Published in final edited form as:

Ann Behav Med. 2014 August ; 48(1): 7–16. doi:10.1007/s12160-013-9579-2.

The Necessity-Concerns-Framework: A Multidimensional Theory Benefits from Multidimensional Analysis

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Abstract

Background—Patients' medication-related concerns and necessity-beliefs predict adherence. Evaluation of the potentially complex interplay of these two dimensions has been limited because of methods that reduce them to a single dimension (difference scores).

Purpose—We use polynomial regression to assess the multidimensional effect of stroke-event survivors' medication-related concerns and necessity-beliefs on their adherence to stroke-prevention medication.

Methods—Survivors (n=600) rated their concerns, necessity-beliefs, and adherence to medication. Confirmatory and exploratory polynomial regression determined the best-fitting multidimensional model.

Results—As posited by the Necessity-Concerns Framework (NCF), the greatest and lowest adherence was reported by those with strong necessity-beliefs/weak concerns and strong concerns/weak necessity-beliefs, respectively. However, as could not be assessed using a difference-score model, patients with ambivalent beliefs were less adherent than those exhibiting indifference.

Conclusions—Polynomial regression allows for assessment of the multidimensional nature of the NCF. Clinicians/Researchers should be aware that concerns and necessity dimensions are not polar opposites.

Keywords

Polynomial Regression; Necessity-Concerns Framework (NCF) and the Beliefs about Medicines Questionnaire (BMQ); Medication Adherence; Stroke Survivors; Bivariate Evaluation Plane

Patient adherence to prescribed treatments, which has been called the 'the key mediator between medical practice and patient outcomes' (1), is known to be predicted by patients' beliefs, particularly those regarding the treatment itself (i.e., beliefs in the necessity of and concerns regarding the treatment; 2, 3). The effects of patients' treatment-related beliefs on

their adherence are delineated in the Necessity-Concerns Framework (NCF; 3), which is a multidimensional theory in that it posits relationships between two separate dimensions—patients' necessity beliefs and concerns regarding medication—and between these two predictors and an outcome (medication adherence). The NCF states that patients implicitly weigh the costs against the benefits of taking a medication when deciding whether or not to adhere to it and that medication adherence will be greater the more patients' beliefs in the necessity of the medication exceed their concerns. Researchers have found support for the NCF in many illness domains, including asthma (4), HIV (5, 6), cystic fibrosis (7), hemophilia (8), renal disease (9), hypertension (10), depression (11), diabetes, cardiac illnesses, and cancer (3), and recently, among stroke survivors (12). Patients' treatment-related beliefs predict their adherence more strongly than do socio-demographic variables (education, gender, age), clinical variables (type of illness, number of medications), and other beliefs (e.g., illness perceptions; 4, 6).

Given the importance of patients' treatment-related beliefs for their adherence behaviors, the NCF holds great promise for interventions that aim to improve medication adherence. While the NCF enjoys wide support, its optimal application would benefit from further advancement in the methods used to evaluate the NCF. Currently, researchers in the field are using suboptimal methods to assess the NCF that threaten the validity of their conclusions and constrain the theoretical hypotheses they can test. Simply put, researchers are collapsing the separate concerns and necessity-belief dimensions into one dimension (necessity beliefs minus concerns) to analyze the multidimensional theoretical relationships posited by the NCF (as depicted in Figure 1a).

The purpose of the current paper is twofold: 1) to demonstrate the usefulness of polynomial regression for studying the NCF and patient adherence; and 2) to use polynomial regression to extend the evidence regarding the importance of the NCF in a stroke-survivor population, for whom adherence to stroke-prevention medications is of utmost importance to prevent stroke recurrence (12, 13).

The Necessity Concerns Framework is a multidimensional theory

The 'necessity beliefs' and 'concerns' subscales of the Beliefs about Medicines Questionnaire (BMQ; 14) were designed to assess the NCF. These positive and negative evaluations of medications, respectively, are separate theoretical dimensions. Not only are they measured on separate subscales, but they have also been shown to be orthogonal to each other in predicting adherence. For example, Aikens et al. (11) found that patients' necessity beliefs and concerns regarding their maintenance-phase antidepressants were unrelated to each other (i.e., did not correlate) and that they independently predicted adherence.

The separate dimensionality of positive and negative evaluations can be traced to earlier social psychological theorists. Cacioppo and colleagues (15, 16) took issue with the fact that positive and negative evaluations were being assessed on unidimensional, bipolar scales (e.g., semantic differentials; if a subject had a positive attitude towards a behavior or object, then he/she was thought to necessarily *not* have a negative attitude towards the behavior or

object), and proposed the ‘bivariate evaluation plane’. The bivariate evaluation plane theory maintains that individuals’ behavior may be determined by reciprocal (when one is high, the other is necessarily low), non-reciprocal (also called ‘co-activated’, meaning a person can be ambivalent about a behavior, having both strong positive *and* strong negative evaluations of it or can be indifferent about a behavior, having weak positive *and* weak negative evaluations of it), or uncoupled positive and negative evaluations. For example, Cacioppo and Gardner (17) demonstrated that blood donation among multi-gallon blood donors was greater when donors’ attitudes towards blood donation were ambivalent rather than indifferent, but greatest when attitudes were reciprocal-positive (strongly positive and weakly negative) and least when attitudes were reciprocal-negative (strongly negative and weakly positive). Similar ‘attitude groups’ have been created from the BMQ necessity beliefs and concerns subscales (i.e., ambivalence, indifference, skepticism, acceptance; 11).

With positive and negative evaluations existing on two separate dimensions, their relationships to an outcome variable exist in three dimensions. The NCF is, therefore, inherently a multidimensional model, which may be represented with a graph such as Figure 1b, which represents patient adherence (the Z-axis) as predicted by different combinations of patients’ necessity beliefs (the X-axis) and concerns (the Y-axis).

Methods to assess the NCF have been constrained to two-dimensions

The methods thus far used to test the bivariate evaluation plane and the NCF are ‘two-dimensional’, because they function to place the separate dimensions of positive and negative evaluations back onto a single dimension. Researchers have either constructed a difference score (necessity beliefs minus concerns; e.g. 6, 11) or artificially categorized patients into attitude groups, which then function as the predictor on a single dimension. See Figure 1a for a graph of a two-dimensional version of the three-dimensional plane in Figure 1b; likewise, see Figure 1c for a two-dimensional representation of artificial ‘attitude groups’ and their differing mean levels of an outcome.

Examples of these constrained analyses include the following: Horne and Weinman (3) constructed a difference score between patients’ necessity beliefs and concerns about their medications for asthma-, renal-, cardiac-, or oncology-related conditions, and found that the difference score significantly predicted patient adherence; they also split the patients into those for whom concerns scores exceeded necessity scores and those for whom necessity scores exceeded concerns scores, finding that the latter group reported significantly lower adherence to medication than the former. Horne et al. (6) similarly calculated a ‘necessity-concerns differential (NCD)’ to represent the relative value of patients’ necessity beliefs to their concerns regarding their medication and compared the average necessity belief score, concerns score, and NCD between artificially dichotomized low and high adherence groups. The authors concluded from a significantly higher NCD in the high adherence group, that their necessity beliefs were more likely to outweigh their concerns than would be the case for the low adherence group.

A final example is the methods used by Cacioppo and Gardner (17) to test the bivariate evaluation plane theory: they categorized participants into groups defined by their high

versus low scores on positive and negative evaluations of blood donation (high/high, high/low, low/high, low/low); they then tested the mean differences in donated blood (gallons) between the groups. Researchers assessing the NCF for predicting adherence in different illness domains have used this method, splitting their sample into attitude groups based on median splits of the data (18, 19) or on scale-center splits of the data (20, 21). While this categorization recognizes the separate dimensionality of the positive and negative evaluations, it functionally and statistically places them on a single dimension.

Some researchers may analyze the effect of necessity beliefs separately from the effect of concerns on adherence (using them as separate predictors in a multiple regression; e.g., 6, 12), but these analyses do not test the fundamental theory of the NCF, which regards the combined effect of the two types of beliefs on adherence, such as what the effect on adherence is when the two types of beliefs are similar in strength or one is relatively stronger than the other; instead, these analyses look at which type of belief accounts for more variance in adherence in the entire sample.

Methods that collapse dimensions provide suboptimal tests of multidimensional theories

Using difference scores and artificial categorization of participants, thereby collapsing two separate predictor dimensions, decreases statistical power (increasing Type II error risk) and confounds the effect of each predictor on the outcome (increasing Type I error risk; e.g., a significant relationship of the difference score to the outcome may be entirely explained by the relationship between only one of the predictors and the outcome, leading a researcher to falsely conclude that the coupled effect of the two predictors is important for the outcome; 22, 23).

These sub-optimal methods also constrain the theoretical relationships between variables. Of primary importance for the NCF, the algebraic difference score constrains (inherently assumes) patients with ambivalent attitudes to be equal in adherence to patients with indifferent attitudes. This can be seen by considering the regression model tested when a researcher uses a difference score to predict an outcome: $Z = b_0 + b_1(X-Y)$; when $X = Y$, $Z = b_0$, regardless of the absolute level of X and Y (whether high or low).

Using artificial ‘attitude groups’ is not a solution to this problem, because, as mentioned, these group-based methods condense the separate predictor dimensions to one (as in Figure 1c). They also decrease statistical power, regardless of how the data is split; further, those who use median splits or other sample-dependent thresholds compromise the generalizability of the results and can lead to false statistical significance (24). See Edwards (22, 25) or Phillips (23) for a more comprehensive review of the problems associated with difference scores and artificial categorizations.

Polynomial regression is a ‘multidimensional method’

Polynomial regression is a ‘multidimensional method’ that utilizes unconstrained predictors in order to test the difference score model as posited in theories or to determine the three-

dimensional relationships as yet un-theorized. Polynomial regression avoids a majority of the statistical problems associated with ‘two-dimensional methods’ and further allows researchers to test more complex theoretical hypotheses. The analysis is ideal for testing hypotheses posited by the NCF and the bivariate evaluation plane theory: it is used when two related, continuous predictors (e.g., two individuals’ perspectives on the same issue, such as positive and negative evaluations of a behavior; or expected and experienced levels of the same construct, such as expected and experienced satisfaction) are used to predict a continuous outcome, such as adherence (26).

Before providing specific hypotheses, we provide here a brief explanation of polynomial regression and how it can be used to study the theorized relationships between individuals’ positive and negative evaluations and a target behavior. Polynomial regression is a ‘multidimensional method’ in that it maintains the positive and negative evaluations on separate dimensions, as they are theorized to be, in their prediction of the outcome. There are two approaches: a confirmatory approach and an exploratory approach.

The confirmatory approach compares an *a priori* hypothesized, constrained model (e.g., the algebraic difference score) with the unconstrained version of the regression model to test whether the constraints are accurate. Figures 1b and 1d illustrate the constrained and unconstrained difference score models that would be compared with the confirmatory approach. When researchers test the algebraic difference score as a single predictor, they are testing the following regression equation, which is graphed in Figure 1a: $Z = b_0 + b_1(X-Y)$; the graph is made as a simple line graph, with b_0 as the intercept and b_1 as the slope of the line. Figure 1b is a three-dimensional version of Figure 1a—both adhere to the constraint on the regression coefficients of the two predictors. Figure 1b illustrates the *polynomial* regression equivalent to testing a difference score—X and Y are not combined in a single predictor through subtraction but are constrained in the same way. The constrained regression equation tested as the difference score model in polynomial regression is $Z = b_0 + b_1X - b_1Y$ (Figure 1b). Figure 1d is a graph of a plane in which the regression coefficients on X and Y are not constrained to be equal and opposite in magnitude. The ‘unconstrained’ regression equation of this graph is the following: $Z = b_0 + b_1X + b_2Y$. Comparing the results of this ‘unconstrained’ regression model with those of the constrained polynomial regression model (illustrated in Figure 1b), a researcher can statistically infer whether the constraint imposed by the difference score is accurate or not.

Polynomial regression is fundamentally a model-fitting process; in the confirmatory approach, a researcher tests the relative model fit of the constrained to the unconstrained polynomial regression models by evaluating four criteria, regarding the accuracy of the constraints implied by the difference-score (or other *a priori* hypothesized model); see the *Analysis Overview* for an explanation of these criteria for assessing the fit of the algebraic difference score model, which is the model posited by the NCF (versus an absolute value difference score model, $|X-Y|$, e.g.). If a researcher wanted to test the relative fit of two constrained models (e.g., an algebraic versus an absolute-value difference score model), then the four criteria for good fit would be evaluated for each of the constrained models, through comparing them to their unconstrained versions; only one model could meet all criteria. Since only the algebraic difference score model is relevant to the NCF, the reader is referred

to the general polynomial regression literature for more information regarding comparison of constrained models (22, 25).

Exploratory polynomial regression is used if the confirmatory approach results in rejection of the constrained model; it is used to test unconstrained models of increasing order (linear, quadratic, cubic, etc.) to find the best fitting polynomial model. The best-fitting model is the last model to explain significant incremental variance in the outcome; for example, if the linear and quadratic models (entered as separate steps in the hierarchical linear regression) both explain significant variance in the outcome but the cubic model does not, then the researcher concludes that the quadratic model is the best-fitting model (22). The regression coefficients of the final model can be graphed in three dimensions and statistically analyzed for hypothesized relationships, such as those posited by the bivariate evaluation plane theory. Confirmatory regression can then be used in a separate sample to test the accuracy of the final model of the exploratory polynomial regression (the same process used for factor analysis of a construct or constructs).

Polynomial regression not only allows for appropriate analysis of linear differences in ambivalent, indifferent, skeptical, and accepting evaluations of medications and adherence (as in Figure 1d) but nonlinear effects as well. For example, see the hypothetical cubic surface in Figure 1e, in which the effect of reciprocal evaluations (adherence along line of incongruence, $Y=-X$) is exponential at the extremes of the necessity-beliefs and concerns scales (adherence increases exponentially as necessity beliefs increase and concerns decrease in equal units and decreases exponentially as concerns increase and necessity beliefs decrease in equal units), with a flat (equivalent) effect of co-activated evaluations (adherence is the same for high X, high Y as for low X, low Y).

The exact process used in the current study for testing the NCF is described in the next section and in the overview of the analyses in the Method section. See Phillips (23) for a more comprehensive review and explanation of polynomial regression for studying three-dimensional (congruence) relationships among health psychological constructs.

The current study: Assessing the NCF in a stroke-survivor population using polynomial regression

In the current study, we assess whether stroke (or transient ischemic attack, TIA) survivors' beliefs regarding their stroke-prevention medications predict their self-reported adherence to those medications as posited by the NCF. Unlike previous research in this area (12), however, we utilize polynomial regression to test hypotheses of the NCF: first, we use confirmatory polynomial regression to explicitly test the constraints of the algebraic difference score model—that is, we use an unconstrained regression model to test whether the constrained models used by other researchers (who use difference scores) are accurate (i.e., represent true relationships among variables in the population), at least within the current sample. Second, since the strict algebraic difference score model is rarely accurate (22, 27), we use exploratory polynomial regression to determine the best-fitting multidimensional model to explain the effects of patients' necessity beliefs and concerns on their adherence. We specifically test the possible differing effects on adherence of patients'

ambivalent, indifferent, skeptical, and accepting attitudes towards their stroke-prevention medications, as posited by the NCF (note: these attitude domains are theoretically relevant to a multidimensional, linear model, and would not be relevant categories if the final model is found to be quadratic or cubic, for example).

Method

Participants and Procedure

Participants (n=600) were recruited into a stroke-prevention intervention trial targeted at stroke and transient ischemic attack (TIA) survivors in underserved communities in New York City (inclusion criteria: age ≥ 40 years, had at least one stroke or TIA in the past 5 years) (see 28, for a report of the larger intervention trial methods). After obtaining informed consent (read aloud when necessary), trained research staff conducted baseline, in-person interviews in English or Spanish at community venues and a large urban teaching hospital. Interviews, conducted prior to the intervention, included demographic variables. The Mount Sinai School of Medicine Human Research Protection Program approved all consent documents and procedures.

Measures

In addition to demographic variables, comorbidities, health utilization and health behaviors, we collected data on necessity beliefs and concerns, and detailed information on medication adherence. The specific necessity beliefs and specific concerns subscales of the Beliefs about Medicines Questionnaire (BMQ; 14) have been shown by many researchers in varied patient populations, including stroke survivors (12), to predict patients' medication adherence.

With respect to the concerns subscale, three items ask participants to rate the degree to which they worry about 'having to take your medicines', 'long-term effects of your medicines', and 'becoming too dependent on your medicines.' The fourth item asks how much 'medicines disrupt your life' and the fifth asks how much 'medicines are a mystery to you'. Based on the results of piloting the BMQ with representatives of our study population, we modified questions from the original instrument to make them more understandable to our study population which had low health literacy. Specifically, instead of asking participants to read each item and then rate their agreement with it, participants were directly asked each question by the interviewer. In addition, the response scale for the included items was reduced from the usual five options ('strongly disagree' to 'strongly agree') to four options (1-'not at all', 2-'a little bit', 3-'somewhat' and 4-'very much'). We were concerned that participants had difficulty understanding the fifth item. This item had a zero corrected item-total correlation with the other concern items, substantially negatively affecting the internal consistency of the scale; it was therefore not included in the composite of the concern items that was used in the statistical analyses.

The necessity subscale asks participants to rate how much 'your health depends on your medications', they would be 'ill without your medications', 'your health in the future depends on your medications', 'your life would be impossible without your medications',

and ‘your medicines protect you from becoming worse.’ We adapted the necessity subscale in the same manner as the concerns subscale and participants were given the same response options as for the concerns items. Therefore, the concerns scale was an average of 4 items with higher scores indicating greater concerns regarding the medicines, and the necessity beliefs scale was an average of 5 items with higher scores indicating greater necessity beliefs regarding the medicines.

Medication adherence was measured using the 8-item Morisky Medication Adherence Scale (MMAS; 29), which is an 8-item measure with 7 yes/no items (e.g., ‘Have you ever stopped taking your medication without telling your doctor because you felt worse when you took it? Yes/No’) and one 5-option item (‘How often do you have difficulty remembering to take all your medicines?’). Conventional scoring was used but reversed so that higher scores represent *greater/better* adherence.

For all three of the above scales, the interviewer did not ask patients to respond about a specific medication, as the patient may have been taking multiple medications within multiple categories with proven efficacy to prevent strokes. Therefore, patients could have answered the items with regards to one or more medicines they were currently taking for prevention of future stroke (for blood pressure control, cholesterol control, and/or blood thinners).

Analysis Overview

All analyses were conducted separately for patients who had suffered only a TIA, since suffering a stroke is more serious and could theoretically affect patients’ beliefs and/or adherence. None of the results differed for TIA-only (n=284) compared to stroke-survivors (n=316), and so the results from combined analyses are reported below.

Confirmatory Polynomial Regression—There are four criteria that must be met using confirmatory polynomial regression in order to find support for the algebraic difference score model (22): first, the model (the unconstrained regression equation: $Z = b_0 + b_1X + b_2Y$) must explain significant variance in the outcome, Z (adherence); second, the regression coefficients for the concerns and necessity subscales must be significant and in the expected direction (i.e., necessity beliefs should significantly, positively predict adherence; concerns should significantly, negatively predict adherence); third, the constraint imposed on the regression coefficients by the two-dimensional model (i.e. that $b_1 = -b_2$ in order for $Z = b_0 + b_1(X - Y)$) should be accurate; this is equivalent to showing that the constrained/two-dimensional model should not significantly decrease explained variance in adherence from the unconstrained/three-dimensional model; lastly, the potential of more complex relationships should be ruled out—higher-order models should not explain significant variance beyond that explained by the linear terms of the unconstrained (and constrained) difference score model. If these criteria are met, then the strict hypotheses as tested by other researchers with regards to the NCF in other patient populations (3, 4, 6, 11) will be supported.

Exploratory Polynomial Regression—In exploratory polynomial regression, polynomial models of increasing order (unconstrained linear, quadratic, and cubic models)

are tested for fit to the data, in a hierarchical regression, with the terms of each order model entered together as a step in the regression. The variance in adherence explained by each model is calculated, and the final, best-fitting model is the highest-order model that explains significant incremental variance in adherence from the preceding lower-order model. The regression coefficients of the final model are used to graph the results in three-dimensions; inference tests may be done to test specific relationships of interest (resources exist online for conducting these tests: see 23, 26). If the final model is linear, these tests will include calculating and testing the significance of the slope of the surface when patients' necessity beliefs and concerns are equal in magnitude; if the final model is quadratic or cubic, these tests will assess slopes and curvatures of the surface to assess how adherence is influenced by different combinations of necessity beliefs and concerns. All analyses were conducted in the current study using SPSS, version 17 (SPSS, Inc.).

Results

Demographics and descriptive statistics of study variables are presented in Table 1. Similar to previous studies, we found that patients' stroke-prevention necessity beliefs and concerns were not related as would be expected if they were opposite ends of the same conceptual dimension (for which they would have a correlation close to -1.0); in fact, the two subscales correlated *positively* with each other, although weakly (Pearson $r(558) = 0.13$, 95% CI = $0.05, 0.21$). If patients were to be grouped into categories by their attitudes towards medications (using a scale-centered split on necessity beliefs and on concerns), approximately 24% would be considered ambivalent, 13% indifferent, 4% skeptical, and 59% accepting.

Confirmatory Polynomial Regression of the algebraic difference score model

The necessity beliefs and concerns variables were scale-centered in order to reduce multicollinearity between the predictors and their higher order terms and to ease interpretation of the polynomial regression results (23, 30). Standardized values for each variable were calculated to identify univariate outliers; 6 patients had necessity-beliefs scores lower than 3 SD from the mean. Analyses were conducted with and without these cases included in the dataset, and results did not differ with their exclusion; therefore, the results reported below are with the 6 cases included in the dataset. Mahalanobis' distance values were calculated to identify potential multivariate outliers, of which there were none.

The results relevant to the four criteria required to support the strict algebraic difference score model, as inherently implied by previous tests of the NCF that used difference scores, are the following: 1.) The unconstrained model ((Adherence) = $b_0 + b_1(\text{necessity beliefs}) + b_2(\text{concerns})$) explained significant variance in patient adherence ($R^2 = 0.17$, $F(2, 552) = 55.58$, $p < 0.001$), meaning there are non-zero effects of the predictors on the outcome (the first necessary but not sufficient condition for demonstrating congruence effects that adhere to a difference score model); 2.) The regression coefficients for necessity beliefs and concerns were in the expected directions and had the expected significance ($b_1 = 0.25$, $p < 0.01$, 95% CI = $0.07, 0.42$, and $b_2 = -0.81$, $p < 0.001$, 95% CI = $-0.96, -0.66$, respectively), which is also a necessary but not sufficient condition for confirming the

difference score model; 3.) However, the unconstrained model predicted significant incremental variance to the constrained model ($F(1,552)=25.70, p<0.001$), which means that the constraint, $b_1=-b_2$, was found to be inaccurate (rather than being equal in magnitude, the regression coefficient on the concerns subscale, -0.81 , was greater in magnitude than that on the necessity-beliefs subscale, 0.25 , so constraining the combined effect of necessity beliefs and concerns on adherence to be necessity beliefs minus concerns is not accurate); 4.) The higher-order terms did not predict significant incremental variance to the unconstrained model ($F(3,549)=2.04, p=0.11$); since the third criterion was not met to confirm the difference score model, this fourth criterion did not strictly need to be assessed.

Exploratory Polynomial Regression

Because the confirmatory analysis resulted in rejection of the strict algebraic difference score model, exploratory polynomial regression was conducted to determine the best-fitting three-dimensional model of the data. The linear terms (X and Y for the scale-centered necessity-beliefs and concerns, respectively) were entered in the first step of the hierarchical regression, the quadratic terms (X^2, Y^2, XY) in the second step, and the cubic terms (X^3, X^2Y, XY^2, Y^3) in the third step. Only the linear unconstrained model was significant. While the interaction term (XY) was significant in the quadratic model ($b=0.29, p=0.014$), the overall quadratic step was not significant (R^2 change $< 0.01, F(3,549)=2.04, p=0.11$); therefore, the final polynomial model that best fits the data is the linear model, which was graphed using the regression coefficients on necessity beliefs and concerns (see Figure 1d). As explained in detail elsewhere (25), since the overall quadratic model was not significant, it would be inappropriate to keep and interpret only the interaction term in the final model. Briefly, there are two reasons why one would not test the interaction term separately from the other quadratic terms: first, the purpose of exploratory polynomial regression is to determine the best fitting shape/order polynomial model (i.e., to determine whether the data are best-fitted by a linear, quadratic, cubic, etc, model) and not to merely maximize variance explained in the outcome with variously-ordered terms. Second, testing the higher-order terms as a set after controlling for the lower-order terms is an omnibus test; similarly to other omnibus tests (e.g. ANOVA), testing or interpreting the individual terms of a model instead of as a set would inflate Type I error.

The graphs of the polynomial regression coefficients can be interpreted by evaluating the outcome and change in the outcome for different combinations of the predictors. For example, to answer the question, ‘what happens to adherence as concerns increase and necessity beliefs decrease in equal units’, one would look at the changes in the outcome along the line in the XY -plane called the line of incongruence (when $X = -Y$). As illustrated in Figure 1d, adherence was highest when necessity beliefs were high and when concerns were low and lowest when necessity beliefs were low and concerns were high (intuitive, reciprocal effects). Equivalently, in congruence terms, adherence was most positively affected along the line of incongruence—i.e., when concerns decreased and necessity beliefs increased in equal measure. A statistical inference test can be conducted to see if the observed change in adherence along this line of incongruence is significant (23, 26). Here the test is whether the slope of the surface (i.e., changes in adherence) when $X=-Y$ is significantly different from zero; this slope was significantly positive (slope = $1.06, t(549) =$

5.70, $p < 0.001$), meaning adherence increased as necessity beliefs increased and concern decreased (in equal units: e.g., from $X, Y = 0, 0$ to $1, -1$ to $2, -2$). Formulas for calculating relevant slopes and curvatures of surfaces are available in existing publications and online (23, 26).

Co-activated, or non-reciprocal effects are also evident and would not have been identified using ‘two-dimensional’ analysis of the difference score (Necessity Beliefs – Concerns), which constrains adherence to be the same for all values of $X-Y$ (to be equal when both X and Y are high and when both X and Y are low, e.g.): specifically, adherence was greater when both concerns and necessity beliefs were low than when both concerns and necessity beliefs were high. This can be seen in Figure 1d by following the surface from the front corner (when X and Y are both low) diagonally to the back corner (when X and Y are both high). This can be seen statistically from the slope of the surface along the line of congruence or co-activated effects (when $X=Y$); this slope was -0.56 ($t(549) = -3.01$, $p = 0.003$), meaning adherence decreased as X and Y both increased (e.g., from $X, Y = 0, 0$ to $1, 1$ to $2, 2$). The differences between the difference score model and the final model can be seen in the differences between Figures 1b and 1d: the three-dimensional representation of the algebraic difference score model (Figure 1b) constrains the adherence levels for when $X = Y$ (whether both are high or low) to be equal, whereas the adherence levels seen in Figure 1d differ when attitudes are ambivalent (X and Y , or necessity beliefs and concerns, are both high) from when they are indifferent (X and Y are both low).

Discussion

In the current study, we used polynomial regression to analyze the coupled effects of stroke survivors’ medication-related concerns and necessity beliefs on their self-reported adherence. O’Carroll et al. (12) were the first, to our knowledge, to test the influence of patients’ concerns and necessity beliefs on adherence to stroke-prevention medication; they tested the separate/independent effects of necessity beliefs and concerns on adherence and did not test the effect of their difference score, finding that only the concerns were significantly related to patient-reported adherence.

The current results extend this research by using polynomial regression to assess the *combined* effects of necessity beliefs and concerns on adherence as posited by the NCF. The results show that while the general premise of the NCF may be correct—that patients are less adherent when concerns outweigh necessity beliefs and are more adherent when necessity beliefs outweigh concerns—the effect of these positive and negative evaluations on adherence is more complex. The confirmatory polynomial regression ruled out a strict difference score model as the best-fitting model—the model that is typically implied by tests of the NCF (i.e., difference-score analyses; e.g., 14). The exploratory polynomial regression found that patients with ambivalent attitudes towards their medications (strong concerns and strong necessity beliefs) had lower reported adherence than did patients with indifferent attitudes (weak concerns and weak necessity beliefs). This is the opposite finding to Cacioppo and Gardner’s (17) study on blood donation, in which more blood was donated by those who were ambivalent rather than indifferent towards blood donation. The more negative association of ambivalent attitudes with adherence compared to indifferent attitudes

in the current study is due to the stronger bivariate effect of patients' concerns on adherence compared to the bivariate effect of patients' necessity beliefs on adherence. It may be that necessity beliefs are more important for blood donation, a singular low-risk event. In contrast, concerns are more important for stroke-prevention medication adherence, requiring daily medication use with known side effects to avoid a high risk, previously experienced event. For a definite interpretation, the blood donation findings would need to be replicated with polynomial regression rather than artificial patient categories.

Polynomial regression is an analysis tool best used in research (rather than practice) to provide the best possible picture of the relationships between patients' beliefs and behavior that can then be translated to use in practice by clinicians. The current results, for example, could be translated into the following guidelines for clinicians: when discussing patients' necessity beliefs and concerns regarding their stroke-prevention medications, a clinician should note not only their relative difference (whether concerns seem to be greater than beliefs in the medication's necessity) but take into account their absolute levels as well (whether both are relatively high or low). Clinicians working with stroke or TIA survivors should be aware that probing for concerns and for necessity beliefs is important but that a *conversation* with patients may be more helpful to clinicians in assessing the combined effects of these two types of beliefs on the patients' adherence to stroke-prevention treatment and in optimizing patient satisfaction, understanding, and subsequent adherence to the medications. Assessing concerns and necessity beliefs as discrete constructs may not be sufficient to understand the interplay of the positive and negative attitudes towards the medications on the patients' likeliness to adhere to those medications. More research would be required to test the feasibility and the effectiveness of addressing patients' concerns and necessity beliefs for increasing adherence to stroke-prevention medications; it is possible that addressing these beliefs (or only one type) is not feasible (interventions might not change these beliefs), or it is possible that even if belief-change is possible, these changes might not result in adherence changes (see 31 for an example of a successful intervention in asthma patients).

The exploratory approach to polynomial regression, like any other exploratory analysis (e.g. exploratory factor analysis), is a model-fitting approach that requires replication or cross-validation before hypotheses are built and tested from the results (see, e.g., 32). Therefore, replication of the current study results is required before any implicated practice changes are implemented.

Some limitations of the current study may have affected the relationships assessed. Regarding use of polynomial regression for assessment of the NCF: the necessity beliefs and concerns of patients regarding their medications are not merely positive and negative attitudes—they are specific to certain aspects or consequences of the medications, which may qualitatively differ from each other (e.g., concerns include the effect of the medication on non-health related issues whereas necessity beliefs focus on benefits of medication for illness). Polynomial regression is used for predictors that can be qualitatively matched on commensurate scales (25). However, the BMQ necessity-beliefs and concerns subscales are designed to be composites that overall represent patients' positive and negative beliefs, or evaluations, towards a treatment. This is not the first paper to discuss necessity beliefs and

concerns as positive and negative evaluations that may be coupled as in the bivariate evaluation plane theory: for example, Aikens et al. (11) specified couplings of concerns and necessity beliefs as attitudes representing patient ambivalence, indifference, skepticism, and acceptance—but they used ‘two-dimensional’ methods to assess differences in these groups on adherence.

A limitation of the data was that patients were asked to report their beliefs about and adherence to medications in general, not for each specific medication; we were unable to parcel evaluations for different medications from each other and for predicting adherence. Patients have been shown to be differentially adherent to medications and concerns and necessity beliefs may be different for different medications; it is therefore possible that different relationships between patients’ necessity beliefs, concerns, and adherence could exist for different medications. However, the medications that the patients named were all relevant for stroke prevention (antithrombotics/blood-thinners, blood pressure medications, and cholesterol lowering medications). Therefore, the grouping of medications does have the advantage of relevancy for this population and health concern, which is why the questions were asked in the way they were.

It is important to note that major changes were made to the BMQ specific items and response frame. Although the changes were discussed and agreed upon with the scales’ originator due to findings of the pilot testing, the alterations to the items limit synthesizing of the current results with other studies that have used the original form of the BMQ. Further, it is possible that subsequent research in this population that uses the original response options may provide different results.

Lastly, the concurrent assessment of the patients’ beliefs and adherence reports limits conclusions regarding how these beliefs may affect future adherence. It is possible that patients’ reports of their beliefs were affected by their reflections on their recent adherence, for example. Therefore, subsequent research will need to utilize a prospective design to test (using a confirmatory polynomial regression approach) the linear model implied by the current results.

The analytic method of polynomial regression holds great promise for future tests of the NCF in varied patient and illness populations, in addition to other theoretical models that are used to assess congruence, or three-dimensional relationships between two predictors and an outcome. The current study’s results, the overall known issues of difference scores and other methods that collapse separate dimensions, and the multidimensional nature of the NCF all strongly indicate that polynomial regression should be used in future studies of patients’ medication-related evaluations and their medication adherence. Although a linear plane was found to be the best-fitting model to the data, other types of surfaces are possible, such as curvilinear or exponential effects (such as the hypothetical cubic surface in Figure 1e). Also, one might hypothesize different surfaces/relationships for those who experience side effects compared to those who do not. For example, if concerns are more serious, then they would have a greater effect on adherence and the combined effect of concerns and necessity beliefs on adherence might change.

In general, future studies could utilize polynomial regression to investigate the three-dimensional relationships posited by the bivariate evaluation plane theory, between positive and negative evaluations of various treatments for various chronic illnesses. Researchers could test whether negative evaluations are more predictive of behavior than positive evaluations for health behaviors in general, or alternatively, if the effects of positive and negative evaluations are illness- and/or treatment-dependent, which would suggest differing approaches by medical providers to promote adherence for different illnesses and/or treatments.

Acknowledgments

Funding: National Institute on Minority Health and Health Disparities [#5P60MD000270] and the National Center for Advancing Translational Sciences [UL1TR000067].

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Figure 1.

Figures 1a–c: Hypothetical, illustrative figures of two- and three-dimensional representations of a difference score model: Figure 1a represents the algebraic difference score model in two-dimensions and is a graph of the regression equation: $Z = b_0 + b_1(X - Y)$, where Z is the outcome, $X - Y$ is the difference score constructed from the predictor variables, b_0 is the intercept, and b_1 is the regression coefficient for the difference score. Figure 1b is the same model as in Figure 1a but in three-dimensions and is a graph of the regression equation: $Z = b_0 + b_1X + b_2Y$. Figure 1b would be a graph of the confirmatory polynomial regression results, if the difference score model had not been rejected in the current study's analysis; in this model, the outcome is the same for all values of X and Y .

when $X=Y$ (the plane is flat along the line $X=Y$), meaning there is no differing effect on the outcome when both X and Y are high versus when both X and Y are low. Figure 1c represents on one dimension the four groups that are created by splitting concerns and necessity-beliefs scales at their median values (a two-dimensional representation of three dimensions).

Figure 1d: Graph of actual results from current analyses: Adherence is highest when necessity beliefs are high and when concerns are low and lowest when necessity beliefs are low and concerns are high (intuitive, reciprocal effects). Co-activated, or non-reciprocal effects are also evident: specifically, adherence is greater when both concerns and necessity beliefs are low than when both concerns and necessity beliefs are high. Note that the concerns and necessity-beliefs variables were scale-centered, so the data have the actual range of -1.5 to 1.5 for each variable.

Figure 1e: Hypothetical, cubic model of the coupled effects of patients necessity beliefs (X) and concerns (Y) on adherence (Z): in this model, adherence is equivalent when X and Y are equal, regardless of absolute levels of X and Y (i.e., when patients are ambivalent or indifferent about their medications). Adherence exponentially increases as necessity beliefs exceed concerns and exponentially decreases as concerns exceed necessity beliefs.

Table 1

Demographic information and descriptive statistics of study variables for the study sample (n=600).

Variable/Characteristic	Possible or Observed Range	Mean (SD) or Percentage
Age	40–90	63.40 (11.22)
Female Gender		59%
Black Race, Non-Hispanic		46.50%
White Race, Non-Hispanic		16%
Hispanic Ethnicity		36%
Number of Stroke/TIA Events	1–14	1.68 (1.28)
Specific Necessity Beliefs	1–4	3.29 (0.76)
Specific Concerns	1–4	1.88 (0.86)
Medication Adherence (Morisky scale)	0–8	6.06 (1.71)