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Predicting Downstream Effects of High Decisional Conflict:
Meta-analysis of the Decisional Conflict Scale

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Predicting Downstream Effects of High Decisional Conflict: Meta-analyses of the Decisional Conflict Scale

By

Qiao Sun

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Abstract

Background: The Decisional Conflict Scale (DCS) is a useful clinical tool in assessing the health care consumers' decisional needs. However, the exact predictive ability of the DCS is unknown.

Objective: To examine the DCS as a proxy measure for patients' knowledge level and as a predictor of downstream effects of high decisional conflict, specifically, decision delay, discontinuance of chosen option, and decisional regret.

Design: Meta-analyses with individual data from 10 clinical trials using the following statistics: descriptive statistics, correlation analysis and logistic regression.

Results: Patients' knowledge deficit has a fair association with the uninformed subscale of the DCS (OR 3.10; 95% CI 1.58-6.05). Patients' decisional delay has a very strong association with the DCS (OR 23.81; 4.66-121.51). Patients' discontinuance of chosen treatment has a varied association with the DCS, very strong for change from status quo (OR 59.37; 4.09-861.05) and fair for change from active treatment (OR 3.39; 1.42-8.00). Patients' decisional regret has a strong association with the DCS (OR 5.52; 3.35-9.12).

Conclusion: When clinicians assess a patient's decisional conflict after counselling, and they find the decisional conflict is low, they can be reasonably assured that the likelihood of downstream decision delay, change from the status quo, or decisional regret will be low. However, low scores on the uninformed scale do not guarantee the patient is well informed; they need to validate the patients' understanding with some follow-up questions. Moreover, the likelihood of discontinuing active treatment even with low decisional conflict is also a possibility.

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Chapter 1: Introduction

1.1 Study objective

The Decisional Conflict Scale (DCS) is a useful clinical tool for assessing health care consumers' baseline decision making needs, tailoring decision support interventions to needs, and evaluating resolution of needs. Preliminary univariate analyses [1-4] indicate that the scale shows promise as a proxy measure for patients' knowledge, and as a predictor of important downstream effects, such as decision delay, discontinuance of chosen option, and decisional regret.

However, the exact predictive power of the DCS has not been established yet. If the DCS is validated to be a good predictor, then practitioners at clinical encounter can be re-assured when relying on good results of the DCS to conclude that patients are knowledgeable and unlikely to have problems later on. Moreover, it reduces the measurement burden of applying other scales such as knowledge tests.

Thus, the aim of the current thesis was to explore the predictive power of the DCS by conducting a pooled analysis of the studies that have employed the DCS in their research on decision support interventions such as the use of a decision aid and/or counselling. To be more specific, the questions that guided this thesis were:

1. Is the uninformed subscale of the DCS a valid proxy for patients' knowledge deficit?
2. Can the DCS be used to predict whether a decision delay will occur?
3. Can the DCS be used to predict whether there will be a discontinuance of the patients' chosen options?

4. Can the DCS be used to predict whether a patient will experience regret towards a decision already made?

If these questions yield positive answers, then by obtaining the DCS of a particular patient, practitioners could get a quick and reliable prediction of the patient's understanding of the clinical problem, and the downstream effects of his/her unresolved decisional conflict.

Toward this end, 10 well designed studies from the Cochrane Systematic Reviews of decision aids [3] were selected and then combined for a pooled analysis to analyse the predictive power of the DCS on patients' knowledge level, decision delay, discontinuance of chosen treatment and regret over the decision.

1.2 Background

1.1.1 The Origin and Development of decision aids in health care area

Decisional Conflict is the uncertainty about which course of action to take when choices among competing actions involve risk, loss, regret, or challenge to personal life values [5]. Decision making and decisional conflicts permeate the health care system, with many decisions literally having life-and-death implications. The goal in decision-making is to select options that, according to the best available scientific evidence, increase the likelihood of desired health outcomes and minimize the chance of undesired consequences. Many decisions in health care, however, do not have clear answers because the benefit/harm ratios are uncertain, marginal or dependent on how people value benefits versus harms. For these types of 'preference-sensitive' decisions, decision making can be suboptimal in that there is a poor match between what patients' values and what is provided. Moreover, there are wide regional variations in the uptake of these

options, with frequent over-use of aggressive procedures that informed patients do not value [5-7].

In the past two decades, several factors pushed researchers in Europe and North America to develop more individualized decision aids for 'preference-sensitive' options to help patients participate in decisions and to ensure that decisions are informed and values-based. These factors include a) the rise of consumerism toward informed choice rather than the more passive informed consent; b) the evidence-based practice movement which disseminates evidence to consumers as well as practitioners; c) the use of consumer-based strategies to reduce wide regional practice variations; and d) the realization that many decisions are 'value-laden' and depend upon the values that patients place upon benefits versus harms [3]. Decision aids are defined as interventions designed to help people make specific and deliberative choices among options (including the status quo) by providing (at the minimum) information on the options and outcomes relevant to a person's health status [3].

Decision aids are used as adjuncts to practitioners' counselling to prepare patients for decision-making. They are designed to help patients participate in the clinical decision-making process and to make informed choices among options that are consistent with their personal values.

Compared with usual health education materials (such as information pamphlets, which provide general information for public consumption), patient decision aids:

1. are more explicit about therapeutic choices;
2. provide detailed descriptions of options and clinically important outcomes and their consequences;

3. provide quantitative information about the likelihood of these outcomes (often tailored to the patient's own clinical risk profile);
4. provide personalized values clarification; and
5. develop skills in deliberation and communication and encourage patients to participate in decision making [7].

Studies have shown that the decision aids improve decision quality by reducing decisional conflict and increasing the likelihood that choices are based on better knowledge; and more realistic expectations, and personal values; at the same time, they also reduce the over-use of aggressive, expensive surgical procedures by 23% without affecting health outcomes, patient anxiety or satisfaction [4].

Decision aids are presented in a number of modes, including booklets, the Internet, audio booklets, and interactive videodiscs.

1.2.2 About the Decisional Conflict Scale (DCS)

In order to study the decision-making process in health care, Dr. Annette O'Connor developed the Decisional Conflict Scale (DCS) [5] to measure a person's perceptions of: personal uncertainty in making a choice about health care options, the modifiable factors contributing to uncertainty, and the quality of the decision made. The DCS can be used to assess baseline needs, to tailor decision supporting interventions to needs, and to monitor progress during and following interventions. The unique contribution of the DCS lies in measuring decision uncertainty that leads to decision delay and in quantifying the modifiable factors contributing to uncertainty, both during the process of deliberation and following the choice. Such information is useful not only in evaluating the impact of decision supporting interventions but also in fine tuning their

development and in tailoring them to particular patients' needs [5]. The DCS was designed according to psychometric rules and uses ordinal scales. The scale has been validated in different countries and used in a variety of studies such as hormone replacement therapy, prenatal testing, anticoagulant therapy, etc. [7].

The DCS has 16 items and a client is asked to respond to each item using a 5 point Likert Scale ranging from strongly agree (usually coded as 1) to strongly disagree (usually coded as 5). The scale has been adjusted to a grade eight reading level and can be completed in 5 to 10 minutes. There is a generic version and a condition-specific version; for the latter version there can be minor adjustments to the wording to suit the decision a person faces. These minor changes have not affected the psychometric properties of internal consistency, responsiveness to change, or discrimination between interventions.

1.2.2.1 The subscales included in the DCS

The DCS has 5 subscales: a) 1 subscale eliciting uncertainty in choosing an option; b) 3 subscales eliciting modifiable factors contributing to uncertainty such as i. feeling uninformed about options, benefits, and harms, ii. feeling unclear about the value of benefits versus harms, and iii. feeling unsupported in decision making; and c) 1 subscale eliciting overall perceived quality of the decision. Using the condition specific (Hormone Replacement Therapy) DCS as an example, the 5 subscales are:

- Uncertainty. Questions include:
    1. This decision is easy for me to make
    2. I'm sure what to do in this decision
    3. It's clear what choice is best for me

- Feeling uninformed. Questions include:
    1. I'm aware of the choices I have to reduce my risk of osteoporosis
    2. I feel I know the benefits of hormone therapy
    3. I feel I know the risks and side effects of hormone therapy
- Feeling unclear about the values. Questions include:
    1. I have enough advice and information about the choices
    2. I know how important the benefits are to me in this decision
    3. I know how important the risks and side effects are to me in this decision
- Feeling unsupported in decision-making. Questions include:
    1. I know which is more important to me (the benefits or the risks)
    2. I am making choice without any pressure from others
    3. I have the right amount of support from others in making this choice
- The perceived decision quality after making a choice. Questions include:
    1. I feel I have made an informed choice
    2. My decision shows what is important to me
    3. I expect to stick with my decision
    4. I am satisfied with my decision

1.2.2.2 Explanation of the result of the DCS

Each response is expressed on a 5-point Likert Scale (1=strongly agree, 2=agree, 3=neither agree nor disagree, 4=disagree, and 5=strongly disagree). Mean scores for each of the 5 subscales and the overall mean scores for the questions on the DCS are calculated for each patient. The mean scores are obtained by summing each response and then divided by the total number of items.

Total DCS scores range from 1 (low decisional conflict) to 5 (high decisional conflict). According to scale norms, patients with a mean score of 2 or less tend to make decisions, and those with a mean score above 2.5 tend to delay decisions [1].

The score can also be converted to range from 0 to 100 [2], but for this study, we used the scoring from 1 to 5.

1.2.2.3 The formats of the DCS

The DCS is available in both patient self-administered and practitioner-administered formats. Also, a shorter version (low literacy/pictorial) of the DCS has been developed. This DCS is a 10-item scale using a simpler response format (yes=1.5, no=4.5, unsure=3) to accommodate the lower literacy groups and to reduce response burden. At the same time, this shorter DCS also was designed to help practitioners to interpret "at a glance" when counselling patients about options tailored to decisional needs. Uncertainty and factors contributing to uncertainty can be detected by checking the items that were circled as "no" or "unsure"[5,6]. Both the generic version and shorter version are available in several languages including English, French, Spanish, Dutch, German, Thai, Japanese, Chinese, and Portuguese [9].

1.2.2.4 Studies on the DCS

Over the past 10 years, in order to improve the quality of medical decision making, studies on the DCS and the decision aids have been of interest for many health care researchers. For example, the Ottawa Health Decision Centre (OHDeC) of the Ottawa Health Research Institute have developed more than 30 decision aids and used the DCS in their before/after evaluation studies and randomized controlled trials [9]. According to the Cochrane Systematic Reviews of Decision Aids for Patients Facing

Health Treatment or Screening Decisions, the DCS and its subscales have been used in around 30 studies. They have found that the DCS is a reliable and valid measure of patients' decisional conflict. Table 1.1 shows the psychometric properties of the DCS and the other scales used in this thesis. The DCS could be used to understand patients' decisional needs and their resolution following interventions with decision aids and counselling [3]. To our knowledge, no studies have yet examined the DCS as a proxy for knowledge or a predictor of downstream effects.

Table 1.1 Psychometric properties of the DCS and other scales used in the thesis (excerpts from http://decisionaid.ohri.ca/eval.html)

Scale	Author	Reliability	Validity	Other
DCS	O'Connor	Test-retest correlations and Cronbach alpha coefficients exceed 0.78	Construct: correlated to related constructs of knowledge, regret, and discontinuance Discriminates between groups: Scale discriminates between those who make and delay decisions (effect sizes range from 0.4 to 0.8)	Responsive to change: In before/after studies of decision supporting interventions (effect size ranges from 0.4 to 1.2 for the total scale). Discriminates between different decision supporting interventions: The scale varies in its ability to discriminate between different decision supporting interventions. The informed subscale has consistently discriminated between interventions (effect size 0.3 to 0.4). The total scores and other subscales have been less consistent in discrimination, with effect size ranging from: 0.2 to 0.3 for the total scale; 0.06 to 0.3 for the uncertainty subscale; 0.3 to 0.4 for the values subscale; 0.0 to 0.3 for the support subscale; and 0.2 to 0.3 for the quality of choice subscale
Regret	O'Connor	Cronbach alpha coefficients ranges from 0.81 to 0.92	Correlated to other related constructs:satisfaction with decision (r=-0.40 to –0.60), decision conflict (r=0.31 to 0.52), overall rated quality of life (r=-0.25 to –0.27)	Groups who differed on feelings about the decision (negative, mixed, or positive) also differed on rated regret: ANOVA F statistic (df 2,190) = 31.1, p< .001. Regret was greater among those who changed their decision than among those who did not.
Knowledge	O'Connor and Dodin	Cronback alpha coefficients range from 0.82 to 0.83	Content: items test knowledge of facts presented in decision aids	Responsive to change: in before/after studies of decision supporting interventions Discriminates between decision aids and usual care controls

Chapter 2: Research design and methods

Meta-analysis is a mature and popular methodology when utilizing information from many studies of the same outcome. Often a combination of studies is more powerful and economical for evaluating the effect of interest. Therefore this thesis used meta-analysis as its research design. We obtained the results by synthesizing the individual subject data from 10 well-performed studies.

2.1 Inclusion of studies

The studies used in this secondary analysis are selected from the Cochrane Systematic Review of decision aids, which is a highly regarded review of completed and ongoing studies of decision aids around the world.

Carefully selected by the leading investigator of the Cochrane Systematic Review (Dr. Annette O'Connor), the current thesis used data from 10 studies that included the measurement of the DCS and the variables of interest, patients' knowledge, delay in decision making, discontinuance of previous treatment choice and decisional regret.

Permissions from the leading researchers of these studies were obtained with the assistance of Dr. Annette O'Connor to use their study and their data for this thesis.

Table 2.1 shows the 10 studies used (listed by principal investigator's name) and the corresponding variables that were measured. The display order of the table is arranged by the order of availability of the permission and data file.

Table 2.1 Characteristic of 10 recruited studies
(Studies have measured the DCS and the variables of interest, listed by the availability order)

No.	Study Name	Focus	Size (Control/DA)	DCS	KD	DD	DisC	DR
1	O'Connor unpublished [10]	Hormone Therapy	95/110	X	X	X	X(9)	X(9)
2	O'Connor 1998 [11]	Hormone Therapy	84/81	X	X	X		
3	Laupacis [12]	Predonating Autologous Blood	60/60	X	X	X		
4	Man Son Hing [13]	Atrial Fibrillation Treatment	148/139	X	X	X	X(6)	X(6)
5	Dodin [14]	Hormone Therapy	49/52	X	X	X		
6	Feldman [15]	Prostate Cancer Treatment	0/56	X				X(3)
7	Siminoff [16]	Breast Cancer Adjunct Therapy	0/395	X				X(3)
8	Morgan [17]	Heart Disease Treatment	94/86	X	X			
9	Murray HRT [18]	Hormone Therapy	102/103	X(3)		X(3)	X(9)	
10	Murray BPH [19]	Benign Prostate Disease	55/57	X(3)			X(9)	

Note
1. Control= size of group that were not exposed to a decision aid; DA=Decision Aid; DCS=Decisional Conflict Scale; KD=Knowledge Deficits; DD=Decision Delay; DisC=Discontinuance of Chosen Option; DR=Decision Regret.
2. Time frame of measurements: X =shortly after counselling; X(n)=n month after counseling.

2.2 Definition of the variables of interest

The variables that were used in the study are described below:

1. **Decisional Conflict Scale Scores** (ordinal 5 point Likert scale, which was converted to an interval scale ranging from 1[low] to 5[high decisional conflict]): The scale was designed to measure difficulty in making a decision, such as uncertainty; factors contributing to uncertainty (feeling uninformed, unclear about personal values, and unsupported in decision making); and the effectiveness of the decision making [5].
2. **Knowledge scores** (scored as an interval scale from 0% [poor] to 100% [excellent]): A 'Knowledge' questionnaire measures respondent's cognizance of a clinical problem, its alternatives, rationale, main benefits, risks and side effects. Items focus on information considered essential for decision- making [6].

   In this thesis, for some of the analyses, the knowledge scores were also converted to a dichotomous variable, using a cut-off of 50%. A score less than or equal to 50% was considered inadequate for decision making and scored a '1' to indicate a knowledge deficit. A score greater than 50% was coded as a '0', as contrary to the '1' coding which means no knowledge deficit.
3. **Decision delay** (nominal scale): deferring of making decision at a specific time point after counselling, scaled nominally as 1 (yes) or 0 (no).
4. **Discontinuance of chosen option** (nominal scale): making a change in an option that was originally chosen, scaled nominally as 1 (yes) or 0 (no).
5. **Decisional regret scores** (ordinal 5 point Likert scale, which was converted to a 100 interval scale ranging from 1 [low] to 100 [high] decisional regret): remorse

or distress over a decision, particularly when the outcome is unfavourable, as measured using a 5 item decisional regret scale [2, Appendix E].

In this study, regret scores were also converted to a dichotomous variable, 1 means regret, 0 means no regret.

2.3 Overview of included studies

The 10 studies recruited for the thesis: a) are from 3 countries (Canada (n=7), US (n=1), Britain (n=2); b) included 8 published and 2 unpublished studies; c) included 8 randomized controlled trials and 2 before/after studies.

All the included studies employed the DCS to quantify the difficulty of decision-making and included the measurement of at least one of the variables of interest. As a result, we have been able to evaluate the DCS and its relation with other variables by combining the individual data from these studies.

Following is the brief introduction of these studies and their match with our study objective.

Study 1: O'Connor's unpublished paper [10] is a randomized controlled trial (control simple pamphlet decision aid preparation plus physician counselling [n=95] versus a complex audio booklet decision aid preparation plus physician counselling [n=110]) of interventions for women considering Hormone Replacement Therapy and the impact on decision making over time. It was conducted in Ottawa, Canada. Data extracted from this trial for the thesis are:

1. DCS scores, 1 week after the intervention of decision aid and counselling [Appendix A-2].
2. Knowledge test score 1 week after the intervention [Appendix B];

3. Decision delay, 1 week after the intervention. Responses were recoded from a choice question of using hormone therapy, not using, using and unsure. Those selecting 'unsure' were classified as a delay [Appendix C];
4. Discontinuance of chosen option, derived by comparing differences between patients' decisions at one week and 9 months after the intervention [Appendix D];
5. Decisional regret, measured at 9 months after intervention [Appendix E].

Study 2: O'Connor 1998's study is a randomized trial (control pamphlet decision aid [n=84] versus a detailed audiobooklet decision aid [n=81]) of self-administered interventions for postmenopausal women considering hormone therapy published by Medical Decision Making [11]. This study was conducted in Ottawa, Canada. Data extracted for this thesis are the following:

1. DCS scores, immediately post intervention [Appendix A-2].
2. Knowledge, immediately post intervention, derived from a 21-item questionnaire with true, false, and unsure responses. The percentages of correct items were calculated; all unsure responses were classified as incorrect [Appendix B].
3. Decision delay, immediately post intervention. Responses were recoded from the choice question "using hormone therapy", options are not using, using and not sure, in which 'unsure' was coded as a delay [Appendix C].

Study 3: Laupacis's study [12] on Blood Transfusion in Heart Surgery was a randomized controlled trial (control preparation plus surgeon counselling [n=60] versus decision aid preparation plus surgeon counselling [n=60]) that aimed to determine the usefulness of a

decision aid for patients undergoing elective open heart surgery. It was conducted in Ottawa, Canada and is being submitted for publication. The data extracted from this study were:

1. DCS scores within a week post intervention [Appendix A-2].
2. Knowledge scores, within a week after intervention including surgeon counselling: A 15-item portion of the questionnaire tested patients' knowledge of information covered in the decision aid. Potential answers were "true", "false" and "unsure" and were scored as the percentage correct; unsure responses were coded as incorrect [Appendix B].
3. Delay, within a week post intervention, recoded from 'my thoughts on the best choice for me' (volunteer donated blood, self-donated blood, unsure) in which 'unsure' responses were coded as a delay [Appendix C].

Study 4: Mon Son Hing's study [13] on Stroke Prevention in Atrial Fibrilaltion was published in the Journal of American Medical Association in 1999. It is a randomized controlled trial (control usual debriefing following study [n=148] versus decision aid and usual debriefing [n=139]) designed to determine whether the use of an audio booklet (AB) decision aid explaining the results of a clinical trial affected the decision-making process of study participants. It was conducted from May 1997 to April 1998 in Ottawa, Canada. The data extracted from the study are following:

1. DCS scores, within a week after post counselling [Appendix A-2].
2. Knowledge, within a week after counselling [Appendix B].
3. Decision delay, within a week after counselling. Patient responses were recoded from the question: 'Patient choices' – Has a decision been made

with your clinician about which treatment you will take to prevent stroke from atrial fibrillation? A 'no' response was classified as a delay [Appendix C].

4. Discontinuance of chosen option. This was ascertained from a 6-month post-counselling questionnaire regarding adherence to the patients' initial choice of therapy [Appendix D].
5. Regret, from the 6-month follow up questionnaire [Appendix E].

Study 5: Dodin 2001[14] was published in Canadian Family Physician in August 2001 and was a randomized clinical trial (control booklet [n=49] versus a decision aid audio-booklet [n=52]) conducted in Quebec City, Canada. Its objective was to compare the efficacy of a decision-making aid with an information document with regard to decision about hormone replacement therapy (HRT). The data extracted from this study included the following:

1. DCS scores, at follow up of the intervention, using the French version [Appendix A-2];
2. Knowledge, at follow up of the intervention, measured by using the French version of the knowledge test regarding Hormone Replacement Therapy [Appendix B].
3. Decision delay, at follow up of the intervention, recoded from the question 'my opinion of hormone therapy'. If the answer was 'unsure' to this question, it was classified as a decision delay [Appendix C];

Study 6: Feldman's study [15] was an uncontrolled trial (n=56) aimed at evaluating the performance of decision aids for patients considering different options for prostate cancer

treatment, conducted in Kingston, Ontario, Canada. Two variables were extracted from the study are:

1. DCS scores, after the counselling using the generic version with slight rewording changes [Appendix A-2];
2. Decisional regret, measured 3 months after making treatment decisions using the Decisional Regret Scale [Appendix E].

Study 7: Siminoff's study [16] (n=395) evaluated the decision aid in the context of examining doctor-patient communication patterns during consultation sessions in which patients with breast cancer decided whether to proceed with adjuvant therapy after the primary surgical intervention. It was conducted in Cleveland, Ohio, and San Antonio, Texas, USA. Two variables from the data file of this study are extracted:

1. DCS scores, after the intervention of a decision aid [Appendix A-2].
2. Decisional regret, measured 3 months after the decision about breast cancer adjuvant therapy was made using the decisional regret scale [Appendix E].

Study 8: Morgan's study [17] evaluated the Ischemic Heart Disease Shared Decision Making Program (IHD SDP). The purpose was to determine if the IHD SDP, when compared with usual practice, improved patients' decision-making. It was a randomized controlled trial (control/decision aid = 94/86) conducted in Toronto, Canada. The data extracted from this study were:

1. DCS scores, after intervention [Appendix A-2].
2. Knowledge, at the time of decision-making. Twenty questions were used in measuring the understanding of the disease [Appendix B].

Study 9: Elizabeth Murray's randomised controlled trial of an interactive multimedia decision aid on hormone replacement therapy (control/decision aid=102/103) in primary care was published in BMJ [18]. It was conducted in the United Kingdom. Data were collected at baseline, three, and nine months after randomization. The data were :

1. DCS scores at three months after randomization [Appendix A-2].
2. Decision delay 3 months following the intervention, recoded from the question 'my choice of treatment'. If the answer was 'undecided ' to this question, it was classified as a decision delay [Appendix C];
3. Discontinuing chosen option, measured from two questions: a) the decision is made at three month post counselling and whether a change of treatment option occurred at 9 months [Appendix D].

Study 10: Murray's randomised controlled trial (control/decision aid=55/57) of an interactive multimedia decision aid on Benign Prostatic Hypertrophy in primary care published by BMJ [19]. This trial was conducted in the United Kingdom. The data extracted for the study were:

1. DCS scores at three months after counselling [Appendix A-2]
2. Discontinuing chosen option, measured from two questions: first is about the decision at three month post counselling and the second is whether a change of treatment option occurred at 9 month follow-up [Appendix D].

2.4 Comparability

The variables (overall mean DCS, knowledge score, decision delay, discontinuance of chosen treatment, and decisional regret) from these 10 different studies are comparable.

2.4.1 DCS

All 10 studies used in the current thesis employed the same DCS with only slightly wording adjustment according to specific clinical decisions. Appendix A includes the actual items used in each of these 10 studies. As shown in Table 2.2, the differences between the DCS used in the studies are summarized as following:

1. The studies of Laupacis and Man Son Hing had extra items in their scales because they elicited patients' perceptions of knowing benefits and risks for each option being considered (self-donated blood vs volunteer-donated blood in the Laupacis study and aspirin versus warfarin in the Man Son Hing study). In these cases, the average of the two responses of the same item in the DCS is calculated to be the response of that item. For example the DCS item of knowing the benefits in Man Son Hing's study was a composite of knowing the benefits of warfarin and knowing the benefits of aspirin.

2. Among these 10 studies, Man Son Hing's study didn't include the item 9 and Feldman's study didn't use item 14, 15 and 16. For the current study, the mean response of the total items of the DCS is considered to be the decision conflict score and the mean score of the total items available for the subscale is considered to be the subscale score.

3. In several studies, an earlier version of the DCS with some negatively phrased to avoid yes-saying bias was used. These negative items were reversed so that all

responses were scaled from 1 to 5 in a consistent direction. Other studies used later DCS versions with consistently positively worded items.

4. Most studies used the condition-specific version of the DCS, adapting the wording to the specific decision. The order of items in the Laupacis was slightly different and was switched to conform with the other studies for analysis purpose.

5. Nine studies used English questionnaires and 1 used a French version.

After combining the individual subject's data, the overall mean DCS scores and the 5 subscales' scores were calculated by summing the items and dividing by the number of the items involved.

Table 2.2 Decisional conflict scales of 10 studies

STUDY (total items)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1. AOC unpublished (10)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
2. AOC 1998 (11)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
3. Laupacis (12)	X	X	X	X	X(2)	X(2)	X	X	X	X	X	X	X	X	X	X
4. Mon Son Hing (13)	X	X	X	X	X(2)	X(2)	X	X(2)		X	X	X	X	X	X	X
5. Dodin (14)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
6. Feldman (15)	X	X	X	X	X	X	X	X	X	X	X	X	X			
7. Siminoff (16)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
8. Morgan (17)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
9. Murray HRT (18)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
10. Murray BPH (19)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Note: X(2) stands for similar item occurs twice in the scale

1. This decision is easy for me to make
2. I'm sure what to do in this decision
3. It's clear what choice is best for me
4. I'm aware of the choices I have to reduce my risk of osteoporosis
5. I feel I know the benefits of hormone therapy
6. I feel I know the risks and side effects of hormone therapy
7. I have enough advice and information about the choices
8. I know how important the benefits are to me in this decision
9. I know how important the risks and side effects are to me in this decision
10. I know which is more important to me (the benefits or the risks)
11. I am making choice without any pressure from others
12. I have right amount of support from others in making this choice
13. I feel I have made an informed choice
14. My decision shows what is important to me
15. I expect to stick with my decision
16. I am satisfied with my decision

2.4.2 Knowledge

Six of the 10 studies measured patients' knowledge score at the same time as they measured the decision conflict score (O'Connor unpublished, O'Connor 1998, Laupacis, Man Son Hing, Dodin, and Morgan). Among them, the three HRT studies (O'Connor unpublished, O'Connor 1998 and Dodin) used exact same 21-item knowledge questionnaire; Laupacis's study used 14-item knowledge questionnaire; Man Son Hing's study used a 23 item questionnaire; and Morgan's study used a 20 item knowledge questionnaire. The knowledge score of all these 6 studies was calculated as a percentage of the correct answers multiplied by 100, so the knowledge score was a 0-100 interval variable. In this thesis, knowledge scoring less than or equal to 50 was defined as a knowledge deficit. Appendix B includes the specific knowledge questionnaires used in those studies.

2.4.3 Decision delay

Six of the 10 studies measured whether a decision is made. The delay variable is derived from this item. The answer of 'unsure' was recoded as Decisional Delay. Appendix C describes the specific questions used in these six studies.

2.4.4 Discontinuance of chosen option

Three of the 10 recruited studies have measured the decision at different time points. The difference between these two decisions is coded as discontinuance of chosen option. Appendix D lists the specific questions used to derive this variable.

2.4.5 Decisional Regret

Four of the 10 recruited studies have used the same 5-item decisional regret scale to measure regret. Appendix E displays the regret scale used in these studies.

2.5 Statistical analyses

Descriptive statistics, correlation analysis and logistic regression were used to describe the data and to probe the correlation and predictive validity of the DCS on patients' knowledge level, decision delay, discontinuance of chosen option, and decisional regret.

There are two primary reasons for choosing logistic regression as our predictive tool. First, from a mathematical point of view, it is a more flexible technique. It has no assumptions abut the distributions of the predictor variables; the predictors do not have to be normally distributed, linearly related, or of equal variance within each group [20, 21]. Second, it lends itself to a clinically meaningful interpretation [22-26]. For example, for a give value of the DCS, clinicians can predict the likelihood that the patient will have adequate knowledge and experience delay, discontinuance, and regret.

Meta analysis was used when combining the individual data from different studies [27-32]. The heterogeneity between the studies was checked before giving a pooled estimate [33-39]. A random effects model was used when the heterogeneity was suspected [40-42]. The relationship between the DCS and the variable of interest was expressed as an odds ratio with 95% confidence limits.

SAS® was the statistical software used for the analyses [43-45].

Chapter 3 Results

A merged database was constructed by combining the individual subject data from the 10 recruited studies. Table 3.1 is the code sheet of the key variables used in this merged database.

Table 3.1 Variable code sheet of the merged DCS database

Variable	Description	Codes (Data Type)
1.	Study name	1 – 10 (nominal)
2.	Group (intervention/control)	0 or 1 (nominal)
3.	The total DCS score	1 – 5 (continuous)
4.	Knowledge score out of 100	0 – 100 (continuous)
5.	Knowledge deficit (dichotomized from variable 4)	0 or 1 (nominal)
6.	Uninformed subscale score	1 – 5 (continuous)
7.	Delay (yes/no)	0 or 1 (nominal)
8.	Discontinuous from unsure of the treatment choice	0 or 1 (nominal)
9.	Discontinuous from status quo of the treatment	0 or 1 (nominal)
10.	Discontinuous from active treatment choice	0 or 1 (nominal)
11.	Regret scale score	1 – 5 (continuous)
12	Regret (dichotomized from variable 11)	0 or 1 (nominal)

Table 3.2 gives the study-specific descriptive statistics for the total DCS score in the merged database. The average total DCS score ranges from 1.68 (Man Son Hing's Atrial Fibrillation Treatment) to 2.72 (Dodin's Hormone Therapy), the standard deviation is from 0.36 to 0.63.

Table 3.2 Descriptive statistics of the total DCS score in the merged database

Study	DCS				
	Valid (N)	Mean	Std. Dev	Min	Max
O'Connor unpublished	184	2.14	0.54	1.00	3.44
O'Connor 1998	148	2.21	0.63	1.00	3.69
Laupacis	109	1.86	0.58	1.00	3.22
Man Son Hing	277	1.68	0.47	1.00	2.78
Dodin	101	2.07	0.58	1.00	4.00
Feldman	56	2.72	0.36	1.62	3.54
Siminoff	384	2.02	0.47	1.00	3.31
Morgan	180	2.12	0.54	1.00	3.38
Murray HRT	178	2.66	0.57	1.13	4.38
Murray BPH	101	2.40	0.49	1.06	3.69

Based on this merged DCS database, the analyses of the association between the DCS and patients' knowledge deficit, delaying of making decision, discontinuance of treatment choice and regret related to the decision were performed. Table 3.3 lists the variables used in the four logistic regression models.

Table 3.3 Information about the four 4 meta-analyses to be performed

Model	Outcome variable	Explanatory variable
1	Knowledge deficit	Uninformed subscale
2	Delay	Total DCS score
3	Discontinuous of treatment choice	Total DCS score
4	Regret	Total DCS score

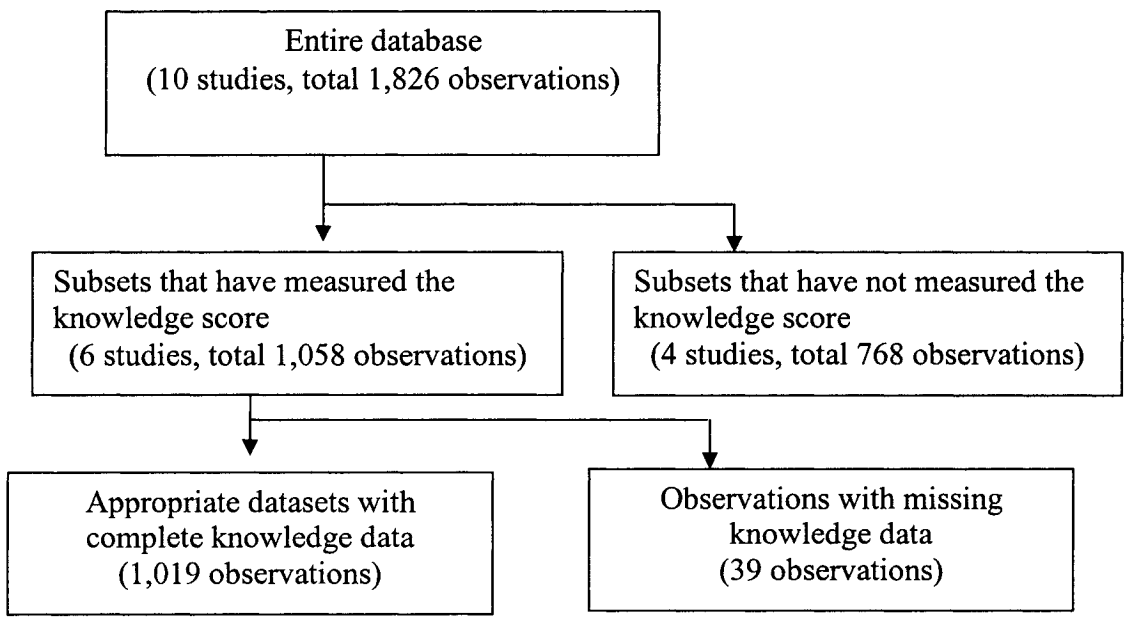
3.1 Knowledge vs the uninformed subscale of DCS study

In this study, the studies that have included the patients' knowledge test were combined in order to find better estimate of the relation between the second subscale of the DCS – uninformed subscale and the patients' knowledge test scores. This subscale bears the closest conceptual relationship to knowledge tests and therefore was most appropriate to use in the analysis.

3.1.1 Generation of knowledge dataset

There are six out of 10 studies included a knowledge test. Figure 3.1.1 gives out the flow chart of the formation of the knowledge dataset. There are 1,019 valid knowledge observations in this dataset. Table 3.1.1 describes the characteristics of the studies.

Figure 3.1.1 Generation of the knowledge dataset



Brief information about the six studies used in the knowledge study is shown in Table 3.1.1. All these six studies are randomized controlled trials.

Table 3.1.1 Characteristics of the studies in the knowledge dataset

No.	Study Name	Design	Focus	Time of Measurement*
1	O'Connor Unpublished [10]	RCT	Hormone therapy	Post counselling
2	O'Connor 1998 [11]	RCT	Hormone therapy	Post counselling
3	Laupacis [12]	RCT	Predonating autologous blood	Post counselling
4	Man Son Hing [13]	RCT	Atrial fibrillation treatment	Post counselling
5	Dodin [14]	RCT	Hormone therapy	Post counselling
6	Morgan [17]	RCT	Heart disease	Post counselling

* time when knowledge test was performed.

3.1.2 Descriptive statistics of the knowledge database

The descriptive statistics for the individual studies are displayed in Tables 3.1.2; this table gives the actual knowledge score as well as the dichotomized knowledge score - the knowledge deficit (cut-off at 50 out of 100, patients who scored less than or equal to 50 are considered to be having knowledge deficit). As shown from the table 3.1.2, the mean knowledge scores range from an average of 66.28 to 76.63, larger than 50, in keeping with a post-intervention profile. These average knowledge scores are consistent with scores following decision aids.

Table 3.1.2 Detailed information for the studies forming the knowledge dataset

Study	Knowledge Score					Uninformed Subscale		
	N	Continuous*		Binary**				
		Mean	SD	Deficit (%)	>50% (%)	N	Mean	SD
O'Connor unpublished	184	76.63	16.23	14 (8%)	170 (92%)	184	1.94	0.57
O'Connor 1998	162	74.07	17.96	21 (13%)	141 (87%)	161	2.01	0.75
Laupacis	106	75.22	19.84	13 (12%)	93 (87%)	110	1.84	0.59
Man Son Hing	286	70.60	17.37	32 (11%)	254 (89%)	283	1.71	0.54
Dodin	101	66.28	17.31	15 (15%)	86 (85%)	101	1.81	0.56
Morgan	180	68.56	18.55	31 (17%)	149 (83%)	180	1.97	0.67

N: Number of valid observations.
SD: standard deviation.
* Knowledge continuance variable.
** Knowledge binary variable (knowledge score <=50 is knowledge deficit, knowledge score > 50 is no knowledge deficit.).

3.1.3 Correlation analysis

In Table 3.1.3, the correlation analyses between the uninformed subscale of the DCS and the knowledge test scores are presented. Two kinds of the correlation coefficients are showed. There is a Pearson r correlation coefficient between the knowledge score (continuous scale) and the uninformed subscale (continuous scale), with results showing that knowledge score is inversely related with the uninformed subscale. This means that if the uninformed subscale increases, the knowledge score decreases. The second coefficient is the point-biserial coefficient of correlation between the knowledge deficit (binary scale, deficit (<=50%) is coded as 1, >50% is coded as 0) and the uninformed subscale (continuous scale), with results showing that knowledge deficit

is positively correlated with the uninformed scale. This means that if the uninformed subscale increases, then the chance of having knowledge deficit increases too. The absolute values of these two correlation coefficients are very similar, as they should be, ranging from 0.05 to 0.37. Although they are not very high, most are statistically significant.

Table 3.1.3 Correlation between knowledge score and the uninformed subscale

Study	N	Pearson r*	Point-biserial**	P
O'Connor unpublished	184	-0.26	0.24	0.0004
O'Connor 1998	161	-0.06	0.05	0.43
Laupacis	106	-0.34	0.23	0.0004
Man Son Hng	285	-0.32	0.25	<.0001
Dodin	101	-0.36	0.37	0.0002
Morgan	180	-0.18	0.14	0.015

N: Valid observations.
* pearson r correlation coefficient between knowledge score and the uninformed subcale.
** point-biserail correlation coefficient between knowledge deficit and the uninformed subscale.

3.1.4 Meta-analysis

By using SAS logistic procedure, taking the uninformed subscale of the DCS as the explanatory variable and knowledge deficit (models based on having knowledge deficit) as the outcome variable, the study specific and common log odds ratios and odds ratio are shown in Table 3.1.4.

Table 3.1.4 Log odds ratio of individual study and pooled in the knowledge dataset

Study	ln(OR)*(95% CI**)	OR (95% CI)	P
1. O'Connor unpublished	1.47 (0.53-2.41)	4.35 (1.70-11.13)	0.002
2. O'Connor 1998	0.18 (-0.45-0.81)	1.20 (0.64-2.25)	0.57
3. Laupacis	1.21 (0.17-2.25)	3.35 (1.19-9.49)	0.02
4. Man Son Hing	1.54 (0.77-2.31)	4.66 (2.16-10.07)	<0.0001
5. Dodin 2001	1.83 (0.71-2.96)	6.23 (2.03-19.30)	0.0014
6. Morgan	0.54 (-0.02-1.10)	1.72 (0.98-3.00)	0.06
Fixed effects model	0.90 (0.60-1.20)	2.46 (1.82-3.32)	<0.0001
Random effects model	1.13 (0.46-1.80)	3.10 (1.58-6.05)	0.008

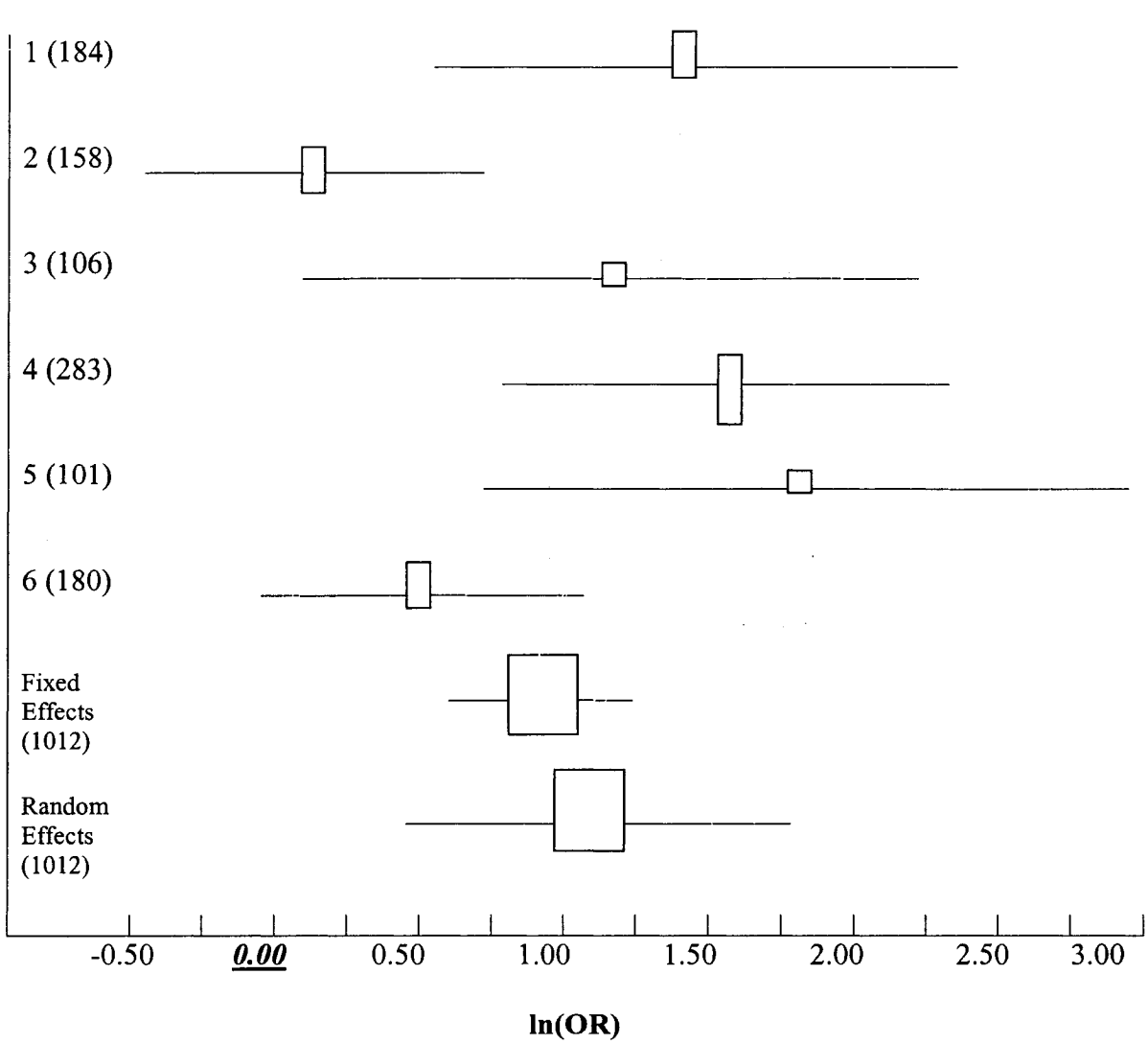
*ln(OR): natural logarithm of odds ratio
**95% CI: 95 percent confidence interval

For common log odds ratio, a fixed effects model (assuming the test effects of the uninformed subscale are same for all studies) was obtained by regressing the knowledge deficit on the uninformed subscale score and study as an indicator variable, yielded log odds ratio of 0.90 (95% CI 0.60-1.20). We tested the interaction by adding the interaction term to this fixed effects model, and the deviance for the model with interaction is 685.631 with 11 degrees of freedom, whereas the deviance for the model without the interaction term was 700.365 with 6 degrees of freedom. So the test of interaction chi-square statistic is 14.734 with 5 degrees of freedom, which has the p value of 0.01, meaning that the interaction between the study and the uninformed subscale is statistically significant, in other words, the test effects of the uninformed subscale are not same in all studies. With the existence of the interaction, a random effects model, making allowance for the heterogeneity between studies, should be used to obtain a valid common estimate and its standard error.

A random effects model using a t test of the individual log odds ratio [46] derives the common log odds ratio of 1.13 (95% CI 0.46-1.80), and is statistically significant at 0.01 level.

Figure 3.1.2 is a graphical display (Forest plot in meta-analysis) of the log odds ratios and their confidence intervals. The confidence interval is indicated by a line, and the point estimate of the log odds ratio is indicated by a rectangle proportional to the study size. This graph also indicates the interaction might be significant as study 2 hardly overlaps with study 4 and study 5.

Figure 3.1.2 Forest plot of the knowledge dataset



3.1.5 Sensitivity analysis

Because all 6 studies included are randomized controlled trials, it is of interest to analyze the data by intervention group. The sensitivity analysis using the intervention group data produces the random effects log odds ratio of 1.36 (95% CI 0.35-2.38) and the control group produces the fixed effects log odds ratio of 0.74 (95% CI 0.36-1.11).

3.1.6 Summary

Although most studies show that the correlations between the knowledge deficit and the uninformed subscale are statistically significant, the coefficients are relatively low and therefore not very impressive.

The p value of the log odds ratio is the measure of whether the predictor is statistically significant. The study specific log odds ratios indicate in the four out of six studies, the uninformed subscale is a significant predictor of patients' knowledge deficit. The odds ratio in logistic regression is a measure of association between the predictor and the outcome variable, and the size of any relationship is measured by the difference (in either direction) from 1.0. Values for odds ratios greater than 2.5 or 3.0 are generally taken to represent the lower limits of a strong association [47]. The study specific logistic regression models show that the knowledge deficit has strong association with the uninformed subscale in 4 out of 6 studies. After pooling all the studies, the common odds ratio from the random effects model (which has a wider confidence interval) is 3.10 (95% CI 1.58-6.05), indicating that with one unit increase of the uninformed subscale, the odds of having knowledge deficit increase 3.10 fold, and could be as low as 1.58 and as high as 6.05 with 95% confidence. So the association between the knowledge deficit and the uninformed subscale is fair.

For the subgroup analysis, as shown in the sensitivity analysis, the decision aid intervention group has log odds ratio of 1.36 (95% CI 0.35-2.38), while the control group has log odds ratio of 0.74 (95% CI 0.36-1.11). Because of the complete overlapping of the two confidence intervals, there is not much difference between the two groups, and both are within the range of the common log odds ratio of 1.13 (95% CI 0.46-1.80). The

point estimates show that on average the uninformed subscale would have slighter better association with the intervention group than with the control group.

Linear regression models using the continuous knowledge score as the dependent variable yielded similar results as the logistic regression models using the dichotomized knowledge score.

3.2 Delay study vs the total DCS score study

This study explored the relation between the total DCS score and the delay variable.

3.2.1 Generation of delay dataset

Undecided or unsure of treatment choices were coded as delays. From the combined database, six studies measured this variable. Figure 3.2.1 shows how the delay dataset was generated and Table 3.2.1 is the details of these 6 studies.

Figure 3.2.1 Generation of the delay dataset

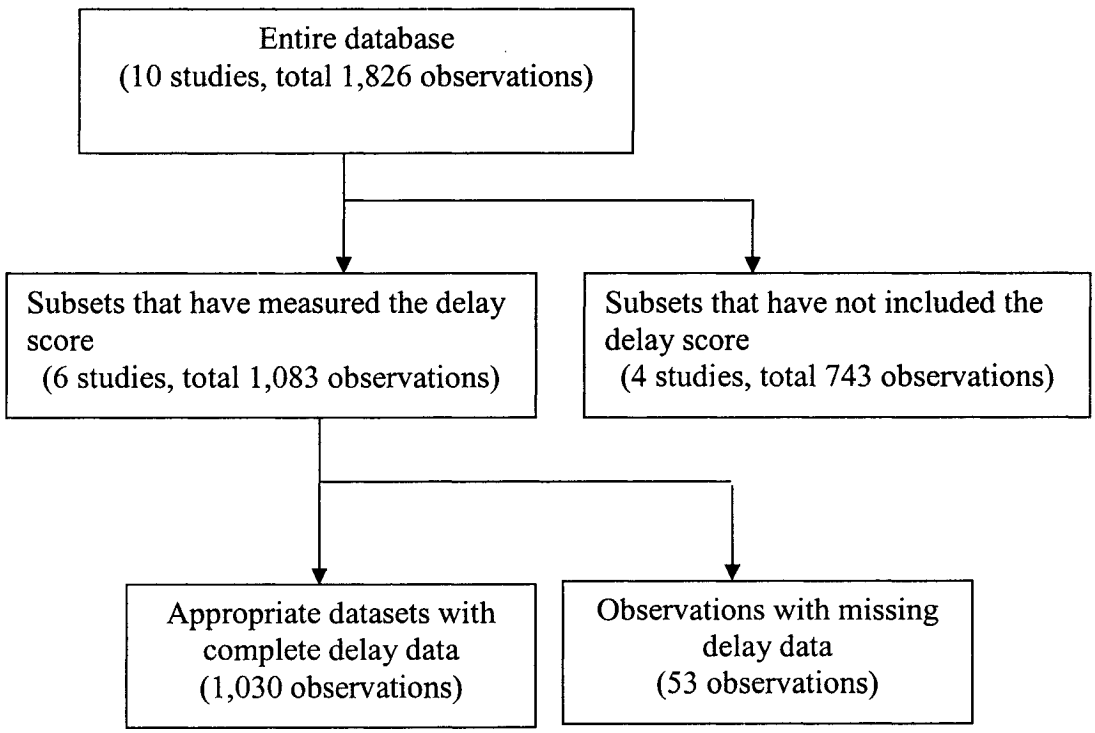


Table 3.2.1 Characteristics of the studies in the delay dataset

No.	Study Name	Design	Focus	Time of measurement*
1	O'Connor unpublished [10]	RCT	Hormone therapy	Post counselling
2	O'Connor 1998 [11]	RCT	Hormone therapy	Post counselling
3	Laupacis [12]	RCT	Predonating autologous blood	Post counselling
4	Man Son Hing [13]	RCT	Atrial Fibrillation treatmen	Post counselling
5	Dodin [14]	RCT	Hormone therapy	Post counselling
6	Murray HRT [18]	RCT	Hormone therapy	3 month post counselling

* time when the delay variable was measured.

3.2.2 Descriptive statistics:

Descriptive statistics for the delay dataset are given in Table 3.2.2. It shows that the proportion of decisional delay ranges from 3% to 36% for the six studies included.

Table 3.2.2 Descriptive statistic of the variables in the delay dataset

No.	Study Name	Delay			DCS		
		N	Delay	No delay	N	Mean	SD
1	O'Connor unpublished	184	46 25%	138 75%	184	2.14	0.54
2	O'Connor 1998	164	43 26%	121 74%	148	2.21	0.63
3	Laupacis	111	24 22%	87 78%	109	1.86	0.58
4	Man Son Hing	285	8 3%	277 97%	277	1.68	0.47
5	Dodin	101	36 36%	65 64%	101	2.07	0.58
6	Murray HRT	185	38 21%	147 79%	178	2.66	0.57

N: valid observations.
SD: standard deviation.

3.2.3 Correlation analysis

Table 3.2.3 shows the point-biserial correlation coefficient between the delay variable and the total DCS score. As shown on the table, they are significantly correlated, ranging from 0.29 to 0.62. This means that if the DCS increases, the chance of decisional delay will increase too. The correlation between delay and the total DCS score is statistically significant for each study.

Table 3.2.3 Point-biserial correlation of delay dataset

Study	N	R	p	Note
O'Connor unpublished	184	0.49	<.0001	Medication
O'Connor 1998	147	0.44	<.0001	Medication
Laupacis	147	0.41	<.0001	Medication
Man Son Hing	275	0.29	<.0001	Medication
Dodin	101	0.62	<.0001	Medication
Murray HRT	174	0.40	<.0001	Medication

3.2.4 Meta-analysis

By using SAS logistic procedure, taking the total DCS score as the explanatory variable and the delay variable as the outcome variable, the study specific and summary log odds ratios and odds ratios are shown in the Table 3.2.4.

Table 3.2.4 Log odds ratio of individual study and pooled in the delay dataset

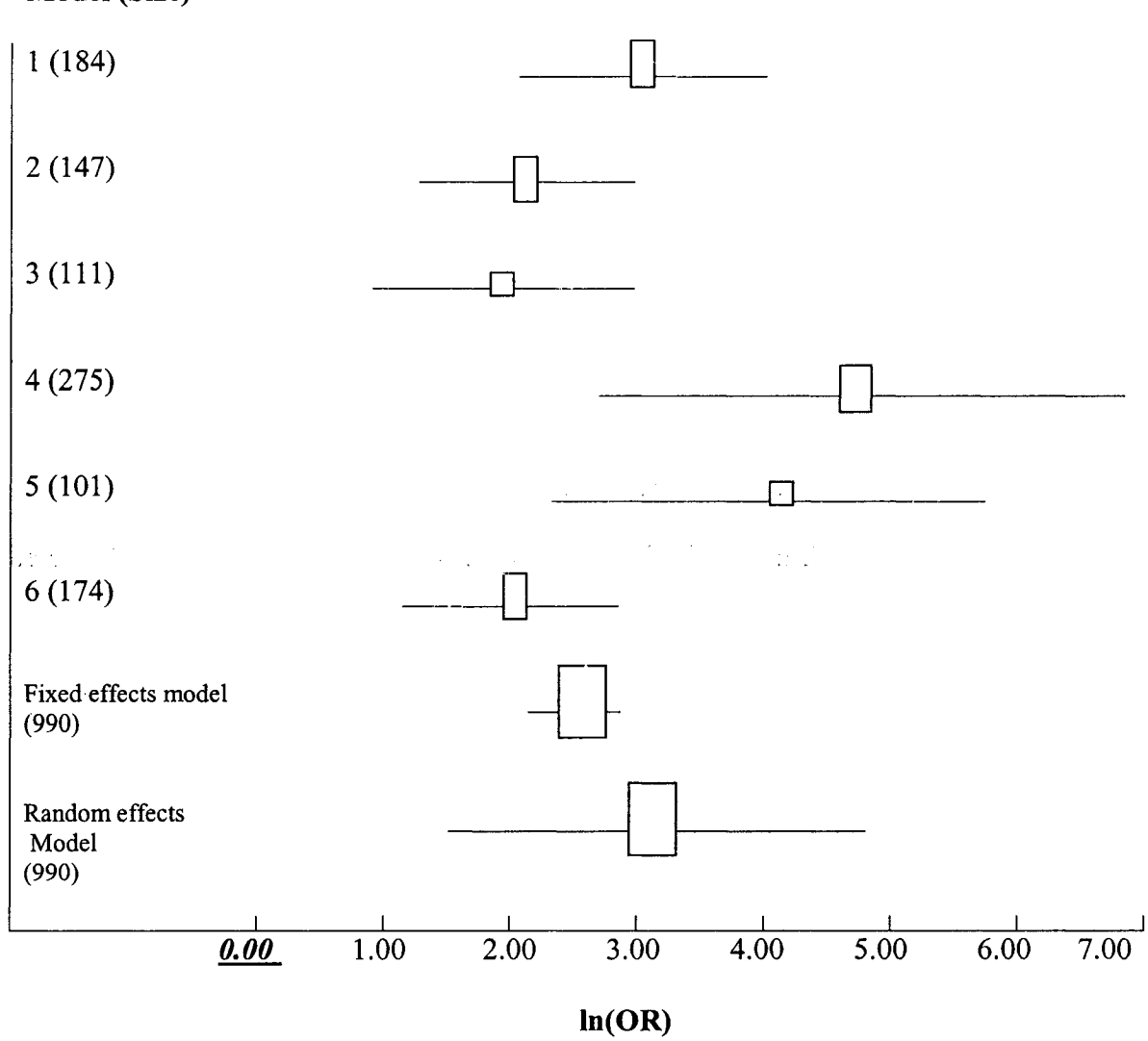
Study	ln(OR) (95% CI)	OR (95% CI)	P value
1. O'Connor unpublished	3.00 (1.96-4.02)	20.01 (7.10-55.70)	<0.0001
2. O'Connor 1998	2.13 (1.24-2.91)	8.41 (3.46-18.36)	<0.0001
3. Laupacis	1.92 (0.93-2.91)	6.82 (2.53-18.36)	0.0002
4. Man Son Hing	5.83 (2.89-6.91)	336.97 (17.99- >999.99)	0.0001
5. Dodin 2001	4.15 (2.45-5.84)	63.43 (11.59-343.78)	<0.0001
6. Murray HRT	2.01 (1.15-2.87)	7.46 (3.16-17.64)	<0.0001
Fixed effects model	2.60 (2.15-3.05)	13.46 (8.58-21.12)	<0.0001
Random effects model	3.17 (1.54-4.80)	23.81 (4.66-121.51)	0.0004

For common log odds ratio, a fixed effects model (assuming the test effect of the DCS are same for all studies) was obtained by regressing the delay variable on the overall DCS score and study as an indicator variable, which yielded log odds ratio of 2.60 (95% CI 2.37-2.83). We tested the interaction by adding the interaction term to the model, and the deviance for the model with interaction is 644.766 with 11 degrees of freedom, whereas the deviance for the model without the interaction term was 660.021 with 6 degrees of freedom, so the test of interaction chi-square statistic is 15.255 with 5 degrees of freedom, the p-value is 0.01, which means the study variable is an effect modifier. In other words, the effect of the DCS is not same in all studies, and a random effects model which makes allowance for the heterogeneity between the studies should be used in this case.

A random effects model using a t test of the individual log odds ratio yields the common log odds ratio is 3.17 (95% CI 1.54-4.80).

Figure 3.2.2 is a graphical display (Forest plot) of the log odds ratios and their confidence intervals. The confidence interval is indicated by a line, and the point estimate of the log odds ratio is indicated by a rectangle proportional to the model size. As seen from the graph, study 4 hardly overlaps with study 2 and study 3, indicating the probable existence of interaction.

Figure 3.2.2 Forest plot of the delay dataset



3.2.5 Sensitivity analysis

As all 6 studies are randomized controlled trials, so the difference between the intervention group and the control group is of interest. Sensitivity analyses using the intervention group data produce a random effects log odds ratio of 15.49 (95% CI -18.30-49.28) and the control group produce a fixed effects log odds ratio of 3.11 (95% CI 2.40-3.83).

3.2.6 Summary

The correlation between delay and the total DCS score is very high. In individual study, the point-biserial correlation coefficient ranging from 0.29 to 0.62, and all are statistically significant at 0.001 level, which are very impressive.

The study-specific logistic regression models indicate that the DCS is a statistically significant predictor of decisional delay for all studies. The odds ratio given by the random effects model is 23.81 (95% CI 4.66-121.51), for one unit increase of the total DCS score, the odds of delaying the decision making is almost 24 fold, with 95% confidence as low as 4.66 and as high as 121.51, and is statistically significant at 0.004 level.

Sensitivity analyses performed on intervention group and control group indicate that the control group (ln(OR) 3.11; 95% CI 2.40-3.83) has similar odds ratio as the total common odds ratio (ln(OR) 3.17; 95% CI 1.54-4.80). Although the intervention group (ln(OR) 15.49; 95% CI -18.30-49.28) shows a larger average sensitivity than the control group, it is not statistically significant from the result given by the t test random effects model.

3.3 Discontinuance vs the total DCS score study

In this section the relation between the overall DCS score and the discontinuance of treatment decisions was studied. There are two subgroups according to the change in direction from the previous choice, e.g. change from status quo, and change from active treatment. The Murray BPH study is excluded from the analysis because it is the only study about surgery, in which not all people can change their decision.

3.3.1 Generation of the discontinuance dataset

The formation of the discontinuance dataset is given by Figure 3.3.1 and the details of the studies included are in the Table 3.3.1.

Figure 3.3.1 Generation of the discontinuance dataset

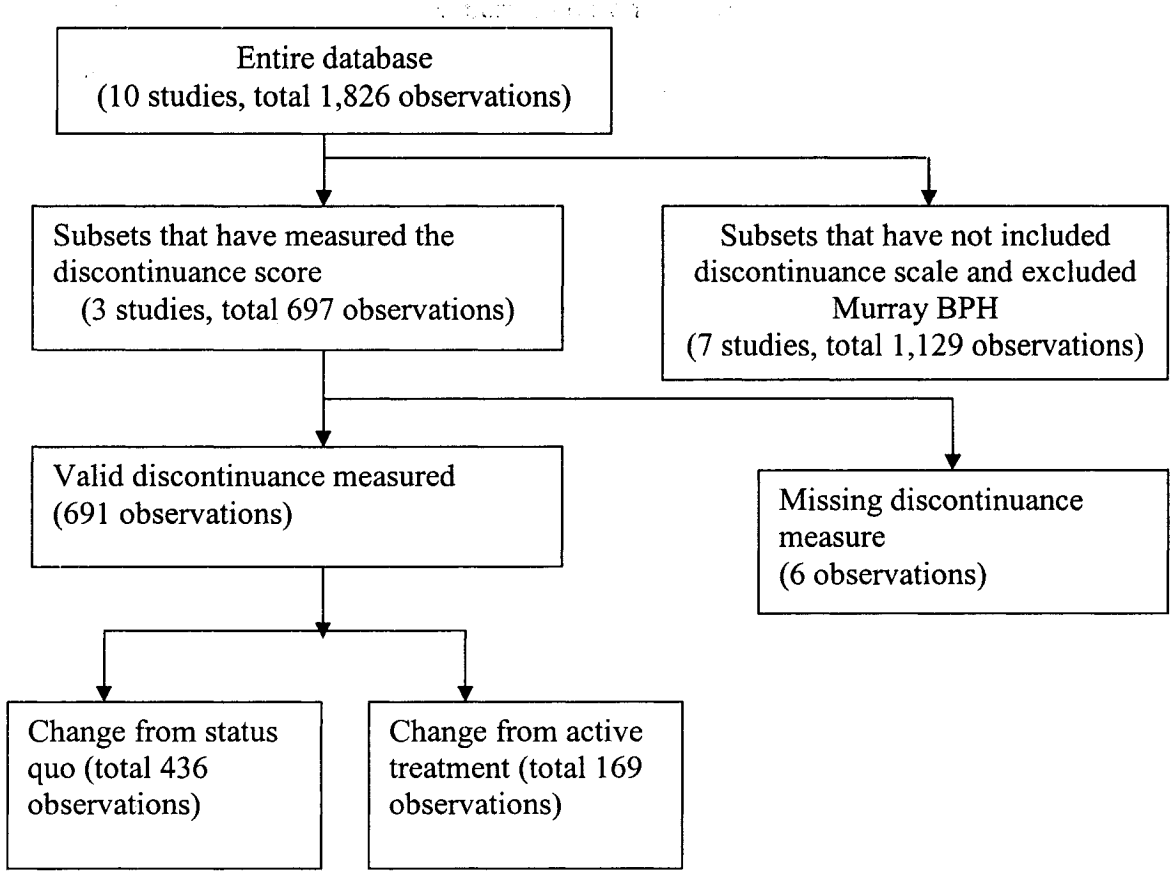


Table 3.3.1 Characteristics of the studies in the discontinuance dataset

No.	Study Name	Design	Focus	Time of Measurement	
				Second decision	**DCS & First decision**
1	O'Connor Unpublished [10]	RCT	Hormone therapy	9 month	Post counselling
2	Mon Son Hing [13]	RCT	Atrial fibrillation	6 month	Post counselling
3	Murray HRT [18]	RCT	Hormone therapy	9 month	3 month post counselling

3.3.2 Descriptive statistics

Table 3.3.2 contains the descriptive statistics of the dataset. As can been seen from the table, for those who initially chose to maintain status quo, with time elapsing, the chance of discontinuing the status quo treatment is rare (2% to 7%); for those people who initially chose to take active treatment, a small proportion of them chose not to continue on with the active treatment (11% to 33%).

Table 3.3.2 Descriptive statistics of the variables in the discontinuance dataset

Type	Sources	Discontinuance			DCS		
		N	Discontinuance	No Discontinuance	N	Mean	Std. Dev
1 Change from status quo*	No hrt (unpublished)	84	2 (2%)	82 (98%)	84	2.02	0.50
	No hrt (Murray HRT)	67	5 (7%)	62 (93%)	62	2.56	0.53
	Aspirin (Man Son Hing)	231	12 (5%)	219 (95%)	224	1.66	0.46
2. Change from active treatment **	Taking hrt (unpublished)	48	16 (33%)	32 (67%)	48	1.95	0.52
	Taking hrt (Murray HRT)	69	14 (20%)	55 (80%)	68	2.51	0.56
	Taking warfarin (Man Son Hing)	27	3 (11%)	24 (89%)	27	1.66	0.42

* change from status quo means discontinuance from previous conservative treatment. In two HRT trials, it means discontinuance from not taking HRT, while in Man Son Hing's study, it means change from taking aspirin.
**change form active treatment means discontinuance from previous aggressive treatment. In two HRT trials, it means discontinuance from taking HRT, while in Man Son Hing's study, it means change from taking warfarin.

3.3.3 Correlation analysis

The point-biserial correlation analyses of the changes of treatment and the total DCS score are displayed in Table 3.3.3. Among these, changes from active treatment consistently have higher correlation coefficients and most of them are statistically significant.

Table 3.3.3 Point-biserial correlation of the discontinuance dataset

Subset		N	Point biserial r	P
1. change from status quo	O'Connor unpublished	84	.19	.05
	Murray HRT	62	.40	.001
	Man Son Hing	224	-.06	.33
2. change from active treatment	O'Connor unpublished	48	.33	.02
	Murray HRT	68	.20	.09
	Man Son Hing	27	.34	.05

3.3.4 Meta-analysis

The meta-analysis excludes the Man Son Hing study because there was a SAS software warning message that quasi-complete separation. Quasi-complete separation means that the dependent variable has one category with a zero observation; when this happens, maximum likelihood estimates do not exists, and the result printed by SAS PROC LOGISTIC should not be used. Therefore, only two HRT trials are combined, and two sub-analyses are performed.

3.3.4.1. Change from status quo

Change from status quo means no longer classifying oneself as 'not taking HRT. Table 3.3.4 is the log odds ratios and odds ratios of the two HRT trials included and common estimate.

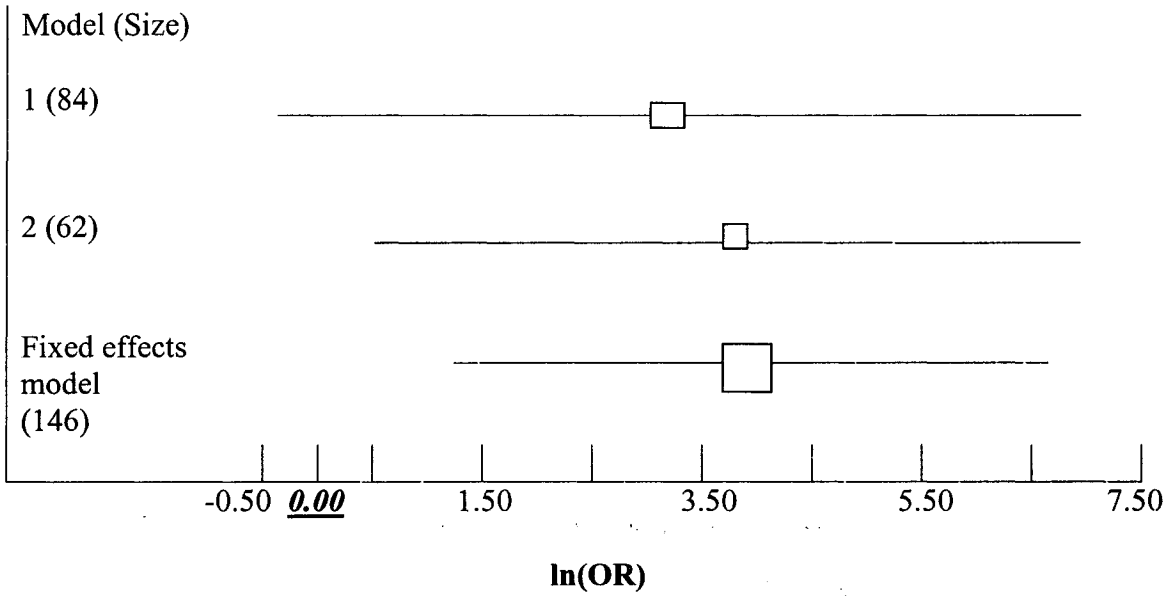
Table 3.3.4 Log odds ratio of the change from status quo sub-dataset

Study	Ln(OR) (95% CI)	OR (95% CI)	P
1. O'Connor unpublished	3.76 (-0.37-6.91)	42.94 (0.69- >999.99)	.07
2. Murray HRT	4.30 (0.71-6.91)	73.70 (2.03- >999.99)	.02
Fixed effects model	4.08 (1.41-6.76)	59.15 (4.10-862.64)	.003

The deviance of the model with the interaction term is 32.877 (df=2), while the model with interaction is 32.840 (df=3), the chi-square statistic 0.037 with 1 degree of freedom has p >0.1, so the there is a lack of evidence that these two HRT are not homogenous, and the fixed effects model yields the common log odds ratio of 4.08 (95% CI 1.41-6.76).

Figure 3.3.2 is the forest plot. The two lines are mostly overlapping with each other, showing the homogeneity between the two studies.

Figure 3.3.2 Forest plot of discontinuance from status quo



3.3.4.2 Change from active treatment

Change from active treatment means change from taking HRT in these two HRT trials. Table 3.3.5 shows the study-specific and common log odds ratios and odds ratios.

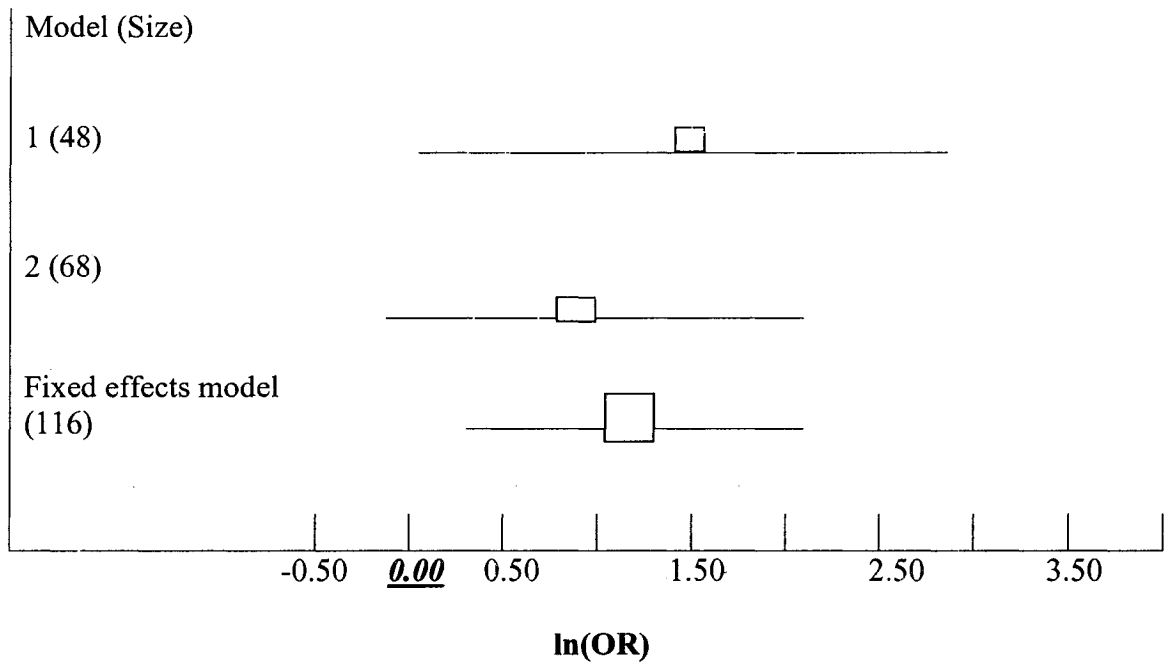
Table 3.3.5 Log odds ratio of the change from active treatment sub-dataset

Study	ln(OR) (95% CI)	OR (95% CI)	P
1. O'Connor unpublished	1.61 (0.16-3.06)	5.00 (1.17-21.33)	.03
2. Murray HRT	0.96 (-0.149-2.07)	2.61 (0.86-7.92)	.09
Fixed effects model	1.22 (0.35-2.08)	3.39 (1.42-8.00)	.006

For common log odds ratio, the deviance for the model without interaction term is 121.757 (df=2), and the deviance with interaction term is 121.253(df=3), chi-square statistic is 0.504 with 1 degree of freedom p-value>0.10, so there is lack of evidence that they are not homogenous and the fixed effects common log odds ratio is 1.22 (95% CI 0.35-2.08).

Figure 3.3.3 is the forest plot, also showing the homogeneity between the two HRT trials.

Figure 3.3.3 Forest plot of discontinuance from active treatment



3.3.5 Summary

For the two HRT studies, people who originally chose active treatment – taking HRT are more likely to change their mind (change rate: O'Connor unpublished: 33%, Murray HRT: 20%) than people who originally chose status quo - not to taking HRT (change rate: O'Connor unpublished: 2%, Murray HRT: 7%).

From the correlation analyses, in general, the change from status quo and the change from active treatment are statistically significantly correlated with the total DCS score.

From meta-analyses, the total DCS score shows strong association with the change from status quo (OR 59.15; 95% CI 4.10-862.64) and fair association with the change from active treatment (OR 3.39; 95% CI 1.42-8.00).

3.4 Regret vs the total DCS score study

This study focused on the association between the regret binary variable and the total DCS score.

3.4.1 Generation of the regret dataset

There are 4 studies that measured the regret scale. Figure 3.4.1 is the formation of the regret dataset and Table 3.4.1 is the details of these 4 studies.

Figure 3.4.1 Generation of the regret dataset

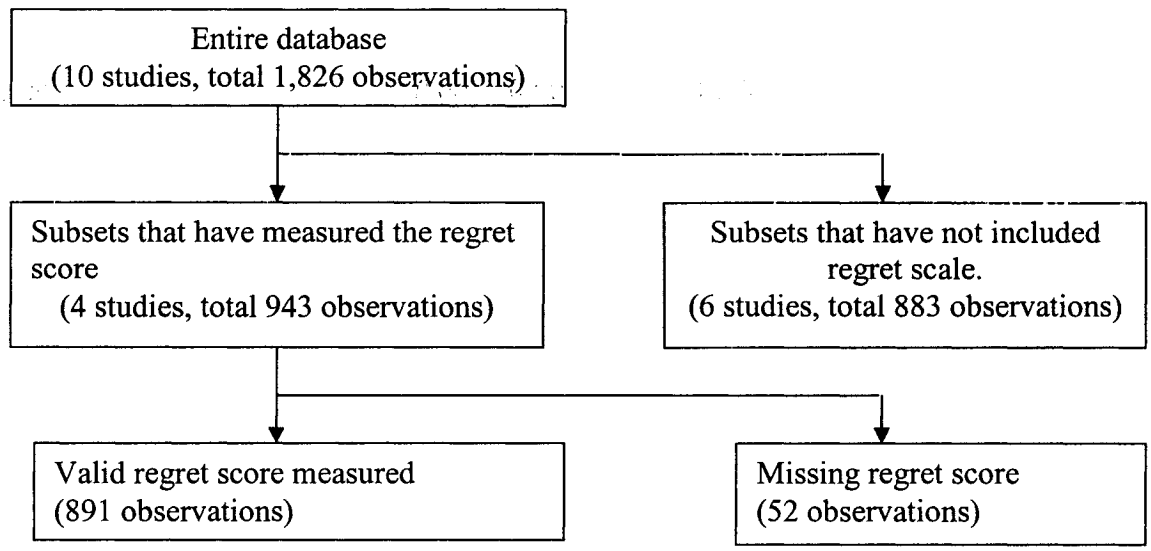


Table 3.4.1 Characteristics of the studies in the regret dataset

No.	Study Name	Design	Focus	Time of Measurement	
				Regret	DCS
1	O'Connor Unpublished [10]	RCT	Hormone therapy	9 month post	Post counselling
2	Mon Son Hing [13]	RCT	Atrial fibrillation treatment	6 month post	Post counselling
3	Feldman [15]	Before/ After	Prostate cancer treatment	3 month post	Post counselling
4	Siminoff [16]	Before/ After	Breast cancer adjunct therapy	3 month post	Post counselling

3.4.2 Descriptive statistics of the regret dataset

The continuous regret score is converted to binary score using a cut off of 2 out of 5. That is, for a regret score larger than 2, it is coded as 1, indicating having regret, and a regret score less or equal to 2 is coded as 0, indicating having no regret. Table 3.4.2 presents descriptive statistics for the regret dataset. With the exception of O'Connor unpublished study, all other studies did not have a high rate of regret (from 6% to 11%), while O'Connor unpublished study has a slighter higher rate of regret (33%).

Table 3.4.2 Descriptive statistics of the regret dataset

Study	Regret Score					DCS		
	N	Continuous		Binary		N	Mean	SD
		Mean	SD	Regret	No regret			
O'Connor unpublished	177	1.92	0.68	58	119	184	2.14	0.54
				33%	67%			
Man Son Hing	271	1.65	0.48	15	256	277	1.68	0.47
				6%	94%			
Feldman	56	1.68	0.47	6	50	56	2.72	0.36
				11%	89%			
Siminoff	387	1.63	0.51	39	339	384	2.02	0.47
				10%	90%			

3.4.3 Correlation

The Pearson r correlation coefficient between the regret score and the total DCS score and the point-biserial correlation coefficient are given in the Table 3.4.3. In most studies, regret is significantly correlated with the total DCS score (except Man Son Hing's study).

Table 3.4.3 Correlation coefficient of the regret dataset

Study	N	r	Point-biserial *	p
O'Connor unpublished	177	.52	.42	<.0001
Man Son Hing	262	.09	.07	0.13
Feldman	56	.32	.14	0.02
Siminoff	378	.39	.22	<.0001

r: Pearson correlation coefficient
*point-biserial correlation coefficient

3.4.3 Meta-analysis

Using SAS logistic regression procedure, taking the regret binary variable as the dependent variable and the total DCS score as the independent variable, the log odds ratio is obtained from the outputs. Table 3.4.4 shows the study-specific and common log odds ratios and odds ratios.

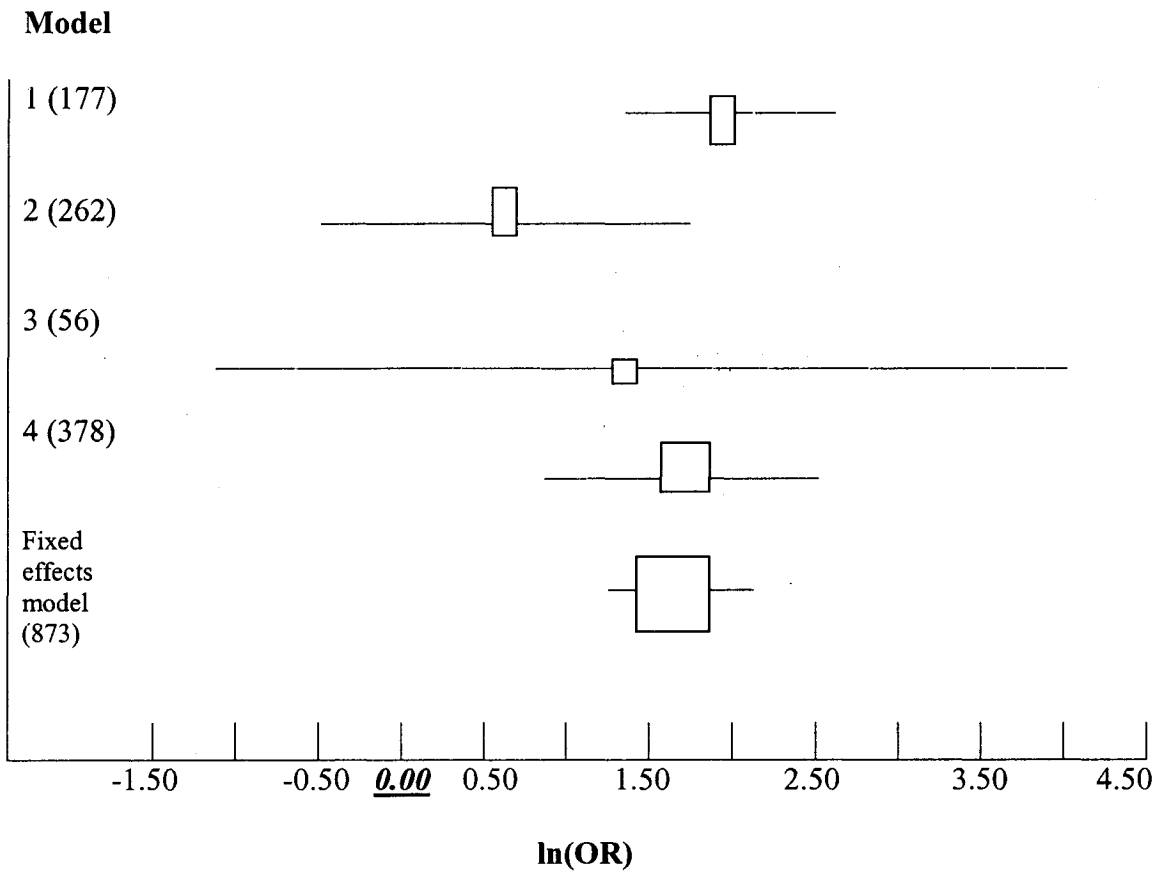
Table 3.4.4 Log odds ratio of the regret dataset

Study	ln(OR) (95% CI)	OR (95% CI)	P value
1. O'Connor unpublished	2.09 (1.28-2.89)	8.08 (3.60-18.00)	<0.0001
2. Man Son Hing	0.63 (-0.54-1.81)	1.88 (0.58-6.11)	.29
3. Feldman	1.51 (-1.16-4.18)	4.53 (0.31-65.37)	.27
4. Siminoff	1.76 (0.92-2.60)	5.81 (2.51-13.46)	<0.0001
Fixed effects model	1.71 (1.21-2.21)	5.53 (3.35-9.12)	<0.0001

The model without interaction's deviance is 568.830 (df=4), while the model with interaction term has deviance of 564.874 (df=7), with chi-square statistics of interaction is 3.956 (df=3, p-value > 0.10), which means there is a lack of evidence that the study variable is an effect modifier here. The fixed effects model gives out common log odds ratio of 1.71 (95% CI 1.21-2.21).

Figure 3.4.2 is the forest plot of this meta-analysis. The graph shows the confidence intervals of the studies are overlapping with each other, indicating that the studies are homogenous.

Figure 3.4.2 Forest plot of the regret dataset



3.4.5 Sensitivity analysis

For intervention group, the test of interaction (chi-square test of interaction is 0.80 (df=3), p>0.10) shows that there is lack of evidence that the four intervention groups are not homogenous, therefore, the fixed effects model gives out the common log odds ratio of 1.61 (95% CI 1.02-2.20).

For only two control groups in the four studies (for the four studies in the regret dataset, only two RCT studies have control groups, the other two before/after trails were

treated as having intervention group only), the test of interaction (chi-square test of interaction is 5.633 (df=1), $p<0.10$) shows the interaction is statistically significant, thus the random effects model should be used. The common log odds ratio is hard to get for these two control groups because the t test random effects approximation is applied only to situations where more than two studies are involved [46]. But here as it is a sensitivity analysis, so we use the fixed effect model to get a sense of the effects, and the fixed effects log odds ratio is 1.90 (95% CI 0.93-2.87).

3.4.6 Summary

The Pearson correlation coefficient for the regret score (continuous) and the DCS score and the point-biserial correlation coefficient for the regret binary variable and the total DCS score yielded similar results, with coefficients ranging from 0.07 to 0.52., Although a relatively big interval, the correlation between the regret scale and the total DCS score is statistically significant for most studies.

The study-specific logistic regressions show that in two out four studies in the dataset the DCS is a statistically significant predictor of decisional regret. The fixed effects model is used to get the common estimate, for one unit increase of the total DCS score, the odds of having regret increase 5.52 fold, and could be as low as 3.35 and as high as 9.12 with 95% confidence, so the meta-analysis shows that the association between the regret and the DCS is strong.

Sensitivity analysis shows that the log odds ratio from the fixed effects model for the intervention group is 1.61 (95% CI 1.02-2.20), very similar to the common log odds ratio of the combined analysis of intervention group and the control group (ln(OR)1.71; 95% CI 1.21-2.21). This similarity might be caused by significantly larger number of

observations in intervention groups (n=655) than the number of observations in the control groups (n=218).

Linear regression models with the regret interval scale as the dependent variable and the total DCS score as the independent variable had similar results as the logistic regression models using the dichotomized regret score.

3.5 Overview of major results

The major findings of the thesis were summarized in Table 3.5. The strongest associations with the DCS include delay and change from the status quo, followed by decisional regret, knowledge and change from active treatment.

Table 3.5 Summary of the major results

Predictor	**Response**	**OR (95% CI)**
Uninformed	Knowledge	3.10 (1.58-6.05)
DCS	Delay	23.81 (4.66-121.51)
DCS	Change from status quo	59.37 (4.09-861.05)
	Change from active treatment	3.39 (1.42-8.00)
DCS	Regret	5.52 (3.35-9.12)

Chapter 4 Discussion

4.1 The DCS uninformed subscale as a predictor of knowledge

As expected, the uninformed subscale of the DCS was inversely correlated to knowledge test score, which means that people who feel more informed will have higher levels of knowledge. The correlation coefficients, however, were not very high. For example, for O'Connor 1998 HRT study, which had the lowest coefficient, further analysis showed that some patients who scored extremely high in the uninformed subscale actually had quite good knowledge tests score (study ID 1160, uninformed score=5.00, knowledge test=65; study ID 3060, uninformed score=4.33, knowledge test=94; study ID 3087, uninformed score=4.00, knowledge test=65); while for those patients (n=47) who scored extremely low in the uninformed subscale (<=2), 42 of 47 actually scored very poorly in the knowledge test (less or equal to 50 out of 100 in the knowledge test).

Several factors might contribute to the poorer than expected correlation. Patients might feel that they should report being informed after treatment intervention, even in fact they haven't fully understood the content yet. Second, people responding to the questions in the uninformed subscale may have been referring to different aspects of knowledge than what was actually tested in the knowledge score. Finally, the studies may be picking up over-confidence in many people, but under-confidence in a subset who feel they do not possess enough information.

Heterogeneity among the individual studies may be due to variation in study population, intervention, design, and study quality. Moreover, the increase in the number of studies increases the chance of statistically detecting heterogeneity. When performing

the meta-analysis on the knowledge dataset, an interaction between the study variable and the uninformed subscale was detected. The most outstanding factor contributing to the heterogeneity was the difference in study populations, that is, a knowledge test in an HRT trial is hardly similar with a knowledge test in an non-HRT trail. For example, the second study - O'Connor 1998 HRT, the average knowledge test score is not bad (74.07), while the average patients' uninformed subscale is the highest (2.01), indicating most patients think they need more information; the fourth study in the dataset – Man Son Hing's Atrial Fibrillation, on average the uninformed subscale is extremely low (1.71), indicating most patients think their knowledge of the disease is enough while in fact their knowledge score is relatively low (70.60), if compared with O'Connor 1998 HRT trial.

The main conclusion to draw from these results is that the uninformed scale of the DCS is not a good proxy for knowledge. Practitioners cannot assume that low scores on the DCS correspond to high knowledge. Therefore, it is important to verify any patient statements of feeling informed or uninformed with an assessment of what they know.

4.2 The DCS as a predictor of delay

As expected, the total DCS scores were strongly associated with decisional delay regarding whether or not to take a medication. The chance of delay is positively correlated with the total DCS score, meaning that the lower total DCS score the lower chance of decision delay.

Heterogeneity was also detected when performing the meta-analysis on this delay dataset. The most obvious factor is the different study population, To be specific, patients in an HRT trial will behave differently about the decisional delay of their treatment choice from patients in a non-HRT trial. For example, for the four HRT trials, there are

relatively consistently proportion of study population who is not able to make a treatment decision (from as low as 21% to as high as 36%), while in Man Son Hing's atrial fibrillation, only a very small proportion (3%) of the patients who couldn't make their treatment choice. The second probable factor is regarding the four HRT trials. Even they are of same study population, the difference in where the trial was taken place might cause the between study variation. Finally, the skewed distribution in the population may have affected the correlations. Therefore, lower coefficients can be expected with low rates of delay (Man Son Hing) compared to much higher rates of delay (Dodin). The conclusion from this study is that the DCS is a strong predictor of decision delay. The implication is that if clinicians find that patients have unresolved decisional conflict after decision aids and counselling, they can expect that a patient is likely to delay their decisions. They may wish to try different strategies to resolve decisional conflict, such as providing more information, helping to clarify personal values, and helping to find support for decision making.

4.3 The DCS as a predictor of discontinuance of chosen option

As expected, the DCS was correlated with discontinuing chosen options. The patients who initially chose to remain in the status quo were most likely to stick with their decision, with the lowest discontinuance rate and the DCS is an excellent predictor of those who will change their minds.

For patients who initially chose to take active treatment, a small portion (11%-33%) of them would change their decision after several months. The DCS is a fair predictor that a patient will discontinue active treatment. The heterogeneity is not

detected in this meta-analysis, because only 2 studies were analysed (fewer study number means less chance of detecting heterogeneity) and the studies focused on the same decision (HRT).

The reason for the difference in the DCS's prediction of changing one's mind from an active treatment choice versus a status quo choice is not clear. It may be that events following the decision to take HRT overshadowed any decisional uncertainty influences on changes (e.g. the benefits or side effects the patients experienced from taking HRT). In contrast, there were no dramatic consequences (benefits or side effects) with the decision to maintain the status quo and the uncertainty around the decision to forgo HRT had a greater influence on subsequent changes in the decision.

4.4 The DCS as a predictor of regret

As expected, lower decisional conflict was strongly associated with lower decisional regret. The homogeneity of the studies indicates that the association between the regret scale and the DCS is stable across different patients population. Also, the relatively small study number (4) means less chance of detecting heterogeneity.

The lower correlation in Man Son Hing's study might result from the outstandingly low average DCS scale of this study (mean total DCS score=1.68), while the normally average DCS score after intervention is around 2. Feldman study's statistically insignificant result (p=0.27) might be caused by relatively small sample size (n=56).

4.5 Study Limitations

Because meta-analysis is the combination of data from several studies to produce a single common estimate, the major limitation of this combined analysis is that one study may have a profound influence on the conclusions [48]. Moreover, the results from this analysis may be applied only populations that are similar to those that were included in this analysis.

Another limitation is relatively small number of studies recruited. Although we tried to include all the studies done to date, at most only 6 studies are combined in a meta-analysis and most of them are HRT trials.

The third limitation is that some studies used slightly different versions of the DCS.

4.6 Further research

This meta-analysis introduces several topics for future studies. First, because of the subtle nature of random effects modeling and lack of trustworthy software even in the hands of experienced statistical researchers [49], only simple non-parametric random effects models for the log odds ratio were used. Hence the predictive performance of the DCS in terms of ROC curves or other measures of predictive performance were not meta-analyzed. In the future more complex random effects models for the log odds ratio and various measures of predictive performance need to be undertaken.

Second, to better understand the relationship between the knowledge test and the uninformed subscale, the relationship between the change of the uninformed subscale of the DCS and the change of knowledge test score should be further studied.

Third, with the emergence of more studies on the DCS, it certainly will be very helpful to continue recruiting more studies for the meta-analysis, in order to expand to more patient population and to increase statistical power as well. The latest figure shows that there are around 30 eligible DCS studies identified.

Fourth, the exploration of the association between the DCS and other downstream effects, such as dissatisfaction with medical decision, also could become an interesting subject for future research.

4.7 Implications

Clinicians using the uninformed subscale of the DCS should not use it as a proxy for knowledge. They should probe patients' knowledge of the facts about options and then provide feedback on the match between the patient's perception and their actual knowledge.

The DCS shows promise as a strong predictor for decision delay, regret, and changing decisions to forgo treatment such as HRT; it is a fair predictor of decisions to discontinue HRT. With further validation from other studies, clinicians may have a better sense of the consequences of unresolved decisional conflict.

From a theoretical perspective, this thesis provided more data on the performance of the scale, especially its validty as a predictor of important outcomes such as decision delay, discontinuance and regret.

4.8 Conclusion

When clinicians assess a patients' decisional conflict after counseling, and they find the decisional conflict is low, they can be reasonably assured that the likelihood of downstream decision delay, regret, and change from status quo decisions will be low. However, low decisional conflict may not guarantee a low likelihood of discontinuing and active treatment. Moreover, low scores on the uninformed scale do not guarantee the patient is well informed; clinicians need to validate the patients' understanding with some follow-up questions.

Chapter 5 Reference

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Chapter 6 Appendices

Appendix A-1 Condition Specific (HRT) Decisional Conflict Scale

Now, thinking about the choice [you just made, you are about to make] please look at the following comments made by some people made when making decision.

Please show how strongly you agree or disagree with these comments by CIRCLING THE NUMBER from 1 (strongly agree) to 5 (strongly disagree) which best shows show how you feel about the choice [you just made, you made, you are about to make].

1	This decision is easy for me to make	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
2	I'm sure what to do In this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
3	It's clear what choice Is best for me	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
4	I'm aware of the choices I have to [reduce my risk of] heart disease and osteoporosis	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
5	I feel I know the benefits of [hormone therapy]	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
6	I feel I know the risks and side effects of [hormone Therapy]	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
7	I have enough advice and information about the choices	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
8	I know how important the benefits are to me in this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree

9	I know how important the risks and side effects are To me in this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
10	I know which is more important to me (the benefits or the risks)	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
11	I am making this choice without any pressure from others	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
12	I have the right amount Of support from others in making this choice	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
13	I feel I have made an informed choice	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
14	My decision show what is important to me	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
15	I expect to stick with my decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
16	I am satisfied with my decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree

 This version was taken from the hormone replacement therapy group trial; instructions to participants differed slightly between groups.

Appendix A-2: The items of the DCS used in the 10 studies

Note: Each items used 5 Likert Scale from strongly agree (1) to strongly disagree (5) as shown on the generic DCS.

Study 1: O'Connor unpublished

1. S3: This decision is easy for me to make
2. S3: I'm sure what to do in this decision
3. S3: It's clear what choice is best for me
4. S3: I'm aware of the choices to reduce my risk of heart disease and osteoporosis
5. S3: I feel I know the benefits of hormone therapy
6. S3 I feel I know the risks & side effects of hormone therapy
7. S3: I have enough advice and information about the choices
8. S3: I know how important the benefits are to me in this decision
9. S3: I know how important the risks and side effects are to me in this decision
10. S3: I know which is more important to me (the benefits or the risks)
11. S3: I am making choice without any pressure from others
12. S3: I have right amount of support from others in making this choice
13. S3: I feel I have made an informed choice
14. S3: My decision shows what is important to me
15. S3: I expect to stick with my decision
16. S3: I am satisfied with my decision

Study 2: O'Connor 1998

1. This decision is easy for me to make
2. I'm sure what to do in this decision
3. It's clear what choice is best for me
4. I'm aware of the choices to reduce my risk of heart disease and osteoporosis
5. I feel I know the benefits of hormone therapy
6. I feel I know the risks & side effects of hormone therapy
7. I have enough advice and information about the choices
8. I know how important the benefits are to me in this decision
9. I know how important the risks and side effects are to me in this decision
10. I know which is more important to me (the benefits or the risks)
11. I am making choice without any pressure from others
12. I have right amount of support from others in making this choice
13. I feel I have made an informed choice
14. My decision shows what is important to me
15. I expect to stick with my decision
16. I am satisfied with my decision

Study 3: Laupacis

1. This choice is easy for me to make.
2. I'm sure what to do in making this choice.
3. It's clear which choice is best.
4. I'm aware of the options I have in making this choice.
5. I feel I know the advantages of volunteer-donated blood.
6. I feel I know the advantages of self-donated blood.
7. I feel I know the disadvantages of volunteer-donated blood.
8. I feel I know the disadvantages of self-donated blood.
9. I am clear about how important advantages of self-donated blood are to me.
10. I am clear about how important disadvantages of self-donated blood are to me.
11. I am clear which is more important to me (the advantages or the disadvantages).
12. I am making this choice without pressure from others.
13. I have the right amount of support from others in making this choice.
14. I have enough advice about the options.
15. I have made an informed choice.
16. My choice shows what is important to me.
17. I expect to stick with my choice.
18. I am satisfied with my choice.

Study 4: Man Son Hing

1. This decision was easy for me to make
2. I was sure what to do in this decision
3. It was clear what choice was best for me
4. I was aware of the choices I had to reduce my risk of stroke from atrial fibrillation
5. I feel I knew the benefits of taking coated aspirin
6. I feel I knew the benefits of taking warfarin
7. I feel I knew the risks and side effects of taking coated aspirin
8. I feel I knew the risks and side effects of taking warfarin
9. I had enough advice and information about the choices
10. I was clear about how important stroke reduction was to me in this decision
11. I was clear about how important the risks and side effects of coated aspirin were to me in this decision
12. I was clear about how important risks and side effects of warfarin to me in this decision
13. I was making this choice without any pressure from others
14. I had the right amount support from others in making choice
15. I feel I made an informed choice
16. My decision shows what is important to me
17. I expect to stick with my decision
18. I am satisfied with my decision

Study 5: Dodin

1. This decision is easy for me to make
2. I'm sure what to do in this decision
3. It's clear what choice is best for me
4. I'm aware of the choices to reduce my risk of heart disease and osteoporosis
5. I feel I know the benefits of hormone therapy
6. I feel I know the risks & side effects of hormone therapy
7. I have enough advice and information about the choices
8. I know how important the benefits are to me in this decision
9. I know how important the risks and side effects are to me in this decision
10. I know which is more important to me (the benefits or the risks)
11. I am making choice without any pressure from others
12. I have right amount of support from others in making this choice
13. I feel I have made an informed choice
14. My decision shows what is important to me
15. I expect to stick with my decision
16. I am satisfied with my decision

Study 6: Feldman (from data file)

1. q.#1 DCS - decision hard to make (end of first interview)
2. q.#2 DCS - unsure of what to do (end of first interview)
3. q.#3 DCS - clear what choice is best for me (end of first interview)
4. q.#4 DCS - aware of the choices I have (end of first interview)
5. q.#5 DCS - benefits of each treatment (end of first interview)
6. q.#6 DCS - know risks and side effects of tx (end of first interview)
7. q.#7 DCS - need more advice and information (end of first interview)
8. q.#8 DCS - know how important benefits of tx are (end of first interview)
9. q.#9 DCS - know how important risks of tx are (end of first interview)
10. q.#10 DCS - hard to decide if benefits more imp than risks or... (end of first interview)
11. q.#11 DCS - feel pressure from others (end of first interview)
12. q.#12 DCS - right amount of support from others (end of first interview)
13. q.#13 DCS - informed choice (end of first interview)

Study 7: Siminoff (from data file)

1. decision is hard for me to make
2. unsure what to do regarding this decision
3. it's clear what choice is best for me
4. aware of choices to reduce risk of recurrence
5. feel I know the benefits of taking more therapy
6. feel I know the risks and side effects of taking more treatment
7. need more advice and information about my treatment choices
8. know how important the benefits are to me in this decision

9. know how important the risks and side effects are to me
10. hard to decide which are more important to me, risks or benefits
11. feel pressure from others in making this decision
12. have the right amount of support from others in making this choice
13. feel I have made an informed choice
14. my decision shows what is most important to me
15. expect t stick with my decision
16. am statisfied with my decision

Study 8: Morgan

1. This decision is hard for me to make
2. I'm unsure what to do in this decision
3. It's clear what choice is best for me
4. I'm aware of the choices I have to treat my heart condition
5. I feel I know the benefits of each treatment
6. I feel I know the risks and side effects of each treatment
7. I need more advice and information about the choices
8. I know how important the benefits of the treatment options are to me in this decision
9. I know how important the risks and side effects of the treatment options are to me in this decision
10. It is hard to decide if the benefits are more important to me than risks, or if the risks are more important than the benefits
11. I feel pressure from others in making this decision
12. I have the right amount of support from others in making this decision
13. I feel I have made an informed decision
14. My decision shows what is most important for me
15. I expect to stick with my decision
16. I am satisfied with my decision

Study 9: Murray HRT

1. This decision was hard for me to make
2. I was unsure what to do in this decision
3. It was clear what choice was best for me
4. I was aware of the choices I had when thinking about potential therapy and the alternatives available
5. I felt I knew the benefits of Hormone Replacement Therapy
6. I felt I knew the risks and side-effects of Hormone Replacement Therapy
7. I needed more advice and information about the choices
8. I knew how important the benefits were to me in htis decision
9. I know how important the risks and side-effects were to me in this decision
10. It was hard to decide if the benefits were more important to me than the risks, or if the risks were more important than the benefits
11. I felt pressure from others in making this decision

12. I had the right amount of support from others in making this choice
13. I feel I have made an informed choice
14. My decision shows what is most important for me
15. I expect to stick with my decision
16. I am satisfied with my decision

Study 10: Murray BPH

1. This decision was hard for me to make
2. I was unsure what to do in this decision
3. It was clear what choice was best for me
4. I was aware of the choices I had to relieve symptoms caused by the prostate
5. I knew the benefits of drug or surgical treatment
6. I knew the risks and side effects of drug or surgical treatment
7. I needed more advice and information about the choices
8. I know how important the benefits were to me in this decision
9. I know how important the risks and side-effects were to me in this decision
10. It was hard to decide if the benefits were more important to me than the risks or if the risks were more important than the benefits
11. I felt pressure from others in making this decision
12. I have the right amount of support from others in making this choice
13. I feel I have made an informed choice
14. My decision shows what is most important for me
15. I expect to stick with my decision
16. I am satisfied with my decision

Appendix B: Knowledge Questionnaire

Study 1: O'Connor unpublished

The 20-item questionnaire using a true/false/unsure response format. The tool measured the women's recognition of the major benefits, risks, and side effects. The total score then converted to a percentage scale. High score means better knowledge.

1. Hormone therapy can be given:			
Early in menopause	True	False	Unsure
Well past the menopause	True	False	Unsure
For 10-20 years	True	False	Unsure
2. Benefits of taking long-term hormone therapy are:			
Protection from breast cancer	True	False	Unsure
Protection from broken hips from osteoporosis	True	False	Unsure
Protection from diabetes	True	False	Unsure
Protection from heart disease	True	False	Unsure
3. Risks of using long-term hormone therapy are:			
Increase risk of breast cancer	True	False	Unsure
Increase risk of broken bones from osteoporosis	True	False	Unsure
Increase risk of diabetes	True	False	Unsure
Increase risk of heart disease	True	False	Unsure
4. Some side effects of long-term hormone therapy are:			
Breast tenderness	True	False	Unsure
Fainting	True	False	Unsure
Irritability	True	False	Unsure
Bloating	True	False	Unsure
Hot flushes	True	False	Unsure
Headache	True	False	Unsure
Menstrual bleeding	True	False	Unsure
Insomnia (can't sleep)	True	False	Unsure
Weight gain	True	False	Unsure

Study 2: O'Connor 1998

The 17-item questionnaire using a true/false/unsure response format. The tool measured the women's recognition of the major benefits, risks, and side effects, which were described in both the decision aid and the pamphlet. The total score then translated to a percentage scale.

1. Benefits of taking long-term hormone therapy are:

Protection from breast cancer	True	False	Unsure
Protection from broken hips from osteoporosis	True	False	Unsure
Protection from diabetes	True	False	Unsure
Protection from heart disease	True	False	Unsure

2. Risks of using long-term hormone therapy are:

Increase risk of breast cancer	True	False	Unsure
Increase risk of broken bones from osteoporosis	True	False	Unsure
Increase risk of diabetes	True	False	Unsure
Increase risk of heart disease	True	False	Unsure

3. Some side effects of long-term hormone therapy are:

Breast tenderness	True	False	Unsure
Fainting	True	False	Unsure
Irritability	True	False	Unsure
Bloating	True	False	Unsure
Hot flushes	True	False	Unsure
Headache	True	False	Unsure
Menstrual bleeding	True	False	Unsure
Insomnia (can't sleep)	True	False	Unsure
Weight gain	True	False	Unsure

Study 3: Laupacis

A 15-item portion of the questionnaire tested patients' knowledge of information covered in the decision aid. Potential answers were "true", "false" and "unsure". One point was given for each correct response and zero for unsure or incorrect responses; answers were expressed as percent correct.

1. All patients having heart surgery are transfused.	True	False	Unsure
2. Transfusions replace blood lost during or after surgery.	True	False	Unsure
3. Patients losing a small amount of blood are transfused.	True	False	Unsure

4. Please indicate whether you think the following statements about volunteer-donated blood are true or false. Circle unsure if you are not sure.

a) It is convenient for the patient	True	False	Unsure
c) Serious complications are rare	True	False	Unsure
d) Infections may be transmitted by blood	True	False	Unsure
e) The wrong blood may be given in error	True	False	Unsure
f) Acquired Immune Deficiency Syndrome (AIDS) is a frequent complication.	True	False	Unsure

5. Please indicate whether you think the following statements about self-donated blood are true or false. Circle unsure if you are not sure.

a) It reduces the chance of contracting a viral disease such

as AIDS or hepatitis from transfusions. True False Unsure
b) There is a greater chance of receiving the wrong blood by error because more transfusions are given. True False Unsure
c) The blood that is not used can be used by another patient. True False Unsure
d) Donating blood may cause symptoms such as fainting or chest pain. True False Unsure
e) There is still a chance of receiving volunteer-donated blood. True False Unsure
f) No extra blood tests or trips to the Centre are required. True False Unsure

Study 4: Man Son Hing

Knowledge was tested using 23 questions about atrial fibrillation, stroke, and the advantages and disadvantages of taking warfarin or aspirin. These questions have responses in "true", "false", and "unsure.".

B. What I now know about atrial fibrillation and stroke

1. Having a stroke means that you have suffered some brain damage. True False Unsure
2. Having a stroke always means you will have to go to a nursing home. True False Unsure
3. Strokes only occur in people older than 80 years of age. True False Unsure
4. Atrial fibrillation is a disturbance of the rhythm of the heart. True False Unsure
5. Having artial fibrillation increases your chance of having a stroke. True False Unsure

C. What I now know about coated aspirin and warfarin

1. If you have atrial fibrillation, does taking coated aspirin:
   - Protect you from stroke? True False Unsure
   - Cure the atrial fibrillation? True False Unsure
   - Protect you from bleeding? True False Unsure
2. If you have atrial fibrillation, does taking warfarin:
   - Protect you from stroke? True False Unsure
   - Cure the atrial fibrillation? True False Unsure
   - Protect you from bleedings? True False Unsure
3. If you take coated aspirin:
   - It increases the chances of stomach pain and heartburn. True False Unsure
   - It increases the chance of severe bleeding. True False Unsure
   - You need to have regular blood testing. True False Unsure
   - You need to restrict alcohol intake. True False Unsure
   - You need to avoid activities that increase the chance of head injury. True False Unsure
   - You need to be aware that taking coated aspirin and certain antibiotics at the same time can lead to potentially dangerous side effects. True False Unsure

4. If you take warfarin:

It increases the chance of stomach pain and heartburn.	True	False	Unsure
It increases the chance of severe bleeding.	True	False	Unsure
You need to have regular blood testing.	True	False	Unsure
You need to restrict alcohol intake.	True	False	Unsure
You need to avoid activities that increase the chance of head injury.	True	False	Unsure
You need to be aware that taking warfarin and certain antibiotics at the same time can lead to potentially dangerous side effects.	True	False	Unsure

Study 5: Dodin

French version of the knowledge test regarding Hormone Replacement Therapy from Ottawa Health Research Institute. High score means better knowledge.

1. Benefits of taking long-term hormone therapy are:

Protection from breast cancer	True	False	Unsure
Protection from broken hips from osteoporosis	True	False	Unsure
Protection from diabetes	True	False	Unsure
Protection from heart disease	True	False	Unsure

2. Risks of using long-term hormone therapy are:

Increase risk of breast cancer	True	False	Unsure
Increase risk of broken bones from osteoporosis	True	False	Unsure
Increase risk of diabetes	True	False	Unsure
Increase risk of heart disease	True	False	Unsure

3. Some side effects of long-term hormone therapy are:

Breast tenderness	True	False	Unsure
Fainting	True	False	Unsure
Irritability	True	False	Unsure
Bloating	True	False	Unsure
Hot flushes	True	False	Unsure
Headache	True	False	Unsure
Menstrual bleeding	True	False	Unsure
Insomnia (can't sleep)	True	False	Unsure
Weight gain	True	False	Unsure

Study 6: Morgan

Totally 20 questions are used in measuring the understanding of the disease. Percentage scale is used.

10. Please read each statement carefully. Circle "T" for true, "F" for false, or if you are unsure of the answer, circle "?" (don't know). Please do not guess.

1. Coronary artery disease is caused by plaques (deposits) that block the blood vessels which surround and supply the heart muscle (the coronary arteries). T F
2. Coronary artery disease does not cause serious complications such as hear attack or death. T F
3. Coronary artery disease itself can be cured by a number of treatments including angioplasty and bypass surgery. T F
4. Most patients who choose ongoing medical therapy alone are often able to discontinue their medication after a few years. T F
5. Medical therapy is almost always successful in completely relieving angina. T F
6. By choosing medical therapy now, a person will be unable to have either bypass surgery or angioplasty in the future. T F
7. Possible side effects from medical therapy include fatigue, headache, decreased concentration and sexual dysfunction. T F
8. During surgery the blocked coronary arteries are bypassed, commonly using blood vessels from the leg and chest. T F
9. Most patients who undergo bypass surgery are hospitalized for fewer than 5 days. T F
10. Each treatment option carries with it some risks of stroke, heart attach or death. T F
11. After bypass surgery or angioplasty, "lifestyle" changes (eg. diet. Smoking cessation, regular exercise) are not as important as when medical therapy is used. T F
12. If bypass surgery "works" and patient has no angina 1 month later, this means that it is unlikely that the angina will ever return. T F
13. When compared with medical therapy, bypass surgery has a hinger risk of immediate complications (such as heart attack, stroke, or death). T F
14. Bleeding requiring a blood transfusion may occur with bypass surgery. T F
15. After bypass surgery some patients experience difficulty concentrating and some memory loss, which usually resolves. T F
16. Angioplasty is similar to an angiogram, but is a more complicated procedure which involves inflating a balloon to open up a blocked artery. T F
17. If angioplasty "works" and the patient has no angina 1 month later. This means that it is unlikely that the angina will ever return. T F
18. When compared with medical therapy, angioplasty has a higher risk of immediate complications (such as heart attack, stroke, or death). T F

19. Some angioplasty patients may require angioplasty or even bypass surgery in the future. T F

20. Occasionally an artery can be damaged during angioplasty and emergency bypass surgery is required. T F

Appendix C: Delay Variable

Delay data is collected from following studies and their corresponding questions:

Study 1: O'Connor unpublished

Questionnaire Set 3, section E: My Thoughts on the Best Choice for Me

Now that you have had a chance to talk to your physician about using long-term hormone therapy, which choice looks good for you?

1. Not using hormone therapy
2. Using hormone therapy
3. I'm not sure ---------- coded as delay

Study 2: O'Connor 1998

Questionnaire Section E: My thoughts on the best choice for me

If your doctor asked you to make a choice about using hormone therapy with the information you now have, which choice loos the best for you:

1. Not using hormone therapy
2. Using hormone therapy
3. I'm not sure ---------- coded as delay

Study 3: Laupacis

Post Questionnaire, Section C: My thoughts on the best choice for me

Now that you have had a chance to consider your options for blood transfusion, which choice looks the best for you?

1. Volunteer-donated blood
2. Self-donated blood (autologus)
3. I'm not sure ---------- coded as delay

Study 4: Man Son Hing

ALRCS Patient Preference Questionnaire

Question 2: After discussing your medical situation with your clinician, what choice of treatment was made to prevent stroke?

1. Continue on coated aspirin to prevent stroke
2. Take warfarin to prevent stroke
3. Unsure ---------- coded as delay

Study 5: Dodin

Second Questionnaire, Section E: My thoughts on the best choice for me

If your doctor asked you right now to make a choice about using hormone therapy with the information you now have, which choice looks the best for you:

1. Not using hormone therapy
2. Using hormone therapy
3. I'm not sure ---------- coded as delay

Study 6: Murray HRT

Second Questionnaire

Question 50: My choice of treatment is/was to:

1. Not use any form of HRT
2. Use HRT
3. I am still undecided ---------- coded as delay

Appendix D Discontinuance Variable

Discontinuance data is(are) derived from following 4 studies.

Study 1: O'Connor unpublished

Questionnaire Set 3 (post counselling), section E: My Thoughts on the Best Choice for Me

Now that you have had a chance to talk to your physician about using long-term hormone therapy, which choice looks good for you?

4. Not using hormone therapy
5. Using hormone therapy
6. I'm not sure

Questionnaire Set 5 (9 month after counselling), section E: My Decision About Hormones

1. Are you currently taking hormones?
    - Yes
    - No
    - Haven't decided yet

Study 2: Man Son Hing

ALRCS Patient Preference Questionnaire

Question 2: After discussing your medical situation with your clinician, what choice of treatment was made to prevent stroke?

4. Continue on coated aspirin to prevent stroke
5. Take warfarin to prevent stroke
6. Unsure

SPAF ALRCS Decision Aid: 6 Month Phone Follow-up

Question 2: Are you presently taking:

1. Coated aspirin
2. Warfarin
3. Other
4. Neither

Study 3: Murray HRT

Second Questionnaire (3 month follow-up)

Question 50: My choice of treatment is/was to:

4. Not use any form of HRT
5. Use HRT
6. I am still undecided

Final Questionnaire (9 month follow-up)

Question 50: My choice of treatment was to:

1. Not use any form of HRT
2. Use HRT
3. I am still undecided

Appendix E Decision Regret Scale

Please reflect on the [first decision that you made about hormone therapy after talking with your family physician]. Please show how strongly you agree or disagree with these statements by circling a number from 1 (strongly agree) to 5 (strongly disagree) which best fits your views about your decision.

1	It was the right decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
2	I regret the choice that was made	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
3	I would go for the same choice if I had to do it over again	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
4	The choice did me a lot of harm	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
5	The decision was a wise One	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree

 This version was taken from the hormone replacement therapy group trial; instructions to participants differed slightly between groups.