Author's response to reviews

Title: Factors influencing the surgery intentions and choices of women with early breast cancer: the predictive utility of an extended Theory of Planned Behaviour

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Version: 2 Date: 13 May 2013

Author's response to reviews: see over
Dear Sirs,

Re: MS 6671990989081593
Factors influencing the surgery intentions and choices of women with early breast cancer: the predictive utility of an extended Theory of Planned Behaviour (Sivell et al)

Thank you for your comments and for the opportunity to revise this manuscript. We have included a copy of the extended Theory of Planned Behaviour questionnaire as an additional file.

The manuscript has been modified to address the reviewers’ comments as far as we are able. Below we outline how the manuscript has been changed. Any changes made to the manuscript itself have been underlined.

Referee 1

Major Compulsory Revisions (clarifications)

1. The paper states that 48 women completed online questionnaires before their surgery and after completion of an online decision support tool (BresDex). Not mentioned in the manuscript is the timing of participation relative to the surgical consult. Did all participants complete the study prior to seeing their surgeon for the first time, or did some complete the study after seeing their surgeon? The timing of study completion has implications for responses to several of the questions, including the primary outcome of intention. Clarification of the timing and its potential impact on responses is needed.

We agree with the reviewer that the timing of the entry of women to this study has implications on the responses participants may give to the questions. It was not possible to approach women before their consultation with their surgeon where they were given their diagnosis for the first time and advised of their surgical treatment options. Therefore, we are not able to determine what women’s views and possible intentions would be prior to a breast cancer diagnosis. However, had we approached women prior to their diagnostic consultation, we may well have caused undue distress and anxiety; we may have alerted them to a possible diagnosis they were not aware of and indeed may not have ultimately been given. For example, they may not have been diagnosed with a malignancy, or indeed
they may have been diagnosed with a more advanced form of the disease where the surgical treatment options of interest in this research study may not have been relevant. We have clarified the timing of when women were approached to take part in the study in the Methods section (Overview subsection):

**Methods**

**Overview**

Women newly diagnosed with early breast cancer (Stage I or II) and who were eligible for a choice of surgical procedures as their primary therapeutic treatment were invited to complete an online questionnaire to assess their views about the available treatment options, and their intentions to choose BCS (the lay term ‘lumpectomy’ was used in the participant information and questionnaires) or mastectomy. Eligible women were identified by their breast care teams; specialist breast care nurses gave these women information on the study following their diagnostic consultation with their surgeon. Ethical approval was granted by the Multi-Centre Research Ethics Committee for Wales. Research governance was granted by Cardiff and Vales NHS Trust (now Cardiff and Vale University Health Board), Sheffield University Teaching Hospitals NHS Trust, Newcastle upon Tyne Hospitals NHS Foundation Trust and Velindre NHS Trust. The questionnaire was completed before surgery and after participants had accessed an online interactive decision support intervention (BresDex) (see Additional File 1).

2. More detail regarding the clinical characteristics of patients enrolled in the study would be helpful. It sounds from the abstract background that the study is limited to those with stages I and II only, but the manuscript should clarify whether any other stages were included. Were those with a family history of breast cancer or a genetic mutation excluded, to ensure all women would be eligible for the surgical options under study? Were the authors able to measure any other factors that could serve as a clinical contraindication to either of the options (for instance large tumor to small breast size ratio can lead to a recommendation for mastectomy because of the difficulty in doing a lumpectomy in this type of patient). Such contraindications could explain differences between intention and choice (when found).

Only those women diagnosed with stage I and II breast cancer, and who were eligible for the surgical options under the study were approached and included in the study. We have clarified this in the Methods section (Overview subsection – see above). The clinical teams who approached patients to participate were fully aware of the criteria. Had women not been eligible for the choice, perhaps due to clinical contraindications, and therefore were recommended for a mastectomy, then they would not have been approached to take part in the study. Women with a family history of breast cancer or a genetic mutation were not excluded from the study *per se* as this fact alone would not have made them ineligible for the choice of surgery.

3. The authors do a very good job of describing all the measures used in this study except surgery choice which is one of the outcomes of the study. When and how was the actual choice of surgery measured--self report, medical chart/how much further after completion of the initial questionnaire was this collected, etc? So when one looks at Table 1 which shows the correlation between intentions and choice, it is not clear what exactly “choice” is referring to—are positive intentions correlated with choice
for BCS (since the intention (since increasing positive intention scores were reflective of intention to opt for BCS). The choice variable measurement and coding needs clarification.

Women’s surgery choice was given to us by the clinical teams, following their surgery. Theoretically the women were able to change their minds as to which surgery they wanted to have, right up to the point of surgery. Therefore, trying to determine their ‘choice’ at the right time would have been difficult. The clinical teams were therefore able to give us objective data on which surgery the women went on to have. We collected these data as soon as possible from the clinical teams after the women had their surgery. We have clarified how we measured choice in Table 1, as requested by the Referee. In addition, we have provided clarification at the end of the Main Outcome Measures subsection of the Methods section:

*Objective data were collected on participants’ choice of surgery; the clinical breast teams notified the research team of the type of surgery participants went on to have (i.e., either mastectomy or BCS).*

**Minor compulsory revisions**

4. Could the authors add clarification to the tables so the reader knows what the Extended TPB multiple regression is of (e.g., of breast cancer treatment intentions)?

At the Referee’s request we have clarified the purpose of the regressions in the titles of each regression table.

**Discretionary Revisions**

5. One factor that research has suggested contributes to choices for more aggressive surgery in breast cancer (i.e., mastectomy over BCS in a case where a woman could choose either) is a lack of understanding that the mastectomy does not, in fact, improve survival relative to BCS. Did the authors consider or at all evaluate the knowledge level of participants regarding the likelihood of survival and recurrence between the 2 options under study?

6. The manuscript may be part of a larger study evaluating the impact of the decision tool on patient choices, since the role of the tool (BresDex) in this manuscript is not clear. Was there a specific reason that patients in this study were asked to view BresDex? The decision tool does not come into the discussion at all, so one wonders whether this study was nested within a larger one evaluating this tool, and a comment to this effect would be helpful.

Questions 5 and 6 are related. The Reviewer is correct in thinking that this study was part of a study evaluating the impact of BresDex; we report an evaluation of the use of BresDex in practice, which included assessment of participants’ knowledge before and after using BresDex. This study is reported in *Patient Education and Counseling*:


We have clarified this at the end of the Introduction:

In the current study we sought to understand the predictors of surgery intentions and choices of a group of women newly diagnosed with early breast cancer and who were invited to use an interactive online decision aid while considering their options for surgery (full details of this study are reported elsewhere) [34]. For the present paper, our objectives were: (1) to assess the degree to which TPB constructs account for surgery intentions and surgery choices; and (2) to understand women’s views of the treatment options for breast cancer using extended TPB constructs.

With regard to question 5, we agree with the reviewer that a lack of understanding of the difference in survival and recurrence rates may influence women to choose mastectomy over breast conservation surgery. However, as reported in our paper published in Patient Education and Counseling, we found high knowledge scores both before and after using BresDex and so in this instance we are not able to conclude that those who chose mastectomy did so due to a lack of understanding. However, we do discuss in the paper published in Patient Education and Counseling, the possible reasons why knowledge scores may have been so high before use of BresDex, including the potential suitability of the tool and the timing of when women may have accessed BresDex in relation to access to other sources of information we may not be aware of. A replication of this study, perhaps utilizing a different scale, would help to clarify these issues.

7. There are many measures and scales being used in this study. Many of these contribute to the field (i.e., the anticipated regret scale). It would be very useful to be able to see an Appendix that includes these items, or make available online as these measures may be used in future work by other researchers.

A copy of the items has been provided with this resubmission as an additional file.
Referee 2

We thank Referee 2 for his/her comments and we are particularly pleased that the Referee shares our view that the use of a theoretical framework provides a structure within which to conduct the study. We now address each of Referee 2’s concerns in turn:

I did though find that the mention of the TRA over and above the TPB description was unnecessary and distracted from the main focus on the TPB.

We raised this issue as a discussion point as we felt that it would be of interest that the constructs from the TPB did not add to the predictive power of the regression model over and above what the constructs from the TRA accounted for.

The abstract refers to the TPB, but not to the specific components that were investigated. I would strongly suggest that some justification for the inclusion of anticipated regret, over and above the standard TPB variables is given at this point, particularly for readers who may be unfamiliar with the TPB constructs.

We have revised the abstract to refer to the specific components that were investigated.

Abstract

Background: Women diagnosed with early breast cancer (stage I or II) can be offered the choice between mastectomy or breast conservation surgery with radiotherapy due to equivalence in survival rates. A wide variation in the surgical management of breast cancer and a lack of theoretically guided research on this issue highlight the need for further research into the factors influencing women’s choices. An extended Theory of Planned Behaviour (TPB) could provide a basis to understand and predict women’s surgery choices. The aims of this study were to understand and predict the surgery intentions and choices of women newly diagnosed with early breast cancer, examining the predictive utility of an extended TPB.

Methods: Sixty-two women recruited from three UK breast clinics participated in the study: 48 women, newly diagnosed with early breast cancer, completed online questionnaires both before their surgery and after accessing an online decision support intervention (BresDex). Questionnaires assessed views about breast cancer and the available treatment options using items designed to measure constructs of an extended TPB (i.e., attitudes, subjective norms, perceived behavioural control, and anticipated regret), and women’s intentions to choose mastectomy or BCS. Objective data were collected on women’s choice of surgery via the clinical breast teams. Multiple and logistic regression analyses examined predictors of surgery intentions and subsequent choice of surgery.

Results: The extended TPB accounted for 69.9% of the variance in intentions (p < .001); attitudes and subjective norms were significant predictors. Including additional variables revealed anticipated regret to be a more important predictor than subjective norms. Surgery intentions significantly predicted surgery choices (p < .01).

Conclusions: These findings demonstrate the utility of an extended TPB in predicting and understanding women’s surgery intentions and choices for early breast cancer.
Understanding these factors should help to identify key components of interventions to support women while considering their surgery options.

We included anticipated regret in the extended TPB because this has been found to enhance the predictive power of the TPB in other studies. It was not our intention to include anticipated regret as a more important construct than the other constructs of the TPB. We do not have scope to provide a full justification for this in the abstract, given the word limit, but we have provided a justification in the Introduction (penultimate paragraph):

A theoretical framework that has been widely applied in studying health behaviour and is likely to provide a basis for predicting and understanding the surgical choices of women newly diagnosed with early breast cancer is the Theory of Planned Behaviour (TPB) [6,7]. The TPB was developed as an extension of the Theory of Reasoned Action (TRA) [25,26], and has been used to predict and explain a broad range of health behaviours [27,28], including breast self-examination [29], depression and medication adherence in breast cancer survivors [30], mammography screening [31] and multiple sclerosis patients' decisions on disease modifying therapy [32]. However, as far as we are aware, the TPB has not been used to understand and predict women's surgery choices for early breast cancer. According to the TPB, a behaviour such as choosing to undergo BCS or mastectomy is predicted by behavioural intentions, which in turn are predicted by attitudes towards the behaviour, subjective norm (how significant others expect one to behave) and perceived behavioural control (in the present case, how easy or difficult it is to make the decision). The difference between the TRA and the TPB is that the latter model incorporates the concept of perceived behavioural control. When the individual does not have complete volitional control over the behaviour in question, the TPB assumes that perceived behavioural control helps to predict intention and (to the extent that the perceptions are accurate) behaviour. The TPB has been extended to include anticipated regret (the regret one anticipates experiencing after engaging in the behaviour, or not engaging in that behaviour) [27], which has been shown to enhance the TPB's utility in predicting intentions in a variety of situations, including those pertaining to health-related decisions [33]. In the current study we use this extended version of the TPB.

The description of the study indicates that some type of intervention was made available to all participants in the study, but no mention is made of accounting for the effect of this intervention as a predictor of surgery uptake. Given that this study incorporates an intervention designed to impact on decisions of these patients, then at the very least the effects of this intervention need to be included and partialled out in the analyses.

As discussed earlier, when addressing Referee 1’s comments, the present study was carried out as part of a wider project evaluating the use of the intervention in practice, where the effects of this intervention on women’s knowledge, readiness to make a decision and intentions for surgery were examined. We have clarified this in the manuscript (as explained above). The intervention is a decision aid and as such is designed to be neutral with respect to surgery choice, not influencing decisions to choose one surgery over another, although we cannot establish this for certain without testing this assumption. However, this study was not a randomized controlled trial; the purpose of the wider study
was to observe and evaluate the use of the intervention in practice with a cohort of the women whom it is intended to support. The participants in this study were not randomized to use/not use the intervention; as a consequence we are unable to determine whether the intervention itself influenced surgery intentions and choices.

Further to this, the authors have made no attempt to consider the possible role of other factors as being predictors of decision making. These analyses should have taken into account the possible effect of demographic and medical/clinical variables such as age, cancer stage, time since diagnosis etc. These variables have also been shown to impact on decisional processes and decisional outcomes and need to be incorporated into the analytic model.

While Referee 2 is correct in saying that demographic and medical/clinical variables have been shown elsewhere to impact on decisional processes and decisional outcomes, there is a certain degree of homogeneity within our sample which led us to exclude these variables from the analytical model. We did not include cancer stage in the analyses because all women in this study were diagnosed with early breast cancer, stage I or II, with all women eligible for the choice of surgery. We did not include all cancer stages in this study because they would not all be eligible for the choice. Similarly, when considering time since diagnosis, all women were approached by their clinical teams to take part in this study either at or immediately following their diagnosis. The time between diagnosis and surgery was also short (a median of 21 days) and so all women in this study had a relatively short time within which to consider their options for surgery. Furthermore, there is no statistically significant difference in time to surgery between those women who had BCS and those who had mastectomy. We did not include age in the analytical model for the same reason; there was no statistically significant age difference between the two groups.

Further to this, I would have liked to see a more in-depth account in the Introduction of the wider literature that details factors associated with surgical decision making in cancer, particularly breast cancer.

There is an extensive body of evidence reported in the literature on the factors associated with surgical decision-making in cancer, particularly breast cancer. In the Introduction, we provide a summary overview of this field, rather than a comprehensive review of the literature in order to keep the paper concise and focused on the study we are reporting. However, we do reference another paper in which we do provide a detailed review and a narrative synthesis of the wider literature describing the evidence for the factors influencing breast cancer patients’ surgery choice:


We have also been more explicit in signposting the reader to this paper in the Background (2nd paragraph):

*Many factors are reported to influence the choices made by women in this situation, including perceived chance of survival [8,16]; concerns about breast loss and local*
tumour recurrence [14]; the surgeon’s (perceived) preferences and clinical guidance [4,14,17,18]; patient-professional communication [19]; patient involvement in decision-making [13]; body image and sexuality [20-23]; and avoidance of the negative side-effects of radiation treatments [19]. We report a more detailed review of the evidence elsewhere [24]. However, the complexities of the decision are not always reflected in the literature, with few studies examining the influence of different factors simultaneously [24]. More generally, there is a lack of theoretically guided research on this issue. Our contention is that applying theoretical models should help us to arrive at a better understanding of women’s surgical choices, which in turn would help to identify ways of supporting women in making these choices.

The limited sample size of this study is a real limitation. The authors state that 144 women were invited, but only 62 participated, which means that they have a recruitment rate of only 43%. Added to this, several women failed to complete the follow up assessment, leaving only 48 women at follow up, of whom 75% chose BCS. The small numbers in the final sample bring into question both the possibility that this study was underpowered, and that it is not a representative sample of women with breast cancer.

We agree with the Referee that the sample size of this study is a limitation and share his/her concerns. This was an extremely difficult cohort of women to recruit. As discussed above, these women were asked to take part in a research study at the time they had received a diagnosis of breast cancer for the first time, and were asked to consider whether they would prefer to have mastectomy or breast conservation surgery within a relatively short period of time. For many women this is a big decision to make at what is naturally a very distressing time. Under these circumstances it is not surprising that there was a degree of attrition at various points in the recruitment and data collection process. Although the final sample size was relatively small, it was large enough to enable us to carry out multivariate analyses with the included variables. We accept the Referee’s point however that this is not necessarily a representative sample of women with breast cancer and have revised the Strengths and Limitations paragraph in the Discussion to clarify this point:

**Strengths and Limitations**

Key strengths of this study are that it is, as far as we are aware, the first to apply an extended TPB to predicting and understanding women’s actual surgery choices for early breast cancer at time the decisions were being made, and that it examined behavioural outcomes, as well as surgery intentions. Many studies applying the TPB do not measure behaviour and if they do, it is often assessed in the form of participant self-report [38]. A limitation of the present study is the relatively small sample size and the fact that the participants may not be a representative sample of women newly diagnosed with early breast cancer. However, these points need to be evaluated in the context of the considerable difficulties involved in recruiting a ‘real world’ sample of this nature. It is important to bear in mind that these women were asked to invest time and effort on a purely voluntary basis at a particularly difficult and stressful time [9]. They had just received a diagnosis of breast cancer and were asked to consider their surgical options and make a decision within a short period of time; the median time between diagnosis and surgery was 21 days. Under these circumstances we were pleased to have been able to
recruit enough women to permit multivariate analyses and to enable us to examine more closely the factors that influenced their surgery choices.

I am also concerned with the item reliability of measures used with Cronbach’s alpha of only 0.62/0.63 being obtained. The authors should consider revising the items included in these measures to improve the reliability index.

We understand the Referee’s concerns about the reliability of these particular measures. We explored the potential for revising the composition of the measures but there was no scope for further improvement the Cronbach’s alpha. Although the reliabilities may be lower than ideal, in our judgment they are not sufficiently low to cast doubt on the assumption that the items are tapping into a common underlying construct.

We believe that these revisions address all the comments and suggestions made, and that the manuscript is stronger as a result. We hope that you agree and look forward to your decision.

Yours sincerely,

Stephanie Sivell