# Why values elicitation techniques enable people to make informed decisions about cancer trial participation

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# Abstract

**Background** Decision aids help patients make informed treatment decisions. Values clarification (VC) techniques are part of decision aids that help patients assimilate the information with their personal values. There is little evidence that these techniques contribute to enhanced decision making over and above the provision of good quality information.

**Objectives** To assess whether VC techniques are active ingredients in enhancing informed decision making and explain how and why they work.

**Methods** Participants were randomly assigned to one of three groups: (i) information only, (ii) information plus implicit task, (iii) information plus explicit task. Thirty healthy women from a UK University participated by making a hypothetical choice between taking part in a clinical trial and having the standard treatment for breast cancer. Verbal protocols were elicited by think-aloud method and content analysed to assess informed decision making; a questionnaire was completed after the decision assessing decision preference, perceptions of decisional conflict and ambivalence. Data were analysed using multivariate statistics.

**Findings** No participants changed their decision preference as a result of the VC techniques. Women in the explicit VC group evaluated more information in accord with personal values, expressed lower ambivalence, decisional uncertainty and greater clarity of personal values than those in the implicit VC and control groups. Feelings of ambivalence about both options were related to decisional conflict.

**Conclusion** Explicit VC techniques are likely to be active ingredients in decision aids. They work by enabling people to deliberate about the decision information in accord with their personal values, which is associated with a better decision experience.

# Introduction

Decision aids are interventions to help people make decisions in a better way than they do naturally.<sup>1</sup> In health care this means interventions to help patients make informed decisions about treatment options.<sup>2,3</sup> An informed decision requires patients to consider information about all the treatment options and their consequences with reference to their personal values, and make a choice based on a trade-off of these evaluations.<sup>2,4–6</sup> There are many screening and treatment choices for which there is clinical equipoise<sup>7</sup> and the patients' values are central to the choice of treatment.<sup>8</sup> In the context of (non) participation in clinical trials, enabling patients to make informed decisions is not only desirable but an ethical imperative.<sup>9</sup>

Decision aids are complex interventions<sup>10</sup> containing at least two component parts: (i) complete, accurate and non-biased information about the available options and their consequences and (ii) techniques eliciting patients' personal values about the decision's consequences to help them arrive at a choice.<sup>1,11</sup> The purpose of the values clarification component is to help people clarify how they feel about the different consequences of options, which consequences are relevant to their personal circumstances, and what trade-offs they need to make to arrive at a choice.<sup>1,12,13</sup> The techniques used for values clarification are broadly categorized into implicit or explicit approaches.<sup>14–16</sup> Implicit approaches structure the decision information in a way that clearly illustrates all options of the choice and their consequences, and encourage patients to consider how they feel about the options (e.g. decision boards, attribute tables). Explicit approaches also structure the information in a way that represents clearly the decision problem but include additional, proactive techniques requiring the patient to engage with the information by rating the degree to which the consequences matter to them.<sup>13,16</sup> The explicit techniques are varied with some using simple Likert or visual analogue scales (e.g. weigh scale exercise) to rate the personal importance of consequences

and some using more complex tasks such as rank ordering the importance of consequences and/or trading-off options or attributes (e.g. standard gamble).<sup>8,12,16-18</sup>

There is evidence that people using decision aids tend to employ more cognitive and emotional strategies, make more robust evaluations of decision information, have less regret, and express greater satisfaction with the decision.<sup>8,19,20</sup> However, evidence is lacking on what the component parts of the decision aid add to the intervention in order to enable better decision making. It is unclear if the values clarification techniques contribute to patients making more informed decisions over and above the improved content and structure of the information within decision aids.<sup>10,19</sup> If values clarification techniques are an active ingredient in the intervention, there is a paucity of evidence identifying whether different types of clarification techniques are more or less effective in different health contexts with decisions of varying complexity and patients with differing experiences and abilities.13,16

The information processing paradigm provides a framework to help us understand how people make sense of the 'information out there' with their cognitions and experiences 'inside'.<sup>4</sup> From this literature, we can hypothesize how the component parts of decision aids help people make better decisions.<sup>19,21,22</sup> For example, by structuring the decision problem as a tree and/or attribute table we provide a visual representation of all the options, attributes and consequences of the decision. This representation of the decision problem increases the likelihood of patients evaluating all the decision relevant information without having to rely on partial information provided by either the information provider and/or the patients' memory. An implicit values clarification statement signposts the need for patients to engage with and evaluate this full information, possibly enabling patients to employ more appropriately their intuitive or usual processes to reach the decision. An explicit values clarification task requires patients to deliberate consciously about their evaluations of the decision information

with their beliefs and provides steps which may help patients to integrate more fully the information 'out there' with values 'inside'.

There is debate as to whether encouraging patients to engage deliberatively and systematically with the decision information rather than relying on more intuitive processes to reach a decision helps or hinders decision making.<sup>23-25</sup> Some argue that by making explicit all the patients' decision processes their evaluation of the decision options and consequences will correspond more closely with their actual experience of decision consequences,<sup>5</sup> i.e. more thorough evaluations lead to more realistic expectations, less conflict with the decision made and a more satisfactory decision experience.<sup>11,19</sup> Others argue that consciously exploring the advantages and disadvantages of all the options increases the uncertainty patients feel towards the choice; the ambivalence generated whilst simultaneously holding both positive and negative evaluations of an option results in a worse decision experience.<sup>26</sup> As ambivalence and decisional conflict tend to be investigated independently, it is unclear how these concepts are related. It is likely that values clarification techniques encourage informed decision making but it is unclear how the increased deliberation impacts on perceptions of ambivalence and decisional conflict during decision making.

The purpose of this experimental study was to assess whether values clarification techniques are active ingredients in decision aid interventions, i.e. additions to a complex intervention over and above the provision of good quality information. In particular, the study aimed to (i) explain how and why these values clarification techniques enable people to make informed decisions, (ii) examine the relationship between ambivalence and decisional conflict, and (iii) assess the impact of increased deliberation on perceived decision experience. As this study is a proof of concept study, it was carried out in a sample of healthy women making a hypothetical choice between taking part in a clinical trial and having the standard treatment for their breast cancer.

# Methods

# Design

A between-subjects design with participants randomly assigned to one of three groups was employed: (i) routine information only (Control), (ii) routine information plus an implicit values clarification task (Implicit), (iii) routine information plus the explicit values clarification task (Explicit). The study employed qualitative and quantitative methods: a think-aloud technique employing verbal protocols that were audio tape-recorded concurrently with decision making, then transcribed and analysed using a thematic content analysis<sup>27-31</sup>; a paper-based questionnaire was completed immediately after participants had made a decision (not) to participate in the trial. The study had ethical approval from the Leeds Institute of Psychological Sciences Ethics Committee in July 2007.

# Sample

All women aged 18 years or older working and/or studying at the University of Leeds, UK, over August to October 2007 were invited to participate via the University's email distribution list. No women volunteering to participate were excluded. Studies employing think-aloud techniques often involve small sample sizes as the collection and analysis of verbal protocol data is time consuming and labour intensive.<sup>32,33</sup> Ten participants per study group, giving an overall sample size of 30, is comparable to the average sample size used in think-aloud studies.<sup>34</sup>

## Materials

# Breast cancer treatment clinical trial scenario

Participants were asked to imagine they had been diagnosed with early stage breast cancer, had had the lump removed by surgery and were discussing treatment options with their doctor, who suggested chemotherapy. Participants were told that the clinic was offering participation in a clinical trial, known by the acronym TACT (Taxotere as Adjuvant chemotherapy) and had to decide whether to take part in the trial or have the standard chemotherapy treatment (Appendix S1). TACT was an international phase-three chemotherapy trial for early stage breast cancer, carried out by the local cancer unit shortly before the time of the study.<sup>35</sup> To enhance the validity of the scenario, participants were asked to consider the impact this diagnosis would have on specific aspects of their life such as work, social life and daily chores<sup>36,37</sup> and/or recollect the experiences of any family and friends who had experienced cancer. All participants were provided with details of the University's counselling service and the hospital's clinical psychological services in case personal issues were raised as a result of taking part in this research.

# Routine decision information

The TACT trial and standard treatment routine information was contained in an A-4 size paperbased booklet and included purpose, details of treatments, possible side effects, benefits and risks. The information readability score was 8.0 (equivalent of an eighth grader/age 14 level).<sup>38</sup>

# Values clarification tasks

The values clarification tasks involved a paperbased summary of the benefits and risks information for both the options situated on either side of a weigh-scale as outlined by O'Connor et al.<sup>13</sup> The implicit task asked women to: (i) review this information; (ii) add any other reasons for choosing or not choosing the options in the space provided; (iii) underline the benefits and risks they thought were more likely to happen. In addition to the steps performed in the implicit task, the explicit task asked women to: (iv) indicate the extent to which each benefit and risk mattered to them using stars (zero stars if it did not matter at all and five if it mattered a lot); (v) indicate their leaning towards taking part in the trial or having the standard treatment on a seven-point scale (Appendix S2).

## Measures

Data were elicited by two methods, the thinkaloud method (qualitative) assessing informed decision making and a paper-based questionnaire (quantitative) assessing socio-demographic infor mation, decision preference and perceptions of decision making experience.

# Informed decision making

A coding frame (Fig. 1) was developed with reference to guidelines on making informed decisions to categorize participants' utterances resulting from the think-aloud method. An informed decision requires individuals to consider information about the consequences of all available options, to evaluate the likelihood and

Option	Attribut	les
Trial	Help oth Possible Addition Lack of f Extra sid effects, monitori New trea	iers, a) benefits, al visits, funding, Je effects, Unknown side Uncertain efficacy, Closer ng, Longer treatment, atment, Randomisation
Standard treatment	Effective No extra research No moni Known s No new Say in tr treatmen	e treatment, side effects, Hamper , itoring side effects, drugs, reatment, Shorter nt
b) Information proces strategies	sing	Example
Attribute referred to		Right if you decide to have the
(repeating or mentio the attribute)	ning	standard treatment there will be no opportunity to receive the new treatment. (No new drugs, just repeated)
(repeating or mentio the attribute) Attribute evaluated (judging the attribute good or bad)	ning e as	standard treatment there will be no opportunity to receive the new treatment. (No new drugs, just repeated) Yep access to treatment that not otherwise availablemm oh ok, that does soundpromising.(New treatment, evaluated as good)

**Figure 1** Think-aloud protocol analysis coding frame: (a) attributes of trial and standard treatment options, (b) categories classifying how the attribute information was processed.

Longer treatment, evaluated as bad for them)

desirability of those consequences in accord with his/her personal values, and make a choice based on trade-offs between these evaluations.<sup>2,4-6,19</sup> Themes were developed that classified the utterances about the information as attributes of standard and trial options. The resulting themes consisted of eleven trial attributes and eight standard treatment attributes (Fig. 1a). Within the themes, categories classified how the information was processed by participants: attributes referred to (either just repeating or mentioning the attribute); attribute evaluated (judging the attribute as a good or bad); attribute evaluated with reference to personal values (rating the attribute as being good or bad for them) (Fig. 1b). The coding frame was applied systematically to all protocols using the qualitative data management software NVivo 7 (QSR International Pty. Ltd. 2006). The data on the number of times the information processing strategies were used within each theme were analysed quantitatively. In addition, for each attribute classified, women received a score - '0' if the information was never evaluated with reference to personal values and '1' if the information was evaluated with reference to personal values at least once. These scores were summed up for all the attributes of the trial and standard treatment to reflect the number of attributes participants evaluated with reference to personal values. Differences in the number of attributes each participant evaluated with reference to personal values were examined using multivariate analysis of variance.

### Socio-demographic information

Age, ethnic origin, occupation, educational level, marital status, personal history of cancer diagnosis and treatment, and people known with cancer in the social network.

## Decision preference

Initial decision preference was assessed after the decision scenario but before receipt of the full trial information using a categorical response (take part in the trial: have the standard treatment; undecided). Final decision preference was assessed after receipt of full trial information

(control group) or after the values clarification task (values clarification groups) using a categorical response (take part in the trial: have the standard treatment).

# Perceptions of decision making experience during decision making

Perceptions of decision making experience during decision making were assessed after the final decision had been made by asking participants to reflect on the entire decision making process.

# Attitudinal ambivalence (felt)

For each option, three items rated the reactions participants felt towards that option<sup>39</sup> (1 = completely one sided reactions/no conflict at all/no indecision at all to 7 = completely mixed reactions/maximum conflict/maximum indecision). Scores on the three scales were summed up for each option; higher scores indicated higher levels of felt ambivalence.

## Attitudinal ambivalence (potential)

For each option, two items rated participants' judgements about the positive and negative attributes ascribed to that option (scored 1–7).<sup>40</sup> The two judgements were combined using the 'Griffin' formula to give the potential ambivalence score for each option<sup>41</sup>: [(P + N)/2] - |P-N|; higher scores reflect equally strong positive and negative judgements and hence greater ambivalence.

# Decisional conflict scale<sup>42</sup>

Perceived decisional conflict was assessed after the final decision for two time points: perceptions during decision making were assessed by asking participants to reflect on the entire decision making process (uncertainty, values clarity, and informed subscales); and perceptions after the decision were assessed by asking participants how they had felt after they had made the decision (uncertainty, values clarity, informed and effective decision making subscales). The scores were converted to the equivalent 0–100 scale; higher scores indicate higher decisional conflict.

# Procedure

The study sessions took place in a quiet room. Participants were allocated to the study groups using random permuted blocks of three to ensure equal numbers of participants in each group as the study progressed. At the beginning of the session, participants received written instructions about how the session would proceed followed by instructions to think-aloud. Participants read the decision scenario and were asked to indicate their initial preference. Following the scenario, they received detailed information about the trial and standard treatment options and were asked for their final decision preference. The explicit and implicit groups received the values clarification tasks after they had read the detailed information but before they were asked for their final decision. Participants were asked to say aloud all thoughts that came to their mind from the time they received the decision scenario until they had indicated their final decision, without needing to explain or justify their approach to the task. The researcher reminded them by saying 'please keep talking' if they remained silent for more than a few minutes. The think-aloud protocols were audio-recorded. Participants completed the paper-based questionnaire on completion of the study task.

## Data analysis

Logistic regression analyses compared between group differences in demographic characteristics and decision preferences; one set compared the explicit and implicit groups with the control, and the other the implicit and explicit groups.

Multivariate analyses of variance with two sets of orthogonal planned comparisons were carried out to test whether the values clarification techniques were more effective in enhancing informed decision making and improving decision making experience than routine information alone and whether the explicit technique is more effective than the implicit one; the first set compared the control group with the mean of implicit and explicit groups and the second the implicit and explicit groups. Where clarification of relationships was needed, pairwise comparisons with Bonferroni correction were performed to explore if either or both were significantly different from the control.<sup>43</sup> Regression analysis was carried out to assess the relationship between decisional conflict and ambivalence.

# Results

Thirty women, aged between 19 and 60 years (mean = 36 years, SD = 13.8) took part in the study. The sample was predominantly Caucasian (n = 28); 17 were students; 14 were married or living as married. The majority (n = 28) knew someone who had, or had previously suffered from, cancer in their social network: 10 had close relatives, 18 distant relatives or friends. The differences by study group with respect to demographic characteristics (Table 1) were not statistically significant. However, as this may be due to the small sample size, the demographic variables were controlled for in subsequent analyses comparing groups.

## Decision preference

No participants changed their decision from their initial preference but of the 13 that were undecided, eight chose to take part in the trial and five to have the standard treatment. The differences in the initial and final trial decision preferences by study group were not significant (Table 1).

#### Informed decision making

When the study groups were compared on the frequency with which the trial and standard treatment attributes were referred to, evaluated and evaluated with reference to personal values, multivariate effects were significant for both the trial attributes (F[6,42] = 2.8, P < 0.05) and the standard treatment attributes (F[6,42] = 4.3, P < 0.01) (Table 2). For trial attributes, the values clarification groups evaluated the attributes more often and evaluated more with reference to personal values than the control

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	Explicit ( $n = 10$ )	Implicit ( $n = 11$ )	Control $(n = 9)$	Total ( <i>n</i> = 30)
Participant characteristics				
Mean age (years)	38.3 (SD = 13.4)	39.8 (SD = 13.5)	28.4 (SD = 12.9)	36 (SD = 13.8)
Occupation: Staff (n)	6	5	2	13
Occupation: Students (n)	4	6	7	17
Marital status: Married /living as married (n)	3	8	3	14
Women with close relatives with cancer (n)	4	6	0	10
Initial decision preference (n)				
Trial	4	4	5	13
Standard treatment	3	0	1	4
Uncertain	3	7	3	13
Final decision preference (n)				
Trial	6	9	6	21
Standard treatment	4	2	3	9

**Table 1** Participant characteristics, initial and final decision preference by group

group. The explicit group evaluated more with reference to personal values than the implicit group (P < 0.10). For standard treatment attributes there was a similar pattern. The values clarification groups evaluated attributes more often than the control group, and the explicit group evaluated more than the implicit group. The explicit group evaluated with reference to personal values more than the implicit group, but the difference between the values clarification and control groups was not significant. Pairwise comparisons (Bonferroni adjusted) confirmed that the implicit group was not significantly different from the control group, leading to this result.

The study groups were compared on the number of attributes each participant evaluated with reference to personal values. A significant main effect was found for both trial (F[2,28] = 7.7, P < 0.01) and standard treatment (F[2,28] = 7.6, P < 0.01) attributes. Planned comparisons show that for both trial and standard treatment attributes, the values clarification groups evaluated more attributes with personal values than the control group and the explicit group evaluated more attributes with personal values than the implicit group (Table 2). Pairwise comparisons (Bonferroni adjusted) revealed no significant differences between the control and the implicit group, however, suggesting that the results in the planned comparisons are driven by the explicit group.

### Felt and potential ambivalence

The multivariate effects for *felt* (F[4,44] = 1.8, n.s.) or *potential* (F[4,44] = 0.41, n.s.) ambivalence were not significant by study group, neither were the main effects for trial or standard treatment. However, the planned comparisons suggested women in the explicit group *felt* significantly less ambivalent about both the trial and standard treatment than those in the implicit group (Table 3). There were no differences between the values clarification and control groups, and pairwise comparisons indicated that the implicit and control groups were not significantly different, indicating a difference between the explicit group and the others.

# Perceptions of decisional conflict

The explicit group women were less uncertain about their decision and less unclear about their values both during decision making and after the decision than those in the implicit group. Differences between the average scores for values clarification groups and control were not significant, and again pairwise comparisons (Bonferroni adjusted) indicated that the implicit and control groups were not significantly different, indicating a difference between the explicit group and the others (Table 3). Overall, women felt more certain about their decision

	iig sulategies by group								
		Explicit	(n = 10)	Implicit	(n = 11)	Contro	(6 = 0)		Danned
		Mean	95% CI	Mean	95% CI	Mean	95% CI	F	comparisons
Frequency with which information pr	rocessing strategies were used								
Trial attributes	Referred to only	7.2	3.3-11.1	7.5	3.9-11.1	4.1	0-8.2	0.84	
Multivariate	Evaluated at all	18.1	14.4 - 21.8	18.8	15.3-22.2	11.8	7.9-15.7	4.0*	C v E R I, P < 0.01;
F[6,42] = 2.8, P < 0.05	Evaluated with reference	9.3	6.7-11.8	6.3	4.0-8.7	3.2	0.5-5.9	5.5*	C v E&I, $P < 0.05$ ; E v I, $P < 0.10$ ;
	to personal values								
Standard treatment attributes	Referred to only	2.2	0.2-4.2	4.6	2.8-6.5	1.0	-1.1 to 3.2	3.3*	
Multivariate $F[6,42] = 4.3, P < 0.01$	Evaluated at all	6.0	4.6-7.5	2.5	1.1 - 3.9	1.7	0.1-3.3	10.2***	C v E&I, $P < 0.05$ ; E v I, $P < 0.01$
	Evaluated with reference	2.9	1.7 - 4.1	0.5	-0.6 to 1.7	0.9	-0.4 to 2.2	4.9*	$E \vee I, P < 0.01$
	to personal values								
Number of attributes evaluated with	reference to personal values,	Multiva	riate F [4,44]	] = 4.1, 1	P < 0.01				
Trial attributes (0–11)		6.7	5.2-8.2	4.1	2.7-5.5	2.6	1.0 - 4.2	7.7**	C v E&I, $P < 0.01$ ; E v I, $P < 0.05$
Standard treatment attributes (0–8	8)	2.4	1.6–3.3	0.5	-0.2 to 1.3	0.5	-0.4 to 1.4	7.6**	C v E&I, $P < 0.10$ ; E v I, $P < 0.01$
* D / UVE ** D / UV1 *** D / U	100 0								

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and clearer about their values after the decision than during decision making; feelings of being informed were unchanged (Table 4).

Relationship between ambivalence and decisional conflict

Felt ambivalence about the trial and standard treatment were positively associated with decisional conflict (r = 0.51, P < 0.01); higher decisional conflict during decision making was associated with higher felt ambivalence about both trial (r = 0.74, P < 0.01) and the standard treatment (r = 0.75, P < 0.01). There was no correlation with potential ambivalence measures (r = 0.31 and r = 0.14, n.s.). Felt ambivalence about both the options explained a total of 73% of the variance in decisional conflict; the unique variance explained by ambivalence about the standard treatment was 18% and the unique variance explained by felt ambivalence about the trial was 17%, the shared variance was explained by both variables was 38% (Table 5).

# Discussion

<sup>a</sup>Values are adjusted for demographic covariates.

The study provides evidence that values clarification techniques are likely to be active ingredients in patient decision aid interventions. All participants perceived themselves to be equally informed suggesting the information component of the decision aid provided knowledge about the decision problem but not how to evaluate this knowledge in accord with their beliefs.<sup>8</sup> However, participants' engagement with the decision information was differentially associated with their study group; those in the explicit group evaluating more attributes more often in accord with their personal values than the implicit or information only groups, and those in the implicit group evaluating the attributes more often than the information only group. Participants in the explicit study group had lower felt ambivalence and decisional conflict scores than the other groups suggesting that deliberating about the seemingly incompatible attributes of both options in accord with your

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Table 3	Attitudinal	ambivalence	and	decisional	conflict	by	group <sup>a</sup>
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	Explicit	(N = 10)	Implicit	(N = 11)	Contro	(N = 9)		Planned
	Mean	95%CI	Mean	95%CI	Mean	95%CI	F	comparisons
Felt ambivalence during decisio	n making	, Multivariate	F(4,44) =	= 1.8, n.s.				
Felt ambivalence, Trial (low-high: 3–21)	3.0	1.8–4.2	4.9	3.8-6.0	3.7	2.4–5.0	2.9*	E v I, P < 0.05
Felt ambivalence, ST (low–high: 3–21)	2.6	1.4-3.8	4.2	3.0-5.3	4.0	2.7-5.3	2.2	E v I, P < 0.10
Potential ambivalence during de	ecision m	aking, Multiva	ariate <i>F</i> (4	,44) = 0.42, r	n.s.			
Potential ambivalence, Trial (low–high: –2 to 7)	1.6	0.1–3.2	2.2	0.7–3.6	3.1	1.5–4.8	0.86	
Potential ambivalence, ST (low–high: –2 to 7)	2.1	0.7–3.4	2.0	0.8-3.3	2.0	0.6–3.4	0	
Perceptions of decisional conflic	ct during	decision mak	ing (low-	high: 0–100),	Multivar	iate <i>F</i> [6,42] =	2.5, P <	0.05
Uncertainty	31.6	12.3-50.9	68.6	50.5-86.7	57.7	37.1-78.3	4.3**	E v I, P < 0.01
Uninformed	30.6	17.7–43.6	25.7	13.6-37.9	19.4	5.5-33.2	0.72	
Unclear values	11.3	-4.4 27.1	48.0	33.2-62.7	33.8	16.9–50.6	6.1***	E v I, P < 0.01
Perceptions of decisional conflic	ct after th	ne decision (lo	ow-high:	0–100), Multi	ivariate <i>F</i> [	8,40] = 1.6,	1.S <b>.</b>	
Uncertainty	21.4	5.8-36.9	49.7	35.1-64.2	34.6	18.0-51.2	3.7**	E v I, P < 0.05
Uninformed	17.9	5.9-30.0	28.0	16.7–39.4	14.4	1.6-27.3	1.4	
Unclear values	15.9	5.3-26.5	30.7	20.8-40.7	24.3	13.0-35.7	2.2	E v I, P < 0.05
Ineffective decision	20.2	7.4-33.1	24.0	11.9–36.0	20.9	7.1–34.6	0.1	

\*P < 0.10, \*\*P < 0.05, \*\*\*P < 0.01.

<sup>a</sup>Values are adjusted for demographic covariates.

Table 4 Paired t-tests for decisional conflict at the time of decision making and after decision

	During de	ecision	After dec	ision	Paired	<i>t</i> -tests
	Mean	SD	Mean	SD	t	Sig.
Uncertainty (good-poor:0-100)	52.5	30.4	35.3	22.7	4.5	0.000
Uninformed (good–poor:0–100)	25.5	18.5	20.8	16.8	1.6	0.111
Unclear values (good-poor:0-100)	31.1	25.6	23.3	15.5	1.9	0.065
Total decisional conflict (3 scales) (good-poor:0-100)	36.3	20.4	26.4	16.0	3.5	0.001

**Table 5** Regression of decisional conflict at the time of decision making onto ambivalence about trial and standard treatment (n = 30)

	β	SE	t	Unique variance explained	R <sup>2</sup>
Model					0.73***
Felt ambivalence, ST	2.041	0.48	4.3***	0.18	
Felt ambivalence,	1.914	0.45	4.2***	0.17	
Trial					
*** <i>P</i> < 0.001.					

own beliefs was associated with a better decision experience than relying on more intuitive strategies.<sup>19</sup> The study found decisional conflict and attitudinal ambivalence to be conceptually similar measures of perceived decisional experience.<sup>41,44</sup> Felt, but not potential ambivalence, was associated with decisional conflict suggesting that decisional conflict occurs only when individuals are aware of the simultaneous positive and negative evaluations of options, not when these evaluations are dormant. This is the first time a link has been demonstrated between a construct used in the applied field of decision aids and that used in the theoretical frameworks of attitude research.

Currently the evidence explaining why the component parts of decision aid interventions

facilitate patient decision making is limited.<sup>8,16,19,45,46</sup> The paucity of evidence is partly attributable to the methods needed to unpack the active ingredients of a decision aid rather than assess its effectiveness. We employed a think-aloud technique to encourage participants to verbalize their thinking about the decision they were making. This is an established technique amongst decision scientists<sup>27,28,47</sup> and is believed to capture accurately the reasoning people usually employ when engaged in decision making. The main difficulty of using a thinkaloud technique to evaluate interventions that encourage deliberation is a possible confound between the think-aloud method and the active components of the decision aid. More specifically, it is feasible that the think-aloud method acted as an intervention to encourage conscious deliberation of the decision information. However, as there was a differential effect of the groups on the informed decision making measures, it seems more likely that conscious deliberation was a result of the values clarification techniques than the research method.

One criticism of the think-aloud technique, and all self-report measures as methods to ascertain people's cognitions, is that they describe only those processes available to conscious attention; processes that are sub-conscious and/or difficult to verbalize are not measured.<sup>48,49</sup> The implication from this would be that people in the implicit and information only groups could have processed the information in the same way as those in the explicit group but did not verbalize these processes either because they were not accessible to conscious report or were not the focus of attention.<sup>50</sup> This criticism is difficult to refute because reasoning is a noumenon<sup>51</sup> - a thing-in-itself whose existence can only be postulated and not directly observed via our senses. We have to use observable manifestations like verbal or written responses to infer about these hidden processes. Our finding that the groups differed on their perceived decision experience provides indirect evidence that the processing of information could not have been the same across the three groups. Decision and behaviour scientists elicit

observable responses to classify aspects of people's reasoning (e.g. stated evaluations of decision attributes, and attitudes and risk perceptions) rather than perceptions of how they reason (e.g. preferences for involvement in decision making and decision making style) and use theoretical frameworks to make predictions about how these phenomena are related. A theoretically informed interpretation of our findings overall is that values clarification techniques increased people's awareness of the justifications/reasons for their choice by bringing the evaluative processes to their conscious attention and it was this increased awareness that led to a better rated decision making experience. The value of these techniques, therefore, lies in managing individuals' attentional resources more effectively by prompting evaluation and assimilation of information.<sup>52</sup>

A particular strength of this study was using measures to describe both the information strategies people employed to make the decision and their perception of the decision experience. By having these measures, we ascertained that, as hypothesized, information provides knowledge about the decision problem only, implicit techniques enable evaluation of attributes only. and explicit techniques enable evaluation of attributes and assimilation with existing beliefs. In addition, we found that deliberation and assimilation of information during decision making was associated with lower decisional conflict and felt ambivalence. In other words consciously attending to and evaluating the positive and negative attributes of the decision options during decision making reduces feelings of conflict and ambivalence about the decision post-choice, i.e. facilitating informed decision making is associated with a better perceived decision experience.

This method meant our sample size was small and lacked the power to detect possible group differences such as those in initial preference and knowledge of people with cancer. In addition, participants were women making a hypothetical rather than a real-world choice. However, there are some reasons to believe that our findings may be relevant to patients making these decisions. First, the decision scenario we used was a choice patients with cancer were making between standard treatment and trial participation in our local NHS Trust. Second, the decision aid component parts were developed with reference to real-world patient decision aids.<sup>8,11,19</sup> Third, most women who participated had had or knew someone with cancer suggesting an understanding of the health area. Fourth, although people's values and preferences are labile,<sup>53</sup> the strategies they employ to process information and make decisions are the same as everyone else.<sup>54</sup>

This study provides evidence for a proof of concept for the effectiveness of values clarification techniques in decision aids on people's decision making. Like the evidence from a phase 2 trial of a biomedical intervention, the next level of evidence could be elicited by carrying out this study in a sample of patients who have had cancer and/or are making a decision about trial participation. We hypothesize that although trial information will lead to patients making informed choices, the use of an explicit values clarification technique within a decision aid will help patients make more informed decisions and improve their decision experience. Despite the findings from this study, a body of evidence is still needed explaining the role of the component parts of decision aids in facilitating patient decision making. For example, in this decision scenario, choosing between standard treatment and taking part in a trial, an explicit values clarification technique was necessary to assimilate the decision attributes with existing values. It may be that for simpler decisions, such as choosing between different treatment options and/or less serious consequences, an implicit values clarification technique is sufficient.55

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# **Conflict of interest**

None.

# **Supporting Information**

Additional Supporting Information may be found in the online version of this article:

**Appendix S1.** Breast cancer treatment clinical trial scenario.

**Appendix S2.** The explicit and implicit values clarification tasks.

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