquisition.

6.1 Realistic expectations

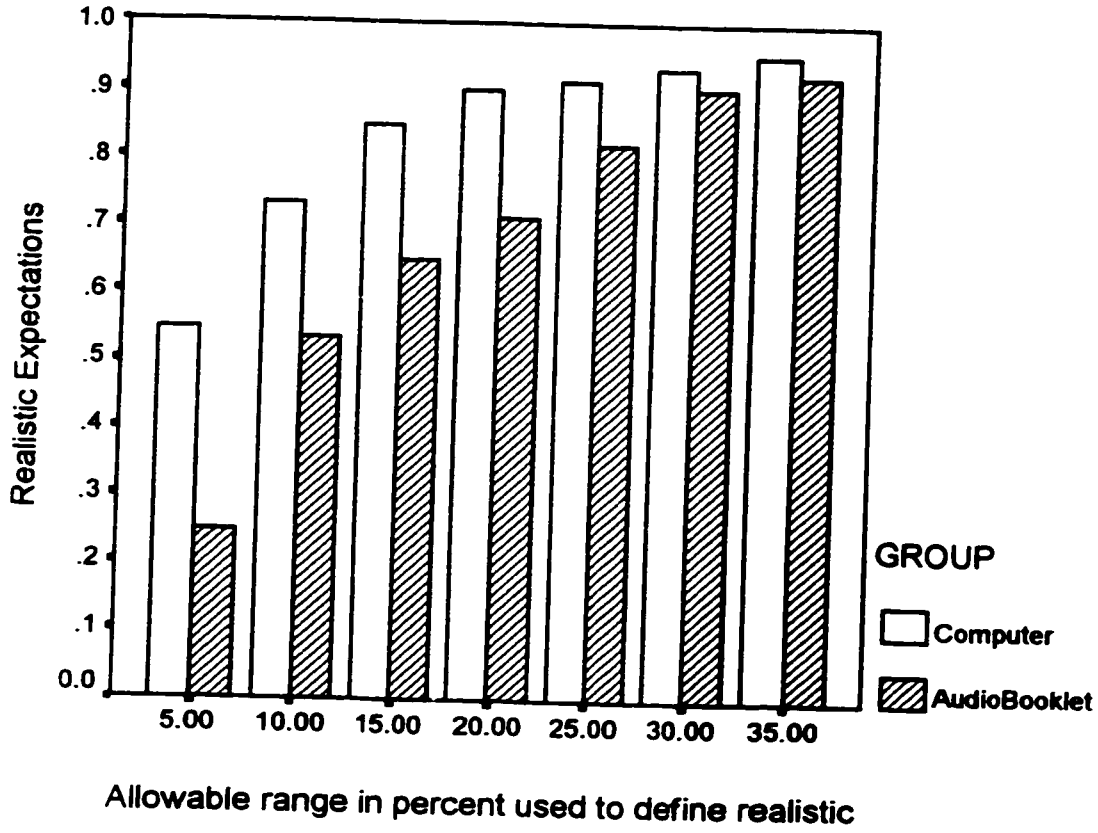
Realistic expectations of disease outcomes, and the risks and benefits of therapies, are a foundation of proper informed decision making. It is upon this foundation that patients' judgements of preferred options are built. Creating realistic expectations has other benefits as well, such as reducing patient worry and distress,[100] as well as enhancing long-term persistence with therapy, and reducing self-reporting of side-effects, and work absenteeism.[2] O'Connor et al. have previously demonstrated improvements in the proportion of participants with RE with the use of the audio-booklet HRT DSI to levels between 50%-70%.[1,2] Although this was a marked improvement over baseline levels in the range of 30%, a fair proportion of participants walked away from the DSI without realistic expectations. There may be several potential reasons for this, as explained by learning theory.[88] Some participants may not, initially, have concentrated on or registered the appropriate risk data. Others, having registered the risk data, may then have forgotten it by the time the decision aid was complete. Still others may have registered and recalled the risk data but incorrectly classified themselves into the wrong risk group, or simply felt that the presented risk data did not reflect their own risk profile. The computerized DSI's feedback module aimed to correct most of these problems. Clearly, if (for whatever reason) a participant felt the presented data did not apply to them, it would be unlikely that a DSI could persuade them otherwise. Therefore, the computerized decision aid

presented general data and risk, and then used a computerized personalized risk-stratification module (based on published data from N.Col et al.) to assign participants to the correct risk group without any need of interpretation on the part of the participant. The computer presented data clearly and highlighted and synchronized the text with the audio. In this way, when risk data were presented, the graphics and sounds focused attention onto the presented materials. Then, later in the decision aid, the participants were asked to recall their own lifetime risks of the various outcomes as previously presented. If they were correct they received positive reinforcement and continued on. If incorrect, they were presented with their personalized risk data again. Although this feedback pattern theoretically could be repeated until the participant answered correctly, there was concern that this might intimidate and/or frustrate participants. Additionally, there is some evidence from learning theory to suggest that repetition, if overdone, can actually reduce learning efficiency by inducing fatigue.[88,90] Therefore, participants were tested only once.

The results of this study confirmed the hypothesis that a computerized assessment and feedback module can significantly improve a participant's recollection and understanding of their particular lifetime risks of various disease outcomes—over results achieved with standard DSIs. The participants who were randomized to the audio-booklet group showed improvements in their RE scores that were similar to that achieved with the same decision aid in two other studies. Therefore it is unlikely that the RE scores observed in the computer group are unique to this study population, and suggest that these results may be generalizable, despite the fact that the study population was relatively well educated.

It was hypothesized that if the designer of a DSI sought only to improve RE within "ballpark" ranges, a feedback module would not be required. However, a narrow margin of within 15% (rather than within the correct *quartile*) was chosen as the definition of "realistic." For lifetime risk data, it was deemed appropriate and desirable for patients to accurately recall their true risk data within a narrower margin. For example, if a patient's true lifetime risk of an outcome is 4%, a correct quartile definition would rank a patient responses of 5% and 25% both as correct, whereas clinically this difference in the patient's impression of the probability of an outcome might cause them to alter their treatment decision. Figure 8 demonstrates that the effectiveness of a feedback module becomes more apparent as one uses smaller error ranges to define RE from 35% to 5%. As can be seen, as the criteria for realistic becomes more strict, the computerized feedback system is able to impart greater RE on participants than is a standard decision aid. This particular graphic also has implications for the design of future DSI studies, since the sensitivity of the results are dependant on the *a priori* definition of realistic.

Figure 8: Realistic expectations as a function of the allowable range used to define "realistic."



6.2 Knowledge

The knowledge questionnaire was developed to be more "difficult" than previous instruments used in evaluating the HRT decision aid, while maintaining their clinical relevance to the patient by emphasizing points that were felt would be important for informed decision making. This choice was made because the two DSIs share identical

factual material. Therefore, general knowledge questionnaires were felt to be unlikely to detect differences in knowledge gains.

Decision aids have been previously been demonstrated to improve participant knowledge about the disease state, and the risks and benefits of therapies and their alternatives; however, general knowledge was not different between the HRT audio-booklet decision aid and an American College of Physicians pamphlet.[2] The current study demonstrates that if an interactive, computerized feedback module is used, overall knowledge can be improved significantly over scores obtained with a standard decision aid. The computer improved knowledge by 18% over baseline compared to 8% in the audio-booklet group. At baseline, participants scored relatively well on this questionnaire most likely because this was a relatively well-educated group. Despite this, there did not appear to be a ceiling effect in knowledge gains. Additionally, four questions in this questionnaire had high endorsement frequencies at baseline, suggesting the need for modification of those items in future studies.[101]

The results are supported by a study of computerized diabetes education on patient knowledge and diabetes control.[84] In that study, a group of diabetics were randomized to an interactive, computerized knowledge program, to a knowledge assessment program with or without "prescriptive" feedback, or to control. The authors found significant improvements in knowledge (and diabetes control), both with the interactive knowledge program and with the knowledge assessment program with feedback, but not in the control groups. As well, the authors found that in the group using the knowledge

assessment program, feedback resulted in greater knowledge gains over those not given feedback.

Overall, it seems clear that for designers of a decision aid who wish to ensure that patients take away certain points, a feedback module aimed at those points can achieve greater than 90% correct response rates (on those points). Alternatively, based on previous studies, if all that is required by the designers is a general improvement in knowledge, then a feedback module is likely not required, as exemplified above with realistic expectations.

6.3 Decisional conflict

Previous evaluations of decision aids have demonstrated a reduction in decisional conflict with the use of these DSIs in comparison to usual care.[5] The computerized intervention was specifically designed and targeted to improve REs and knowledge. It did not specifically include a module to target decisional conflict. Therefore, it is unlikely that the computerized decision aid could lower decisional conflict significantly more than the standard HRT decision aid, unless the reduction was related to the uninformed sub-scale, through improved knowledge of the benefits and risks. Also, the majority of the participants of this study were not at a point of true decision making, and were asked to make a *hypothetical* decision regarding the use of HRT.

The computerized DSI did, in fact, appear to reduce overall decisional conflict, and particularly the uninformed sub-scale, but these changes did not reach statistical significance. Based on the smaller standard deviations observed in decisional conflict in

this study, it was estimated that a total sample size of over 150 patients would be required to show a clinically significant reduction in DC to below a value of 2.0, the range associated with patients who go on to make a decision.[8] Clearly, further work will be required to assess the impact of the improved knowledge and RE afforded by the computerized DSI on DC. Ideally, this study needs to be repeated on a group of menopausal women who are truly at the point of making a decision.

6.4 Realistic risk group selection

The assessment of a participant's correct selection of her risk group as low, medium or high risk was not a primary objective of this study, but these data were collected. It was hypothesized that some individuals might have poor post-intervention RE not because of poor registration or recall of the presented data, but because they truly mis-classified themselves into a wrong risk group and, in so doing, learned risk data that was not intended for them. The current audio-booklet HRT DSI presents data for both average and high-risk individuals. The computerized DSI tells the individual her lifetime risks based on completion of the interactive risk calculator. Neither explicitly tells the individual her risk group classification, but the computer, by not allowing the option of choosing risk data based on perceived risk group, thereby avoids the potential of this type of mis-classification error. Of particular interest was the question of what proportion of individuals would classify themselves correctly—both before and after a DSI intervention—if not explicitly told what risk group they fell into. Less than half of the participants in either group correctly classified their risk group at baseline. Although this

proportion rose with the use of the interventions, presumably through subjects learning what risk factors they had, only 63% in the computer group, and 45% in the audio-booklet group correctly identified their risk groups. This finding did not affect the other aspects of the study. Low- and medium-risk subjects used the average group risk data presented in the audio-booklet, and therefore their mis-classification did not affect analysis of the RE score. Clearly, these results indicated that even for common conditions, such as heart disease and osteoporosis, participants cannot accurately classify themselves into risk groups. Therefore, where a DSI presents data for various risk groups, before a participant uses the DSI, a practitioner needs to explain which group they fall into, so they could concentrate on the appropriate data. Ideally, DSIs should be tailored to present only that data applicable to the participant.

6.5 Impact on the decision made

This study was not designed to look at the impact of the interventions on the decision made; however, it was possible to assess whether subjects were more sure of their choice, or if they changed their decision after the use of the DSI. Overall, no apparent group differences could be found; for most of the individuals having a strong leaning at onset, this was not altered by either intervention. This may reflect the study population, which was predominately making a *hypothetical* decision, and the relatively small overall sample size for this endpoint. However, the results are very similar to the results obtained in O'Connor's before/after study of the audio-booklet decision aid. In that study participants were also making a hypothetical decision, 65% of the participants were leaning towards a

decision at the onset of the study and remained leaning in the same direction at the end of the study, while 16%, who were unsure, remained unsure.[1] Therefore, in all, the audio-booklet had no impact on the decision for 81% of the participants. The study comparing the audio-booklet DSI to the ACP pamphlet also could not demonstrate a difference in those choosing or declining HRT between these interventions.[2] It therefore appears that DSIs have the potential to alter the decision of those who are unsure at baseline, but not of those who are polarized.[1,2,5] The absence of these changes-in-decision represents the individual nature of this decision for women, who may have had previous experience with the decision, and underscores why the decision made is not, alone, a reliable measure of quality decision making.

6.6 Preference

Prior to the initiation of this study, it was hypothesized that the computerized feedback module might improve knowledge, and realistic expectation, but at the potential cost of decreased satisfaction with the decision aid if the self-testing module was long, tedious, or intimidating. In fact, the results are somewhat complex. The majority of patients exposed to the feedback loop felt that it was helpful, and enjoyed it. Informally, most indicated that the interactive self-testing made the intervention fun and interesting. However, in those not exposed to the feedback module (audio-booklet group), the opposite was true (when they were asked this question hypothetically). This suggests that some of the participants in this group may have had a previous negative experience with this type of feedback, or imagined it in a way that was different from the way it was actually delivered. This also

suggests that, if a feedback module is included in a decision aid, special measures need to be taken to alleviate participant's perceived anxiety about self-testing.

Despite apparently equal enjoyment of the two interventions, the participants preferred a booklet-based DSI. In discussion with the participants, they related the ease and convenience of a booklet format, and felt that peri-menopausal women of this current generation my not have access to computers. The participants' expressed concerns are in contrast to the formal results of this study, wherein the majority of the participants felt comfortable with, and had access to, both computers and the Internet. Additionally, the 1999 report of the USIC, presented earlier, supports the formal results of this study, and would suggest that the participants' impression of accessibility to computers and the Internet is not accurate, or at least may shortly become a moot issue.[62]

The sample of patients enrolled in this study cannot be considered a truly random sample of peri-menopausal women. Therefore, it is possible that for this target population at this particular time, the incorporation of a paper-based self-testing feedback module into an audio-booklet format decision aid would be most appropriate. However, whether a paper feedback scheme can duplicate the results of the computer-based system remains to be seen and, from a practical perspective, a paper-based scheme would present some difficulties in DSIs that address different diseases in the same tool. For instance, in the HRT decision aid there would have to be different versions for the different potential combinations of risk (from low to high) for each of the three diseases, and could become extremely complex—with multiple page jumps— if all groups were considered. The ease with which a computer can implement programmed instruction is stunning and, in

particular, is completely transparent to the user. The same aid in a paper format requires the active participation of the user, in keeping track of what section to jump to and what data applies to them, and the possibility of misreading information always exists. From a practical perspective, given the recent huge increase in computer use, and the continued growth and assimilation of this technology, it is likely that comfort with this format will soon equal comfort with paper formats. Perhaps the most compelling evidence to support this is the previously presented USIC data on the number of years it has taken various technologies to penetrate 30% of the U.S. population.[62]

6.7 Sources of bias and study limitations

Bias was minimized in the conduct of this study through the use of a randomized design with allocation concealment. However, as with all studies evaluating DSIs, blinding was partial at best. It is not possible to blind the participant to the intervention. However, this effect was minimized as much as possible by not informing participants of the format of the other intervention. Additionally, since study formed the groundwork for a Master's thesis, the majority of the interviews, and all of the data extraction, entry and analysis were performed by the principal investigator. This less-than-ideal process was unavoidable. As originally planned, the group assignment key was to be held secret until after the analysis (as indicated in the thesis proposal), but the audio-booklet group data sheets include an extra-questionnaire to identify the participants true risk profile, a task handled automatically in the computer group. Therefore, blinding of the data analysis was not possible.

During the interviews, the investigator remained silent after the introduction and explanation of the study and the questionnaires, and more often than not left the room until the procedure was complete. Help was given only when asked for. One patient randomized to the computer group was experiencing a flare of multiple sclerosis and needed help moving the computer mouse. This same patient would have required help with the audio tape, and turning pages of the booklet as well.

The patients included in this study were not a random sample of the population, and would have to be considered a convenience sample. While this should not have biased the study, given the randomized design, it is a limitation. The main reason for this "choice" of sampling method was strictly a practical one. There were not the resources to randomly select peri-menopausal women from the general population. Ideally, this type of study should be run from the primary care practices of family physicians' offices, with the unit of randomization being a particular physician's practice.[2]

This group of participants was relatively well educated, with 44% having at least some college education, and 44% a university degree. These percentages differ from those seen in the previous HRT DSI studies, which more closely matched the regional census data, showing a similar 44% with at least some college education, but with only 15% having a university degree.[1,2] However, this fact should not have biased the results of this study, as there were no differences between the two intervention groups for this measure. However, participants in the audio-booklet group, although not differing in age from those in the computer group, were more likely to be not menstruating, and to be on HRT. This fact could have potentially biased the study, since persons whose periods had stopped, and

especially those taking HRT, would be expected to have discussed HRT with their physician, or at least to have researched the topic. If this was the case, then one would expect that the audio-booklet group would have performed better on the knowledge and realistic expectation questionnaires than did the computer group or, at very least, have biased the study in favor of the audio-booklet group, which was not the case.

The generalizability of this study to lower education levels is, however, a potential issue. The 1999 report of the USIC[62] has shown that Internet and computer use is expanding to include lower income and lower education groups. However, based on this study one cannot conclude that individuals with lower levels of education, even if they have access to this technology, would fare as well as the participants in this study. Interestingly, the results of the RE scores in this study are similar to previously reported scores using the same audio-booklet intervention among a less highly educated sample,[1,2] therefore, it may be that education level may not be a primary factor in some endpoints.

Despite the evidence presented previously, this study might still be criticized on the grounds that some individuals either lack access to, or feel uncomfortable with, computer technology, thereby putting further into question the generalizability of the results. Therefore, a further clarification is in order. Although this study is a comparison of a computerized vs. a non-computerized decision aid format, it is perhaps more fitting to suggest that it is a comparison of two identical interventions, but with one using a knowledge feedback system. So considered, the fact that one intervention is computer-based is not the crucial factor in these results, in that the same effect could have been achieved using two audio-booklet DSIs, where one group might have had a research

assistant to stop the tape and provide the same feedback system—either verbally or through written material. In other words, had this been a different study, comparing two similar DSI, but where in one arm the researcher systematically coached the participants with the correct responses, we would have stated that the results were "biased" by the researcher. In fact, this is what the computer was designed to do. The computer is merely a tool to efficiently provide this form of programmed instruction and interactive feedback. To this end, the computerized DSI did not require any computer knowledge, it was set up to be simply "point-and-click" through the use of a mouse or touch screen. The interactivity involved no more than the pressinf of a large "continue" button, and pointing to the correct responses during the feedback segments. Otherwise, the intervention required no further input. Therefore, we feel that even individuals who are not comfortable with computers could use this intervention, and we suspect that the comfort with computers expressed by the participants will neither bias nor reduce the generalizability of the results of this study.

This study assessed post-intervention outcomes shortly after the intervention. It is unclear whether the improvements in RE and knowledge would persist days, weeks or months after the intervention. However, data exists to suggest that improvements do persist during the time of active decision making.

The impact of improved RE and knowledge suggests improved decision making and reduced decisional conflict. However, this study was not designed or powered to assess either. Clearly, a follow-up to this work is required to assess the persistence of these improvements and the impact on the other decision support framework outcomes.

6.8 Conclusion

The addition of a computer-controlled, programmed knowledge assessment and feedback system to an otherwise identical DSI results in improvements in realistic expectations and knowledge. These improvements are most marked when participants are required to recall risk data with little error (<15%). These results now open the door for further study on the impact of these improved scores on actual decision making. As well, the results of this study suggest potential application of this type of feedback system in other areas of medicine, such as in the area of informed consent.

7 Appendices

Appendix 1 - Questionnaires and Consent

- Consent Form
- Pre and Post Questionnaires

Consent Form

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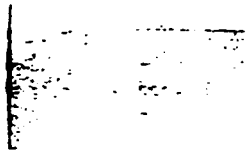

Contact: Dr. A. Rostom -A1 Endoscopy Unit - Civic Campus - 761-4603
Investigators: Alaa Rostom, Annette O'Connor, Peter Tugwell, George Wells.

Ethics Approval Number: 1998147-01H

HRT Decision AID Trial

Consent Form

We are conducting a study to determine which of two educational methods is best for women who are thinking about taking hormone replacement therapy for menopause.

Participation in this study is voluntary. If you agree to participate, you will be given one of the two educational presentations. The specific presentation you receive will be determined at random then you will be asked to answer a few questions about your experience. The whole exercise should take about one hour to go through the presentation, and about 20 minutes to answer a few questions for us.

There are no risks associated with participating in this study. And your medical care or that of your family members will not be affected in any way whether or not you choose to participate.

As part of this study, we would like you to answer some questions to help us determine if the presentation is effective. We also would like to know what you liked and disliked about the presentation. The questions you will answer are **NOT A TEST**. There are no right or wrong answers. We will not be recording your name or your specific responses. We are just trying to determine if the presentation was effective.

The benefits to you will include: 1) learning about what menopause is; 2) learning about some common problems that may affect some women in menopause; 3) learning about how women can reduce the chances of getting some of these problems; 4) learning about the benefits and risks of taking hormone therapy for menopause; and 5) you will be participating in a scientific study that will advance our knowledge and could help other patients as well. After the study is complete we can send you the results if you would like.

I,_____have read and understood the purpose of this study and would like to participate and to learn more about menopause and hormone therapy.

Signature:_____

Date:_____

Witness:_____

Pre and post Questionnaires

Pre-Questionnaire

Hormone Replacement Therapy Decision Aid Study

ID#_____

Alaa Rostom MD FRCP(C)

What I Know About Menopause and Hormones...

Please **check only one box** for each of the following questions.

1. **Which of the following about heart disease is FALSE:**
   - ☐ Heart disease results from narrowing of the arteries that feed the heart muscle.
   - ☐ Heart disease can cause chest pain and/or shortness of breath.
   - ☐ Heart disease is common after menopause.
   - ☐ Heart disease is mostly caused by stress.

2. **Which of the following is NOT a risk factor for heart disease:**
   - ☐ Early family history
   - ☐ Diabetes
   - ☐ Smoking
   - ☐ High blood pressure
   - ☐ Being a woman

3. **Which of the following can LOWER your risk of heart disease?**
   - ☐ Smoking
   - ☐ High blood pressure
   - ☐ Lower cholesterol levels
   - ☐ Limit amount of physical activity.

4. **Which of the following statements regarding osteoporosis is FALSE:**
   - ☐ Osteoporosis is a condition of weak brittle bones that break easily.
   - ☐ Menopause and hormones do not affect osteoporosis.
   - ☐ Osteoporosis commonly affects the hips, spine, and wrists.
   - ☐ Some medical conditions and drugs can worsen osteoporosis.

5. **A major risk factor for osteoporosis is:**
   - ☐ High bone density
   - ☐ Being overweight.
   - ☐ Having an early menopause.
   - ☐ Having high blood pressure.
   - ☐ Having high cholesterol

6. **You can decrease your chances of getting osteoporosis by:**
   - ☐ Losing weight.
   - ☐ Having enough calcium in your diet.
   - ☐ Drinking one glass of wine with supper each night.
   - ☐ Lowering your cholesterol.

7. **Which of the following statements about breast cancer is true:**
   - ☐ Breast cancer is uncontrolled growth of abnormal breast tissue.
   - ☐ Breast cancer is more common in younger women.
   - ☐ Breast cancer cannot be found by breast self examination
   - ☐ Breast cancer never spreads to other parts of the body.

8. **Which of the following statements about breast cancer is FALSE:**
   - ☐ Breast cancer is more common in women with a family history of breast cancer.
   - ☐ The risk of breast cancer is higher in women who have never had children.
   - ☐ Breast cancer can be detected early by regular breast exams and mammograms (Xray of the breast).
   - ☐ Early detection of breast cancer does not improve the chances of a cure

9. **Which of the following is TRUE about hormone therapy:**
   - ☐ Hormone therapy replaces the estrogen and progesterone lost after menopause.
   - ☐ Hormone therapy can cause pregnancy
   - ☐ Hormone therapy increases the risk of heart disease.
   - ☐ Hormone therapy protects against breast cancer.

10. **Which of the following is FALSE about hormone therapy:**
   - ☐ Hormone therapy gives increased protection from heart disease.
   - ☐ Hormone therapy gives increased protection from osteoporosis.
   - ☐ Hormone therapy gives relief from menopause symptoms.
   - ☐ Hormone therapy gives increased protection from cancer.

11. **The Side effects of Hormone therapy include all EXCEPT:**
   - ☐ Weight gain.
   - ☐ Breast tenderness.
   - ☐ Vaginal bleeding.
   - ☐ Hot flushes.
   - ☐ Bloating

My Chances of Heart Disease

Without Hormone Therapy:

1. Do you consider yourself to be (check one Box):

- ☐ **Low Risk** for Heart Disease ?
- ☐ **Average Risk** for Heart Disease ?
- ☐ **High Risk** for Heart Disease ?

2. If 100 women **like you** were to decide **NOT** to take hormones, how many will have heart disease some time in their life ? (check one Box)

- ☐ **100** out of 100 — **Everyone** will have Heart Disease in their lifetime
- ☐ **95-99** out of 100
- ☐ **90-94** out of 100
- ☐ **85-89** out of 100
- ☐ **80-84** out of 100
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- ☐ **1-4** out of 100
- ☐ **0** out of 100 — **No-one** will have Heart Disease

With Hormone Therapy:

3. If 100 women **like you** were to **take hormone therapy**, how many will have heart disease some time in their life ? (check one Box):

- ☐ **100** out of 100 — **Everyone** will have Heart Disease in their lifetime
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- ☐ **1-4** out of 100
- ☐ **0** out of 100 — **No-one** will have Heart Disease

My Chances of Broken Hips From Osteoporosis

Without Hormone Therapy:

1. Do you consider yourself to be (check one Box):

- ☐ **Low Risk** for broken hips from osteoporosis ?
- ☐ **Average Risk** for broken hips from osteoporosis ?
- ☐ **High Risk** for broken hips from osteoporosis ?

2. If 100 women **like you** were to decide **NOT** to take hormones, how many will have broken hips from osteoporosis some time in their life ? (check one Box):

- ☐ **100** out of 100 — **Everyone** will have a Broken Hip in their lifetime
- ☐ **95-99** out of 100
- ☐ **90-94** out of 100
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With Hormone Therapy:

3. If 100 women **like you** were to take hormone therapy, how many will have broken hips from osteoporosis some time in their life ? (check one Box):

- ☐ **100** out of 100 — **Everyone** will have a Broken Hip in their lifetime
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- ☐ **1-4** out of 100
- ☐ **0** out of 100 — **No-one** will have a Broken Hip

My Chances of Breast Cancer

Without Hormone therapy:

1. Do you consider yourself to be (check one Box):

- ☐ **Low Risk** for breast cancer ?
- ☐ **Average Risk** for breast cancer ?
- ☐ **High Risk** for breast cancer ?

2. If 100 women **like you** were to decide **NOT** to take hormones, how many will have breast cancer some time in their life ? (check one Box):

- ☐ **100** out of 100 **Everyone** will have BREAST
- ☐ **95-99** out of 100 CANCER in their lifetime
- ☐ **90-94** out of 100
- ☐ **85-89** out of 100
- ☐ **80-84** out of 100
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- ☐ **5-9** out of 100
- ☐ **1-4** out of 100
- ☐ **0** out of 100 **No-one** will have BREAST CANCER

With Hormone Therapy:

3. If 100 women **like you** were to take hormone therapy, how many will have breast cancer some time in their life ? (check one Box):

- ☐ **100** out of 100 **Everyone** will have BREAST
- ☐ **95-99** out of 100 CANCER in their lifetime
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- ☐ **1-4** out of 100
- ☐ **0** out of 100 **No-one** will have BREAST CANCER

My Opinion of Hormone Therapy

We want to know what your opinion is about hormones before you review the information we will give you.

If your doctor asked you right now to make a choice about using hormone therapy, please show where you would be on the scale below by placing a check in the box.

Note: If you have not entered menopause, please consider what you think you would do and place a check in one of the boxes below.

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Yes Hormones **Unsure** **No Hormones**

My Difficulty in Making this Choice

Now thinking about the choice you just made, please look at the following comments made by some women when deciding about hormone therapy.

Please show how strongly you agree or disagree with these statements by checking the box from ***strongly agree*** to ***strongly disagree*** which best shows how you feel about the choice you just made.

1. **This decision is easy for me.**
   - ☐ strongly agree
   - ☐ agree
   - ☐ neither agree or disagree
   - ☐ disagree
   - ☐ strongly disagree

2. **I'm sure of what to do in this decision.**
   - ☐ strongly agree
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   - ☐ neither agree or disagree
   - ☐ disagree
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3. **It's clear what choice is best for me.**
   - ☐ strongly agree
   - ☐ agree
   - ☐ neither agree or disagree
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   - ☐ strongly disagree

4. **I am aware of the choices I have to reduce my risk of heart disease and osteoporosis.**
   - ☐ strongly agree
   - ☐ agree
   - ☐ neither agree or disagree
   - ☐ disagree
   - ☐ strongly disagree

5. **I feel I know the benefits of hormone therapy.**
   - ☐ strongly agree
   - ☐ agree
   - ☐ neither agree or disagree
   - ☐ disagree
   - ☐ strongly disagree

6. **I feel I know the risks and side effects of hormone therapy.**
   - ☐ strongly agree
   - ☐ agree
   - ☐ neither agree or disagree
   - ☐ disagree
   - ☐ strongly disagree

Post-Questionnaire

Hormone Replacement Therapy Decision Aid Study

ID#_____

Alaa Rostom MD FRCP(C)

What I Know About Menopause and Hormones...

Please **check only one box** for each of the following questions.

1. **Which of the following about heart disease is FALSE:**
   - ☐ Heart disease results from narrowing of the arteries that feed the heart muscle.
   - ☐ Heart disease can cause chest pain and/or shortness of breath.
   - ☐ Heart disease is common after menopause.
   - ☐ Heart disease is mostly caused by stress.

2. **Which of the following is NOT a risk factor for heart disease:**
   - ☐ Early family history
   - ☐ Diabetes
   - ☐ Smoking
   - ☐ High blood pressure
   - ☐ Being a woman

3. **Which of the following can LOWER your risk of heart disease?**
   - ☐ Smoking
   - ☐ High blood pressure
   - ☐ Lower cholesterol levels
   - ☐ Limiting your physical exercise.

4. **Which of the following statements regarding osteoporosis is FALSE:**
   - ☐ Osteoporosis is a condition of weak brittle bones that break easily.
   - ☐ Menopause and hormones do not affect osteoporosis.
   - ☐ Osteoporosis commonly affects the hips, spine, and wrists.
   - ☐ Some medical conditions and drugs can worsen osteoporosis.

5. **A major risk factor for osteoporosis is:**
   - ☐ High bone density
   - ☐ Being overweight.
   - ☐ Having an early menopause.
   - ☐ Having high blood pressure.
   - ☐ Having high cholesterol

6. **You can decrease your chances of getting osteoporosis by:**
   - ☐ Losing weight.
   - ☐ Having enough calcium in your diet.
   - ☐ Drinking one glass of wine with supper each night.
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7. **Which of the following statements about breast cancer is true:**
   - ☐ Breast cancer is uncontrolled growth of abnormal breast tissue.
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   - ☐ Hormone therapy replaces the estrogen and progesterone lost after menopause.
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   - ☐ Hormone therapy gives increased protection from heart disease.
   - ☐ Hormone therapy gives increased protection from osteoporosis.
   - ☐ Hormone therapy gives relief from menopause symptoms.
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11. **The Side effects of Hormone therapy include all EXCEPT:**
   - ☐ Weight gain.
   - ☐ Breast tenderness.
   - ☐ Vaginal bleeding.
   - ☐ Hot flushes.
   - ☐ Bloating

My Chances of Heart Disease

Without Hormone Therapy:

1. Do you consider yourself to be (check one Box):

- ☐ **Low Risk** for Heart Disease ?
- ☐ **Average Risk** for Heart Disease ?
- ☐ **High Risk** for Heart Disease ?

2. If 100 women **like you** were to decide **NOT** to take hormones, how many will have heart disease some time in their life ? (check one Box)

- ☐ **100** out of 100 — **Everyone** will have Heart Disease in their lifetime
- ☐ **95-99** out of 100
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- ☐ **5-9** out of 100
- ☐ **1-4** out of 100
- ☐ **0** out of 100 — **No-one** will have Heart Disease

With Hormone Therapy:

3. If 100 women **like you** were to **take hormone therapy**, how many will have heart disease some time in their life ? (check one Box):

- ☐ **100** out of 100 — **Everyone** will have Heart Disease in their lifetime
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- ☐ **0** out of 100 — **No-one** will have Heart Disease

My Chances of Broken Hips From Osteoporosis

Without Hormone Therapy:

1. Do you consider yourself to be (check one Box):

- ☐ **Low Risk** for broken hips from osteoporosis ?
- ☐ **Average Risk** for broken hips from osteoporosis ?
- ☐ **High Risk** for broken hips from osteoporosis ?

2. If 100 women **like you** were to decide **NOT** to take hormones, how many will have broken hips from osteoporosis some time in their life ? (check one Box):

- ☐ **100** out of 100 — **Everyone** will have a Broken Hip in their lifetime
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- ☐ **0** out of 100 — **No-one** will have a Broken Hip

With Hormone Therapy:

3. If 100 women **like you** were to take hormone therapy, how many will have broken hips from osteoporosis some time in their life ? (check one Box):

- ☐ **100** out of 100 — **Everyone** will have a Broken Hip in their lifetime
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- ☐ **0** out of 100 — **No-one** will have a Broken Hip

My Chances of Breast Cancer

Without Hormone therapy:

1. Do you consider yourself to be (check one Box):

- ☐ **Low Risk** for breast cancer ?
- ☐ **Average Risk** for breast cancer ?
- ☐ **High Risk** for breast cancer ?

2. If 100 women **like you** were to decide **NOT** to take hormones, how many will have breast cancer some time in their life ? (check one Box):

- ☐ **100** out of 100 **Everyone** will have BREAST
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With Hormone Therapy:

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- ☐ **0** out of 100 **No-one** will have BREAST CANCER

My Opinion of Hormone Therapy

We want to know what your opinion is about hormones now that you have reviewed the information.

If your doctor asked you right now to make a choice about using hormone therapy, please show where you would be on the scale below by placing a check in the box.

Note: If you have not entered menopause, please consider what you think you would do and place a check in one of the boxes below.

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Yes Hormones **Unsure** **No Hormones**

My Difficulty in Making this Choice

Now thinking about the choice you just made, please look at the following comments made by some women when deciding about hormone therapy.

Please show how strongly you agree or disagree with these statements by checking the box from ***strongly agree*** to ***strongly disagree*** which best shows how you feel about the choice you just made.

1. **This decision is easy for me.**
   - ☐ strongly agree
   - ☐ agree
   - ☐ neither agree or disagree
   - ☐ disagree
   - ☐ strongly disagree

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3. **It's clear what choice is best for me.**
   - ☐ strongly agree
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4. **I am aware of the choices I have to reduce my risk of heart disease and osteoporosis.**
   - ☐ strongly agree
   - ☐ agree
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5. **I feel I know the benefits of hormone therapy.**
   - ☐ strongly agree
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6. **I feel I know the risks and side effects of hormone therapy.**
   - ☐ strongly agree
   - ☐ agree
   - ☐ neither agree or disagree
   - ☐ disagree
   - ☐ strongly disagree

What I thought of the Presentation...

1. **The presentation was an enjoyable learning experience.**
   - ☐ strongly agree
   - ☐ agree
   - ☐ neither agree or disagree
   - ☐ disagree
   - ☐ strongly disagree

2. **The length of this presentation (NOT including the questionnaire) was:**
   - ☐ too short
   - ☐ about right
   - ☐ too long

3. **I think the way the information was presented helped me to learn about hormone therapy:**
   - ☐ strongly agree
   - ☐ agree
   - ☐ neither agree or disagree
   - ☐ disagree
   - ☐ strongly disagree

4. **Feed back questions during the presentation would help me to remember and understand the facts.**
   - ☐ strongly agree
   - ☐ agree
   - ☐ neither agree or disagree
   - ☐ disagree
   - ☐ strongly disagree

5. **During the presentation, I would NOT like to answer questions that test my understanding of the presentation:**
   - ☐ strongly agree
   - ☐ agree
   - ☐ neither agree or disagree
   - ☐ disagree
   - ☐ strongly disagree

6. **I would recommend this presentation to a friend or relative:**
   - ☐ strongly agree
   - ☐ agree
   - ☐ neither agree or disagree
   - ☐ disagree
   - ☐ strongly disagree

7. **I feel comfortable using computers:**
   - ☐ strongly agree
   - ☐ agree
   - ☐ neither agree or disagree
   - ☐ disagree
   - ☐ strongly disagree

8. **I feel comfortable using the Internet to find information:**
   - ☐ strongly agree
   - ☐ agree
   - ☐ neither agree or disagree
   - ☐ disagree
   - ☐ strongly disagree

9. **Which of the following do you feel is the best way to present the information you received about hormone replacement therapy:**
   - ☐ Pamphlet or booklet
   - ☐ Booklet with an audio tape for explanation
   - ☐ Video tape
   - ☐ Computer CD-ROM program
   - ☐ The Internet.

10. **Do you own or have access to:(Check a many as appropriate).**
   - ☐ A cassette tape player.
   - ☐ A videocassette recorder
   - ☐ A computer with a CD-ROM player
   - ☐ The Internet.

More About You...

1. Are you currently taking hormone replacement therapy ?: ☐ Yes ☐ No.

2. Have you taken hormone therapy for menopause in the past ?: ☐ Yes ☐ No.

   If Yes for how long ?:
   - ☐ Less than six months
   - ☐ For six months to a year.
   - ☐ For one to two years.
   - ☐ For more than two years

4. Have you ever discussed taking hormone therapy with you doctor ?: ☐ Yes ☐ No.

5. How old are you ? _____years.

6. Have you had any menstrual periods in the last year? ☐ Yes ☐ No.

7. What is the highest level of schooling that you completed ? (please check one):

   - ☐ Less than grade 9:
   - ☐ Some High School:
   - ☐ High School Diploma:
   - ☐ Some College:
   - ☐ Some University:
   - ☐ College Degree:
   - ☐ University Degree:

Appendix 2 - The Decision Aids

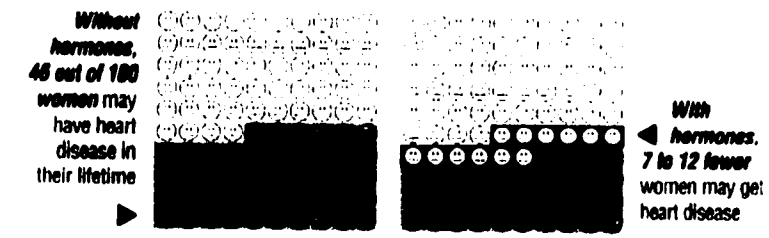
- The Audio-booklet Decision Aid
- The Computerized Decision Aid

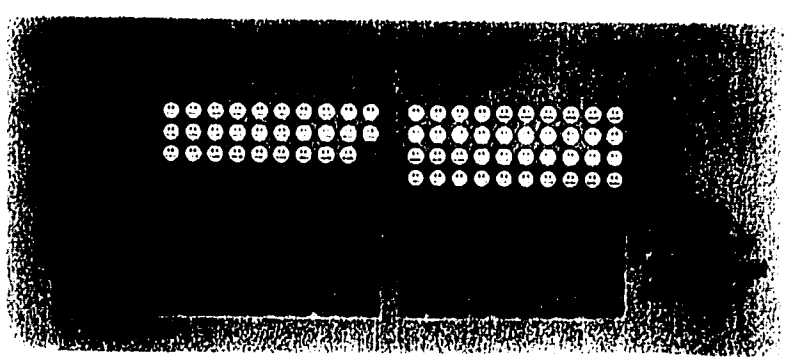
The audio-booklet decision aid - 1

Protection From Heart Disease...

- Trials show estrogen taken alone or with progestin: keeps cholesterol levels low[1]; controls clot-forming factors[2]; may keep heart vessels wide and pliable.[3]
- Trials studying effects on heart attacks and angina are underway (HERS study, Women's Health Initiative)
- Over 30 non-trial studies show women who take estrogen have lower rates of heart disease and increase their average life span 1 to 2 years.
- The benefits of taking estrogen plus progestin are not as well known so a range of benefits is described below

The "average" 50 year old woman

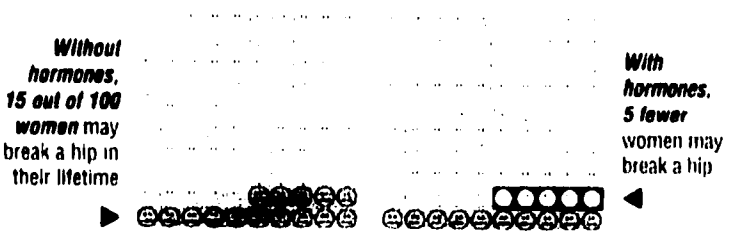


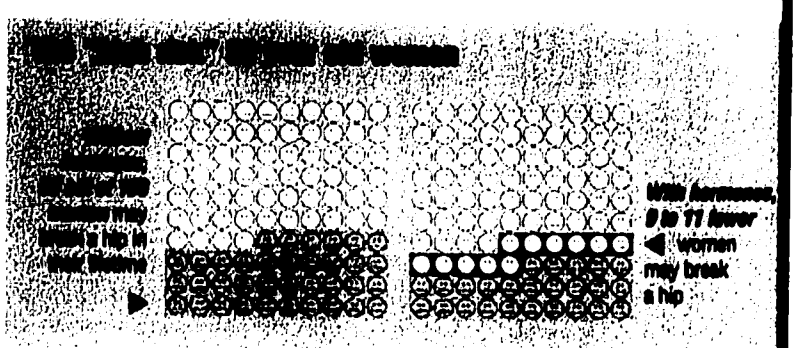


Protection From a Broken Hip From Osteoporosis...

- Trials show hormone therapy prevents bone loss after menopause.[4]
- Trials studying effects on fracture rates are underway (Women's Health Initiative)
- Over 11 non-trial studies show women who take estrogen have lower rates of spinal and hip fractures and increase their average length of life by about 1 year.[5]

The "average" 50 year old woman





The audio-booklet decision Aid - 2

Osteoporosis

Weak brittle bones

- Break very easily (even a cough or a bug): hip, wrist, spine.
- Broken bones in the spine result in a stooped, round shouldered "dowager's hump" and loss of height of up to 6 inches.
- Common after menopause due to loss of hormones which speeds up bone loss.
- 1 in 3 women will have broken bones in their spine (vertebra).[7]
- 1 in 6 women will break their hips, half of them by age 79[8]. Of those who break a hip, 1 in 5 die from complications and 1 in 3 will never walk again.[9]

How Women Describe the Effects of Osteoporosis Fractures ..

[redacted]

Pain sitting, standing, or walking.
Difficulty bending, lifting, carrying.
Difficulty shopping and doing housework.

[redacted]

Afraid of falling, overdoing things.
Frustration and Anger. Self-consciousness

[redacted]

Limited travel, social activity

The Major Risk Factor ...

Low bone density
(triples your risk)

A "bone densitometry" test will detect this problem. It is not for everyone but is suggested if[10]...

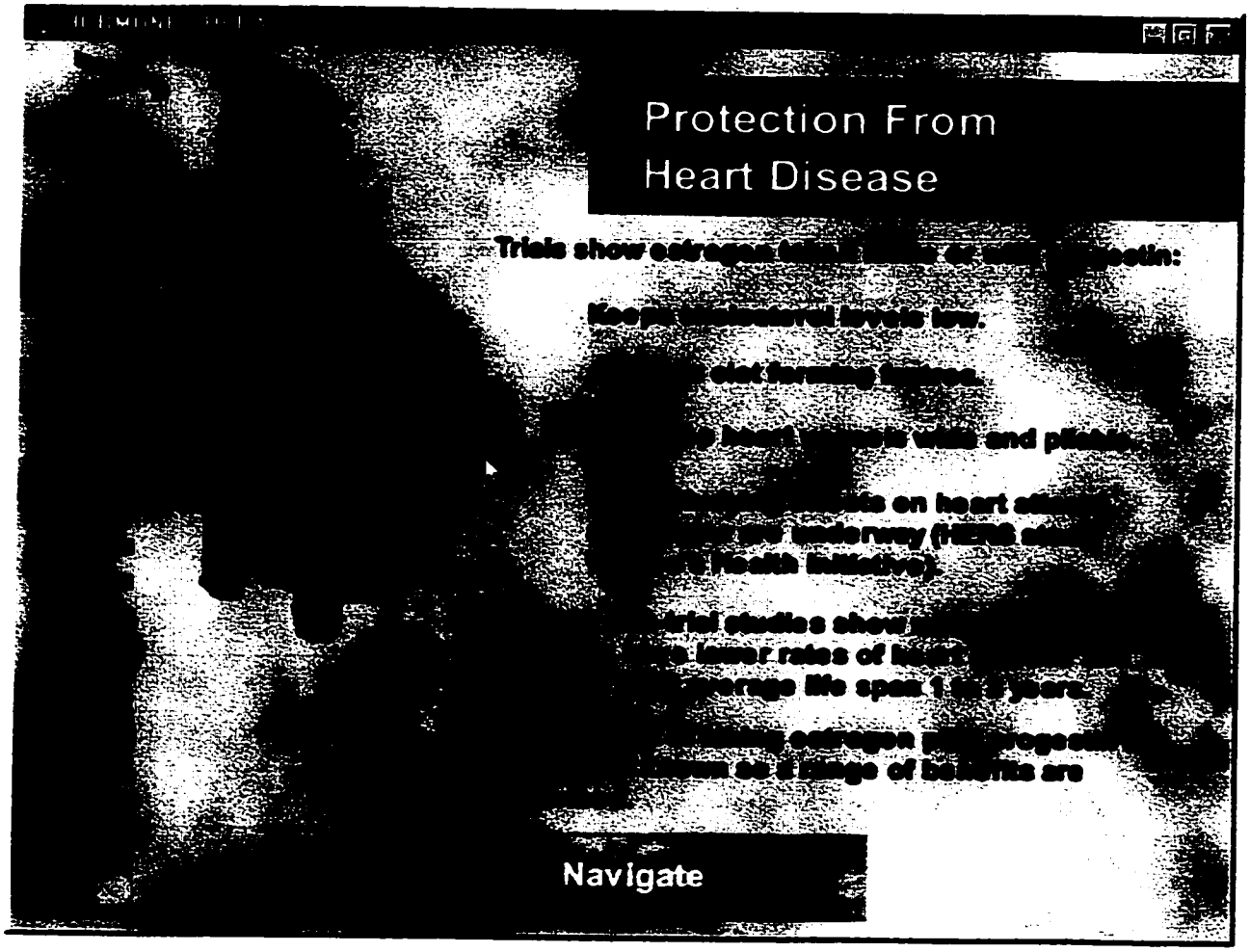
- your family has a history of osteoporosis, or
- you had an early menopause (before 40-45) either naturally or by removal of your ovaries, or
- you missed periods when you were younger because of eating disorders, stress or competitive exercise, or
- you have taken any of these medications: long-term cortisone, anti-epileptics, high dose thyroid, chemotherapy or heparin, or
- you have parathyroid disease, or
- your decision about taking hormone therapy would depend on knowing if you have low bone density.

Lowering Your Risk ...

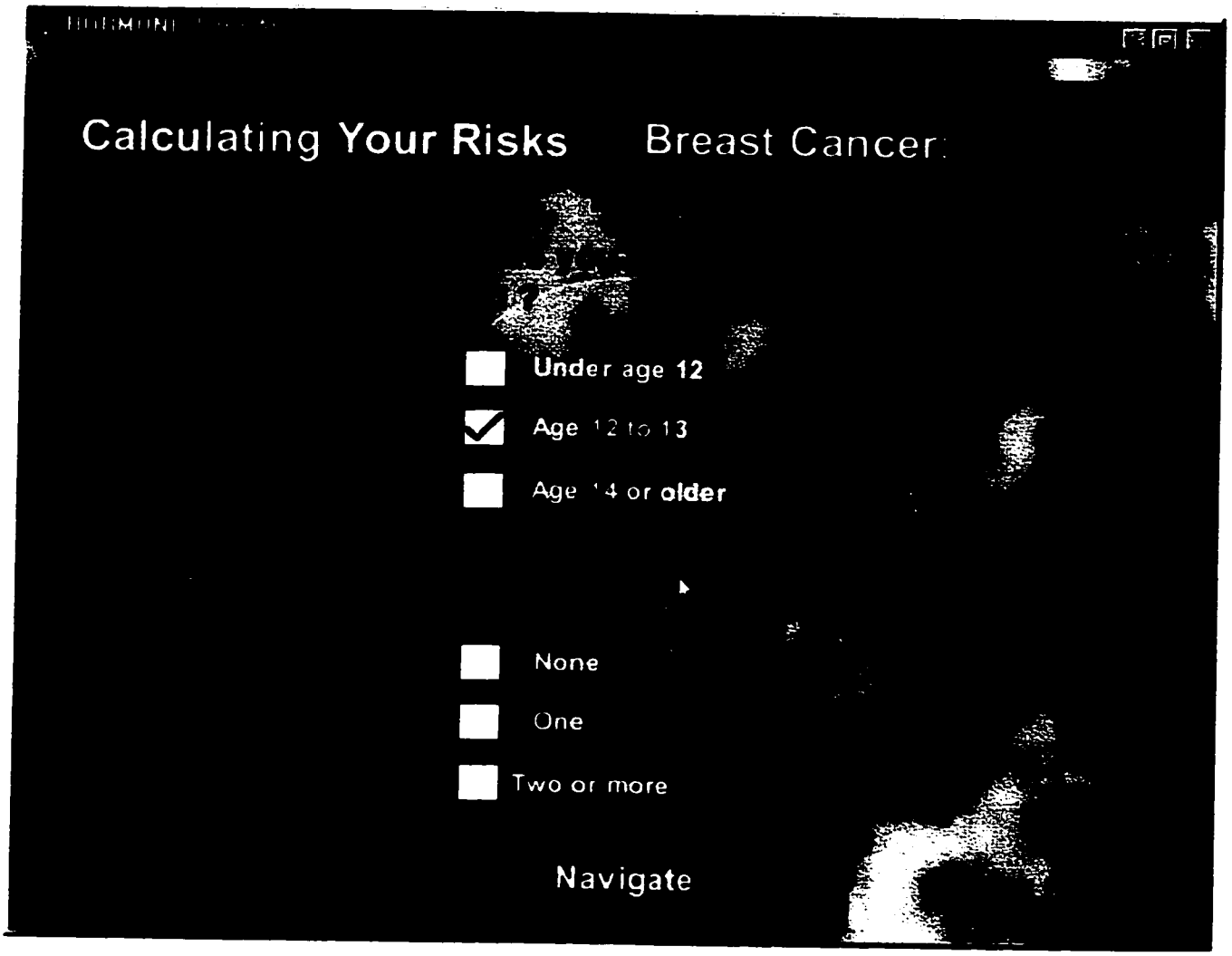
- take 3-4 servings of foods high in calcium per day or take daily supplements of:
  Calcium carbonate or
  Calcium citronate -
  1000 - 1500 mg
  Vitamin D - 400-800
  International Units
- exercise regularly, especially weight bearing

- avoid smoking, excess alcohol and caffeine

The computerized decision aid - 1



The computerized decision aid - 2



Appendix 3 - Risk Calculator

- Risk calculator questionnaire.
- Questionnaire scoring system.
- Life-time risk look-up tables.
- Curve-Fitting output
- Formulas used in computerized risk calculator.

Baseline Risk Data Questionnaire[95]

1 How old were you when your periods first started ?
- ☐ Under age 12
- ☐ Age 12 to 13
- ☐ Age 14 or older

2 How many breast biopsies have you had ?
- ☐ None
- ☐ One
- ☐ Two or more

3 How old were you when you gave birth to your first child ?
- ☐ Under age 20.
- ☐ Age 20 to 24.
- ☐ Age 25 to 29 OR I have NO children.
- ☐ Age 30 or older.

4 How many of your close relatives (mother, sisters) have had breast cancer ?
- ☐ None
- ☐ One
- ☐ Two or more

5 What is your usual SYSTOLIC blood pressure ?
- ☐ I don't know.
- ☐ 100 or less.
- ☐ 101 to 120.
- ☐ 121 to 140.
- ☐ 141 to 160.
- ☐ 161 to 180.
- ☐ 181 or greater.

6 What is your total cholesterol / HDL ratio ?
- ☐ 3 or less.
- ☐ 3.1 to 5.
- ☐ 5.1 to 7.
- ☐ 7.1 to 9.
- ☐ Greater than 9.
- ☐ Don't Know

7 Do you have DIABETES ?
- ☐ Yes.
- ☐ No.

8 Do you smoke (now or in the past year) ?
- ☐ Yes.
- ☐ No.

9 Have you ever been told you have Left Ventricular Hypertrophy (thickening of the heart muscle diagnosed by an electrocardiogram or an echocardiogram of the heart) ?
- ☐ Yes.
- ☐ No.

10 Check as many as apply:
- ☐ My Mother Broke her hip or wrist.
- ☐ I have hyperthyroidism.
- ☐ I currently use long acting sedatives.
- ☐ I am on my feet less than 4 hours per day.
- ☐ I am unable to rise from a chair without assistance.
- ☐ My resting heart rate is usually greater than 80 beats per minute.

11 My height is:
- ☐ Taller than 5 feet 7 inches.
- ☐ Between 5' 4" and 5' 7".
- ☐ 5 feet 4 inches or shorter.

12 I would rate my overall state of health as:
- ☐ Excellent.
- ☐ Good.
- ☐ Fair.

13 My weight now compared to when I was age 25 is:
- ☐ At least 40% less.
- ☐ Between 20% and 40% less.
- ☐ Within 20% of what it was.
- ☐ Between 20% to 40% more.
- ☐ At least 40% more.

14 My bone mineral density is:
- ☐ Normal.
- ☐ One standard deviation less than normal.
- ☐ Two standard deviations less than normal.

CoI scoring system:[95]

Breast Cancer Risk

Question		**Risk Points**
A. Age when Periods first started		
	under 12	0.20
	12-13	0.10
	14 or older	0.01
B. Number of previous breast biopsies		
	0	0.00
	1	0.24
	2	0.48
C. Age at 1st live birth	**D. Number of close relatives with breast cancer**	
under 20 years	0	0.00
	1	0.96
	2	1.92
20-24 years	0	0.22
	1	0.99
	2	1.75
25-29 years	0	0.44
	1	1.01
	2	1.59
30 years or older	0	0.66
	1	1.04
	2	1.43

Breast cancer risk score = A + B + (C&D)

Heart Disease

Question	Risk Point	Question	Risk Point
A. Systolic BP		**B. Total Cholesterol/HDL ratio**	
100	0.00	2.0	0.00
105	0.04	2.5	0.16
110	0.09	3.0	0.29
115	0.13	3.5	0.40
120	0.17	4.0	0.50
125	0.20	4.5	0.58
130	0.24	5.0	0.66
135	0.27	5.5	0.72
140	0.31	6.0	0.79
145	0.34	6.5	0.84
150	0.37	7.0	0.90
155	0.40	7.5	0.95
160	0.43	8.0	0.99
165	0.46	8.5	1.04
170	0.48	9.0	1.08
175	0.51	9.5	1.12
180	0.54	1.0	1.15
185	0.56		
190	0.58		

Question	Risk Point
C. If you have diabetes	0.38
D. If you smoke	0.28
E. If you have left ventricular hypertrophy	0.59
Total	**A+B+C+D+E**

Hip fracture risk point

Question	Risk Point
If your mother fractured hip or wrist	1
If you ever had hyperthyroidism	1
If you currently use long acting sedatives	1
If you are on your feet less than 4h/day	1
If you are unable to rise from a chair without assistance	1
If your resting pulse rate is >80 beats/min	1
Your height....	
If you are taller than 5' 7"	2
If you are between 5' 4" and 5' 7" tall	1
If you are 5' 4" or shorter	0
If you rate your health as....	
Excellent	0
Good	1
Fair	2
If you now weigh....	
at least 40% less than at age 25	2
20-40% less than at age 25	1
within 20% of weight at age 25	0
20-40% more than at age 25	-1
at least 40% more than at age 25	-2
If you know your bone mineral density	
normal	0
1 standard deviation below mean	1
2 standard deviations below mean	2
don't know	0

Total hip risk score = sum of all of above.

Heart Disease - Lifetime Risk Data - Adapted From Col et al[95,96].

Age	<60		60-68		>69	
Score	no HRT	HRT	no HRT	HRT	no HRT	HRT
0.1	6.3	3.9	5.4	3.4	4.2	2.7
0.2	7.9	5	6.7	4.3	5.3	3.3
0.3	9.7	6.1	8.3	5.2	6.5	4.1
0.4	11.9	7.5	10	6.4	7.9	5
0.5	14.3	9.1	12	7.7	9.6	6.1
0.6	17	10.9	14.3	9.2	11.4	7.3
0.7	20	13	16.7	10.8	13.5	8.7
0.8	23.3	15.2	19.4	12.6	15.8	10.2
0.9	26.8	17.7	22.3	14.6	18.3	11.9
1	30.5	20.3	25.3	16.7	20.9	13.7
1.1	34.4	23.1	28.5	19	23.7	15.7
1.2	38.4	26.1	31.9	21.4	26.7	17.7
1.3	42.4	29.2	35.2	23.9	29.7	19.9
1.4	46.4	32.3	38.6	26.5	32.9	22.2
1.5	50.3	35.6	42.1	29.1	36	24.6
1.6	54.2	38.8	45.4	31.8	39.2	27
1.7	57.9	42	48.7	34.5	42.3	29.5
1.8	61.4	45.2	51.9	37.2	45.4	31.9
1.9	64.7	48.3	55	39.8	48.4	34.4
2	.	.	57.9	42.4	51.3	36.8

```
MODEL:  MOD_15.


Independent: score

  Dependent Mth    Rsq  d.f.       F  Sigf      b0       b1

   H60_NHRT LIN   .990    17 1714.50  .000 -1.6491 34.1649
   H60_HRT  LIN   .980    17  849.16  .000 -2.9175 25.5123
   H65_NHRT LIN   .988    17 1427.44  .000 -1.4825 28.7298
   H65_HRT  LIN   .979    17  808.90  .000 -2.1667 20.8035
   H70_NHRT LIN   .983    17  966.72  .000 -2.4158 25.4526
   H70_HRT  LIN   .974    17  633.05  .000 -2.4684 18.0421
```

Hip Fracture - Lifetime Risk Data - Adapted From Col et al[95,96].

Age	<60		60-68		>69	
Score	no HRT	HRT	no HRT	HRT	no HRT	HRT
-1	15.3	8.3	15.9	8.7	22.2	12.5
0	18.9	10.3	19.6	10.8	27.2	15.4
1	24	13.2	25	13.8	34.4	19.7
2	34.4	19.2	35.9	20.2	48.7	28.5
3	50.2	28.8	52.3	30.2	69.8	42.2
4	73	43.3	76	45.4	99	62.6
5	100	67.4	100	70.8	.	95.4

MODEL: MOD_20.

Independent: score

Dependent	Mth	Rsq	d.f.	F	Sigf	b0	b1
OS60_NHR	EXP	.986	4	288.87	.000	19.2158	.3172
OS60HRT	EXP	.984	4	245.83	.000	10.4832	.3348
OS65NHRT	EXP	.987	4	296.50	.000	19.9774	.3180
OS65HRT	EXP	.984	4	245.19	.000	10.9885	.3351
OS70NHRT	EXP	.988	4	321.06	.000	27.7029	.3043
OS70HRT	EXP	.985	4	256.26	.000	15.7102	.3271

Breast Cancer - Lifetime Risk Data - Adapted From Col et al[95,96].

Age	<60		60-68		>69	
Score	no HRT	HRT	no HRT	HRT	no HRT	HRT
0	2.4	3.3	3.9	5.6	3.4	4.8
0.1	2.6	3.7	4.3	6.1	3.7	5.3
0.2	2.9	4	4.7	6.8	4.1	5.9
0.3	3.2	4.4	5.2	7.4	4.5	6.4
0.4	3.5	4.9	5.7	8.2	.	.
0.5	3.9	5.4	6.3	9	5.5	7.8
0.6	4.3	5.9	6.9	9.9	6.1	8.6
0.7	4.7	6.5	7.6	10.8	6.7	9.4
0.8	5.2	7.2	8.4	11.9	7.3	10.3
0.9	5.7	7.9	9.2	13	8.1	11.3
1	6.3	8.7	10.1	14	8.8	12.4
1.1	6.9	9.6	11.1	15.6	9.7	13.6
1.2	7.6	10.6	12.2	17	10.7	14.9
1.3	8.4	11.6	13.3	18.6	11.7	16.3
1.4	9.2	12.7	14.6	20.3	12.8	17.8
1.5	10.1	14	15.9	22.1	14	19.4
1.6	11.1	15.3	17.4	24	15.4	21.1
1.7	12.2	16.8	19	26.1	16.8	23
1.8	13.4	18.4	20.7	28.3	18.3	25
1.9	14.7	20.1	22.6	30.6	20	27.1
2	16.1	21.9	24.6	33.1	21.8	29.3
2.1	17.7	23.9	26.7	35.7	23.7	31.7
2.2	19.3	26.1	28.9	38.4	25.7	34.2
2.3	21.1	28.3	31.3	41.2	27.9	36.8
2.4	23	30.8	33.7	44.1	30.2	39.5
2.5	25.1	33.4	36.4	47	32.6	42.3

Output - Curve Fitting analysis

Independent: score

Dependent	Mth	Rsq	d.f.	F	Sigf	b0	b1
B60_NHRT	EXP	.998	23	11933.2	.000	5.3401	.8793
B60HRT	EXP	.928	23	294.31	.000	7.0407	.8927
B65_NHRT	EXP	.999	23	21143.5	.000	4.0327	.9008
B65_HRT	EXP	.998	23	10006.8	.000	5.8684	.8614
B70_NHRT	EXP	.999	23	24001.0	.000	3.4959	.9125
B70_HRT	EXP	.998	23	11847.5	.000	5.0514	.8766

Formulas used in computerized risk calculator

Nested case routine code sample

```
 Case age of
  1:
   -- under age 60

   set BreastRskNoHrt= integer(5.3401*(exp(BreastScore*0.8793)))
   set BreastRskHrt=integer(7.0407*(exp(BreastScore*0.8927)))
   Set HeartRskNoHrt=integer(34.1649*HeartScore-1.6491)
   Set HeartRskHrt=integer(25.5123*HeartScore-2.9175)
   set HipRskNoHrt= integer(19.2158*(exp(hipScore*0.3172)))
   set HipRskHrt= integer(10.4832*(exp(hipScore*0.3348)))


  2:
   -- 65 year old

   set BreastRskNoHrt= integer(4.0327*(exp(BreastScore*0.9008)))
   set BreastRskHrt= integer(5.8684*(exp(BreastScore*0.86140)))
   Set HeartRskNoHrt=integer(28.7298*HeartScore-1.4825)
   Set HeartRskHrt=integer(20.8035*HeartScore-2.1667)
   set HipRskNoHrt= integer(19.9774*(exp(hipScore*0.3180)))
   set HipRskHrt= integer(10.9885*(exp(hipScore*0.3351)))


  3:
   -- 70 year old

   set BreastRskNoHrt= integer(3.4959*(exp(BreastScore*0.9125)))
   set BreastRskHrt= integer(5.0514*(exp(BreastScore*0.8766)))
   Set HeartRskNoHrt=integer(25.4526*HeartScore-2.4158)
   Set HeartRskHrt=integer(18.0421*HeartScore-2.4684)
   set HipRskNoHrt= integer(27.7029*(exp(hipScore*0.3043)))
   set HipRskHrt= integer(15.7102*(exp(hipScore*0.3271)))

end Case
```

Appendix 4 - Formulas Used

- Sample size calculation
- Confidence intervals

Sample size determination[98]

Total sample size:

$$2N = 4 (Z + Z)^2 \quad ^2 / \ ^2$$

Confidence Interval for Proportions[99]

$$P_L = \frac{(2np + c_{\alpha/2}^2 - 1) - c_{\alpha/2}\sqrt{c_{\alpha/2}^2 - (2 + 1/n) + 4p(nq + 1)}}{2(n + c_{\alpha/2}^2)}$$

$$P_U = \frac{(2np + c_{\alpha/2}^2 + 1) + c_{\alpha/2}\sqrt{c_{\alpha/2}^2 + (2 - 1/n) + 4p(nq - 1)}}{2(n + c_{\alpha/2}^2)}.$$

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