Attitudinal and Social Predictors of Adherence to Oral Endocrine Therapy:

A Psychometrically-Informed Model

Abstract

There is a need for a psychometrically-informed model identifying attitudinal and social factors explaining adherence to oral endocrine therapy (OET) for women with hormone receptor positive breast cancer. This study tested a model with variables selected by stringent psychometric criteria, including benefit and burden attitudes, patient-practitioner alliance and confusion, and positive and negative interpersonal interactions. A sample of 150 current or past OET users completed self-report scales. Fourteen correlations and six mediated pathways implied by the model were tested. All hypothesized associations were significant. This preliminary study suggests the model is a valuable framework for OET adherence research and intervention.

Keywords: adherence, breast cancer, social support, attitude, physician-patient relationships.

Attitudinal and Social Predictors of Adherence to Oral Endocrine Therapy: A Psychometrically Informed Model

For women diagnosed with hormone receptor positive breast cancer, oral endocrine therapy (OET) medications are prescribed that can reduce the odds of recurrence by 39% and mortality by 33% (Early Breast Cancer Trialists' Collaborative Group, 2011). However, OET requires significant commitment (daily or twice-daily pills for up to ten years), which can be problematic for treatment adherence. As many as 1 in 3 breast cancer survivors take medication inconsistently (*implementation variability*; McCowan et al., 2013), and up to 50% prematurely discontinue the treatment (*non-persistence*; Makubate et al., 2013). Both implementation variability and non-persistence represent serious problems; nonadherent women have higher odds of mortality and recurrence (Makubate et al., 2013) and poorer quality of life (McCowan et al., 2013). Many large-scale interventions have been staged to increase OET adherence. However, systematic literature reviews suggest a large number of adherence interventions have been unsuccessful (Finitsis et al., 2019; Heiney et al., 2019). Many unsuccessful interventions focus on education or other "one-way" communication with patients; these interventions rely on the implicit assumption that adherence can be significantly improved by targeting self-regulation and decreasing unintentional nonadherence (forgetting), but this assumption may be untenable (Gadkari and McHorney, 2012). A more promising approach may include a focus on attitudinal and social variables that predict adherence, because there is evidence these types of variables are relevant across the cancer trajectory, including during treatment phases (Gadkari and McHorney, 2012; Kangas and Gross, 2020; Lepore, 2001). As a first step, there is a need to develop a theoretically-motivated and psychometrically-informed model of attitudinal and social predictors

of adherence to OET. Such a model would point to new targets for interventions to improve adherence.

One notable challenge in developing this type of model involves two key psychometric issues: variable distinctiveness and scale discrimination. First, previous research has identified an unmanageably large number of possible attitudinal-social predictors (for reviews, see Moon et al., 2017; Sawesi et al., 2014), yet the distinctiveness of these variables has not been established, and there is likely to be a high degree of redundancy. Even established models of health behavior change may display conceptual and empirical overlap both between and within models (Moon et al., 2019); this is problematic because it leads researchers to waste resources by targeting redundant predictor variables, which in turn, limits the scope of the research and produces results that lack precise meaning. Second, many scales assessing possible attitudinal-social predictors of adherence elicit skewed responses that demonstrate poor discrimination in item response theory analyses (Brier et al., 2017; Sanford et al., 2018). If used in research, such scales will shrink effect sizes, reduce power, and fail to detect potentially important outcomes.

To address this challenge, it would be valuable to build and test a model of attitudinal-social adherence predictors using only concepts measured with scales that pass three key psychometric criteria. First, *factor validity* is needed to demonstrate that each variable can be isolated as a unique and singular construct that is not combinable with other factors. Second, tests of *incremental convergent validity* need to demonstrate that the variable makes a unique contribution over and above other similar variables in explaining variance in target outcomes. Third, item response theory analyses need to demonstrate that the variable can be assessed with high *discrimination* across a full range of patient experiences. Following a thorough literature review of attitudinal-social predictors of OET adherence, we identified two attitude variables and

four social variables meeting these psychometric criteria. As described below, we propose a model in which the attitude variables directly predict adherence, and the social variables have effects on adherence that are partly mediated by the attitude variables.

First, *perceived benefit* and *perceived burden* are the two basic attitudes toward treatment distilled from psychometric research (Sanford and Rivers, 2019). Each attitude can be measured with high factor validity, incremental convergent validity, and discrimination. Perceived benefit involves a perception that treatment is effective and adherence is useful. Perceived burden involves a perception of barriers or difficulties that make treatment aversive. Empirical research and theory support the importance of these two attitudes (Chan and Horne, 2018; Milata et al., 2018; Nguyen et al., 2014). A sizable body of work suggests adherence is largely determined by attitudinal factors (Gadkari and McHorney, 2012), which some recent theories suggest may act as a "filter" through which other variables influence adherence outcomes (Burke et al., 2018). These attitudes are expected to have direct effects on treatment adherence.

Second, *alliance* and *confusion* are two key patient perceptions distilled from psychometric work regarding patient relationships with healthcare providers (Rivers and Sanford, 2019; Sanford et al., 2018). Both perceptions demonstrate high factor validity, incremental convergent validity predicting key patient outcomes, and good discrimination across a wide range of patient experiences. Alliance represents perceiving a warm, trusting, and supportive relationship with one's healthcare provider, whereas confusion represents feeling insufficiently informed or experiencing lingering questions after meetings with one's healthcare provider. Patients with strong alliance are more likely to trust medical advice, promoting adherence to OET and positive treatment attitudes (Kahn et al., 2007; Vermeire et al., 2001). In contrast, feeling insufficiently informed about OET is associated with poorer adherence and

maladaptive treatment attitudes (Kahn et al., 2007; Pellegrini et al., 2010). Therefore, we expect both alliance and confusion to have unique relationships with treatment adherence, mediated by attitudes of perceived benefit and burden.

Third, perceived *positive interactions* and *negative interactions* are two key dimensions of social support distilled from psychometric work on the ways people experience close interpersonal relationships when coping with stressful life situations (Rivers and Sanford, 2018; Sanford et al., 2016). Perceptions of affectively positive interactions (e.g., expressions of optimism, provisions of comfort, or quality time together) and affectively negative interactions (e.g., criticism, neglect, or withdrawal) are distinct, sharing a near-zero correlation; they demonstrate good factor validity, incremental-convergent validity, and good discrimination (Rivers and Sanford, 2018; Sanford et al., 2016). The social-cognitive processing model of adjustment to cancer suggests that these mutual interactions influence breast cancer adjustment by promoting or interfering with cancer-related cognitive processing (e.g., attitudes of benefit and burden; Bright and Stanton, 2018; Lepore, 2001). Therefore, we expect perceived positive and negative interactions to have unique relationships with treatment adherence, mediated by attitudes of perceived benefit and burden. Also, given the distinct functions of positive and negative interactions in predicting affective outcomes (Rivers and Sanford, 2018), we predict that positive interactions will be primarily associated with perceived benefit and negative interactions will be primarily associated with perceived burden.

In sum, the current model is unique in focusing primarily on attitudinal-social variables isolated in previous psychometric work as distinct and measurable with high discrimination. This approach maximizes the utility of the model because it reduces redundancy and attenuation of effects while increasing theoretical clarity. The goal of the current study was to provide a

preliminary test of the specific variables and pathways proposed by the model, and thereby to establish a foundation for more resource-intensive longitudinal work using large samples and multiple methods of assessment. If empirically supported, the model could help identify new targets for developing interventions to improve OET adherence.

Method

Participants and procedures

The sample comprised 150 female breast cancer survivors (M_{age} = 59.9, *SD* = 12.7 years). Of these, 92 (61.3%) were currently taking OET medications, 39 (26%) had completed their recommended course, and 19 (12.7%) had prematurely discontinued treatment. Regarding OET medications, 61 (40.7%) were prescribed only aromatase inhibitors, 46 (30.7%) were prescribed only tamoxifen, 41 (27.3%) had been prescribed both, and two participants were uncertain. Regarding other treatments, 143 (95.3%) received surgery, 112 (74.7%) received radiation, and 88 (58.7%) received chemotherapy. Regarding race and ethnicity, 129 (86%) participants identified as non-Hispanic White, 11 (7.3%) as Black/African-American, four as Hispanic/Latina (2.6%), three as Asian-American (2.0%), and three (2.0%) as other races.

Participants were recruited via Qualtrics panels of people matching eligibility criteria for the current study (female English-speaking U.S. residents with a history of breast cancer). Women reporting being prescribed OET were included (those never prescribed OET were diverted to a different study). The survey included foil items (to detect dishonest reporting), attention checks (to detect inattentive responding), and a speeder check (to detect overly fast responding). People failing one or more of these validity checks were excluded from the study. After indicating informed consent by clicking a button, all participants completed the same general questionnaire; however, instructions were tailored to each participant based on whether

they were currently or previously taking OET. Women currently taking OET described their present experience. Women who previously completed OET described the time when "it required the most effort to continue adjuvant therapy." Women who prematurely discontinued described one month before they stopped. After completing the survey, participants were compensated with gift cards or online credit points with an approximate value of $2.00. The study protocol was reviewed and assigned exempt status by (IRB redacted, #1482357).

Measures

Means and ranges for all measures are in Table 1.

Treatment attitudes. Attitudes toward treatment were assessed using the Perceived Benefit and Perceived Burden scales from the Treatment Adherence Perception Questionnaire (TAPQ; Sanford and Rivers, 2020). Each scale includes five items. Example present-tense items include: "Assuming you take adjuvant therapy medication, how effective do you think this medication is in accomplishing the things it is supposed to accomplish?" (benefit), and "How much would you agree that taking adjuvant therapy medication can feel like a weight on your life?" (burden). After summing, total scores may range from 5 to 30 (benefit) and from 5 to 29 (burden; higher scores indicate more benefit or burden). Cronbach's alphas were .92 (benefit) and .91 (burden).

Patient-provider relationship. Alliance (seven items) and confusion (five items) were assessed using the Medical Consultation Experience Questionnaire (Sanford et al., 2018). Example present-tense items are "Compared to a typical doctor, how much do you feel like part of a team with your oncologist?" (alliance) and "Do you have questions that your oncologist or another medical expert might be able to answer?" (confusion). After summing, total scores may

range from 7 to 39 (alliance), and from 5 to 25 (confusion; higher scores indicate more alliance or confusion). Cronbach's alphas were .93 (alliance) and .88 (confusion).

Close interpersonal relationships. Positive and negative interactions in close interpersonal relationships were assessed using the Interpersonal Resilience Inventory (Rivers and Sanford, 2020), a version of the Couple Resilience Inventory (Sanford et al., 2016) adapted to be applicable to all close personal relationships. Respondents are given a definition of "significant adult people" that clarifies this includes nonprofessional relationships with expectations of mutual support (e.g., partners, family, friends). Then, each dimension is assessed using eight items in which participants rate the frequency of specific types of dyadic interaction. Example present-tense items are "In your relationship with a significant adult person in your life, one of you was attentive to the other's needs" (positive), and "In your relationship with a significant adult person in your life, one of you was critical or hostile or blamed the other" (negative). After summing, total scale scores may range from 0 to 56 (higher scores indicate more frequent interactions). Cronbach's alphas were .88 (positive interactions) and .86 (negative interactions).

Treatment adherence. Self-reported implementation adherence was assessed using the TAPQ (Sanford and Rivers, 2020). This measure was selected because it demonstrates higher discrimination compared to other self-report adherence measures (Sanford and Rivers, 2020). The scale used in the present study consisted of 5 items (one item was omitted because it could not be worded in the past tense). An example present-tense item is, "On how many of the last seven days did you take adjuvant therapy medication?" (past-tense, "At that time, in a typical week…"). Preliminary analyses indicated responses were more skewed than in the original validation study; therefore, each item was normalized using the Rankit method (recommended

by Solomon and Sawilowsky, 2009). Higher scores indicated better adherence. Cronbach's alpha was .72.

Data Analysis

First, exploratory analyses were conducted to determine if there were differences between women based on type of medication, retrospective reporting, or treatment persistence. To investigate possible effects of medication type, general linear model equations were estimated in which two orthogonal contrasts predicted each variable in the study. The first contrast compared women taking only aromatase inhibitors (AIs; coded .5) with women taking only tamoxifen (coded -.5) and women taking both (coded 0). The second contrast compared women taking both (coded .33) with the two groups of women taking only one (both coded -.66).

To investigate effects regarding retrospective reporting and treatment persistence, general linear model equations were estimated in which each variable was predicted by two simple contrasts (comparing a reference group, coded 0, with one of the other groups, coded 1). The first contrast compared women that completed treatment (reference) with women currently taking OET, testing the effect of *retrospective reporting* using only women reporting OET persistence. The second contrast compared women who completed treatment (reference) with women who discontinued treatment, testing the effect of *treatment persistence* using only retrospective reporters. Outcome variables were transformed to *z*-scores prior to analysis. Therefore, the effect size for each contrast can be interpreted like a *d*-statistic (the difference between means in standard deviation units).

To test the viability of the theoretical model, we computed zero-order correlations testing all implied bivariate associations. Follow-up analyses were performed to test robustness after controlling for medication type and retrospective reporting using a series of partial correlations.

Finally, we tested a series of mediation models (containing a predictor, mediator, and outcome), each estimated separately to evaluate whether the overall theoretical model was plausible. All models were estimated in the R package lavaan (Rosseel, 2012). Indirect effects were tested using standard errors from 5,000 bootstrap draws.

Data Sharing Statement

De-identified participant data for all the variables reported in this study, along with syntax files, output files, and an explanatory memo are shared on FigShare.

Results

Table 1 shows the general linear model contrast results. Women who had only taken AIs (relative to only tamoxifen) reported better adherence, and women who had taken both (relative to only one) reported greater confusion. Importantly, only one small effect was associated with retrospective reporting. Specifically, compared to women currently completing treatment, women who were retrospectively reporting their completed treatments reported more confusion. Results regarding treatment persistence indicated that, compared to women who completed treatment, women who eventually discontinued treatment reported poorer adherence, greater perceived burden, and less perceived benefit. However, the group discontinuing treatment was small (n = 19).

Table 2 shows the zero-order correlations. According to the model, adherence should be associated with all other variables. These correlations are in the right column of Table 2, and all are significant. In addition, the two attitude variables (benefit and burden) should each be associated with social variables; however, only benefit was expected to correlate with positive interaction and only burden was expected to correlate with negative interaction. Altogether, there were six hypothesized correlations with the attitude variables, and these results are listed in the

first two columns of Table 2. All hypothesized correlations were significant. As a follow-up analysis, partial correlations were tested controlling for both medication type and retrospective reporting (comparing all current to all past responders). All hypothesized correlations remained significant after accounting for medication type and retrospective reporting.

Table 3 shows the coefficients from mediation models. For patient-provider relationship variables, all four indirect effects were significant. Mediation results regarding perceived interactions were consistent with hypothesized differences between types of interaction. Specifically, positive interactions only had indirect effects through benefit, and negative interactions only had indirect effects through burden.

Discussion

Previous psychometric work has identified sets of predictor variables involving attitudes toward treatment and interpersonal processes that are relevant for OET adherence and can be assessed with good factor validity, incremental-convergent validity, and high discrimination. The present study took a preliminary step in testing a model specifically based on these variables, and results were noticeably robust. Two types of attitudes (benefit and burden), two dimensions of patient-provider relationships (alliance and confusion), and two dimensions of perceived interactions in close interpersonal relationships (positive and negative), were all correlated with adherence. In addition, all hypothesized correlations and mediated effects were significant. Moreover, the demonstration of significant mediating pathways represents a meaningful step forward relative to most research predicting OET adherence, which often involves primarily univariate analyses (Moon et al., 2017). These preliminary results demonstrate the value of attending to psychometric issues and suggest that the model could be promising for use in future work.

A significant strength of the current model is the influence of psychometric work on the selection and measurement of predictor variables. The NIH Science of Behavioral Change approach (Nielsen et al., 2018) recommends psychometric work as an essential step in model creation; failing to clearly identify, conceptualize, and assess each variable produces attenuated or confounded results. This is a common problem with adherence research (Burke et al., 2018). For example, many studies examining OET adherence have found null effects of psychosocial variables similar to those included in the model (Bender et al., 2014; Bright and Stanton, 2018; Moon et al., 2017; Stanton et al., 2014), including adherence attitudes or beliefs (Bender et al., 2014; Brier et al., 2017). These studies have often used instruments with problematic psychometric characteristics, including skew (Bender et al., 2014; Brier et al., 2017; Bright and Stanton, 2018) and low or untested reliability (Bright and Stanton, 2018; Stanton et al., 2014). In contrast, the present study used only scales passing stringent psychometric criteria and all hypothesized pathways were significant.

This psychometric approach also allows for precise distinctions between unique predictors. For example, in the current study, perceived benefit was uniquely associated with positive interactions, and perceived burden with negative interactions. These results are consistent with previous work suggesting these components are distinct (Rivers and Sanford, 2018; Sanford et al., 2016; Sanford and Rivers, 2019). In contrast, less psychometrically-focused models have failed to demonstrate distinctions between key subcomponents of adherence attitudes (Jones et al., 2014) and interpersonal processes (Xu and Burleson, 2004). This issue is particularly important because a large body of literature examines OET adherence using a variety of indistinguishable predictors (Moon et al., 2017; Sawesi et al., 2014). Results of the present

study suggest a psychometrically-informed approach leads to meaningful conclusions regarding distinguishable psychosocial variables.

As this study presents preliminary tests of a new model, there are several limitations. First, the current study is small and cross-sectional, limiting the possible analyses. The sample was also heterogeneous and skewed young and non-Hispanic White. Longitudinal studies with larger and more representative samples are necessary to test temporal precedence of mediation effects and other complex analyses. Second, only self-report adherence was assessed, and some participants reported retrospectively. Although self-report adherence is especially useful for developing novel models (Burke et al., 2018; Nguyen et al., 2014), it is also important to examine more objective indicators of implementation adherence (e.g., electronic medication event monitors). Finally, it is important to consider the context in which these experiences occur across the medication management continuum and their impact on implementation adherence and treatment persistence (Bartlett Ellis et al., 2020).

In conclusion, the current paper presents a preliminary study introducing a plausible, theoretically-motivated, and psychometrically-informed model of adherence to OET in which the influence of interpersonal processes is mediated by attitudes of benefit and burden. These results suggest that the model provides a valuable framework to further OET adherence research and possible targets for interventions. This model and general approach utilizing psychometric and theoretical criteria to identify key variables and processes may also have applicability to other treatment contexts involving oral anticancer agents.

Declaration of conflicting interests

The authors declare no potential conflicts of interest.

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Table 1

Means and general linear model contrasts

Variable	Obtained range	Mean (*SD*)	Model 1		Model 2	
			AIs (vs. tamoxifen)	Two (vs. one)	Current (vs. completed)	Discontinued (vs. completed)
Adherence [a]	-8.10 - 2.65	-0.26 *(2.57)*	0.42*	-0.28	0.19	-1.00**
Attitudes						
Benefit	6 - 28	20.05 (*5.52*)	0.26	-0.20	0.08	-1.47***
Burden	5 - 29	14.74 (*7.18*)	-0.27	0.08	-0.19	0.68*
Patient-provider relationship						
Alliance	7 - 39	26.91 (*8.28*)	0.25	-0.11	0.00	-0.14
Confusion	5 - 25	12.39 (*4.74*)	-0.22	0.49**	-0.43*	0.31
Close interpersonal relationships						
Positive interactions	0 - 53	32.29 (*11.77*)	0.25	0.14	0.25	-0.05
Negative interactions	0 - 51	18.97 (*12.77*)	-0.19	0.13	-0.30	0.14

* $p < .05$ ** $p < .01$ *** $p < .001$

[a] Normalized score; high score indicates greater adherence.

Note: each contrast indicates the size of difference between two groups in standard deviation units.