Predicting Adherence With the Glaucoma Treatment Compliance Assessment Tool

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Glaucoma is the second leading cause of irreversible vision loss worldwide.1 Treating glaucoma using self-administered topical ocular hypotensive eye drops prevents disease progression with its associated vision loss.2,3 Like most chronic diseases, good adherence is essential to maximize the benefits of treatment.4–8 However, 30% to 80% of glaucoma patients have poor adherence.9–11 Thus, clinicians and researchers should understand and treat poor adherence to limit vision loss from glaucoma. In addition, researchers do not have a method to assess why glaucoma patients fail to use their glaucoma drops every day.

Multiple researchers have evaluated the factors related to medication adherence in glaucoma patients to identify the most salient barriers and facilitators to optimal adherence.12–28 Sleath et al26 explored self-efficacy, which is having the confidence necessary to carry out the tasks needed to manage glaucoma, and found a strong correlation between their Glaucoma Medication Adherence Self-Efficacy Scale and objectively monitored glaucoma medication adherence. Ruiz et al2 reported that patient satisfaction with glaucoma therapy (eg, expectations about treatment, ease of use, adverse effects, and impact on the quality of life) was associated with adherence. While these studies have provided key information regarding factors associated with eye drop adherence, their study designs included only a subset of factors that could potentially impact eye drop adherence and small proportions of research subjects who were poorly adherent.

The objective of this study is to determine the key predictors of electronically monitored glaucoma medication adherence among participants with poor self-reported adherence, the patients most likely to benefit from interventions to improve adherence. It uses the Glaucoma Treatment Compliance Assessment Tool (GTCAT), a questionnaire based on the Health Belief Model, which includes multiple constructs examining cues-to-action, barriers, susceptibility, benefits, severity, patient-physician relationship, health status, depression, and self-reported adherence.21,24–28

If the GTCAT is predictive of electronic adherence with good psychometric properties, clinicians and researchers may use it as a tool to determine patient-specific health behavior factors that are related to glaucoma adherence and personalize the approach to treat these factors.

METHODS

Participants

This study included participants from the Support, Educate, Empower (SEE) personalized glaucoma coaching program pilot study (Clinical-Trials.gov, Identifier #NCT03159247) at the University of Michigan Kellogg Eye Center. Participants had a diagnosis of any type of glaucoma, glaucoma suspect, or...
ocular hypertension. The inclusion criteria were: (1) glaucoma, glaucoma suspect, or ocular hypertension; (2) 40 y and older; (3) used ≥ 1 glaucoma medication; (4) spoke English; and (5) self-administered their glaucoma medication(s). We excluded those with cognitive impairment (defined as a diagnosis of dementia or memory loss) or severe mental illness (defined as a diagnosis of schizophrenia, bipolar disorder, or a major depressive episode with psychotic features) as they could not participate in the glaucoma coaching program. The University of Michigan (Ann Arbor, MI) Institutional Review Board approved the study. We obtained informed consent from all eligible and interested participants. All study methods complied with the Declaration of Helsinki guidelines.

Recruitment

The study coordinator sent letters to eligible glaucoma patients summarizing the study along with an option to opt-out of the study. If they did not opt-out, the study coordinator called them by telephone to assess adherence to their medication(s). If the participant voiced interest in the study, the research associate obtained verbal consent to ask screening questions to assess glaucoma medication use. The study used 2 validated scales to assess self-reported adherence, the Chang Adherence measure,19 and the Morisky Medication Adherence Scale.16,20 Those who self-reported <95% adherence over the past month on the Chang measure and scored ≤ 6 on the Morisky scale were considered to have poor adherence by self-report. Upon enrollment, the study coordinator entered the participants’ ocular hypotensive medication(s) and dosing schedule into the AdhereTech system, which is an objective electronic adherence monitoring system using medication monitors that look like pill bottles (AdhereTech, New York, NY). Patients had a different monitor for each of their ocular hypotensive medications. The monitoring system recorded the time and date of each bottle opening and transmitted the data in real-time to a database through the cellular network.

We defined an adherent event when the subject took the medication within a specified time window of the dose taken on the previous day, as described in the SEE program pilot study protocol paper.30 Specifically, we defined the time windows as 24 ± 4 hours for medications dosed once per day, 24 ± 2 hours for medications dosed twice per day, and 24 ± 1.3 hours for medications dosed 3 times per day because the biological efficacy of drops prescribed multiple times per day wanes when not taken on time. When calculating adherence for medications dosed more than once a day, we compared the current day’s doses to the previous day’s corresponding doses rather than simply the previous, same-day dose, as lifestyle and sleeping patterns can result in medication times that are not equally spaced. This method of calculating adherence allows for gradual changes in the time the subject takes the medication without overly penalizing the patient.31,32 For participants on >1 medication, we aggregated it to the personal level by dividing the total number of doses of all medication(s) taken on time by the total number of doses of all medication(s) prescribed.

The researchers calculated adherence monthly during the 3-month monitoring period and designated the median monthly adherence as the baseline adherence score. The analysis used median adherence to help mitigate the effects of regression to the mean.

GTCAT

An interviewer administered the GTCAT21,24,29 (short version, v2019.1, Copyright 2019, Legacy Health) at enrollment using 2 changes to avoid redundant statements with other SEE statements. In place of the GTCAT statement #26 “My overall health is excellent,” the study examined health status using the National Institutes of Health Short-Form 12 (NIH-SF-12) general health question, “In general, would you say your overall health is?” It was scored as follows: Poor (1), Fair (2), Good (3), Very Good (4), and Excellent (5).33,34 The questionnaire assessed depression at the 3-month visit using the Patient Health Questionnaire-9 (PHQ-9)35 in place of the GTCAT statement #27, “Over the past 4 weeks I have never felt blue, downhearted, or depressed.” It was scored as follows: (1) Major Depression—severe (score > 20); (2) Major Depression—moderately severe (score 15 to 19); (3) Major depression—mild, or dysthymia, or minor depression (score 10 to 14); (4) Minimal Symptoms (score 5 to 9); (5) No symptoms (score 0 to 4).35

To provide specific Health Belief Model constructs, the analysis created summary scores for the constructs of barriers, benefits, cues-to-action, self-efficacy, severity, and susceptibility according to previous guidelines.29 These constructs belong to the Health Belief Model36–38 and are defined as follows: perceived susceptibility (ie, the subjective perception of the risk of acquiring a condition or disease), perceived severity (ie, the perception on the seriousness of acquiring an illness or disease, or not treating it), perceived benefits (ie, the perception of the effectiveness of various treatments available to control or cure the illness or disease), perceived barriers (ie, the perceived obstacles to following the health care provider recommendations), cues-to-action (ie, the stimulus subjects need to trigger the decision-making process to pursue a recommended health action), and self-efficacy (ie, the subjects’ level of confidence in their ability to successfully perform a health behavior).

Data Analysis

Construct Validity

Construct validity measures whether statements categorized into a construct (such as the Health Belief Model constructs) actually measure this construct. We used SPSS statistics (version 21.0; International Business Machines Corporation, Armonk, NY) to perform a principal component analysis for construct validity. We used an orthogonal Varimax rotation with pairwise elimination of missing data with a moderate cutoff (>0.50) for factor loadings. We used eigenvalues (>1.0) and examination of the scree plot to determine the number of components.

Rasch Analysis

We used the R Rasch analysis package and Latent Trait Models under IRT (ltm) for Rasch analysis.39 Within eRm, the analysis used the less restrictive partial credit model,40 which assigns one parameter to each combination of items and responses and allows different numbers of response categories. With these packages, we determined “person measures,” which can be used to express where each respondent falls on a linear scale representing compliance as measured by the GTCAT:39,41 We determined “item difficulty” of each GTCAT item and thresholds for each ordinal response category.42 We examined person and item measures, for fit to the Rasch model using infit and outfit item fit statistics. We tested the fit using mean-square statistics (MSQ) of the standardized residuals. Infit and
outfit statistics MSQ values between 0.7 and 1.3 are considered acceptable.\textsuperscript{28,42} Finally, we evaluated differential item functioning, which assesses whether the items have a different fit for higher or lower mean levels of adherence or higher or lower item scores.\textsuperscript{45,46}

**Predictive Validity**

We used SPSS statistics (version 21.0; International Business Machines Corporation) and R (version 3.5.0; R Foundation for Statistical Computing) to create linear regression models using standard model building techniques\textsuperscript{47} to determine predictive ability. Adherence was highly left-skewed \((P=0.001,\ \text{Kolmogorov-Smirnov test})\). The square of adherence was parametric \((P=0.20,\ \text{Kolmogorov-Smirnov test})\) and was therefore used as the dependent variable.

We determined the association of adherence to the GTCAT using 4 analyses: (1) univariate analysis of individual GTCAT statements; (2) a multivariable analysis of the full GTCAT (27 statements including PHQ-9 depression and health status); (3) a multivariable analysis using only those statements from Analysis #1 with \(P<0.10\); and, finally (4) a multivariable analysis including GTCAT statements from Analysis #3, and using a backward step-wise selection procedure that removes statements based on the Akaike information criterion.

### RESULTS

**Participants**

The study enrolled 100 participants. Five participants dropped out of the study before the adherence monitoring started, or did not complete 3 months of monitoring. One \((n=1)\) participant refused to fill out the survey. Therefore, we include \(n=94\) patients in this current manuscript. We did not find differences in socioeconomic or demographic characteristics of those included \((n=94)\) to those not included \((n=6)\), \(P>0.1\) for all (data not shown).

Table 1 shows the demographic, socioeconomic, and medical characteristics. Overall, the study group included a high proportion of nonwhite ethnicities. The average adherence was 73.8\% (SD = 21.04\%; range: 13\% to 100\%), and includes a left-skewed distribution (data not shown).

**Construct Validity**

The principal component analysis converged with 6 components including 16 GTCAT statements. These 6 components explained 74.1\% of the variance. These statements represented the GTCAT constructs of barriers, benefits, cues-to-action, self-efficacy, severity, and the patient-physician relationship. Overall, this suggests that several of the Health Belief Model constructs are associated with adherence in this sample.

**Descriptive Analysis**

Table 2 and Figure 1 show the distribution of the answers and their corresponding percentages for all of the 27 Statements of the GTCAT. Table 3 includes a summary of the statements grouped by Health Belief Model constructs. The GTCAT identified multiple statements with low scores from research participants. For example, only 54\% of participants answered Statement 1, “My personal knowledge of the symptoms of glaucoma is excellent,” which suggests that they would benefit from education regarding glaucoma. Over 88\% agreed with Statement 10 “Sometimes I forget to use my eye drops,” but <32\% agreed with statement 23 “I use reminders to take my eye drop medications,” in this group, it might be useful to problem solve and encourage the use of reminders. Only 50\% of the responders agreed with the statements 16 “My eye drops cause me no pain or discomfort” which could be addressed by the care team. Similarly, in statement 17 “My eye drops are difficult to use” near 20\% of subjects agreed, and may suggest the need for teaching eye drop delivery techniques, or use of a delivery aid.

Table 3 includes summary scores of each of the Health Belief Model constructs,\textsuperscript{28,37,38} which include barriers, benefits, cues-to-action, self-efficacy, severity, and susceptibility. Overall, it shows that the constructs of lack of cues-to-action, “severity,” and “susceptibility” received the lowest combined scores (25\%, 39\%, and 41\%, respectively with 4 or 5 Likert scores). Overall, this suggests that interventions to improve adherence could focus their efforts on addressing these Health Belief Model constructs.

**Rasch Analysis**

The GTCAT person measures (mean \pm SD) were 0.38 \pm 0.17 logits. The percentage of miss-fitting persons

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**TABLE 1. Demographic, Socioeconomic, and Medical Characteristics in the Support, Educate, Empower (SEE) Study**

| Characteristic                                      | Participants \((N=94)\) [n (%)] |
|----------------------------------------------------|----------------------------------|
| Age \[mean (±SD, range)\]                           | 63.2 (± 10.5, 40-88)             |
| Sex (female)                                       | 47 (48.9)                        |
| Ethnicity                                          |                                  |
| Caucasian                                          | 51 (54.3)                        |
| African American                                   | 33 (35.1)                        |
| Asian                                              | 8 (8.5)                          |
| Other or unknown                                   | 2 (2.1)                          |
| Education                                          |                                  |
| Less than high school                              | 3 (3.2)                          |
| High school diploma                                | 8 (8.5)                          |
| Some college                                       | 23 (24.5)                        |
| College degree                                     | 33 (35.1)                        |
| Graduate degree                                    | 27 (28)                          |
| Household income per year \(\$(\)                   |                                  |
| < 25,000                                           | 17 (19.1)                        |
| 25,000-50,000                                     | 24 (25.5)                        |
| 51,000-100,000                                    | 28 (29.8)                        |
| ≥ 100,000                                         | 20 (21.3)                        |
| Health insurance (yes)                             | 91 (96.8)                        |
| Baseline adherence \[mean (SD)\]                   |                                  |
| No. glaucoma medication \[mean (SD, range)\]       | 1.75 (0.85, 1-4)                 |
| VF MD in better seeing eye \[mean (SD)\] (dB)      | −2.73 (4.32)                     |
| VF MD in worse seeing eye \[mean (SD)\] (dB)       | −6.66 (6.92)                     |
| BCVA OD (%)                                        |                                  |
| 20/20                                              | 50.00                            |
| 20/25                                              | 21.28                            |
| 20/30                                              | 13.83                            |
| 20/40                                              | 5.32                             |
| 20/50 or worse                                     | 9.56                             |
| BCVA OS (%)                                        |                                  |
| 20/20                                              | 51.06                            |
| 20/25                                              | 23.40                            |
| 20/30                                              | 17.02                            |
| 20/40 or worse                                     | 5.32                             |
| 20/50 or worse                                     | 3.18                             |

BCVA indicates best-corrected visual acuity; MD, mean deviation; VF, visual field.
TABLE 2. Glaucoma Treatment Compliance Assessment Tool Distribution in the Support, Educate, Empower (SEE) Study

| Statements                                                                 | Disagree a Lot (%) | Disagree a Little (%) | No Opinion/Don’t Know (%) | Agree a Little (%) | Agree a Lot (%) |
|---------------------------------------------------------------------------|--------------------|-----------------------|---------------------------|-------------------|-----------------|
| 1. My personal knowledge of the symptoms of glaucoma is excellent         | 12.77              | 17.02                 | 14.89                     | 42.55             | 12.77           |
| 2. A person can have glaucoma and not know it                             | 0.00               | 2.13                  | 7.45                      | 18.09             | 72.34           |
| 3. Eye pain is a common symptom of glaucoma                               | 23.40              | 17.02                 | 43.62                     | 9.57              | 6.38            |
| 4. Major vision loss from glaucoma can be prevented with treatment        | 2.13               | 4.26                  | 10.64                     | 31.91             | 51.06           |
| 5. Vision lost from glaucoma is permanent                                 | 0.00               | 1.06                  | 27.66                     | 18.09             | 53.19           |
| 6. I completely agree with my doctor’s diagnosis of glaucoma in my eye(s) | 1.09               | 2.17                  | 8.70                      | 23.91             | 64.13           |
| 7. I have lost none of my vision due to glaucoma                          | 18.09              | 25.53                 | 23.40                     | 15.96             | 17.02           |
| 8. If I lost the same amount of vision over the next five years as I have over the past five, it would have no effect on my quality of life | 26.60              | 19.15                 | 25.53                     | 14.89             | 13.83           |
| 9. Over the last month I have not missed taking my eye drops              | 30.85              | 39.36                 | 2.13                      | 20.21             | 7.45            |
| 10. Sometimes I forget to use my drops                                    | 2.13               | 7.45                  | 2.13                      | 52.13             | 36.17           |
| 11. Sometimes I fall asleep before dosing time                            | 20.21              | 8.51                  | 3.19                      | 47.87             | 20.21           |
| 12. Sometimes the drops aren’t with me when it is time to take them       | 29.79              | 18.09                 | 2.13                      | 35.11             | 14.89           |
| 13. Sometimes I am out of drops                                           | 57.45              | 9.57                  | 2.13                      | 25.53             | 5.32            |
| 14. I need assistance putting drops in my eyes                            | 80.85              | 6.38                  | 4.26                      | 8.51              | 0.00            |
| 15. I suffer from side effects when using my drops                        | 56.99              | 10.75                 | 12.90                     | 12.90             | 6.45            |
| 16. My eye drops cause me no pain or discomfort                           | 13.83              | 34.04                 | 1.06                      | 12.77             | 38.30           |
| 17. My eye drops are difficult to use                                     | 55.32              | 22.34                 | 5.32                      | 17.02             | 0.00            |
| 18. I think I will go blind in 10 years if I DO NOT use my eye drops      | 13.83              | 9.57                  | 35.11                     | 18.09             | 23.40           |
| 19. A friend or family member’s experience with eye drops has encouraged me to use my eye drops | 25.81              | 4.30                  | 37.63                     | 15.05             | 17.20           |
| 20. I can place the eye drops into my eye correctly without any assistance| 2.13               | 5.32                  | 3.19                      | 18.09             | 71.28           |
| 21. There are things I can do to control my glaucoma                       | 1.06               | 3.19                  | 13.83                     | 25.53             | 56.38           |
| 22. I can afford my eye drops                                             | 4.30               | 6.45                  | 5.38                      | 20.43             | 63.44           |
| 23. I use reminders to take my eye drop medications                       | 40.22              | 22.83                 | 5.43                      | 20.65             | 10.87           |
| 24. My doctor answers my questions                                        | 2.13               | 2.13                  | 2.13                      | 21.28             | 72.34           |
| 25. I am happy with my eye doctor                                         | 56.99              | 34.04                 | 1.06                      | 12.77             | 38.30           |
| 26. General health scale (SF-12)*                                         | 2.13               | 3.19                  | 4.26                      | 12.77             | 38.30           |
| 27. Depression scale (PHQ-9)†                                             | 1.06               | 3.19                  | 4.26                      | 12.77             | 77.66           |

*Using the National Eye Institute SF-12 question. “In general, would you say your overall health is?” We scored Poor, Fair, Good, Very Good, and Excellent into Likert scores 1, 2, 3, 4, and 5, respectively.
†Using the PHQ-9 with score > 10 (major depression-moderate), score 10 to 14 (major depression-mild, dysthymia, or minor depression), score 5 to 9 (minimal symptoms), and score 0 to 4 (no symptoms) into Likert scores 1, 2, 3, 4, and 5, respectively.
PHQ-9 indicates Patient Health Questionnaire-9; SF-12, 12-item Short Form Survey.

Predictive Validity

When using all 27 GT CAT statements (including health status and depression), the GT CAT had an $R^2$ of 0.51 ($P = 0.005$) for objective adherence. Eleven statements were associated with adherence ($P < 0.09$ for all) in univariate analysis. These statements were related to knowledge (statements 4, 5, 6, and 21), lack of cues-to-action (statements 10 and 12), barriers (statements 13 and 22), self-efficacy (statement 14), self-reported adherence (statement 9), and depression (PHQ-9, statement 27). Overall, this reduced model with 11 statements had an $R^2$ of 0.45 ($P < 0.001$). Seven of these statements were selected into a multivariate model with an $R^2$ of 0.44 ($P < 0.001$). Overall, this suggests that the full GT CAT and a subset of GT CAT statements were associated with adherence in this study group.

DISCUSSION

This study investigated the factors related to glaucoma adherence using the GT CAT and objective, electronic measures of adherence in a patient population with poor self-reported adherence. The study also validated the...
GTCAT for use in a group with poor self-report of adherence to ocular hypotensive medications. We found that: (1) the GTCAT has good construct validity and satisfies the Rasch model in this population; (2) has good predictive validity when used alone ($R^2 = 0.44$, $P < 0.001$); and (3) identifies specific constructs from the Health Belief Model that health care providers may address to improve adherence. Overall, clinicians and researchers may use the GTCAT to identify individual, patient-specific factors to inform personalized interventions and optimize glaucoma adherence.

The psychometric results of the current study showed similar results and build on the findings of previous studies using the longer version (original 47-item GTCAT) and the short version 27-item GTCAT. These studies showed good psychometric properties including test-retest reliability, predictive validity, organizational structure for the Health Belief Model, and measures from item response theory (eg, Rasch analysis). The same version (GTCAT short) also showed good Rasch and construct validity when translated into Portuguese.

The $R^2$, or the coefficient of determination, is a statistical measure of the goodness-of-fit and indicates the amount of variation explained by analysis. The current study showed a satisfactory $R^2$ of 0.51 when using all GTCAT statements for objective adherence using an electronic dose monitor. In comparison to other questionnaires, authors have reported low to moderate correlations in the $R^2$ range of 0.02 to 0.59, when explaining subjective and objective measures of adherence to medical treatment.

The GTCAT measures specific constructs related to adherence: barriers, benefits, cues-to-action, patient-physician relationship, physical and mental health, self-reported adherence, susceptibility, severity, self-efficacy, and glaucoma knowledge. Rees and colleagues found a high proportion of unintentional nonadherence (eg, forgetting) associated with a lower belief in the necessity of eye drops, which is represented by the FIGURE 1. Distribution of answers with the corresponding percentage for the statements of the Glaucoma Treatment Compliance Assessment Tool. Support, Educate, Empower (SEE) Study 2020. * Identifies the statements where higher agreement represented less adherence. $* P < 0.05; ** P < 0.001$. PHQ-9 indicates Patient Health Questionnaire-9; SF-12, 12-item Short Form Survey.

TABLE 3. Summary Scores of Each of the Health Belief Model Constructs

| Construct          | Summary Scores | 1 (Lowest Score) | 2 (Neutral) | 3 (Highest Score) |
|--------------------|----------------|------------------|-------------|-------------------|
| Barriers           |                | 14.45            | 30.58       | 4.13              | 12.51         | 38.33         |
| Benefits           |                | 2.13             | 4.26        | 10.64             | 31.91         | 51.06         |
| Cues-to-action     |                | 30.49            | 31.72       | 12.35             | 12.86         | 12.57         |
| Knowledge          |                | 4.04             | 6.59        | 21.49             | 24.26         | 43.62         |
| Self-efficacy      |                | 5.80             | 7.67        | 12.85             | 17.48         | 56.21         |
| Severity           |                | 15.96            | 20.21       | 24.47             | 17.56         | 21.81         |
| Susceptibility     |                | 13.83            | 9.57        | 35.11             | 18.09         | 23.40         |

Summary scores represent the average agreement to the statements that belong to the same construct. Statements 3, 8, 10-15, and 17 were reversed so that higher agreement implied higher adherence. Score 1 represents the poorest adherence, score 5 represents the highest adherence.
the GTCAT constructs of lack of cues-to-action, severity, susceptibility, and benefits. In particular, cues-to-action (ie, lack of reminders to perform a health-related action), and low perceived severity (ie, the condition not perceived as serious enough to trigger a health-related behavior) showed the lowest summary GTCAT score (<25% and 39% of positive answers, respectively). However, the benefits of treatment has a high summary score (83% had positive answers). Other manuscripts addressed barriers, patient-provider relationship, and have found a high association with adherence.57–62 Overall, this may suggest this study population may benefit from interventions to address multiple constructs of poor adherence.

Our study and others have shown the importance of mental health for adherence to glaucoma treatment. Two studies in persistency (using prescription databases to determine continued use of prescribed medication over time) showed that depressive symptoms could decrease persistency by 29% \( (P < 0.005) \) 63,64. Another study in veterans found that anxiety disorders were also negatively associated with adherence.65 Boland et al66 also showed that depression was associated with poor adherence \( (P < 0.05) \). Newman-Casey et al57 identified life stress to have a similar effect. This suggests that clinicians should try to identify comorbid conditions of mental health among glaucoma patients particularly if they have poor adherence.

This study provides valuable information on a population that self-identifies as poorly adherent, and includes a high proportion of minorities. However, it has limitations. The fact that the participants knew they were electronically monitored may have overestimated the adherence rate (Hawthorne effect), though we purposefully used the median monthly adherence over 3 months to mitigate this effect.31,32 The electronic tracker was a container similar to a pill bottle that did not directly attach to the eye drops bottle; failure to replace the dropper inside the tracker and properly close the lid may have resulted in missing records. The study population included a high proportion (97%) of those with health care insurance; and the results may not be similar in cohorts without insurance because lack of insurance decreases adherence to medications.57,67–69 As stated in the methods, the GTCAT included 2 statements [SF-12 (general health) and PHQ-9 (depression)] in place of similar GTCAT statements to avoid redundant statements with the much larger overall SEE questionnaire. While slightly different, the GTCAT questions of general health and depression have performed similarly in previous studies.21,23

In conclusion, the GTCAT identified multiple, patientspecific factors to inform personalized interventions and optimize glaucoma adherence. Future studies could use the GTCAT to identify and evaluate the effect of targeted interventions in those with poor adherence.

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