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Framing options as choice or opportunity: does the frame influence decisions?

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Complete List of Authors:	Abhyankar, Purva; University of Leeds, Leeds Institute of Health Sciences Summers, Barbara; University of Leeds, Leeds University Business School Velikova, Galina; University of Leeds, Leeds Institute for Molecular Medicine, St James's Institute of Oncology Bekker, Hilary; University of Leeds, Institute of Health Sciences;
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Title: Framing options as choice or opportunity: does the frame influence decisions?[1]

Authors:

Purva Abhyankar, PhD, Leeds Institute of Health Sciences, University of Leeds, UK

Barbara A Summers, PhD, Centre for Decision Research, Leeds University Business School, UK

Galina Velikova, MD, PhD, Leeds Institute for Molecular Medicine, St James's Institute of Oncology, University of Leeds, UK

Hilary L Bekker, PhD, Leeds Institute of Health Sciences, University of Leeds, UK

Corresponding author:
Purva Abhyankar
Nursing, Midwifery and Allied Health Professions Research Unit
University of Stirling
Unit 13 Scion House
Stirling University Innovation Park
Stirling
FK9 4NF
Email: purva.abhyankar@stir.ac.uk

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Abstract

Objective: Health professionals must enable patients to make informed decisions about healthcare choices through unbiased presentation of all options. This study examined whether presenting the decision as 'opportunity' rather than 'choice' biased individuals' preferences in the context of trial participation for cancer treatment.

Method: Self-selecting healthy women (N=124) were randomly assigned to the following decision frames: opportunity to take part in the trial (opt-in), opportunity to be removed from the trial (opt-out), and choice to have standard treatment or take part in the trial (choice). The computer-based task required women to make a hypothetical choice about a real-world cancer treatment trial. The software presented the framed scenario, recorded initial preference, presented comprehensive and balanced information, traced participants' utilisation of information during decision making and recorded final decision. A post-task paper questionnaire assessed perceived risk, attitudes, subjective norm, perceived behavioural control and satisfaction with decision.

Results: Framing influenced women's immediate preferences. Opportunity frames, whether opt-in or opt-out, introduced a bias as they discouraged women from choosing standard treatment. Using the choice frame avoided this bias. The opt-out opportunity frame also affected women's perceived social norm; women felt others endorsed the trial option. The framing bias was not present once patients had had the opportunity to view detailed information on the options within a patient decision aid format. There were no group differences in information acquisition and final decisions. Sixteen per cent changed their initial preference after receiving full information.

Conclusions: A 'choice' frame, where all treatment options are explicit is less likely to bias preferences. Presentation of full information in parallel, option-by-attribute format is likely to 'de-bias' the decision frame. Tailoring of information to initial preferences would be ill-advised as preferences may change following detailed information.

Keywords: framing; informed decision making; patient choice; trial participation; opt-in/opt-out; decision aids

Introduction

Healthcare policies worldwide recommend patients be enabled to make informed decisions about their healthcare choices, especially when the decision is 'preference sensitive' i.e. there is no single best option available.[1] To enable informed decision making, it is essential that health professionals a) present all available options and information about options in a balanced manner and b) encourage patients to engage with the information to evaluate it in accordance with their own values.[2,3,4] Balance refers to complete and unbiased presentation of all the relevant options and the information about those options—in content and in format—in a way that enables individuals to process this information without their choices being influenced by the presentational aspects.[5]

From years of research in decision psychology, we know that the way information is presented can have unintended effects on the way it is attended to, perceived and processed. These unintended effects include biases in people's judgements and choices. This 'framing effect' is described as biasing people's judgements and choices because people make different decisions when the same information is packaged differently.[6] A classic example of the framing effect is presenting risk information either positively or negatively. For example, people's preferences are seen to reverse when the same decision problem is presented either in terms of 'losses' (400 of 600 patients will die) or 'gains' (200 of 600 patients will be saved).[7-9] Framing effects are believed to occur due to a focussing phenomenon.[10,11] When faced with a decision, people construct a mental representation of the decision which contains the information needed to make the choice.[12] As the capacity of the working memory is limited, not all aspects of the decision situation can be included in this representation. A major determinant of what information enters the mental representations is the description of the decision situation, as people attend selectively to the information provided. Information explicitly presented about the decision is more likely to be included within the representation for evaluation than information implicit in the decision problem. The resulting mental representation is then used to make decisions quickly without too much cognitive effort, but this means that relevant information about the decision may be omitted. Different presentations of the same situation can therefore induce people to form markedly different mental representations, which in turn, lead to different choices.

Most framing research in the healthcare context has focussed on the way information about probabilities of outcomes associated with different options is presented; for example, presenting the probabilities positively vs. negatively [13,14] or in absolute vs. relative terms.[15,16] Relatively little research has investigated how framing the presentation of decision options affects people's choices. Research from outside the health context, however, suggests that people's choices and perceptions of options vary when the decision options are presented in slightly different ways. A commonly used frame in everyday conversation is the offering of options as an opportunity (i.e. a single option is explicit and the decision is presented as an opportunity to pursue that option) rather than a choice (i.e. all options are explicit and the decision is presented as a choice between two or more options).[10] Unlike the choice frames which make all available options explicit, the available alternatives are often implicit within the opportunity frames. The effect of this type of framing on people's decisions and information seeking was first demonstrated in a non-medical context by Jones et al.[10] Presenting an option as an opportunity was found to be associated with an increased willingness to choose that option and a reduction in questions about other alternatives, compared with when the option was presented as a choice.[11,17] Many health-related options are presented as opportunities - for instance "Would you like to have this test/treatment/take part in the trial?"- where the alternative of continuing without a test/treatment or having standard treatment is implicit. There is evidence to suggest that this type of framing may be, advertently or inadvertently, taking place in routine clinical practice. For example, health professionals are reported to use communication methods that emphasise benefits over risks, make explicit or implicit recommendations, and position an option as the only sensible choice.[18-24] However, presenting options as an opportunity or choice is rarely recognised as a 'frame' that may influence and/or bias people's choices, causing changes from a situation in which both options are salient. In consequence, little research has explored systematically the effect of the opportunity versus choice frame within different decision contexts.

Although opportunity framing makes only one option explicit, there are two types of opportunity frame which differ in terms of the option that occurs if no action is taken (the default option). The decision may be presented as an opportunity *to pursue* an option (opt-in) or as an opportunity *not to pursue* an option (opt-out). The opt-in frame presents the option as novel and implies a loss of that option if no action is taken. The opt-out frame presents the option as routine and implies the loss of that option if

action is taken. Within the healthcare context, a number of examples can be found where the options are presented in either an opt-in or an opt-out frame.[25] For example, most screening and immunisation options are presented in an opt-in frame where people are invited to have a test or a vaccine, whereas others such as organ donation and HIV testing are, in some countries, presented in an opt-out frame where these services are offered as routine/default with an opportunity to refuse them.[25,26] Evidence in both medical and non-medical contexts suggests that people make different choices depending on whether the options are presented as opt-in or opt-out; presenting an option in an opt-out frame is often found to increase the uptake of that option compared to when it is presented in an opt-in frame.[27-33] The increased attractiveness of the option in the opt-out frame is believed to be due to the frame's impact on people's representation of the option as socially valued or endorsed by others, so less cognitive effort is involved in accepting the default, and to the lower levels of regret experienced by people when harm results from a decision not to take action.[30,34-36]

Most research has focussed on comparing the effects of opt-in and opt-out frames; however, these frames have rarely been viewed as variants of opportunity frames and contrasted with a choice frame as a baseline. It is therefore unclear how using opt-out versus opt-in to express an opportunity will change decisions relative to a choice frame. It may be that, despite the differences in choices resulting from the opt-in and opt-out frames, the important feature of such frames is that both make salient the uptake of the option they explicitly present. Both the frames may therefore nudge people to focus on the option that is explicit in the frame, though one increases the uptake of the option more than the other by presenting it as a default/routine. Alternatively it may be that the opt-in and opt-out frames produce take-up rates on either side of choice, as opt-out nudges decision makers towards uptake of the option while opt-in reduces the chances of them taking the option. A third alternative would be that opt-in and choice produce similar effects, because in both cases the decision maker starts from a position of not taking the option and has to take action to do so, whereas opt-out produces higher uptake because the default is to take the option. While the expected result is unclear, the choice frame, nonetheless, removes the implicit nudging by presenting all options explicitly and would therefore seem most appropriate for supporting informed decision making.

Most framing research has evaluated the effect of framing on people's judgements and choices. However, it remains unclear if framing leads to judgements and choices that are more or less informed. To enable informed decision making, it is crucial that the presentation of options and information be complete, unbiased and encourages people to evaluate all available options and their attributes in accordance with their own values.[2,3] It is largely unknown whether and which frames bias or enhance decision making and in what contexts. This makes it difficult to determine the optimal way in which options and information should be presented to ensure choices are not biased. Jones et al[10] argue that presenting an option within a choice frame leads to a more complete and balanced representation of the decision problem in terms of both explicit presentation of all available options and absence of any subtle nudging of people's attention towards or away from a single option. Certainly if this framing effect is evident in health-related decisions, presenting options as a choice rather than an opportunity is likely to have prescriptive implications for facilitating informed decision making.

This article describes the first study to investigate systematically the choice versus opportunity frame within a health context. The study evaluates the choice versus opportunity frame – both opt-in and opt-out versions - on decisions in the context of trial participation for cancer treatment. Cancer clinical trial choices are complex decision contexts as the decisions about trial participation are often nested or subsumed within decisions about treatment.[37] The offer of trial participation complicates the treatment decision by introducing the prospect of a better outcome but with uncertainties associated with treatment allocation, effects and outcomes. Although patients are provided with written trial information, often the option is initially offered verbally during consultation with health professionals.[37,38] Evidence suggests that patients make these decisions instantaneously, using a range of heuristic strategies such as selectively attending to information, forming early impressions based on quick evaluations of initial information, or settling on a satisfactory option without considering alternatives.[37-43] This suggests that patients are likely to be influenced by the way trial options are verbally presented, even before they consider the written information, so the framing of the initial description of the decision they receive is important. We initially hypothesised that people receiving either of the opportunity frames would be more likely to choose the trial than those receiving the choice frame, on the basis that participants in Jones et al. (1998) when faced with opt-in frames

tended to choose the option more often, and we would expect opt-out frames to increase this tendency by making the opportunity the default option. Given the tendency for people to seek information that confirms their decision[34] we hypothesised that any bias in the initial decision resulting from the use of opportunity frames could affect the later processing of decision information leading to less informed decisions.

Method

Sample

All women aged 18 years or older working and/or studying at the University of Leeds, UK were invited to participate via the University's email distribution list. No women volunteering to participate were excluded. There are ethical concerns about carrying out this type of research in a sample of patients making actual trial participation choices as there is a risk of influencing the choices that may affect their health, illness and possibly mortality. In this applied context, we need to have confidence that any manipulation, at the least, causes no additional harm and may even benefit the patient making the choice. This study is therefore carried out in a sample of healthy women making a hypothetical choice about trial participation but using information from a real-world cancer treatment trial. This study is expected to provide some proof of concept data, as in a 'phase II' trial addressing whether these framing effects affect healthcare choices.[44] The Leeds Institute of Psychological Sciences Ethics Committee approved the study in June 2006. 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.

Design and procedure

The study employed an experimental between-subjects design with random allocation to one of the three decision-framing conditions: (1) Decision problem framed as an *opportunity* to take part in a clinical trial (opt-in); (2) Decision problem framed as an *opportunity* to be removed from a clinical trial (opt-out); (3) Decision problem framed as a *choice* between taking part in a clinical trial or having standard treatment. As the order in which options are presented may influence people's choices[45-46], the sequence in which the trial and standard treatment alternatives were described in the *choice*

frame was counterbalanced so that half received the trial option first (T-S) and half the standard treatment option first (S-T).

The study was carried out in a decision lab using computers situated on partially-enclosed desks. The Mouselabweb software programme[47] was used to manage the randomisation to condition, present the decision information and task, and trace participants' information usage concurrently with the task. At the beginning of the session, participants received written instructions outlining how the session would proceed. The software programme asked participants to input the identification number and reference number appearing on the instructions sheet. The reference number specified to the MouselabWeb programme which framing condition the participant was allocated to: 1. opt-in, 2. opt-out, 3. choice S-T, and 4. choice T-S. Participants were allocated to the framing conditions in randomly permuted blocks with the pattern 1, 2, 3, 1, 2, 4, 1, 2, 3… and so on to ensure that there were equal numbers of participants in each framing condition, with the choice condition being counterbalanced. Participants were unaware that they were allocated to different framing conditions using the reference number. Following evidence from previous literature[18,37,38] and input from a practicing oncology consultant on the study team, the study was designed to mimic how cancer treatment and trial options are offered in a real-world setting. Treatment and trial decisions are sometimes first presented and discussed verbally during clinical consultations, before the written information is provided. To replicate this process in a controlled laboratory setting, we first presented participants with a brief decision scenario (Figure 1) and asked them to indicate their initial preference in response to the scenario. Following the scenario, they received detailed information about the trial and standard treatment options (Figure 2) and were asked for their final decision preference. Participants filled out the paper questionnaire after completion of the computer task. Figure 3 summarises the study procedure. The study was piloted on the first nine participants and modifications were made to the study materials following participant feedback and data inspection. Participants from the pilot were included in the main data as the modifications were not expected to change the key aspects of their behaviour.

<Insert Figures 1, 2 and 3 about here>

Materials

The decision scenario and framing intervention

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); TACT was an international phase-three chemotherapy trial for early stage breast cancer, carried out by the local cancer unit.[48] A breast cancer scenario was used as it is one of the most common and high profile cancers, likely to be known to most people through media or experience of family/friends. 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 and to recollect the experiences of any family and friends who had experienced cancer.[49]

The decision scenario and the accompanying questions eliciting initial and final decision preference were framed either as a 'choice' or an 'opportunity'. The choice frame explicitly stated that there were two options and asked participants to choose between those options. The opportunity frames made only the trial option explicit and asked participants to decide whether to follow or not to follow that option. There were two versions of the opportunity-frame: opt-in and opt-out, both with the same option explicit but differing in the defaults. The opt-in condition presented the decision as an opportunity to take part in the trial with standard treatment as the implicit default. The opt-out condition presented the decision as an opportunity to opt-out of the trial with trial participation as the default (Figure 1).

Detailed decision information

The information about the TACT trial and the standard treatment was adapted for use on the computer (Figure 2). The information about the two decision options was arranged in adjacent columns. The information was presented in concealed boxes labelled by questions relating to the box content which were accessed by clicking on the box (Figure 4). The box remained open as long as the cursor was inside the box and closed when the cursor was moved out of the box. Each box opening counted as an acquisition of information. The information readability score was 8.0 (equivalent of an eighth grader / age 14 level)[50].

<Insert Figure 4 about here>

Measures

Data were elicited by two methods – responses recorded by the computer during the decision task and the paper questionnaire completed after the task – and assessed the following:

Responses recorded by the computer:

- Decision preference - initial decision preference was assessed before the receipt of detailed information using a categorical response: take part in the trial, have the standard treatment or undecided. The final decision preference was assessed after the receipt of full information using a categorical response: take part in the trial or have the standard treatment. (Figure 1). The option of refusing both options was not presented because, in real-world practice, this is not often considered a reasonable option.
- Information acquisition measures - MouselabWeb software recorded the total number of information boxes acquired, the number of times they were reacquired, and the amount of time spent on each box (Figure 4). From these data, process tracing indices were computed[51]: depth of search was calculated separately for trial and standard treatment information as the proportion of available information examined; reacquisition rate was calculated as the total number of information pieces examined minus the total number of first acquisitions, divided by the total number of information pieces examined. A higher depth of search and reacquisition rate indicates a more systematic decision process.

Paper questionnaire:

- 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 cognitions about risks included: perceived likelihood and severity of side effects for the trial and the standard treatment using 7-point Likert scales, scored 1=not at all likely/not at all severe to 7=very likely/very severe.
- Decision cognitions informed by the *Theory of Planned Behaviour* (TPB)[52] included: *attitude* towards taking part in the TACT trial assessed using four semantic differential scales ('Bad-Good', 'Beneficial-Harmful', 'Risky-Safe' and 'Reassuring-Worrying'), scored 1 to 7; two *subjective norm* items ('people who are important to me' and 'my doctor'), scored 1=strongly disagree to 7=strongly agree); three *perceived behavioural control* items assessing whether

or not taking part in the trial is up to the participant, scored 1=strongly disagree to 7=strongly agree. The Cronbach's alpha for the three scales were 0.77, 0.49 and 0.44 respectively[2].

- Satisfaction with the decision was assessed using the six-item validated Satisfaction with Decision Scale[53] assessing the degree to which participants felt their decision was of good quality, informed, consistent with personal values, satisfactory and implementable (scored 1=strongly disagree to 5= strongly agree). Higher scores indicate higher satisfaction with the decision (Cronbach's alpha = 0.85).

Data analysis

First, homogeneity of framing groups with respect to demographic characteristics was assessed using analysis of variance (ANOVA) and chi-squared tests. Second, analyses were performed to identify the effects framing had on women's decision making. If differences are found between the frames in terms of information acquisition, decision related cognitions and final decision outcome measures, there are two ways these might arise (and, indeed, both might be present):

1) The frame, because of the internal representation of the problem it invokes, leads to changes in the ways people acquire information and think about the decision, and this leads to changes in the option they choose. Here the frame is affecting the decision in the usual way we expect in framing effects.

2) It may be that the initial decision people make leads to changes in the ways they acquire information and think about the decision, and affects the option they choose. This could occur, for example, if people spent more time looking at information related to the option they initially chose. If the frame affects the initial decision, it would then affect the final decision through the impact the initial decision has on processing

In identifying whether the first or the second case applies, the role of the initial decision provides evidence. In the second case, frame will affect the initial decision, but the effect on other outcomes will be via the initial decision. In this case the initial preference should explain differences in the other outcomes and the effect of frame should no longer be significant when initial decision is included in the model.

[2] The two items assessing subjective norms used two different referent groups. As people may have different beliefs about different referent groups, the two items are not expected to show high internal consistency. The internal consistency of the three items assessing perceived behavioural control was lower than the usual cut-offs (0.44). However, a factor analysis on these items indicated that all three items had loadings of >0.6 on a single factor, suggesting that the items were measuring the same underlying construct.

Framing effects on initial preference and final decision were examined using chi-squared tests and multinomial logit analyses. Multinomial logit analyses examined the group differences in initial preference using two sets of models; the first set compared the 'trial' category with the 'standard treatment' and 'undecided' categories; the second set provided comparisons of the 'standard treatment' and 'undecided' categories. In each set of models, the choice group served as the reference category against which each of the opportunity frame groups was compared. The output from these models indicates the change in the predicted odds of an outcome for a unit change in the predictor (denoted by the beta co-efficient). Framing effects on information acquisition, decision cognitions and decision quality were assessed using multivariate analyses of variance (MANOVA). Significant univariate effects were followed up using pairwise comparisons with Bonferroni adjustment.

Results

One hundred and twenty-four women, aged between 18 and 54 years (Mean=26 years, SD=8.5), took part in the study. No participants dropped-out once an initial contact had been made. The sample was predominantly Caucasian (75%); over half (66%) were students and 75% were single. Three percent had been previously diagnosed with cancer[3] and the rest (97%) knew someone with cancer in their social network, of whom 30% were close relatives, 43% were distant relatives and 24% were friends, colleagues or other acquaintances. There were no differences among the framing conditions with respect to age ($F[2,119]=1.7$, n.s.), number of people known with cancer ($F[2,121]=.15$, n.s.), ethnicity (χ^2 =4.2, df=2, n.s.), marital status (χ^2 =2.2, df=2, n.s.) and experience of cancer (χ^2 =2.1, df=2, n.s.) (Table 1). Significant differences among framing conditions were observed by occupation (χ^2 =6.3, df=2, $p<.05$) but further analyses revealed no significant differences between students and staff with respect to initial preference and final decision, information acquisition, decision cognition and quality measures. Framing effects were examined by comparing the opt-in (N=42), opt-out (N=41) and choice (N=41) framing conditions. The two counterbalancing versions of the choice frame were collapsed into a single category as no significant differences were found between the two versions with respect to any of the dependent measures.

[3] To test the possibility that women with a diagnosis of cancer may have thought and acted differently, analyses were conducted with and without these participants. As there was no difference between the findings, the results for the whole sample are reported.

<Insert Table 1 about here>

Framing effects

Framing effect on initial preference

When asked about their initial preference following the decision scenario and before receipt of full information, 64% indicated a definite preference (48% to take part in the trial; 16% to have the standard treatment), and 36% were undecided.

Framing affected initial preferences (χ^2 = 13.18, df=4, p=.010, effect size w=0.33) (Figure 5). A post-hoc power calculation, using G*Power[54,55] and the effect size w from the statistical test output, indicated that the power of the χ^2 test of whether framing affects initial preferences is 0.85, suggesting that the study was adequately powered to test this hypothesis. Those in the opportunity frames were less likely to choose the standard treatment rather than the trial when compared to those in the choice frame (for opt-in, β=-0.14, p=0.042, Odds Ratio = 0.259,[4] with 95%CI 0.070 to 0.954; and for opt out; β= -1.9, p=.008, Odds Ratio =0.148, with 95%CI 0.036 to 0.601). Women in the opportunity frames were also more likely to be undecided than to choose the standard treatment (for opt-in; β= 1.6, p=.016, Odds Ratio = 5.146 with 95%CI 1.356 to 19.524; and for opt-out β=1.5, p=.041 Odds Ratio = 4.694 with 95%CI 1.068 to 20.631). There were no significant differences between the opt-in and opt-out conditions. Although these models are underpowered due to the sample size, they provide further insight into the differences between groups illustrated in Figure 5.

<Insert Figure 5 about here>

Framing effect on final decision

After receipt of full information, 76% decided to take part in the trial and 24% decided to have the standard treatment. No significant results were found by the chi-squared test of the distribution of the final decision across the three framing conditions (χ^2 =1.9, df=2, *p=.38, Eta=0.125*) (Figure 6). Logistic regression analyses confirmed these findings.

<Insert Figure 6 about here>

[4] The odds ratio relates to the change in odds of taking up an option between the base group and the focal group to which it applies. It is calculated as the odds after a unit change in the independent variable (dummy variables for group membership in this case) divided by the odds for the base category. An odds ratio greater than 1 represents an increasing chance of taking the option, and an odds ratio below 1 indicates a decreasing chance. Here the odds ratio of 0.259 indicates a decreasing chance of choosing standard treatment with odds of 1:3.86 (3.86=1/0.259).

Of those who had indicated a definite preference before receiving full information, 16% changed their decision after receipt of full information; 10% switched to taking part in the trial and 6% to having the standard treatment. Logistic regression analyses showed no differences by frame in the propensity to change decision (Table 2).

<Insert Table 2 about here>

Framing effect on information acquisition measures

MANOVA analysis on the information acquisition measures showed no significant main effects of opt-in, opt-out and choice framing on total amount of information acquired and reacquisition rate ($F[8,238]=1.05$, $p=.39$) or depth of search ($F[8,238]=.84$, $p=.57$) (details of the measures in each group of dependent variables can be found in Table 3).

<Insert Table 3 about here>

Framing effect on decision cognitions

Details of the dependent variables in each analysis can be found in Table 4. There were no significant multivariate effects of frame for perceived risk and severity of side effects ($F[8, 236]=1.2$, $p=.31$). A significant multivariate effect of frame was found for the Theory of Planned Behaviour measures ($F[6, 236]=2.9$, $p=.009$); with a significant univariate effect for subjective norm ($F[2, 119]=4.3$, $p=.015$). Pairwise comparisons with Bonferroni correction indicated that participants in the opt-out condition were more likely to infer that the trial would be an option recommended by significant others than those in the choice condition ($p=.021$).

<Insert Table 4 about here>

To explore the route by which the frame affected subjective norm, differences in subjective norm were first examined by initial preference. Second, the effect of frame on subjective norm was investigated with initial preference as a covariate. A significant multivariate effect of initial preference was found for the TPB measures ($F[6,236]=5.9$, $p<.001$) with a significant univariate effect for attitude and subjective norm. Pairwise comparisons with Bonferroni correction indicated that those who preferred the trial had a more favourable attitude to the trial and greater subjective norm perceptions compared to the standard treatment choosers and the undecided (all $p<0.001$). To examine if the effects of frame on the TPB variables remained significant after controlling for the differences by initial decision, initial decision was included as a covariate in a MANCOVA. The multivariate effect of frame remained significant ($F[6,234]=2.7$, $p=.014$) with a significant univariate effect for subjective norm ($F[2,118]=3.4$,

p=.037) and similar findings in pairwise comparisons for subjective norm (p=.038) to those found without the covariate. These findings suggest that framing affected women's subjective norm in the way usually associated with framing effects and not just via an impact on initial choice.

Framing effect on satisfaction with decision

The effect of framing on women's satisfaction with the decision was assessed using one way analysis of variance. The findings suggest that the three framing conditions did not differ with respect to satisfaction with the decision (F[2,120]=.24, *p=.78)* (Table 4).

Discussion

This study is the first, to the authors' knowledge, to test the effect of the opportunity versus choice frame for a healthcare decision. We demonstrated a framing bias arising from presenting trial participation as an opportunity, whether opt-in or opt-out, versus as a choice, as women's immediate preferences varied depending on the frame. When the decision was presented as an opt-in or opt-out opportunity, women were more likely to prefer the trial option or to be undecided than to have the standard treatment, compared to when it was presented as a choice. This bias was possibly due to the opportunity frames focussing women's attention on the trial option which was explicit in these frames; the choice frame avoided this bias possibly by drawing attention to other alternatives. The opt-out opportunity frame also affected women's evaluations of the degree to which the trial option would be endorsed by significant others (health professionals). Sixteen per cent of participants changed their initial preference about trial participation after receiving detailed information but information acquisition and final decision preference were not affected by the frames. Findings from this study suggest presenting the decision as a 'choice' is less likely to bias people's preferences. Further, encouraging people to view balanced and comprehensive information presented in a parallel, option-by-attribute format *before* eliciting preferences can 'de-bias' the decision frame, removing its effect on choice.

Unlike past studies,[22,26,28,31,35] this study found no difference in preferences between the opt-in and opt-out framing groups. There are several explanations for this variation in findings. First, the framing bias may be greater or smaller depending on the type and/or context of the decision, for example

different levels of effects may be found for donating organs after death, choosing treatment to live longer, choosing treatments for another person, and so on. Second, the framing bias may depend on how much detail is provided about the healthcare option. In this study, we made the trial option in both the opportunity frames explicit, which may have led participants to focus more on this option than on the implicit option of the standard treatment. Third, the framing bias may be greater or smaller depending on the values and experiences of the individuals so studies of people making real-world versus hypothetical decisions may find different effect levels. For example, the lack of difference between the two opportunity frames may have been due to a lower rate of choosing to participate in the trial in the opt-out group than might be expected relative to the opt-in group. This lower participation rate may reflect the negative attitudes of some participants to trial participation, which in the opt-out condition could reduce their tendency to accept the default option of the trial. In this study, it was not possible to assess participants' attitudes to trial participation before the decision as such measurement may impact the decision by making some values more salient than others. However, attitudes to trial participation, assessed after the decision, were found to be related to participants' initial decision of trial participation, particularly so in the opt-out frame. A logistic regression analysis revealed that attitudes significantly predicted the initial trial participation decision in both opportunity frames. Although the measure of attitudes was collected after the decision, these findings suggest that the effect of framing may depend on the nature and strength of pre-existing attitudes towards the options. Given the possibility of an unmeasured interaction effect of the opt-out frame and pre-existing attitudes, further research should examine the moderating role of attitudes in framing effects.

The frame did influence women's perceptions of social norm; women were more likely to infer that people who were important to them and the health professionals would support the trial option when it was presented as an opt-out. The opt-out frame presents the trial option as the default, i.e. what would happen if no action were taken; the implication is that the opt-out frame casts the trial option as a social norm and by doing so, leaks information about the writer/speaker's preference.[56,57] Consistent with the explanations offered for the increased attractiveness of default options, the heightened perceptions of social norm may have contributed to an increased preference for the trial option in two possible ways. First, the trial option could be seen as an implicit recommendation from the health professional, thereby providing a rationale for its preference.[30,58]Second, the trial could be seen as the

morally appropriate option, i.e. something people 'should do', making it harder to opt-out.[31,59] Both possibilities are consistent with McKenzie et al's[58] explanation that the writer/speaker's choice of description implicitly leaks information about their own preferences about the option as well as their beliefs about what others should do. They showed that, compared to opt-in frames, people are more likely to infer from the opt-out frames that the option described is the writer/speaker's preferred option and that therefore other people ought to choose the default. It is interesting that, despite the above possibilities, women's final decisions were unaffected by the frame. It is possible that the effect of the implicit recommendation in the opt-out frame was tempered by their subsequent evaluation of the full information. Future research should further explore the relationship between default framing, subjective norm and deliberation.

This study not only demonstrates the biasing effect of opportunity frames, but also suggests a potential way of ameliorating it through provision of balanced and comprehensive information about the options prior to eliciting preferences. Prior findings indicate that strength of framing biases decreases when individuals are encouraged to deliberate on the decision problem by providing detailed information about the options[60-62] or the context[63], by asking individuals to provide rationales for their decisions[64] and by inducing individuals to engage in analytical thinking[65]. In this study, it is possible the detailed information minimised the effects of frame by encouraging more systematic processing of information. It is worth noting that the content and structure of the information we provided was designed to encourage active deliberation. The standard treatment and trial information presented within the computer task was structured with reference to decision aid guidelines. Equivalent information was presented in parallel, option-by-attribute table format, as illustrated in Figure 4, which allowed the attributes of each option to be compared and contrasted at a glance.[5] Most patient information presents treatment options in a fixed linear sequence, which forces patients to consider the options and their attributes in the given order. The linear presentation of options is more likely to encourage biasing in what is attended to and/or evaluated, for instance, through primacy or recency effects.[66] It is possible a more traditional presentation of trial information would have resulted in a more pronounced framing effect on participants' acquisition, and evaluation, of decision information. Future research should compare the linear and parallel, option-by-attribute formats of presentation and explore their impact on framing effects.

This study is unique in that it investigates a novel aspect of framing, addresses an important clinical context, employs a robust experimental design and involves measures of what information is attended to. The study does have potential limitations to its generalization. Nonetheless it provides proof of concept data, which can underlie further research. First, a self-selecting sample of healthy women making a hypothetical choice about trial participation may not generalize to patients making these decisions or to those with other types of cancer. There is evidence that people's values change depending on their health state[67], which may influence their treatment choices. We suspect this sample had relatively stable values as all indicated they had experience of cancer, either as a previous patient or as an acquaintance of someone with cancer. More importantly, we expect that these results would be replicated in the real-world and in other contexts, because the study explores how an individual's construction of a decision problem is influenced by the presentation of options, rather than the evaluation of the information contained within the decision problem. It is likely that the same metacognitive processes would be employed by individuals whether or not they were patients.[68,69] This issue can be explored further in phase III type trials with populations that have more direct involvement with cancer (e.g. survivors/family/patients). Second, the sample in this study had a much higher rate of trial participation than is observed in the real world. This could be due to the hypothetical nature of the decision[70] or higher levels of education in the sample. We acknowledge that patients making these decisions in the real-world may be quite different in age, gender or educational status from participants of this study. Nevertheless, the aim of this study was to demonstrate that different decision frames can lead to different choices; this can be further tested in more representative populations and contexts.

Third, provision of the 'undecided' option at the initial but not the final decision complicates the comparison of findings, as 'undecided' may reflect that participants have no clear preference or that they are not sure enough to express or act on their preference. However, a forced-choice question to elicit an initial decision preference was not appropriate in this study. It may have biased participants' subsequent information processing, cognitions and the final decision due to the potential tendency to feel more committed to the chosen option and process any subsequent information in a way that confirms this choice[34]. Inclusion of the undecided option helped confirm the focusing effect of the frames; women receiving the opportunity frames were not only more likely to choose the trial but also

more likely to be undecided than to choose the standard treatment option. Inclusion of an undecided option to elicit final decision was also not appropriate because, often in reality, patients must choose one or the other. Thus, final decision by the initially undecided participants may reflect either a change from 'no preference' to a clear preference for the trial or the standard treatment option, or the expression of an initial preference which had not been strong enough to be expressed at the initial decision stage. Fourth, presentation of options and information via computer may compromise the study's external validity. As described earlier, this study replicated the clinician-delivered information in a controlled laboratory experiment to investigate whether framing affects people's information acquisition (i.e. what information is accessed, for how long and how often) along with their choices and cognitions. To allow collection of these data, information needed to be presented in such a way that only one piece of information is visible at a time.[51]The computer based approach was needed to facilitate presentation of information and acquisition of data, which would have been difficult with paper-based information.

These findings have implications for those delivering services to enhance patients' informed decision making about treatment, testing and trial options. First, the routine practice of presenting healthcare and clinical trial options using an opportunity frame (opt-in or opt-out) can lead to significant biases in people's preferences. Bias is less likely to occur when all options are presented explicitly using a choice frame. Saying "Do you want to have the standard treatment or take part in the trial" instead of "Do you want to take part in a trial" changes the decision representation to include two options rather than one, allowing individuals to consider all available options. Framing an option as an opt-out versus an opt-in seems to leak information interpreted as an endorsement of the option. It is unclear whether this frame affects informed decision making; it may change the value of a component part of the evaluation but not the ability to reason systematically about it. For some decisions where there is a 'correct' behaviour (e.g. illness prevention programmes), it may be argued that framing an option as an opt-out enables people to make an informed choice, rather than an informed decision, and this level of engagement with the information is sufficient.[29,30] In these contexts, the opt-out framing may nudge people towards the desired behaviour without removing their freedom to choose differently. Second, these effects are ameliorated by the provision of full information about the risks and benefits of both options when presented in a readable, easily accessible and comparable way, i.e. full patient

information can de-bias the decision context and enable patients to re-evaluate labile preferences.[62,64] This is particularly important because in the real-world setting, patients may not often be provided with full information, in an accessible and comparable format, immediately after the initial trial offer. Third, women's trial preferences change when they receive more information and/or have time to consider the decision information.[71,72] Tailoring information according to a first preference will limit the likelihood patients are able to make informed decisions.

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The authors have no conflicts of interest to declare.

Tables

Table 1: Characteristics of participants by framing groups

	Opt-in (N=42)	Opt-out (N=41)	Choice (N=41)
Average (SD) age in years	28.2 (9.5)	25.3 (8.7)	25.0 (6.9)
Ethnicity: White, N(%)	32 (76%)	34 (83%)	26 (63%)
Occupation: student N (%)	23 (55%)	33 (80%)	26 (63%)
Marital status: single N(%)	29 (69%)	30 (73%)	34 (83%)
Women with close relatives with cancer N(%)	13 (31%)	15 (37%)	9 (22%)
Average (SD) number of people known with cancer	2.4 (1.5)	2.4 (1.3)	2.3 (1.2)

Table 2: Change in decision by faming conditions

	Opt-in (N=42)	Opt-out (N=41)	Choice (N=41)
Change in decision among those with definite initial preference N(%)	**4 (10%)**	**2 (5%)**	**7 (17%)**
From Trial to Standard treatment	*2 (5%)*	*1 (2.5%)*	*2 (5%)*
From Standard treatment to Trial	*2 (5%)*	*1 (2.5%)*	*5 (12%)*
Final decision among those initially undecided N(%)	**19 (45%)**	**13 (31%)**	**12 (29%)**
Choosing Trial	*14 (33%)*	*8 (19%)*	*9 (21%)*
Choosing Standard treatment	*5 (11%)*	*5 (12%)*	*3 (7%)*

Table 3: Mean (SD) for information acquisition measures by frame

	Opt-in (N=42)	Opt-out (N=41)	Choice (N=41)	Partial Eta Squared
Total amount of information examined Multivariate F[8,238]=1.05, p=.39				0.034
Proportion of information searched	.74 (.20)	.76 (.18)	.69 (.26)	.017
Total time spent on information screen	6.6 min. (2.7)	6.5 min (2.1)	6.2 min (2.7)	.001
Average time spent per information piece	5.4 sec.(2.1)	5.6 sec.(2.1)	5.4 sec.(1.9)	.004
Reacquisition rate	.19 (.09)	.19 (.08)	.19 (.11)	.002
Depth of search Multivariate F[8,238]=.84, p=.57				.027
Proportion of information examined on trial	.79 (.23)	.85 (.19)	.74 (.28)	.029
Proportion of information examined on standard treatment	.63 (.24)	.59 (.21)	.58 (.29)	.005
Proportion of time spent on trial information	.55 (.12)	.59 (.07)	.53 (.14)	.039
Proportion of time spent on standard treatment information	.16 (.07)	.15 (.06)	.15 (.08)	.004

Table 4: Mean (SD) for decision related cognitions by frame

	Opt-in (N=42)	Opt-out (N=41)	Choice (N=41)	Partial Eta Squared
Perceived risk and severity of side effects (low-high; 1-7) Multivariate F[8, 236]=1.2, p=.31				.039
Severity of trial side effects	5.3 (1)	5.3 (1)	4.9 (1)	.006
Risk of trial side effects	6 (1.2)	6 (1.3)	5.8 (1.1)	.013
Severity of ST side effects	5.4 (1)	5.3 (1)	5.1 (.9)	.011
Risk of ST side effects	5.8 (1.4)	6 (1)	5.8 (1.2)	.024
Theory of Planned Behaviour measures Multivariate F[6, 236]=2.9, p=.009				.069
Attitude towards trial (Unfavourable-Favourable; 4-28)	16.7 (.7)	17.1 (.7)	16.9 (4.7)	.001
Subjective norm (low-high; 2-14)	8.9 (4)	10.1 (4)	8.7 (2.1)	.068
Perceived Behavioural Control (low-high; 3-21)	17.2 (3)	18.1 (3)	17.2 (2.9)	.022
Satisfaction with decision (low-high; 6-30) F[2,120]=.24, *p=.78*	24.1 (2.9)	24.3 (3.7)	23.8 (3.3)	.004

Figure Legends

Figure 1: Decision scenario with framing intervention

Figure 2: Summary of content of information on decision options

Figure 3: Study procedure flow chart

Figure 4: Decision information presented on computer screen

Figure 5: Initial preference in opt-in, opt-out and choice conditions

Figure 6: Final decision in opt-in, opt-out and choice conditions

Figure 1: Decision scenario with framing intervention

Imagine that you are in the consultation with your doctor. The doctor is discussing with you what treatments you could have for your cancer. Your doctor suggests that you have chemotherapy. Chemotherapy may offer a good chance of destroying any cancer cells that may have been left behind.

There is an opportunity to take part in a clinical trial. You are suitable to take part in this trial. (Opt-in)

All patients are automatically entered in a clinical trial. You are suitable for this trial and will be automatically entered. There is an opportunity to be removed from this trial. (Opt-out)

You are suitable to take part in a clinical trial. You have two options. Option one is to have the standard treatment. Option two is to take part in the clinical trial. (Choice)

The clinical trial is known by the short-form TACT. The clinical trial compares two different chemotherapy treatments, A and B. Treatment A involves drugs that have been used for your type of cancer for many years. Treatment B uses drugs called Taxanes. At present, taxanes are only used for treating breast cancer which has already spread to other parts of the body. The TACT trial aims to find out whether adding a taxane drug called Docetaxel to other chemotherapy drugs will reduce the chance of breast cancer coming back. If you decide to take part, a computer will randomly allocate you to either treatment A or B.

Question for Opt-in

Do you want to take part in the trial?

1. Yes, I want to take part in the trial
2. No, I do not want to take part in the trial
3. I am uncertain about my decision (Included in the initial decision preference only)

Question for Opt-out

Do you want to be removed from the trial?

1. Yes, I want to be removed from the trial
2. No, I do not want be removed from the trial
3. I am uncertain about my decision (Included in the initial decision preference only)

Question for Choice

Do you want to take part in the trial or have the standard treatment?

1. I want to take part in the trial
2. I want to have the standard treatment
3. I am uncertain about my decision (Included in the initial decision preference only)

Figure 2: Summary of content of information on decision options

TACT trial	Standard treatment
• Purpose of the trial • Treatment details: Drugs being tested; number of cycles, frequency of cycles, duration of treatment, and method of treatment delivery. • Possible side effects of both drugs • Method of treatment allocation and the rational for randomisation • Advantages of taking part in the trial (access to potentially more effective treatment, closer monitoring of your health, helping future patients, randomisation) • Disadvantages of taking part in the trial (random allocation to treatment, uncertainty of additional benefits, additional clinic visits, unexpected side effects)	• Purpose of treatment • Treatment details: drugs involved, number of cycles, frequency of cycles, duration of treatment and method of treatment delivery • Possible side effects • Advantages of having the standard treatment (treatment not selected randomly, known side-effects) • Disadvantages of having the standard treatment (no opportunity to receive new treatment)

Figure 3: Study procedure flow chart

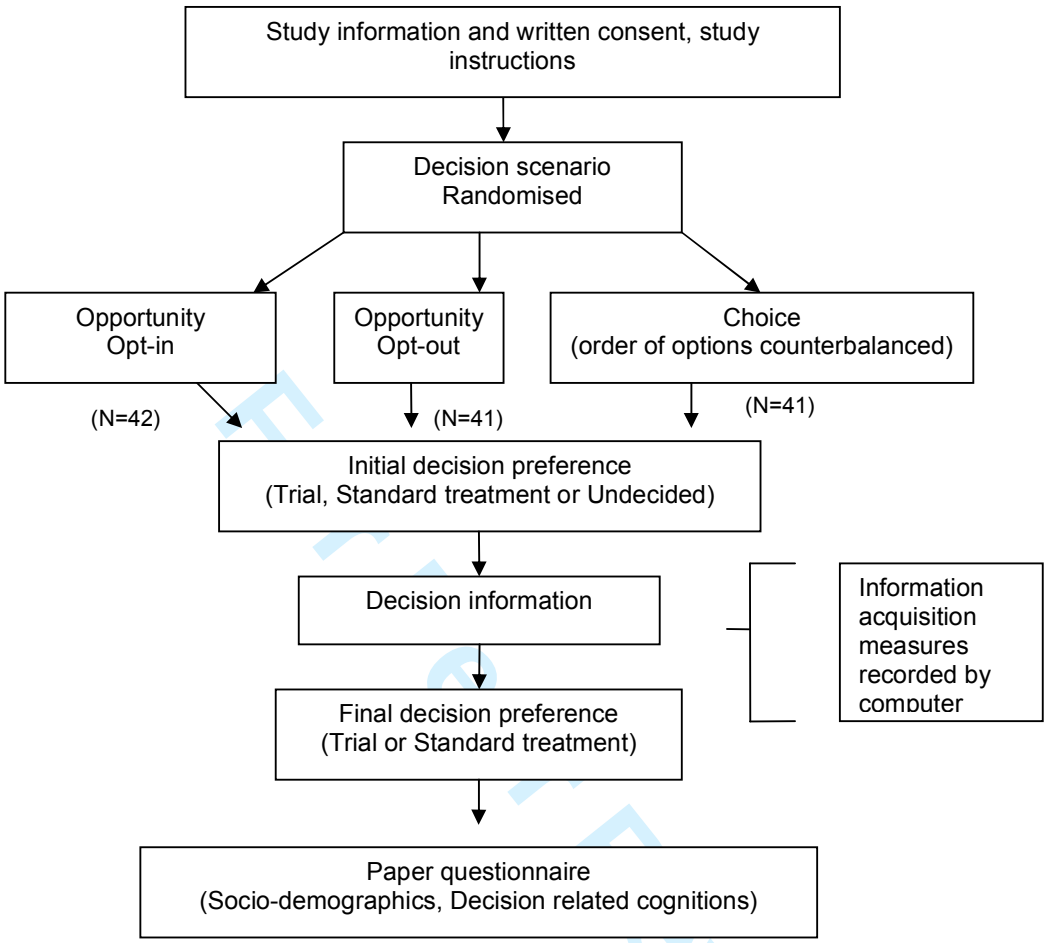


Figure 4: Decision information presented on computer screen

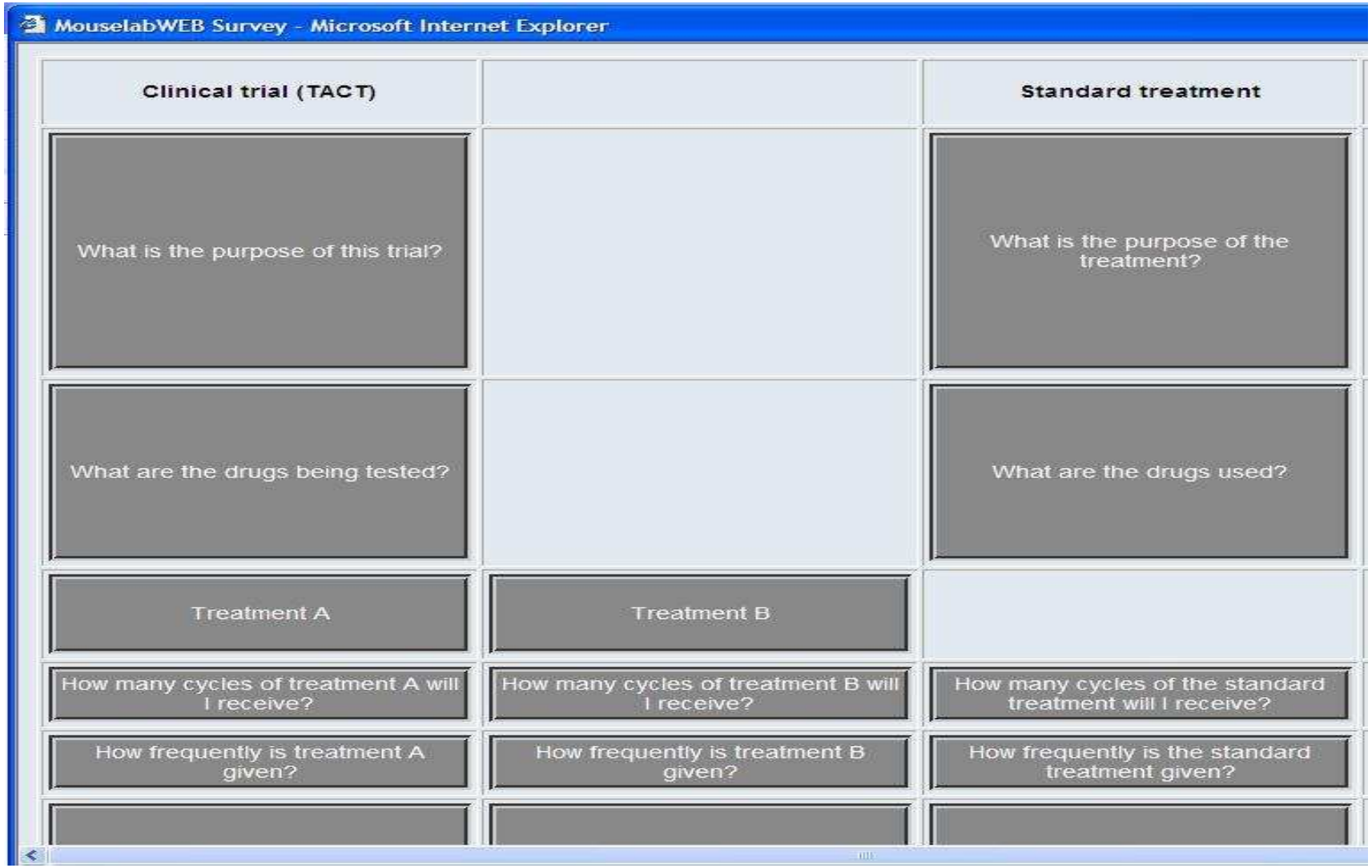


Figure 5: Initial preference in opt-in, opt-out and choice conditions

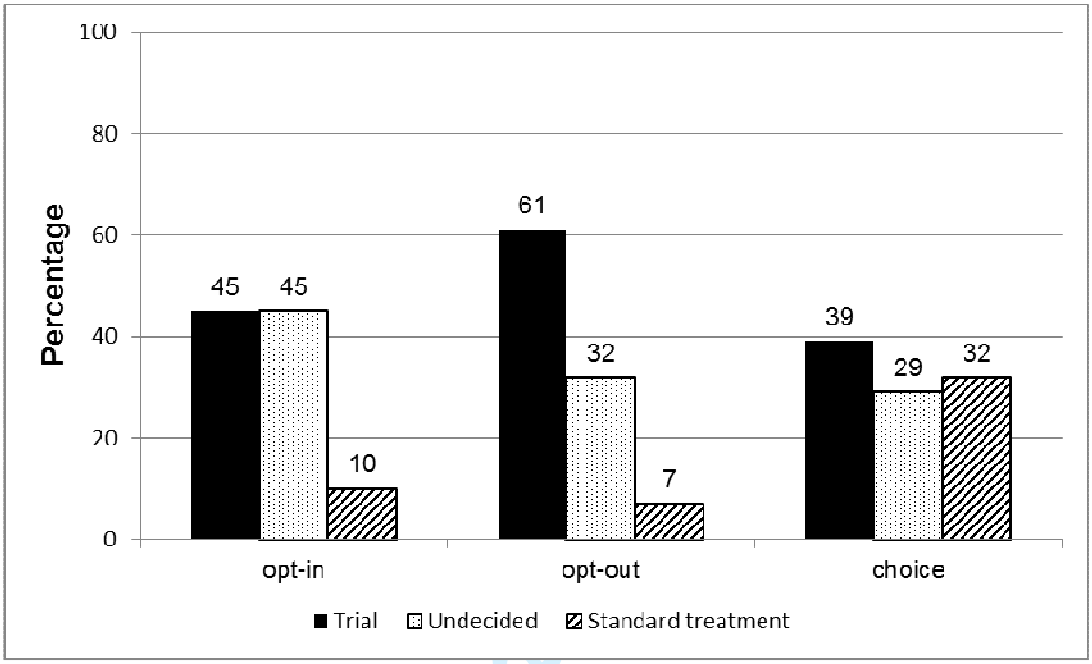
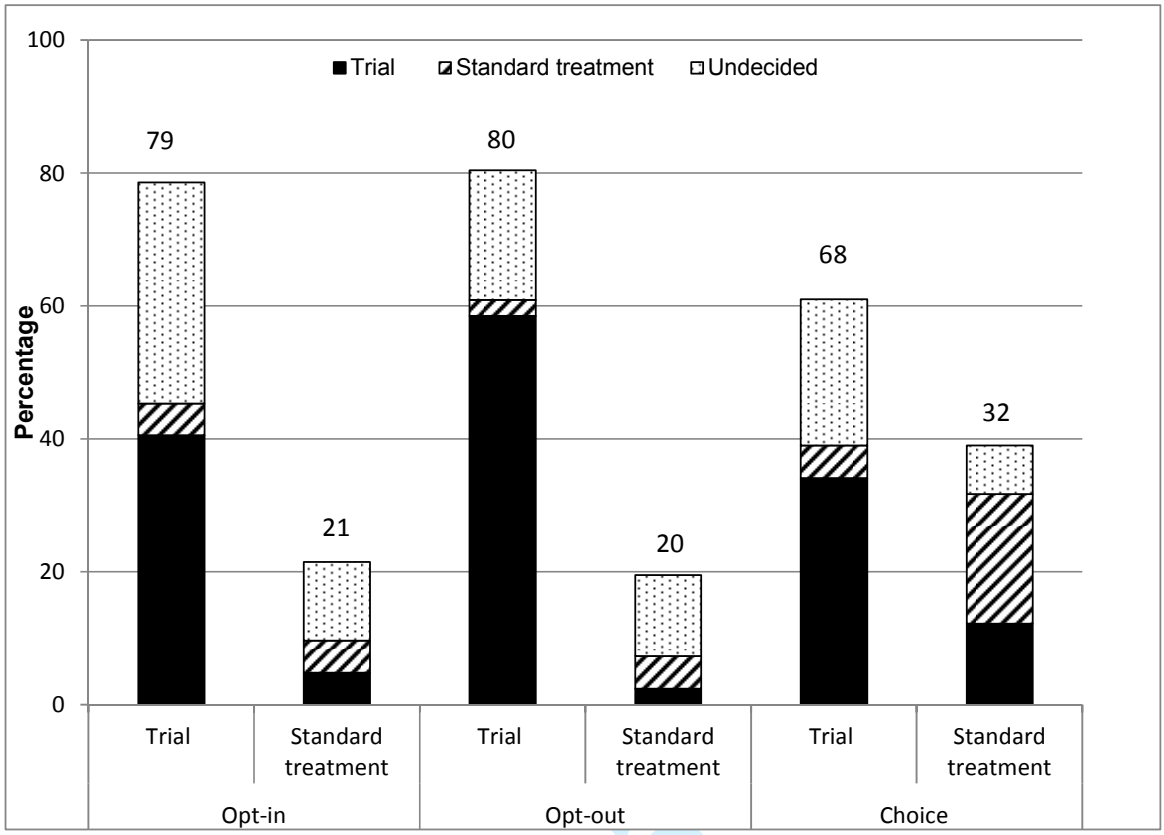


Figure 6: Final decision in opt-in, opt-out and choice conditions stacked by initial preference



Title: Framing options as choice or opportunity: does the frame influence decisions?[1]

Authors:

Purva Abhyankar, PhD, Leeds Institute of Health Sciences, University of Leeds, UK

Barbara A Summers, PhD, Centre for Decision Research, Leeds University Business School, UK

Galina Velikova, MD, PhD, Leeds Institute for Molecular Medicine, St James's Institute of Oncology, University of Leeds, UK

Hilary L Bekker, PhD, Leeds Institute of Health Sciences, University of Leeds, UK

Corresponding author:
Purva Abhyankar
Nursing, Midwifery and Allied Health Professions Research Unit
University of Stirling
Unit 13 Scion House
Stirling University Innovation Park
Stirling
FK9 4NF
Email: purva.abhyankar@stir.ac.uk

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Abstract

Objective: Health professionals must enable patients to make informed decisions about healthcare choices through unbiased presentation of all options. This study examined whether presenting the decision as 'opportunity' rather than 'choice' biased individuals' preferences in the context of trial participation for cancer treatment.

Method: Self-selecting healthy women (N=124) were randomly assigned to the following decision frames: opportunity to take part in the trial (opt-in), opportunity to be removed from the trial (opt-out), and choice to have standard treatment or take part in the trial (choice). The computer-based task required women to make a hypothetical choice about a real-world cancer treatment trial. The software presented the framed scenario, recorded initial preference, presented comprehensive and balanced information, traced participants' utilisation of information during decision making and recorded final decision. A post-task paper questionnaire assessed perceived risk, attitudes, subjective norm, perceived behavioural control and satisfaction with decision.

Results: Framing influenced women's immediate preferences. Opportunity frames, whether opt-in or opt-out, introduced a bias as they discouraged women from choosing standard treatment. Using the choice frame avoided this bias. The opt-out opportunity frame also affected women's perceived social norm; women felt others endorsed the trial option. The framing bias was not present once patients had had the opportunity to view detailed information on the options within a patient decision aid format. There were no group differences in information acquisition and final decisions. Sixteen per cent changed their initial preference after receiving full information.

Conclusions: A 'choice' frame, where all treatment options are explicit is less likely to bias preferences. Presentation of full information in parallel, option-by-attribute format is likely to 'de-bias' the decision frame. Tailoring of information to initial preferences would be ill-advised as preferences may change following detailed information.

Keywords: framing; informed decision making; patient choice; trial participation; opt-in/opt-out; decision aids

Introduction

Healthcare policies worldwide recommend patients be enabled to make informed decisions about their healthcare choices, especially when the decision is 'preference sensitive' i.e. there is no single best option available.[1] To enable informed decision making, it is essential that health professionals a) present all available options and information about options in a balanced manner and b) encourage patients to engage with the information to evaluate it in accordance with their own values.[2,3,4] Balance refers to complete and unbiased presentation of all the relevant options and the information about those options—in content and in format—in a way that enables individuals to process this information without their choices being influenced by the presentational aspects.[5]

From years of research in decision psychology, we know that the way information is presented can have unintended effects on the way it is attended to, perceived and processed. These unintended effects include biases in people's judgements and choices. This 'framing effect' is described as biasing people's judgements and choices because people make different decisions when the same information is packaged differently.[6] A classic example of the framing effect is presenting risk information either positively or negatively. For example, people's preferences are seen to reverse when the same decision problem is presented either in terms of 'losses' (400 of 600 patients will die) or 'gains' (200 of 600 patients will be saved).[7-9] Framing effects are believed to occur due to a focussing phenomenon.[10,11] When faced with a decision, people construct a mental representation of the decision which contains the information needed to make the choice.[12] As the capacity of the working memory is limited, not all aspects of the decision situation can be included in this representation. A major determinant of what information enters the mental representations is the description of the decision situation, as people attend selectively to the information provided. Information explicitly presented about the decision is more likely to be included within the representation for evaluation than information implicit in the decision problem. The resulting mental representation is then used to make decisions quickly without too much cognitive effort, but this means that relevant information about the decision may be omitted. Different presentations of the same situation can therefore induce people to form markedly different mental representations, which in turn, lead to different choices.

Most framing research in the healthcare context has focussed on the way information about probabilities of outcomes associated with different options is presented; for example, presenting the probabilities positively vs. negatively [13,14] or in absolute vs. relative terms.[15,16] Relatively little research has investigated how framing the presentation of decision options affects people's choices. Research from outside the health context, however, suggests that people's choices and perceptions of options vary when the decision options are presented in slightly different ways. A commonly used frame in everyday conversation is the offering of options as an opportunity (i.e. a single option is explicit and the decision is presented as an opportunity to pursue that option) rather than a choice (i.e. all options are explicit and the decision is presented as a choice between two or more options).[10] Unlike the choice frames which make all available options explicit, the available alternatives are often implicit within the opportunity frames. The effect of this type of framing on people's decisions and information seeking was first demonstrated in a non-medical context by Jones et al.[10] Presenting an option as an opportunity was found to be associated with an increased willingness to choose that option and a reduction in questions about other alternatives, compared with when the option was presented as a choice.[11,17] Many health-related options are presented as opportunities - for instance "Would you like to have this test/treatment/take part in the trial?"- where the alternative of continuing without a test/treatment or having standard treatment is implicit. There is evidence to suggest that this type of framing may be, advertently or inadvertently, taking place in routine clinical practice. For example, health professionals are reported to use communication methods that emphasise benefits over risks, make explicit or implicit recommendations, and position an option as the only sensible choice.[18-24] However, presenting options as an opportunity or choice is rarely recognised as a 'frame' that may influence and/or bias people's choices, causing changes from a situation in which both options are salient. In consequence, little research has explored systematically the effect of the opportunity versus choice frame within different decision contexts.

Although opportunity framing makes only one option explicit, there are two types of opportunity frame which differ in terms of the option that occurs if no action is taken (the default option). The decision may be presented as an opportunity *to pursue* an option (opt-in) or as an opportunity *not to pursue* an option (opt-out). The opt-in frame presents the option as novel and implies a loss of that option if no action is taken. The opt-out frame presents the option as routine and implies the loss of that option if

action is taken. Within the healthcare context, a number of examples can be found where the options are presented in either an opt-in or an opt-out frame.[25] For example, most screening and immunisation options are presented in an opt-in frame where people are invited to have a test or a vaccine, whereas others such as organ donation and HIV testing are, in some countries, presented in an opt-out frame where these services are offered as routine/default with an opportunity to refuse them.[25,26] Evidence in both medical and non-medical contexts suggests that people make different choices depending on whether the options are presented as opt-in or opt-out; presenting an option in an opt-out frame is often found to increase the uptake of that option compared to when it is presented in an opt-in frame.[27-33] The increased attractiveness of the option in the opt-out frame is believed to be due to the frame's impact on people's representation of the option as socially valued or endorsed by others, so less cognitive effort is involved in accepting the default, and to the lower levels of regret experienced by people when harm results from a decision not to take action.[30,34-36]

Most research has focussed on comparing the effects of opt-in and opt-out frames; however, these frames have rarely been viewed as variants of opportunity frames and contrasted with a choice frame as a baseline. It is therefore unclear how using opt-out versus opt-in to express an opportunity will change decisions relative to a choice frame. It may be that, despite the differences in choices resulting from the opt-in and opt-out frames, the important feature of such frames is that both make salient the uptake of the option they explicitly present. Both the frames may therefore nudge people to focus on the option that is explicit in the frame, though one increases the uptake of the option more than the other by presenting it as a default/routine. Alternatively it may be that the opt-in and opt-out frames produce take-up rates on either side of choice, as opt-out nudges decision makers towards uptake of the option while opt-in reduces the chances of them taking the option. A third alternative would be that opt-in and choice produce similar effects, because in both cases the decision maker starts from a position of not taking the option and has to take action to do so, whereas opt-out produces higher uptake because the default is to take the option. While the expected result is unclear, the choice frame, nonetheless, removes the implicit nudging by presenting all options explicitly and would therefore seem most appropriate for supporting informed decision making.

Most framing research has evaluated the effect of framing on people's judgements and choices. However, it remains unclear if framing leads to judgements and choices that are more or less informed. To enable informed decision making, it is crucial that the presentation of options and information be complete, unbiased and encourages people to evaluate all available options and their attributes in accordance with their own values.[2,3] It is largely unknown whether and which frames bias or enhance decision making and in what contexts. This makes it difficult to determine the optimal way in which options and information should be presented to ensure choices are not biased. Jones et al[10] argue that presenting an option within a choice frame leads to a more complete and balanced representation of the decision problem in terms of both explicit presentation of all available options and absence of any subtle nudging of people's attention towards or away from a single option. Certainly if this framing effect is evident in health-related decisions, presenting options as a choice rather than an opportunity is likely to have prescriptive implications for facilitating informed decision making.

This article describes the first study to investigate systematically the choice versus opportunity frame within a health context. The study evaluates the choice versus opportunity frame – both opt-in and opt-out versions - on decisions in the context of trial participation for cancer treatment. Cancer clinical trial choices are complex decision contexts as the decisions about trial participation are often nested or subsumed within decisions about treatment.[37] The offer of trial participation complicates the treatment decision by introducing the prospect of a better outcome but with uncertainties associated with treatment allocation, effects and outcomes. Although patients are provided with written trial information, often the option is initially offered verbally during consultation with health professionals.[37,38] Evidence suggests that patients make these decisions instantaneously, using a range of heuristic strategies such as selectively attending to information, forming early impressions based on quick evaluations of initial information, or settling on a satisfactory option without considering alternatives.[37-43] This suggests that patients are likely to be influenced by the way trial options are verbally presented, even before they consider the written information, so the framing of the initial description of the decision they receive is important. We initially hypothesised that people receiving either of the opportunity frames would be more likely to choose the trial than those receiving the choice frame, on the basis that participants in Jones et al. (1998) when faced with opt-in frames

tended to choose the option more often, and we would expect opt-out frames to increase this tendency by making the opportunity the default option. Given the tendency for people to seek information that confirms their decision[34] we hypothesised that any bias in the initial decision resulting from the use of opportunity frames could affect the later processing of decision information leading to less informed decisions.

Method

Sample

All women aged 18 years or older working and/or studying at the University of Leeds, UK were invited to participate via the University's email distribution list. No women volunteering to participate were excluded. There are ethical concerns about carrying out this type of research in a sample of patients making actual trial participation choices as there is a risk of influencing the choices that may affect their health, illness and possibly mortality. In this applied context, we need to have confidence that any manipulation, at the least, causes no additional harm and may even benefit the patient making the choice. This study is therefore carried out in a sample of healthy women making a hypothetical choice about trial participation but using information from a real-world cancer treatment trial. This study is expected to provide some proof of concept data, as in a 'phase II' trial addressing whether these framing effects affect healthcare choices.[44] The Leeds Institute of Psychological Sciences Ethics Committee approved the study in June 2006. 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.

Design and procedure

The study employed an experimental between-subjects design with random allocation to one of the three decision-framing conditions: (1) Decision problem framed as an *opportunity* to take part in a clinical trial (opt-in); (2) Decision problem framed as an *opportunity* to be removed from a clinical trial (opt-out); (3) Decision problem framed as a *choice* between taking part in a clinical trial or having standard treatment. As the order in which options are presented may influence people's choices[45-46], the sequence in which the trial and standard treatment alternatives were described in the *choice*

frame was counterbalanced so that half received the trial option first (T-S) and half the standard treatment option first (S-T).

The study was carried out in a decision lab using computers situated on partially-enclosed desks. The Mouselabweb software programme[47] was used to manage the randomisation to condition, present the decision information and task, and trace participants' information usage concurrently with the task. At the beginning of the session, participants received written instructions outlining how the session would proceed. The software programme asked participants to input the identification number and reference number appearing on the instructions sheet. The reference number specified to the MouselabWeb programme which framing condition the participant was allocated to: 1. opt-in, 2. opt-out, 3. choice S-T, and 4. choice T-S. Participants were allocated to the framing conditions in randomly permuted blocks with the pattern 1, 2, 3, 1, 2, 4, 1, 2, 3… and so on to ensure that there were equal numbers of participants in each framing condition, with the choice condition being counterbalanced. Participants were unaware that they were allocated to different framing conditions using the reference number. Following evidence from previous literature[18,37,38] and input from a practicing oncology consultant on the study team, the study was designed to mimic how cancer treatment and trial options are offered in a real-world setting. Treatment and trial decisions are sometimes first presented and discussed verbally during clinical consultations, before the written information is provided. To replicate this process in a controlled laboratory setting, we first presented participants with a brief decision scenario (Figure 1) and asked them to indicate their initial preference in response to the scenario. Following the scenario, they received detailed information about the trial and standard treatment options (Figure 2) and were asked for their final decision preference. Participants filled out the paper questionnaire after completion of the computer task. Figure 3 summarises the study procedure. The study was piloted on the first nine participants and modifications were made to the study materials following participant feedback and data inspection. Participants from the pilot were included in the main data as the modifications were not expected to change the key aspects of their behaviour.

<Insert Figures 1, 2 and 3 about here>

Materials

The decision scenario and framing intervention

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); TACT was an international phase-three chemotherapy trial for early stage breast cancer, carried out by the local cancer unit.[48] A breast cancer scenario was used as it is one of the most common and high profile cancers, likely to be known to most people through media or experience of family/friends. 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 and to recollect the experiences of any family and friends who had experienced cancer.[49]

The decision scenario and the accompanying questions eliciting initial and final decision preference were framed either as a 'choice' or an 'opportunity'. The choice frame explicitly stated that there were two options and asked participants to choose between those options. The opportunity frames made only the trial option explicit and asked participants to decide whether to follow or not to follow that option. There were two versions of the opportunity-frame: opt-in and opt-out, both with the same option explicit but differing in the defaults. The opt-in condition presented the decision as an opportunity to take part in the trial with standard treatment as the implicit default. The opt-out condition presented the decision as an opportunity to opt-out of the trial with trial participation as the default (Figure 1).

Detailed decision information

The information about the TACT trial and the standard treatment was adapted for use on the computer (Figure 2). The information about the two decision options was arranged in adjacent columns. The information was presented in concealed boxes labelled by questions relating to the box content which were accessed by clicking on the box (Figure 4). The box remained open as long as the cursor was inside the box and closed when the cursor was moved out of the box. Each box opening counted as an acquisition of information. The information readability score was 8.0 (equivalent of an eighth grader / age 14 level)[50].

<Insert Figure 4 about here>

Measures

Data were elicited by two methods – responses recorded by the computer during the decision task and the paper questionnaire completed after the task – and assessed the following:

Responses recorded by the computer:

- Decision preference - initial decision preference was assessed before the receipt of detailed information using a categorical response: take part in the trial, have the standard treatment or undecided. The final decision preference was assessed after the receipt of full information using a categorical response: take part in the trial or have the standard treatment. (Figure 1). The option of refusing both options was not presented because, in real-world practice, this is not often considered a reasonable option.
- Information acquisition measures - MouselabWeb software recorded the total number of information boxes acquired, the number of times they were reacquired, and the amount of time spent on each box (Figure 4). From these data, process tracing indices were computed[51]: depth of search was calculated separately for trial and standard treatment information as the proportion of available information examined; reacquisition rate was calculated as the total number of information pieces examined minus the total number of first acquisitions, divided by the total number of information pieces examined. A higher depth of search and reacquisition rate indicates a more systematic decision process.

Paper questionnaire:

- 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 cognitions about risks included: perceived likelihood and severity of side effects for the trial and the standard treatment using 7-point Likert scales, scored 1=not at all likely/not at all severe to 7=very likely/very severe.
- Decision cognitions informed by the *Theory of Planned Behaviour* (TPB)[52] included: *attitude* towards taking part in the TACT trial assessed using four semantic differential scales ('Bad-Good', 'Beneficial-Harmful', 'Risky-Safe' and 'Reassuring-Worrying'), scored 1 to 7; two *subjective norm* items ('people who are important to me' and 'my doctor'), scored 1=strongly disagree to 7=strongly agree); three *perceived behavioural control* items assessing whether

or not taking part in the trial is up to the participant, scored 1=strongly disagree to 7=strongly agree. The Cronbach's alpha for the three scales were 0.77, 0.49 and 0.44 respectively[2].

- Satisfaction with the decision was assessed using the six-item validated Satisfaction with Decision Scale[53] assessing the degree to which participants felt their decision was of good quality, informed, consistent with personal values, satisfactory and implementable (scored 1=strongly disagree to 5= strongly agree). Higher scores indicate higher satisfaction with the decision (Cronbach's alpha = 0.85).

Data analysis

First, homogeneity of framing groups with respect to demographic characteristics was assessed using analysis of variance (ANOVA) and chi-squared tests. Second, analyses were performed to identify the effects framing had on women's decision making. If differences are found between the frames in terms of information acquisition, decision related cognitions and final decision outcome measures, there are two ways these might arise (and, indeed, both might be present):

1) The frame, because of the internal representation of the problem it invokes, leads to changes in the ways people acquire information and think about the decision, and this leads to changes in the option they choose. Here the frame is affecting the decision in the usual way we expect in framing effects.

2) It may be that the initial decision people make leads to changes in the ways they acquire information and think about the decision, and affects the option they choose. This could occur, for example, if people spent more time looking at information related to the option they initially chose. If the frame affects the initial decision, it would then affect the final decision through the impact the initial decision has on processing

In identifying whether the first or the second case applies, the role of the initial decision provides evidence. In the second case, frame will affect the initial decision, but the effect on other outcomes will be via the initial decision. In this case the initial preference should explain differences in the other outcomes and the effect of frame should no longer be significant when initial decision is included in the model.

[2] The two items assessing subjective norms used two different referent groups. As people may have different beliefs about different referent groups, the two items are not expected to show high internal consistency. The internal consistency of the three items assessing perceived behavioural control was lower than the usual cut-offs (0.44). However, a factor analysis on these items indicated that all three items had loadings of >0.6 on a single factor, suggesting that the items were measuring the same underlying construct.

Framing effects on initial preference and final decision were examined using chi-squared tests and multinomial logit analyses. Multinomial logit analyses examined the group differences in initial preference using two sets of models; the first set compared the 'trial' category with the 'standard treatment' and 'undecided' categories; the second set provided comparisons of the 'standard treatment' and 'undecided' categories. In each set of models, the choice group served as the reference category against which each of the opportunity frame groups was compared. The output from these models indicates the change in the predicted odds of an outcome for a unit change in the predictor (denoted by the beta co-efficient). Framing effects on information acquisition, decision cognitions and decision quality were assessed using multivariate analyses of variance (MANOVA). Significant univariate effects were followed up using pairwise comparisons with Bonferroni adjustment.

Results

One hundred and twenty-four women, aged between 18 and 54 years (Mean=26 years, SD=8.5), took part in the study. No participants dropped-out once an initial contact had been made. The sample was predominantly Caucasian (75%); over half (66%) were students and 75% were single. Three percent had been previously diagnosed with cancer[3] and the rest (97%) knew someone with cancer in their social network, of whom 30% were close relatives, 43% were distant relatives and 24% were friends, colleagues or other acquaintances. There were no differences among the framing conditions with respect to age ($F[2,119]=1.7$, n.s.), number of people known with cancer ($F[2,121]=.15$, n.s.), ethnicity (χ^2 =4.2, df=2, n.s.), marital status (χ^2 =2.2, df=2, n.s.) and experience of cancer (χ^2 =2.1, df=2, n.s.) (Table 1). Significant differences among framing conditions were observed by occupation (χ^2 =6.3, df=2, $p<.05$) but further analyses revealed no significant differences between students and staff with respect to initial preference and final decision, information acquisition, decision cognition and quality measures. Framing effects were examined by comparing the opt-in (N=42), opt-out (N=41) and choice (N=41) framing conditions. The two counterbalancing versions of the choice frame were collapsed into a single category as no significant differences were found between the two versions with respect to any of the dependent measures.

[3] To test the possibility that women with a diagnosis of cancer may have thought and acted differently, analyses were conducted with and without these participants. As there was no difference between the findings, the results for the whole sample are reported.

<Insert Table 1 about here>

Framing effects

Framing effect on initial preference

When asked about their initial preference following the decision scenario and before receipt of full information, 64% indicated a definite preference (48% to take part in the trial; 16% to have the standard treatment), and 36% were undecided.

Framing affected initial preferences (χ^2 = 13.18, df=4, p=.010, effect size w=0.33) (Figure 5). A post-hoc power calculation, using G*Power[54,55] and the effect size w from the statistical test output, indicated that the power of the χ^2 test of whether framing affects initial preferences is 0.85, suggesting that the study was adequately powered to test this hypothesis. Those in the opportunity frames were less likely to choose the standard treatment rather than the trial when compared to those in the choice frame (for opt-in, β=-0.14, p=0.042, Odds Ratio = 0.259,[4] with 95%CI 0.070 to 0.954; and for opt out; β= -1.9, p=.008, Odds Ratio =0.148, with 95%CI 0.036 to 0.601). Women in the opportunity frames were also more likely to be undecided than to choose the standard treatment (for opt-in; β= 1.6, p=.016, Odds Ratio = 5.146 with 95%CI 1.356 to 19.524; and for opt-out β=1.5, p=.041 Odds Ratio = 4.694 with 95%CI 1.068 to 20.631). There were no significant differences between the opt-in and opt-out conditions. Although these models are underpowered due to the sample size, they provide further insight into the differences between groups illustrated in Figure 5.

<Insert Figure 5 about here>

Framing effect on final decision

After receipt of full information, 76% decided to take part in the trial and 24% decided to have the standard treatment. No significant results were found by the chi-squared test of the distribution of the final decision across the three framing conditions (χ^2 =1.9, df=2, *p=.38, Eta=0.125*) (Figure 6). Logistic regression analyses confirmed these findings.

<Insert Figure 6 about here>

[4] The odds ratio relates to the change in odds of taking up an option between the base group and the focal group to which it applies. It is calculated as the odds after a unit change in the independent variable (dummy variables for group membership in this case) divided by the odds for the base category. An odds ratio greater than 1 represents an increasing chance of taking the option, and an odds ratio below 1 indicates a decreasing chance. Here the odds ratio of 0.259 indicates a decreasing chance of choosing standard treatment with odds of 1:3.86 (3.86=1/0.259).

Of those who had indicated a definite preference before receiving full information, 16% changed their decision after receipt of full information; 10% switched to taking part in the trial and 6% to having the standard treatment. Logistic regression analyses showed no differences by frame in the propensity to change decision (Table 2).

<Insert Table 2 about here>

Framing effect on information acquisition measures

MANOVA analysis on the information acquisition measures showed no significant main effects of opt-in, opt-out and choice framing on total amount of information acquired and reacquisition rate ($F[8,238]=1.05$, $p=.39$) or depth of search ($F[8,238]=.84$, $p=.57$) (details of the measures in each group of dependent variables can be found in Table 3).

<Insert Table 3 about here>

Framing effect on decision cognitions

Details of the dependent variables in each analysis can be found in Table 4. There were no significant multivariate effects of frame for perceived risk and severity of side effects ($F[8, 236]=1.2$, $p=.31$). A significant multivariate effect of frame was found for the Theory of Planned Behaviour measures ($F[6, 236]=2.9$, $p=.009$); with a significant univariate effect for subjective norm ($F[2, 119]=4.3$, $p=.015$). Pairwise comparisons with Bonferroni correction indicated that participants in the opt-out condition were more likely to infer that the trial would be an option recommended by significant others than those in the choice condition ($p=.021$).

<Insert Table 4 about here>

To explore the route by which the frame affected subjective norm, differences in subjective norm were first examined by initial preference. Second, the effect of frame on subjective norm was investigated with initial preference as a covariate. A significant multivariate effect of initial preference was found for the TPB measures ($F[6,236]=5.9$, $p<.001$) with a significant univariate effect for attitude and subjective norm. Pairwise comparisons with Bonferroni correction indicated that those who preferred the trial had a more favourable attitude to the trial and greater subjective norm perceptions compared to the standard treatment choosers and the undecided (all $p<0.001$). To examine if the effects of frame on the TPB variables remained significant after controlling for the differences by initial decision, initial decision was included as a covariate in a MANCOVA. The multivariate effect of frame remained significant ($F[6,234]=2.7$, $p=.014$) with a significant univariate effect for subjective norm ($F[2,118]=3.4$,

p=.037) and similar findings in pairwise comparisons for subjective norm (p=.038) to those found without the covariate. These findings suggest that framing affected women's subjective norm in the way usually associated with framing effects and not just via an impact on initial choice.

Framing effect on satisfaction with decision

The effect of framing on women's satisfaction with the decision was assessed using one way analysis of variance. The findings suggest that the three framing conditions did not differ with respect to satisfaction with the decision (F[2,120]=.24, *p=.78)* (Table 4).

Discussion

This study is the first, to the authors' knowledge, to test the effect of the opportunity versus choice frame for a healthcare decision. We demonstrated a framing bias arising from presenting trial participation as an opportunity, whether opt-in or opt-out, versus as a choice, as women's immediate preferences varied depending on the frame. When the decision was presented as an opt-in or opt-out opportunity, women were more likely to prefer the trial option or to be undecided than to have the standard treatment, compared to when it was presented as a choice. This bias was possibly due to the opportunity frames focussing women's attention on the trial option which was explicit in these frames; the choice frame avoided this bias possibly by drawing attention to other alternatives. The opt-out opportunity frame also affected women's evaluations of the degree to which the trial option would be endorsed by significant others (health professionals). Sixteen per cent of participants changed their initial preference about trial participation after receiving detailed information but information acquisition and final decision preference were not affected by the frames. Findings from this study suggest presenting the decision as a 'choice' is less likely to bias people's preferences. Further, encouraging people to view balanced and comprehensive information presented in a parallel, option-by-attribute format *before* eliciting preferences can 'de-bias' the decision frame, removing its effect on choice.

Unlike past studies,[22,26,28,31,35] this study found no difference in preferences between the opt-in and opt-out framing groups. There are several explanations for this variation in findings. First, the framing bias may be greater or smaller depending on the type and/or context of the decision, for example

different levels of effects may be found for donating organs after death, choosing treatment to live longer, choosing treatments for another person, and so on. Second, the framing bias may depend on how much detail is provided about the healthcare option. In this study, we made the trial option in both the opportunity frames explicit, which may have led participants to focus more on this option than on the implicit option of the standard treatment. Third, the framing bias may be greater or smaller depending on the values and experiences of the individuals so studies of people making real-world versus hypothetical decisions may find different effect levels. For example, the lack of difference between the two opportunity frames may have been due to a lower rate of choosing to participate in the trial in the opt-out group than might be expected relative to the opt-in group. This lower participation rate may reflect the negative attitudes of some participants to trial participation, which in the opt-out condition could reduce their tendency to accept the default option of the trial. In this study, it was not possible to assess participants' attitudes to trial participation before the decision as such measurement may impact the decision by making some values more salient than others. However, attitudes to trial participation, assessed after the decision, were found to be related to participants' initial decision of trial participation, particularly so in the opt-out frame. A logistic regression analysis revealed that attitudes significantly predicted the initial trial participation decision in both opportunity frames. Although the measure of attitudes was collected after the decision, these findings suggest that the effect of framing may depend on the nature and strength of pre-existing attitudes towards the options. Given the possibility of an unmeasured interaction effect of the opt-out frame and pre-existing attitudes, further research should examine the moderating role of attitudes in framing effects.

The frame did influence women's perceptions of social norm; women were more likely to infer that people who were important to them and the health professionals would support the trial option when it was presented as an opt-out. The opt-out frame presents the trial option as the default, i.e. what would happen if no action were taken; the implication is that the opt-out frame casts the trial option as a social norm and by doing so, leaks information about the writer/speaker's preference.[56,57] Consistent with the explanations offered for the increased attractiveness of default options, the heightened perceptions of social norm may have contributed to an increased preference for the trial option in two possible ways. First, the trial option could be seen as an implicit recommendation from the health professional, thereby providing a rationale for its preference.[30,58]Second, the trial could be seen as the

morally appropriate option, i.e. something people 'should do', making it harder to opt-out.[31,59] Both possibilities are consistent with McKenzie et al's[58] explanation that the writer/speaker's choice of description implicitly leaks information about their own preferences about the option as well as their beliefs about what others should do. They showed that, compared to opt-in frames, people are more likely to infer from the opt-out frames that the option described is the writer/speaker's preferred option and that therefore other people ought to choose the default. It is interesting that, despite the above possibilities, women's final decisions were unaffected by the frame. It is possible that the effect of the implicit recommendation in the opt-out frame was tempered by their subsequent evaluation of the full information. Future research should further explore the relationship between default framing, subjective norm and deliberation.

This study not only demonstrates the biasing effect of opportunity frames, but also suggests a potential way of ameliorating it through provision of balanced and comprehensive information about the options prior to eliciting preferences. Prior findings indicate that strength of framing biases decreases when individuals are encouraged to deliberate on the decision problem by providing detailed information about the options[60-62] or the context[63], by asking individuals to provide rationales for their decisions[64] and by inducing individuals to engage in analytical thinking[65]. In this study, it is possible the detailed information minimised the effects of frame by encouraging more systematic processing of information. It is worth noting that the content and structure of the information we provided was designed to encourage active deliberation. The standard treatment and trial information presented within the computer task was structured with reference to decision aid guidelines. Equivalent information was presented in parallel, option-by-attribute table format, as illustrated in Figure 4, which allowed the attributes of each option to be compared and contrasted at a glance.[5] Most patient information presents treatment options in a fixed linear sequence, which forces patients to consider the options and their attributes in the given order. The linear presentation of options is more likely to encourage biasing in what is attended to and/or evaluated, for instance, through primacy or recency effects.[66] It is possible a more traditional presentation of trial information would have resulted in a more pronounced framing effect on participants' acquisition, and evaluation, of decision information. Future research should compare the linear and parallel, option-by-attribute formats of presentation and explore their impact on framing effects.

This study is unique in that it investigates a novel aspect of framing, addresses an important clinical context, employs a robust experimental design and involves measures of what information is attended to. The study does have potential limitations to its generalization. Nonetheless it provides proof of concept data, which can underlie further research. First, a self-selecting sample of healthy women making a hypothetical choice about trial participation may not generalize to patients making these decisions or to those with other types of cancer. There is evidence that people's values change depending on their health state[67], which may influence their treatment choices. We suspect this sample had relatively stable values as all indicated they had experience of cancer, either as a previous patient or as an acquaintance of someone with cancer. More importantly, we expect that these results would be replicated in the real-world and in other contexts, because the study explores how an individual's construction of a decision problem is influenced by the presentation of options, rather than the evaluation of the information contained within the decision problem. It is likely that the same metacognitive processes would be employed by individuals whether or not they were patients.[68,69] This issue can be explored further in phase III type trials with populations that have more direct involvement with cancer (e.g. survivors/family/patients). Second, the sample in this study had a much higher rate of trial participation than is observed in the real world. This could be due to the hypothetical nature of the decision[70] or higher levels of education in the sample. We acknowledge that patients making these decisions in the real-world may be quite different in age, gender or educational status from participants of this study. Nevertheless, the aim of this study was to demonstrate that different decision frames can lead to different choices; this can be further tested in more representative populations and contexts.

Third, provision of the 'undecided' option at the initial but not the final decision complicates the comparison of findings, as 'undecided' may reflect that participants have no clear preference or that they are not sure enough to express or act on their preference. However, a forced-choice question to elicit an initial decision preference was not appropriate in this study. It may have biased participants' subsequent information processing, cognitions and the final decision due to the potential tendency to feel more committed to the chosen option and process any subsequent information in a way that confirms this choice[34]. Inclusion of the undecided option helped confirm the focusing effect of the frames; women receiving the opportunity frames were not only more likely to choose the trial but also

more likely to be undecided than to choose the standard treatment option. Inclusion of an undecided option to elicit final decision was also not appropriate because, often in reality, patients must choose one or the other. Thus, final decision by the initially undecided participants may reflect either a change from 'no preference' to a clear preference for the trial or the standard treatment option, or the expression of an initial preference which had not been strong enough to be expressed at the initial decision stage. Fourth, presentation of options and information via computer may compromise the study's external validity. As described earlier, this study replicated the clinician-delivered information in a controlled laboratory experiment to investigate whether framing affects people's information acquisition (i.e. what information is accessed, for how long and how often) along with their choices and cognitions. To allow collection of these data, information needed to be presented in such a way that only one piece of information is visible at a time.[51]The computer based approach was needed to facilitate presentation of information and acquisition of data, which would have been difficult with paper-based information.

These findings have implications for those delivering services to enhance patients' informed decision making about treatment, testing and trial options. First, the routine practice of presenting healthcare and clinical trial options using an opportunity frame (opt-in or opt-out) can lead to significant biases in people's preferences. Bias is less likely to occur when all options are presented explicitly using a choice frame. Saying "Do you want to have the standard treatment or take part in the trial" instead of "Do you want to take part in a trial" changes the decision representation to include two options rather than one, allowing individuals to consider all available options. Framing an option as an opt-out versus an opt-in seems to leak information interpreted as an endorsement of the option. It is unclear whether this frame affects informed decision making; it may change the value of a component part of the evaluation but not the ability to reason systematically about it. For some decisions where there is a 'correct' behaviour (e.g. illness prevention programmes), it may be argued that framing an option as an opt-out enables people to make an informed choice, rather than an informed decision, and this level of engagement with the information is sufficient.[29,30] In these contexts, the opt-out framing may nudge people towards the desired behaviour without removing their freedom to choose differently. Second, these effects are ameliorated by the provision of full information about the risks and benefits of both options when presented in a readable, easily accessible and comparable way, i.e. full patient

information can de-bias the decision context and enable patients to re-evaluate labile preferences.[62,64] This is particularly important because in the real-world setting, patients may not often be provided with full information, in an accessible and comparable format, immediately after the initial trial offer. Third, women's trial preferences change when they receive more information and/or have time to consider the decision information.[71,72] Tailoring information according to a first preference will limit the likelihood patients are able to make informed decisions.

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The authors have no conflicts of interest to declare.

Tables

Table 1: Characteristics of participants by framing groups

	Opt-in (N=42)	Opt-out (N=41)	Choice (N=41)
Average (SD) age in years	28.2 (9.5)	25.3 (8.7)	25.0 (6.9)
Ethnicity: White, N(%)	32 (76%)	34 (83%)	26 (63%)
Occupation: student N (%)	23 (55%)	33 (80%)	26 (63%)
Marital status: single N(%)	29 (69%)	30 (73%)	34 (83%)
Women with close relatives with cancer N(%)	13 (31%)	15 (37%)	9 (22%)
Average (SD) number of people known with cancer	2.4 (1.5)	2.4 (1.3)	2.3 (1.2)

Table 2: Change in decision by faming conditions

	Opt-in (N=42)	Opt-out (N=41)	Choice (N=41)
Change in decision among those with definite initial preference N(%)	**4 (10%)**	**2 (5%)**	**7 (17%)**
From Trial to Standard treatment	*2 (5%)*	*1 (2.5%)*	*2 (5%)*
From Standard treatment to Trial	*2 (5%)*	*1 (2.5%)*	*5 (12%)*
Final decision among those initially undecided N(%)	**19 (45%)**	**13 (31%)**	**12 (29%)**
Choosing Trial	*14 (33%)*	*8 (19%)*	*9 (21%)*
Choosing Standard treatment	*5 (11%)*	*5 (12%)*	*3 (7%)*

Table 3: Mean (SD) for information acquisition measures by frame

	Opt-in (N=42)	Opt-out (N=41)	Choice (N=41)	Partial Eta Squared
Total amount of information examined Multivariate F[8,238]=1.05, p=.39				0.034
Proportion of information searched	.74 (.20)	.76 (.18)	.69 (.26)	.017
Total time spent on information screen	6.6 min. (2.7)	6.5 min (2.1)	6.2 min (2.7)	.001
Average time spent per information piece	5.4 sec.(2.1)	5.6 sec.(2.1)	5.4 sec.(1.9)	.004
Reacquisition rate	.19 (.09)	.19 (.08)	.19 (.11)	.002
Depth of search Multivariate F[8,238]=.84, p=.57				.027
Proportion of information examined on trial	.79 (.23)	.85 (.19)	.74 (.28)	.029
Proportion of information examined on standard treatment	.63 (.24)	.59 (.21)	.58 (.29)	.005
Proportion of time spent on trial information	.55 (.12)	.59 (.07)	.53 (.14)	.039
Proportion of time spent on standard treatment information	.16 (.07)	.15 (.06)	.15 (.08)	.004

Table 4: Mean (SD) for decision related cognitions by frame

	Opt-in (N=42)	Opt-out (N=41)	Choice (N=41)	Partial Eta Squared
Perceived risk and severity of side effects (low-high; 1-7) Multivariate F[8, 236]=1.2, p=.31				.039
Severity of trial side effects	5.3 (1)	5.3 (1)	4.9 (1)	.006
Risk of trial side effects	6 (1.2)	6 (1.3)	5.8 (1.1)	.013
Severity of ST side effects	5.4 (1)	5.3 (1)	5.1 (.9)	.011
Risk of ST side effects	5.8 (1.4)	6 (1)	5.8 (1.2)	.024
Theory of Planned Behaviour measures Multivariate F[6, 236]=2.9, p=.009				.069
Attitude towards trial (Unfavourable-Favourable; 4-28)	16.7 (.7)	17.1 (.7)	16.9 (4.7)	.001
Subjective norm (low-high; 2-14)	8.9 (4)	10.1 (4)	8.7 (2.1)	.068
Perceived Behavioural Control (low-high; 3-21)	17.2 (3)	18.1 (3)	17.2 (2.9)	.022
Satisfaction with decision (low-high; 6-30) F[2,120]=.24, *p=.78*	24.1 (2.9)	24.3 (3.7)	23.8 (3.3)	.004

Figure Legends

Figure 1: Decision scenario with framing intervention

Figure 2: Summary of content of information on decision options

Figure 3: Study procedure flow chart

Figure 4: Decision information presented on computer screen

Figure 5: Initial preference in opt-in, opt-out and choice conditions

Figure 6: Final decision in opt-in, opt-out and choice conditions

Figure 1: Decision scenario with framing intervention

Imagine that you are in the consultation with your doctor. The doctor is discussing with you what treatments you could have for your cancer. Your doctor suggests that you have chemotherapy. Chemotherapy may offer a good chance of destroying any cancer cells that may have been left behind.

There is an opportunity to take part in a clinical trial. You are suitable to take part in this trial. (Opt-in)

All patients are automatically entered in a clinical trial. You are suitable for this trial and will be automatically entered. There is an opportunity to be removed from this trial. (Opt-out)

You are suitable to take part in a clinical trial. You have two options. Option one is to have the standard treatment. Option two is to take part in the clinical trial. (Choice)

The clinical trial is known by the short-form TACT. The clinical trial compares two different chemotherapy treatments, A and B. Treatment A involves drugs that have been used for your type of cancer for many years. Treatment B uses drugs called Taxanes. At present, taxanes are only used for treating breast cancer which has already spread to other parts of the body. The TACT trial aims to find out whether adding a taxane drug called Docetaxel to other chemotherapy drugs will reduce the chance of breast cancer coming back. If you decide to take part, a computer will randomly allocate you to either treatment A or B.

Question for Opt-in

Do you want to take part in the trial?

1. Yes, I want to take part in the trial
2. No, I do not want to take part in the trial
3. I am uncertain about my decision (Included in the initial decision preference only)

Question for Opt-out

Do you want to be removed from the trial?

1. Yes, I want to be removed from the trial
2. No, I do not want be removed from the trial
3. I am uncertain about my decision (Included in the initial decision preference only)

Question for Choice

Do you want to take part in the trial or have the standard treatment?

1. I want to take part in the trial
2. I want to have the standard treatment
3. I am uncertain about my decision (Included in the initial decision preference only)

Figure 2: Summary of content of information on decision options

TACT trial	Standard treatment
• Purpose of the trial • Treatment details: Drugs being tested; number of cycles, frequency of cycles, duration of treatment, and method of treatment delivery. • Possible side effects of both drugs • Method of treatment allocation and the rational for randomisation • Advantages of taking part in the trial (access to potentially more effective treatment, closer monitoring of your health, helping future patients, randomisation) • Disadvantages of taking part in the trial (random allocation to treatment, uncertainty of additional benefits, additional clinic visits, unexpected side effects)	• Purpose of treatment • Treatment details: drugs involved, number of cycles, frequency of cycles, duration of treatment and method of treatment delivery • Possible side effects • Advantages of having the standard treatment (treatment not selected randomly, known side-effects) • Disadvantages of having the standard treatment (no opportunity to receive new treatment)

Figure 3: Study procedure flow chart

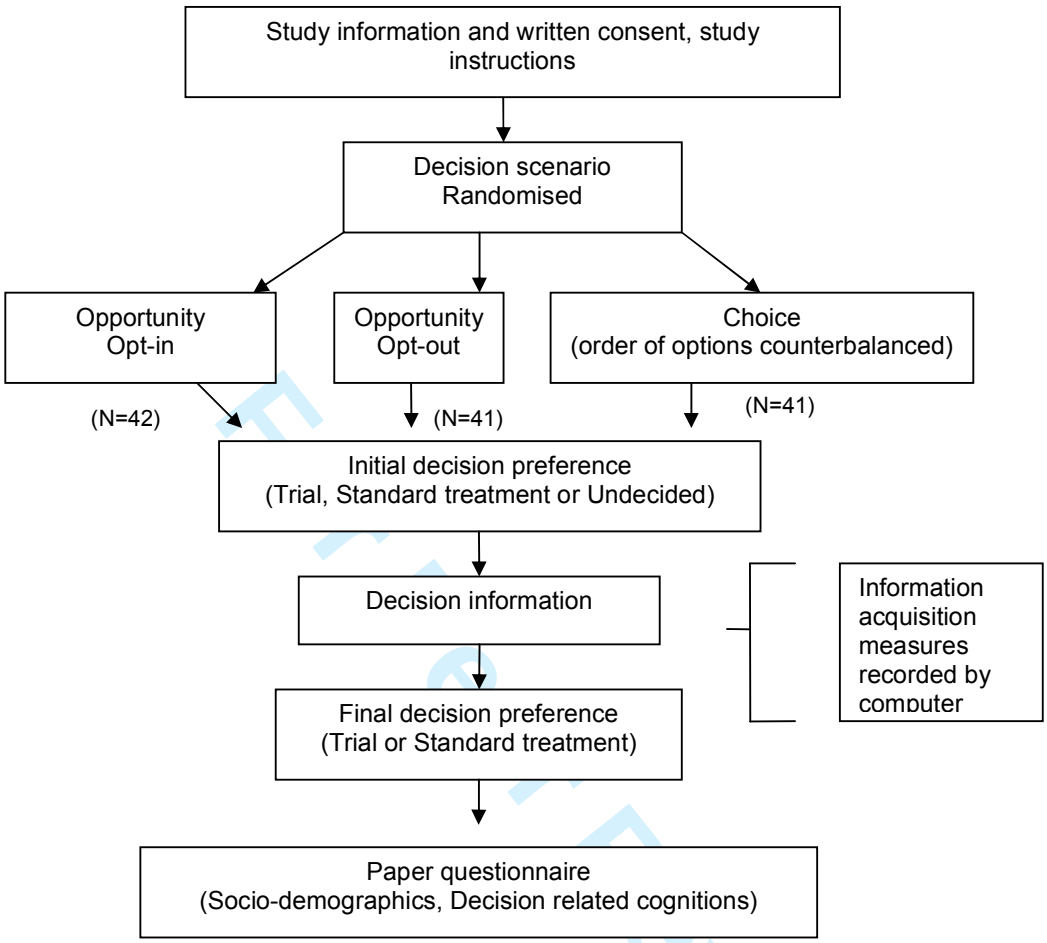

Figure 4: Decision information presented on computer screen

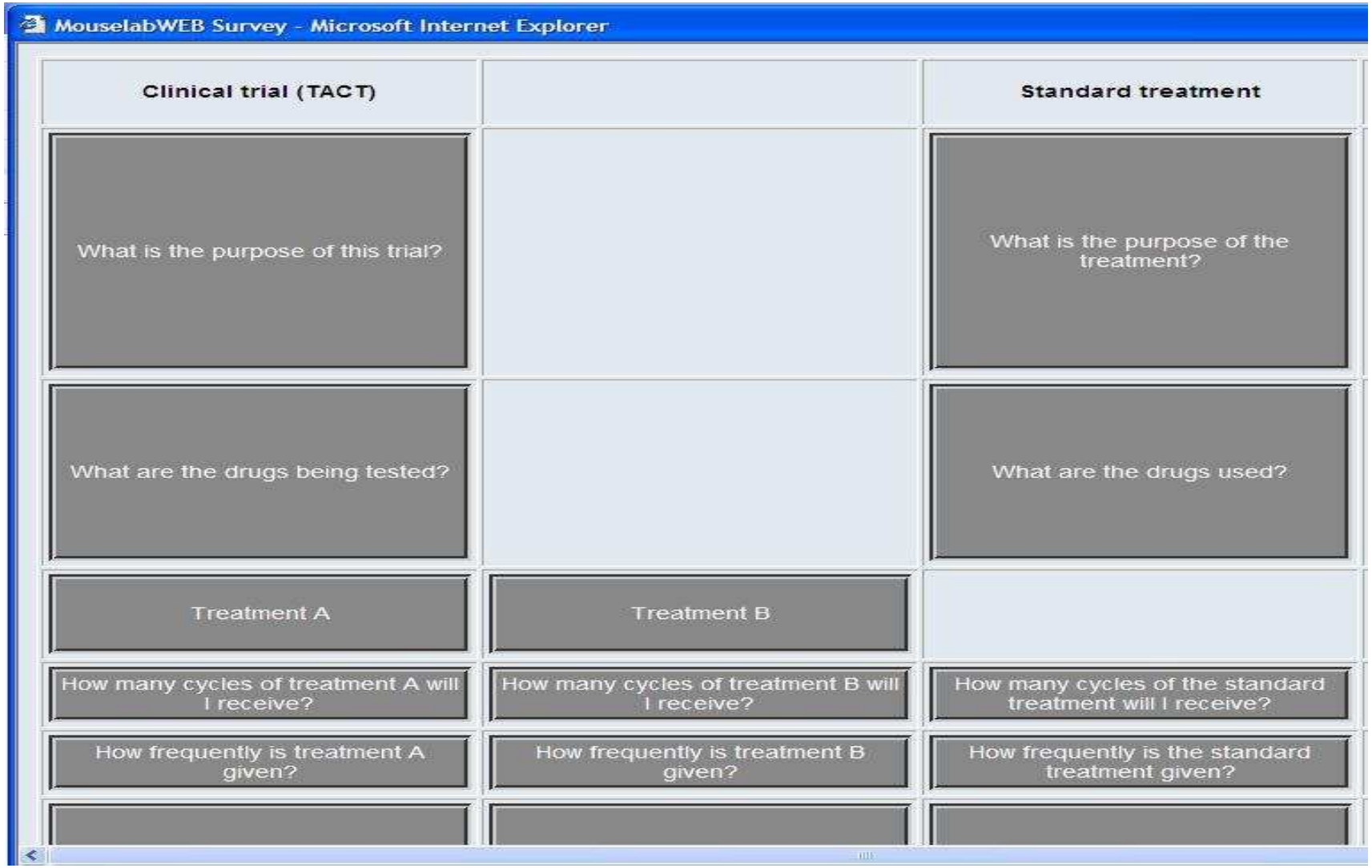

Figure 5: Initial preference in opt-in, opt-out and choice conditions

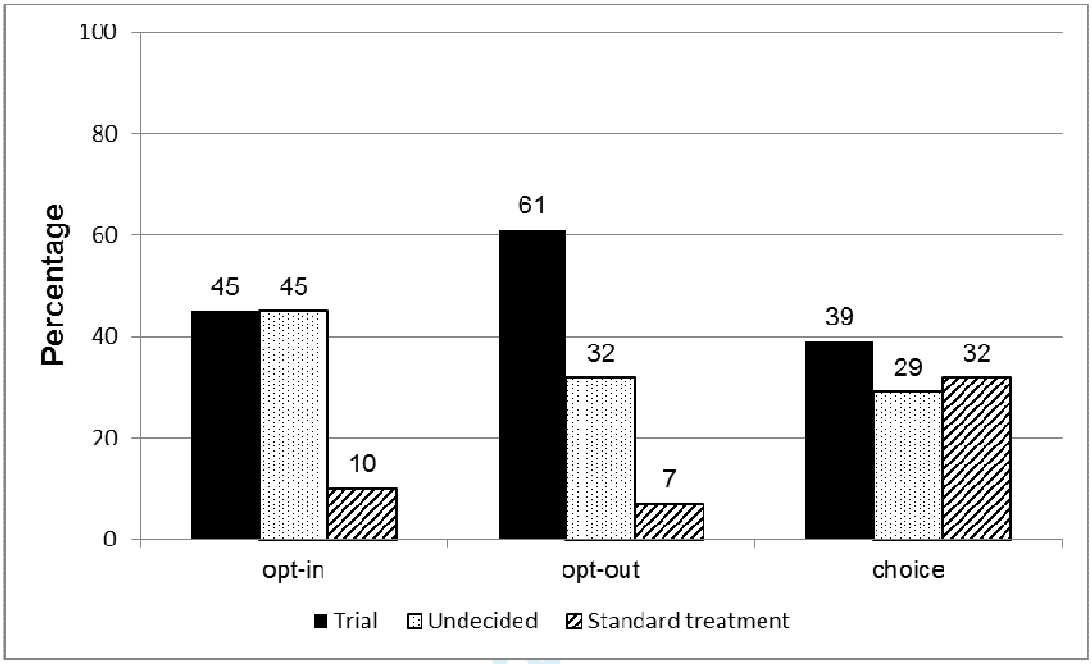

Figure 6: Final decision in opt-in, opt-out and choice conditions stacked by initial preference