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Applying the Theory of Planned Behavior to Examine Adjuvant Endocrine Therapy Adherence

Intentions

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Abstract

Objective: Adherence to adjuvant endocrine therapy (AET) in breast cancer survivors is suboptimal. Using the theory of planned behavior (TPB), this study aimed to identify the strongest predictors from the TPB of AET intentions and past behavior and assessed whether ambivalence and anticipatory emotions increased the predictive capacity of TPB.

Methods: 280 women diagnosed with hormone positive (HR+) breast cancer who filled at least one prescription of AET responded to a survey measuring TPB constructs, attitudinal ambivalence, and anticipatory emotions. The outcomes were intentions to adhere to AET and past medication adherence (previous two weeks).

Results: The TPB explained 66% of intentions to adhere to AET ($p < 0.001$). Ambivalence did not improve the TPB model's predictive value. When emotions were included with TPB, the model explained 70% of adherence intentions $F(11,226) = 52.84, p < .001$ ($R^2_c = .70$). This increase of 4% in predictability was statistically significant ($\Delta R^2 = 0.04$), $F(6, 226) = 7.90, p < .001$. Women who self-reported non-adherence in the past two weeks differed significantly in the TPB variables, ambivalence, and anticipatory emotions from adherent women. Non-adherent participants reported lower future intentions to adhere $F(1, 236) = 5.63, p = .018$.

Conclusions: Results suggest key concepts, such as anticipatory positive emotions, that should be addressed in future interventions to enhance AET adherence and survivorship.

Background

Adherence is the process by which patients take their medications as prescribed and includes initiation (taking the first dose), discontinuation (stopping taking medication) and implementation or adherence (degree to which actual dosing corresponds to the prescribed dosing since first to last dose) [1]. Non-adherence to prescribed medications results in avoidable costs, morbidity and mortality [2]. Yet, around 50% of patients across chronic conditions are non-adherent [3], even despite life-threatening conditions, such as breast cancer. Breast cancer is women's second highest cause of cancer death [4]. Adjuvant endocrine therapy (AET) is recommended for HR+ breast cancer survivors as it significantly reduces recurrence and mortality [5, 6]. AET involves taking one pill daily for at least five years. Adherence is necessary to obtain full benefits [5, 6]. However, only between 41-72% of breast cancer survivors are adherent to AET in clinical practice [7].

Studies have identified clinical, healthcare, demographic, and psychosocial factors associated with AET adherence [8]. Because psychosocial factors are modifiable, they are promising intervention targets. Interventions that promote AET adherence are limited [9]. Utilizing conceptual models to examine the relationship between psychosocial factors and adherence increases their potential for informing the development of successful interventions [10]. Yet, few studies have done so.

This study used the theory of planned behavior (TPB) [11] to examine psychosocial factors related to AET adherence intentions. The TPB regards the intention to perform a behavior as the most proximal determinant of a behavior. Beliefs influence attitudes, subjective norms, and perceived control, which in turn independently influence intentions. Attitudes are either positive or negative evaluations of a behavior [12]. Subjective norms refer to the perceived social pressure to perform a behavior. They include descriptive norms (what is commonly done) and prescriptive norms (what is commonly approved) [13]. Perceived control refers to the perceived ease or difficulty of performing a behavior and it exerts a direct influence on the behavior. Perceived control includes self-efficacy (confidence in the ability to perform a behavior) and controllability (the extent to which behavior performance is up to the individual) [14]. Non-adherence has been broadly classified as intentional (conscious decision to miss medication) and unintentional (e.g. forgetting) [15], which have been associated with different predictors in AET adherence [16]. This study focuses only on intentional adherence, given the TPB focus on volitional behavior.

The TPB explains between 39-49% of the variance in intentions to perform a variety of health behaviors and 19-36% of the variance in behaviors [12, 17]. However, a meta-analysis that used the TPB to assess adherence in chronic illness showed a lower explanatory power (33% for intentions; 9% of adherence behaviors) [10]. To our knowledge, only Moon and colleagues' study [18] used the TPB to examine AET adherence in breast cancer survivors. They found that constructs from the TPB and from another conceptual model explained 46% of AET intentional adherence but only 17% of unintentional adherence.

While the TPB has proven to be a valuable conceptual model, some critics have raised concerns about the TPB's validity, utility, and its limited focus on rational reasoning [19].

Adding other constructs to the TPB may improve the capacity to predict adherence and inform interventions. Attitudinal ambivalence, having both positive and negative attitudes towards a behavior [20], plays a moderating role in the TPB. The relationship between attitude-intentions-behavior is weaker for people with high ambivalence [21, 22]. Some qualitative studies suggest that survivors feel ambivalent towards AET (beneficial for survival but detrimental for quality of life due to side effects (e.g. joint pain, hot flashes) [23, 24]. To our knowledge, ambivalence towards AET has never been quantitatively measured.

Motivational predictors, such as future-oriented emotions, have the potential to modify intentions and behavior by increasing the salience of future rewards and punishments thereby activating relevant appraisals and action tendencies [25]. There is evidence that future-oriented emotions enhance the TPB's predictive power [26]. Future-oriented emotions include *anticipatory* and *anticipated emotions*. Anticipatory emotions are experienced in the present when thinking about future events (e.g., feeling fear now, if I think I may get an abnormal mammogram result). Anticipated emotions are an affective forecast about how would one feel in the future if certain events occur (e.g., anticipating I would feel fear if I receive an abnormal result) [26]. Research in cancer has mostly focused on anticipated emotions [27-29]. Including anticipatory emotions is important, as they constitute independent predictors of health behaviors/intentions [26-29]. This study focuses only on anticipatory emotions.

Only two studies to date have provided empirical data on emotions about AET [30, 31]. Walker and colleagues [31] found that women who held more positive emotions and fewer negative emotions were more likely to be adherent. Stanton and colleagues [30] found that endorsement of more negative emotions was associated with lower adherence. These studies assessed emotions in relation to AET rather than AET adherence. Emotions were not

operationalized as future-oriented and no theoretical framework was provided. To our knowledge, no prior study has assessed anticipatory emotions towards AET in the context of the TPB.

The aims of the study were to (1) identify which TPB constructs are most strongly associated with AET adherence intentions; (2) examine whether ambivalence predicts AET intentions over and above the TPB constructs; (3) evaluate whether anticipatory emotions contribute to predict AET intentions over and above the TPB constructs; and (4) explore the associations between TPB constructs, ambivalence, and anticipatory emotions with past adherence behavior.

Based on the TPB [11], we hypothesized that women with more positive attitudes, who perceive that taking AET is normative and more approved, and those with higher perceived control would have higher intentions to adhere to AET. Since ambivalence reduces the association between attitudes and intentions [21, 22], we expected that survivors with higher ambivalence would have lower adherence intentions. Based on prior research [30, 31] we hypothesized that participants who endorse positive emotions less strongly and negative emotions more strongly would report lower adherence intentions.

Methods

Procedures

This study was nested within a larger prospective study focused on long-term adherence to AET. This study and subsequent analysis in this paper is cross-sectional. Details of the primary study have been described elsewhere [32]. Women who were ≥ 21 years old, had been diagnosed with invasive non-metastatic HR+ breast cancer, who filled an AET prescription, and who spoke English or Spanish were eligible. We recruited participants from integrated health

care systems, hospitals, and community outreach. RAs consented interested participants. Participants in this study had been in the larger study for at least 12-months and were still taking AET. Georgetown University Institutional Review Board approved all procedures.

Participants

Data were analyzed from 280 women. Women were 58.8 years old on average (SD=10.51), most (75.4%) were White, had a college education or higher (89.3%), and were diagnosed with Stage I breast cancer (46.8.1%) (Table 1).

Measures

Based on recommended guidelines [33], we developed a scale to capture TPB constructs. Items had a 7-point Likert type response (from *strongly agree* to *strongly disagree*) and referred to the specific behavior of taking hormonal medication every day for the years they had left of therapy.

Outcome. Behavioral intentions was captured with two items: intention (“I intend to take my hormonal medication every day for the years I have left on therapy”) and behavioral expectation (“The probability of taking my hormonal medication every day for the years I have left on therapy is very high”). The two items had a significant positive correlation $r=.86$; $p < .001$ and were combined to create an intention index ($\alpha = .92$). Adherence behavior was measured by one item [34]: “People sometimes miss their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your hormonal therapy medication?.” Participants responded yes/no.

Predictors. Positive attitudes were assessed with two items (i.e., positive/good; $\alpha = .88$) and negative attitudes with two items (i.e., negative/bad; $\alpha = .87$). These four items (negative recoded) were averaged to create a general attitude index (four items, $\alpha = .82$). Two items

measured perceived control (i.e. self-confidence/up to me; $\alpha = .27$). Since the alpha was low, each item was analyzed separately. Two items assessed subjective norms (i.e., descriptive/prescriptive). Two items assessed direct attitudinal ambivalence including a cognitive aspect (i.e., doubts) and an emotional aspect (mixed emotions). Indirect attitudinal ambivalence was calculated following the best-supported index: $(P+N / 2-|P - N|)$ where P and N represent the mean positive and mean negative attitudes respectively [35]. Anticipatory emotions were assessed by asking participants to what extent they felt right now six different positive emotions (e.g., *calm*) and six negative emotions (e.g., *frustrated*) when thinking about taking AET.

Covariates. Socio-demographic variables and cancer stage.

Statistical Analysis

Descriptive statistics illustrate the sample's demographic and clinical characteristics, TPB predictors, attitudinal ambivalence, and anticipatory emotions. A repeated measure MANOVA was conducted to compare the mean of all positive emotions with the mean of negative emotions. In the bivariate analysis, AET intentions were the outcome. The association between intentions and other predictors was assessed using simple regression. Only the socio-demographic and clinical variables that were significant at the .05 levels in the bivariate analyses were included in the multivariable analyses. Two models were built using linear regression via stepwise variable selection with block entry to assess whether the TPB's predictions could be improved. All variables were standardized. Items were not re-scaled, normalized punctuations sum scores (z scores) were used in the linear regression in order to improve the interpretability of the regression coefficients. A second step of the regression model (TPB + Ambivalence) tested if ambivalence (direct and indirect) would improve TPB's predictions. The variables from the TPB were entered in the first step creating the TPB model. The second step added indirect and direct

attitudinal ambivalence. A second stepwise regression model (TPB + Anticipatory Emotions) tested if positive anticipatory emotions would improve the TPB's predictions. The variables from the TPB were entered in the first step and the positive anticipatory emotions were added in the second step. Finally, as an exploratory analysis we conducted binary logistic regression analysis using introduction method and the TPB variables, ambivalence, and positive anticipatory emotions as predictors of past adherence. Additionally, ANOVA tests measured differences in TPB's variables, ambivalence, and positive anticipatory emotions between participants who reported being adherent vs. non-adherent **in the past two weeks**. All analyses used SPSS version 15.

Results

The intention mean-expectation was high ($M=6.16$, $SD=1.47$). Participants reported high positive attitudes and low negative attitudes about taking AET. Women also reported high-perceived control. Both descriptive and prescriptive norms were high. Participant's ambivalence to AET was low. Positive emotions were significantly reported with higher intensity ($M=5.35$, $SD = 1.49$) than negative emotions ($M=2.13$, $SD=1.26$), $F(1, 251)= 422.75$, $p<.001$, $\eta_p^2=.63$). Thus, the following regression analyses utilized only positive anticipatory emotions. Lastly, 21.2% reported missing the medication in the past two weeks.

In the bivariate analyses general attitudes, positive attitudes, perceived control, and perceived subjective norms had significant positive correlations with adherence intentions while negative attitudes were significantly negatively correlated with intentions. The three attitudinal ambivalence variables were significantly negatively correlated with AET adherence intentions. Positive anticipatory emotions were significantly associated with AET adherence intentions

while negative emotions were significantly negatively correlated with adherence intentions (Table 2).

AIM 1. TPB– AET Intentions

Sociodemographic factors and stage were not significantly associated with AET intentions and they were not included in the regression model. The regression model including TPB constructs to predict intentions was significant ($p < 0.001$) with a corrected R_c^2 of 0.66 indicating 66% of the variance in adherence intention was explained by the model. Prescriptive norms and feeling self-confident about taking AET were significantly and positively associated with intentions (see Table 3).

AIM 2. TPB with Ambivalence - AET Intentions

Direct and indirect attitudinal ambivalence were added in the second step to the TPB regression model. The TPB variables predicted 66.3% of intentions ($R_c^2 = .663$), $F(5, 237) = 96.19$; $p < .001$. The model did not improve with direct and indirect ambivalence, $F(3, 234) = 1.09$; $p = .35$. None of the attitudinal ambivalence variables were significant and did not explain additional variance beyond the TPB.

AIM 3. TPB with Positive Anticipatory Emotions- AET Intentions

In the first step TPB predicted 65.4% of AET intentions ($R_c^2 = .654$), $F(5, 232) = 90.59$, $p < .001$. When adding positive anticipatory emotions in the second step, TPB and positive anticipatory emotions explained 70% of AET intentions $F(11, 226) = 52.84$, $p < .001$ ($R_c^2 = .70$). This was a statistically significant improvement with an increase in the variance explained of 4% ($\Delta R^2 = 0.04$), $F(6, 226) = 7.90$, $p < .001$. Significant predictors included *calm*, *hopeful*, *prescriptive norm*, *descriptive norm*, and *confidence* (Table 3). A follow-up regression analysis using positive

anticipatory emotions without controlling for the TPB showed a significant model $F(6,251)=59.40, p < .001$, explaining 57% of intentions to adhere ($R^2_c = .57$).

AIM 4. TPB, Ambivalence, Anticipatory Emotions–AET Past Behavior

Results from the logistic models showed that of the TPB variables, only “self-confident” was a statistically significant predictor of past adherence behavior (OR = 0.61 CI 0.39, 0.96 $p=0.034$) though model classification was good with an AUC of 0.71 (CI 0.63, 0.79). When adding attitudinal ambivalence in the second step, the model did not show any improvement (AUC = 0.71, CI: 0.63, 0.79) with none of the ambivalence items being statistically significant predictors of behavior (all $p>0.05$). Positive anticipatory emotions did not change significantly the predictions from the TPB (AUC = 0.71, CI 0.63, 0.80). However when binary logistic regression was conducted using only positive anticipatory emotions, the model maintained reasonable classification of past adherence behavior (AUC = 0.67, 0.59, 0.76) and calm was the strongest predictor (OR = 0.57 CI 0.32, 1.02 $p = 0.057$). The odds ratios of less than one indicate that higher levels of confidence and calm are reduced with a lower odds of being non-adherent in the past two weeks.

ANOVA analysis comparing the TPB variables between non-adherent women and adherent women in the past two weeks found significant differences in all variables except descriptive norms and perceived control (“up to me”) (Table 4). Non-adherent women reported higher indirect ambivalence and direct cognitive (doubts) and affective ambivalence (mixed emotions) toward AET. Non-adherent women also reported lower positive attitudes, lower confidence, and lower prescriptive norms (Table 4). In contrast, women who were adherent in the past two weeks reported higher positive anticipatory emotions (vs. non-adherent) ($\alpha = .93$) (Table 4). Importantly, women who were non-adherent in the past two weeks reported lower

intention to continue therapy in the future ($M=5.87$, $SD= 1.50$), $F(1, 236)= 5.63$, $p=.018$.

Spearman correlation between intention and adherence behavior was $r= -.20$, $p=.001$. Thus, the higher adherence intention in the future, the lower reporting of intentionally missing the medication over the last two weeks. Since the correlation between the past adherence behavior and intention was significant, we repeated the linear regressions with TPB, ambivalence, and emotions adding past adherence behavior. Results showed that this variable was not a significant predictor in those models.

Conclusions

Findings suggest that the TPB is a valuable conceptual framework to examine AET adherence intentions in breast cancer survivors. The TPB model explained 66% of adherence intentions. The explanatory power was higher compared to the 33% reported in a meta-analysis of adherence intentions in chronic illness [10].

Self-efficacy was the most robust TPB predictor of adherence intentions and the only significant predictor of **past** adherence behavior. The importance of self-efficacy coincides with the meta-analysis of adherence in chronic conditions [10] and with Moon and colleagues' [18] study about AET in particular. However, a recent systematic literature review [8] only retrieved three papers that measured self-efficacy and found a positive association between self-efficacy and AET adherence. Future studies should examine strategies to increase survivors' confidence in adhering to AET.

The impact of subjective norms in adherence warrants further attention. None of the 61 studies included in a recent systematic review [8] measured subjective norms. Prescriptive norms were associated with adherence intentions in our study. Thus, including significant others in adherence interventions could maximize patients' perceptions of support and approval. Breast

cancer survivors share experiences, emotions, and information about AET in online groups [36]. A case study of an online discussion thread on tamoxifen showed how one survivor initiated treatment due to peer pressure [37]. Further research on this area is necessary.

Literature on emotions suggests that they are important predictors of cancer-related behaviors [38]. Contrary to most studies to date [27-29], our study examined anticipatory emotions. Positive anticipatory emotions alone were good predictors of adherence intentions. The addition of positive anticipatory emotions significantly enhanced the predictive capacity of the TPB. This improvement is meaningful and supports prior efforts of broadening the TPB [39]. Future studies should assess anticipated emotions to determine the strongest predictors in the context of AET since they may have a different impact.

The present findings also highlight the need to move beyond negative emotions. *Calm* and *hopeful* had the strongest associations with adherence intentions. Cancer prevention and control interventions have mostly targeted negative emotions [38]. There is evidence that positive social emotions (e.g., pride) can increase individual's willingness to restrain from pursuing short-term hedonic goals in favor of future long-term gains [40]. This could be especially relevant for AET adherence since women may have to endure the side effects in the short term for greater chances of survival in the long-term.

Study Limitations

Due to the cross-sectional nature of the analysis, it is not possible to establish causal relationships. Another limitation was the lack of a prospective measure of adherence behavior and the use of intention as the primary outcome. While intention is the most proximal determinant of behavior [11], given the documented gap between intention and behavior [12, 19] findings should be interpreted with caution. Nevertheless, the finding that intentions were

significantly correlated with past adherence behavior, suggests that measures of intention are associated with actual behavior. Although we included an adherence behavioral outcome (adherence in the past two weeks), it was only measured with a single item. Thus, findings should be interpreted with caution. Given that the adherence behavior item only captured intentional non-adherence, findings may not apply to unintentional adherence. Another limitation included the use of single items for the two components of perceived control due to the low reliability. **Future studies should also include indirect belief measures.** Despite the limitations, the study had several strengths. To our knowledge, this is among the first studies to examine psychosocial correlates of AET adherence intentions using a well-established theoretical framework and the first to explore the contribution of ambivalence and anticipatory emotions to the TPB in this area.

Clinical Implications

This study constitutes an important step to explore further the synergy between basic emotions research and cancer prevention and control [38]. Assessing emotions towards AET in clinical practice could be an efficient strategy to identify women who may be less likely to adhere to AET [30]. Given the lack of success of most AET adherence interventions [9], findings from this study can inform future interventions to target untapped psychosocial factors to enhance adherence to AET and survivorship.

Ethical Compliance: All procedures performed in this study were approved by the Georgetown University's Institutional Review Board (IRB #2011-275) and performed in accordance with the ethical standards of the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Conflict of Interest: There is no conflict of interest to disclose from the authors.

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