Validation, reliability, and specificity of CliniCom™ Psychiatric Assessment Software


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ABSTRACT

The purpose of this study was to determine the specificity and reproducibility of CliniCom™ Psychiatric Assessment Software to appropriately diagnose five prevalent mental health disorders. This online assessment tool incorporates proprietary algorithms for its propensity assessment. Unlike other questionnaires, which require a survey per specific mental disorder, CliniCom can simultaneously assess multiple mental disorders for an individual. CliniCom was concordant with other commonly used assessment tools in diagnosing five prevalent disorders including: Attention Deficit and Hyperactivity Disorder, Generalized Anxiety Disorder, Major Depressive Disorder, Obsessive Compulsive Disorder, and Social Phobia. The online tool was overall 78% concordant in diagnosing the same disorder during a test-retest analysis. When subjects exhibited two, three, or four disorders, the tool was less consistent in diagnosing the same set of disorders during the test-retest analysis (53% concordant). However, if evaluated as individual disorders within subjects, the more persistent disorders had a higher rate of concordance: MDD (83.3%), ADHD (81.0%), and OCD (68.4%). This study proposes CliniCom as an online assessment tool that demonstrates specificity in identifying specific psychiatric conditions and shows reproducibility over multiple administrations.

1. Introduction

Reliable and accurate assessment information is critical for proper diagnosis, as well as recommendation and institution of appropriate treatment plans within mental health clinical settings. Studies have demonstrated that automated, computerized intake assessments provide not only a quicker, but also valid method of obtaining useful and pertinent patient information prior to a patient’s first visit (Brandt et al., 2013; Cunningham et al., 2009; Kurt et al., 2004). During an interview or first time appointment, errors in medical or psychiatric history may arise due to interview technique, interviewee’s response or lack thereof, omission of relevant information, or clinical diagnosis and decisions based upon perceived misinformation (Parkin, 2000) or lack of sufficient time. Arguably, sensitive topics such as drug and alcohol use or suicidal thoughts are more likely to be accurately conveyed on an online assessment than when reported directly to a clinician (Parkin, 2000). Computerized assessments can assist in the diagnostic process by systematically collecting all pertinent information and prioritizing a clinician’s time by formulating an educated initial diagnosis prior to the first meeting with the patient.

To further complicate diagnoses, psychiatric comorbidity has been reported as a frequent occurrence (Maj, 2005). For instance, psychiatric comorbidity is observed in patients that suffer from Attention Deficit and Hyperactivity Disorder with estimates of 50–80% comorbidities of antisocial, substance abuse, anxiety, and mood disorders (Marchetta et al., 2008). To date, assessment tools require separate questionnaires for each psychiatric disorder to make a specific diagnosis of each, as indicated by the availability of multiple reliable and validated assessments. To our knowledge, there has not been a study conducted demonstrating the specificity and reproducibility of a web-based psychiatric assessment.

CliniCom™ Psychiatric Assessment Software (hereafter referred to as CliniCom) has demonstrated the specificity in identifying psychiatric conditions and shows reproducibility over multiple administrations.
CliniCom) is the first, web-based, secure, intuitive, psychiatric assessment tool. Clinicom was developed over the past 10 years by Dr. Nelson M. Handal, Psychiatrist with Dothan Behavioral Medicine Clinic and Harmonex Neuroscience Research. Clinicom uses proprietary algorithms based upon mental health research, clinical practice expertise, and the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria. This assessment tool has the capability to suggest multiple psychiatric conditions alone or together (i.e., psychiatric comorbidity). Users are able to complete the assessment from any computer or mobile device. Clinical reports are generated by gathering information directly from the patient, parent(s), or guardian(s) prior to the initial office visit. Based upon the tool’s proprietary algorithms, Clinicom suggests one or more psychiatric diagnoses from all of the data gathered.

Attention Deficit and Hyperactivity Disorder (ADHD), Generalized Anxiety Disorder (GAD), Major Depressive Disorder (MDD), Obsessive Compulsive Disorder (OCD), and Social Phobia (SP) are among the most prevalent of psychiatric disorders; therefore, these disorders were evaluated in this study. Because established patients had also completed corresponding assessment instruments (e.g., the Hamilton Anxiety Rating Scale for GAD), we chose to highlight these disorders for illustration of specificity in a retrospective study reviewing completed assessments.

Specificity between Clinicom and other commonly used instruments for each diagnosis was examined using concordance analysis. In this study, Clinicom was considered a sensitive and specific test in concordance with assessments used to assist in the diagnosis of ADHD, GAD, MDD, OCD, and SP. Clinicom was also shown to be reproducible through a prospective test-retest analysis with a 78% concordance rate at the level of individual disorder diagnosis.

The objectives of this study were to:

1) Retrospectively demonstrate that Clinicom provides results consistent with other commonly used assessment tools when used to diagnose the same five prevalent psychiatric conditions.

2) Prospectively demonstrate the reproducibility of results obtained from Clinicom by assessing the frequency with which the diagnoses were consistent in test and retest conditions.

2. Methods

2.1. Clinicom Psychiatric Assessment Software

Clinicom (Harmonex) is an online self-assessment tool that uses proprietary algorithms of propensity testing to determine not only the type(s) of psychiatric disorder(s) a patient is likely exhibiting, but also the degree of severity. The information collected from the patient includes individual and family health history, social history, answers to mental health questions, self-assessment of severity of symptoms, quality of life assessment, and current and past treatments. The questions were developed using several years of responses in a clinical setting modulating spurious results. The disorders examined included: Attention Deficit Hyperactivity Disorder (ADHD), Generalized Anxiety Disorder (GAD), Major Depressive Disorder (MDD), Obsessive Compulsive Disorder (OCD), and Social Phobia (SP).

The control assessment tools associated with ADHD included the QbTest (a device used for assessing the core symptoms of ADHD) and the Neuropsychiatric Electroencephalogram-Based Assessment (NEBA) (an ADHD confirmatory support for a completed clinical evaluation or as support for the clinician’s decision to pursue further testing following a clinical evaluation). Both FDA cleared instruments were selected due to the author’s clinical interest. The Hamilton Anxiety Rating Scale (HAM-A) for GAD, the Patient Health Questionnaire-9 (PHQ-9) for MDD, the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) for OCD, and the Social Phobia Inventory (SPIN) for SP were also assessed for specificity with their respective disorders.

2.2. Comparison of Clinicom to control instruments

2.2.1. Patients

A retrospective comparison of the Clinicom assessment results to control instrument results for the selected disorders was performed to determine the consistency of the online tool with commonly used instruments. The comparison analyses were conducted using only data from patients for whom results for both Clinicom and the corresponding control instruments were collected. Retrospective data was provided for this comparison. The Institutional Review Board (IRB) through the Alabama College of Osteopathic Medicine in Dothan, Alabama approved the protocol. Informed consent was not required because this was a retrospective analysis with fully redacted subject information.

2.2.2. Assessment of Clinicom and control instruments

Consistency or specificity of the Clinicom assessment tool was determined by measuring the percent agreement, or concordance, between a diagnosis determined from the respective control instruments and Clinicom. This was a measure of how well Clinicom and the control instrument agreed on a specific diagnosis. Diagnostic concordance was scored if the diagnosis, indicated as presence or absence of the disorder, was in agreement for both Clinicom and the respective control instrument. If diagnosis resulted in disagreement (i.e., a “yes” from Clinicom and a “no” from the control instrument), then this was considered a discordant result.

Percent concordance and the corresponding 95% confidence interval (CI) were calculated using the Clopper–Pearson method to evaluate the specificity of the assessment tool (Clopper and Pearson, 1934).

2.3. Test-retest reliability

2.3.1. Patients

First-time, self-referred patients, who were scheduled for an appointment at Dothan Behavioral Medicine Clinic (Dothan, Alabama) were emailed the link to the Clinicom assessment for completion prior to their first appointment. Patients then attended their scheduled doctor’s visit. Prior to concluding the visit, patients who were eligible were informed of the test-retest reliability assessment and asked to participate in the follow-up if the patient met eligibility criteria. These criteria included, being between the ages of 19 and 50 years old and being able to complete the assessment. Written informed consent was obtained prior to the second test from each patient. The test-retest reliability assessment was performed by administering the Clinicom tool remotely prior to the first office visit (Baseline Visit when they saw the clinician) and again at two weeks after Baseline.

2.3.2. Assessment of test-retest

Reproducibility of the Clinicom assessment tool was determined by measuring the percent agreement, or concordance, between the original test and retest within the same subject. Concordance was determined at both the disorder level as well as at the subject-set level. For the concordance analysis, the original test and retest results were paired by subject and matched by disorders diagnosed in each test.

Disorder level concordance was scored if the same disorder was diagnosed during both the original test and retest within the same subject. If no matching disorder occurred then the disorder level test was considered discordant. If a subject was diagnosed with one disorder during the first test and then diagnosed with a different disorder during the retest, this counted as two discordant events for that subject.

Subject-set level concordance had a more restrictive set of concordance criteria. This level required that the same complete set of disorders be diagnosed in both the test and retest for the same subject. If one or more disorders were missed, or if new disorders were added during the retest, then the subject’s diagnosis was considered to be
Percent concordance and the corresponding 95% confidence interval (CI) were calculated using the Clopper–Pearson method to evaluate the reliability of the assessment tool (Clopper and Pearson, 1934). The Venn diagrams were created using the VennDiagram package for the R statistical software platform (Chen and Boutique, 2011).

3. Results

3.1. Comparison of CliniCom to control instruments

A total of 273 records were examined, including 54 for ADHD, 34 for GAD, 80 for MDD, 73 for OCD, and 32 for SP. The CliniCom assessment tool was capable of reporting concurrent diagnoses within a single patient by designating the primary psychiatric illness and reporting any comorbidities, as well as the severity of the psychiatric illness. The number of concurrent diagnoses determined per psychiatric illness was not limited to the five diagnoses assessed. For many patients, concurrent diagnoses were observed within each of the five psychiatric illnesses. In general, OCD had the highest incidence of multiple psychiatric diagnoses with up to eleven additional comorbid disorders being diagnosed.

Concordance at the diagnosis level between CliniCom and the control instruments was determined for each tested disorder. Assessments for GAD (HAM-A), OCD (Y-BOCS), and MDD (PHQ-9) were the most concordant at 88.2%, 87.7%, and 82.5%, respectively. SP (SPIN) was 75.0% concordant and ADHD (NEBA) was 70.4% concordant. Diagnosis of ADHD with QbTest was discordant with the CliniCom outcomes, resulting in only a 33.3% match between the assessments. The discordance between CliniCom and the QbTest test was significantly discordant ($p = 0.0143$; Fig. 1). For diagnosing ADHD, the same subjects ($n = 54$) were tested with both assessments, QB and NEBA. The percent concordance by disorder and overall diagnosis level with corresponding CI and $p$-values is summarized in Fig. 1.

3.2. Test-retest reliability

A total of 80 subjects completed the test-retest assessments for up to five psychiatric diagnoses (ADHD, GAD, MDD, OCD, or SP) and any co-occurring psychiatric diagnoses. One record refers to a diagnosis that was obtained from the CliniCom assessment. Because the online assessment is able to report concurrent diagnoses within a subject, multiple records could be obtained from one subject. A total of 222 records (with two subjects having no diagnosis reported) for the original test were recorded with an average of $2.8 \pm 1.5$ (mean $\pm$ standard deviation) disorders reported per subject. During the retest, a total number of 217 records (with three subjects having no diagnosis reported) were recorded with an average of $2.7 \pm 1.5$ (mean $\pm$ standard deviation) disorders reported per subject. The distribution of the number of diagnosed disorders per subject is reported in Fig. 2. These results indicate that the psychiatric comorbidity distribution was similar between both the original test and retest outcomes. Diagnoses within a subject could change (i.e. a disorder was added or removed) between the test and retest scenarios. Therefore, the subjects in each category of the retest were not necessarily the same subjects in the original test.

The distribution of the specific disorders was similar between the original test and retest (Fig. 3). Since subjects could be diagnosed with multiple disorders, the disorders were not mutually exclusive to the subject.

Disorder level concordance varied by the number of subjects

<table>
<thead>
<tr>
<th>Disorder</th>
<th>NEBA</th>
<th>QB</th>
<th>Y-BOCS</th>
<th>HAM-A</th>
<th>SPIN</th>
<th>PHQ-9</th>
</tr>
</thead>
<tbody>
<tr>
<td>n *</td>
<td>54</td>
<td>54</td>
<td>73</td>
<td>34</td>
<td>32</td>
<td>80</td>
</tr>
<tr>
<td>Discordant</td>
<td>29.6%</td>
<td>66.7%</td>
<td>12.3%</td>
<td>11.8%</td>
<td>25.0%</td>
<td>17.5%</td>
</tr>
<tr>
<td>Concordant</td>
<td>70.4%</td>
<td>33.3%</td>
<td>87.7%</td>
<td>88.2%</td>
<td>75.0%</td>
<td>82.5%</td>
</tr>
<tr>
<td>95% CI b</td>
<td>56.4%, 82.0%</td>
<td>21.1%, 47.5%</td>
<td>77.9%, 94.2%</td>
<td>72.6%, 96.7%</td>
<td>56.6%, 88.5%</td>
<td>72.4%, 90.1%</td>
</tr>
<tr>
<td>$p$-value</td>
<td>0.0028</td>
<td>0.0143 *</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>0.0047</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

* $n$ is equal to number of subjects

b $p > 0.05$ indicates the test-retest outcomes are possibly random; $p \leq 0.05$ indicates the test-retest outcomes are not random.

* Because the percent concordance is less than 50%, the $p$-value is indicating that CliniCom is significantly discordant with QB.
diagnosed for each disorder and the persistence of the disorder. Diagnosis for MDD and ADHD, considered to be persistent disorders, were the most concordant at 91.8% and 91.5%, respectively. OCD was concordant at 86.4%. Diagnosis for the less persistent disorders of GAD and SP were less concordant at 81.0% and 79.0%. The overall disorder level concordance, a measure of how frequent all disorders identified in the original test were again identified for the same subjects in the retest, was 77.9% (CI: 72.1%, 82.9%, \( p < 0.0001 \); Table 1).

Subject-set level concordance had a more restrictive set of criteria: in order for a subject’s diagnosis to be concordant, the exact same set of disorders had to be diagnosed in the test and the retest (no more and no less). The subject-set level concordance was calculated to be 52.5% (CI: 41.0%, 63.8%, \( p = 0.6547 \); Table 2). Despite this lower concordance value, varying degrees of disorder level concordance are present among subjects that were discordant at the subject-set level. The concordance by individual disorder for subjects that exhibited subject-set level discordance is visualized using Venn diagrams in Fig. 4. Of the 38 subjects who exhibited discordant subject-set level diagnoses, 14 were diagnosed with SP in the original test and 12 were diagnosed with SP in the retest. Only 6 of those subjects were diagnosed with SP in both the test and retest, resulting in 42.9% concordance. Similarly, GAD had a 52.9% concordance. The more persistent disorders of MDD, ADHD, and OCD had a higher concordance of 83.3%, 81.0%, and 68.4%, respectively (Table 3).

4. Discussion

The development of a psychiatric assessment tool requires that the test is not only specific or accurate (the measure of how accurately the tool presents the proper diagnosis), but also that the result is reliable or reproducible (the measure of how consistent diagnosis results are between test and retest) (Aboraya et al., 2005; Carmines and Zeller, 1979). In the field of psychiatry, assessment tools rely on the classification and diagnostic system presented in DSM-5 (Diagnostic and Statistical Manual of Mental Disorders) as diagnosis criteria for psychiatric disorders. This publication describes the online assessment tool CliniCom as a method for assisting in the diagnosis of five prevalent psychiatric disorders.

When CliniCom assessments were retrospectively compared to the respective control instruments for each disorder, the online assessment tool was found to be concordant with all five tested disorders as indicated in Fig. 1. ADHD was compared to two FDA-cleared assessments tools: QbTest (Hall et al., 2017) and NEBA Scores (Gloss et al., 2016). CliniCom was found to be more highly concordant with the NEBA
assessments than with the QBTest (see Results); however, it was also observed that there was a similar lack of concordance between the QBTest and NEBA as was observed between QBTest and CliniCom. It should be noted, that the NEBA assessment is indicated as a confirmatory diagnostic tool for ADHD, whereas the QBTest is more typically used to guide medication management (FDA, 2012; 2013; Gloss et al., 2016; Hall et al., 2017; Ramtvedt et al., 2013). The lack of concordance between CliniCom and NEBA with the QBTest may not be surprising given that CliniCom and the NEBA assessments are used as diagnostic assistance tools for ADHD, whereas the QBTest is used frequently as a management tool for ADHD. Therefore, it was concluded that CliniCom is sufficiently concordant with the respective assessment tools to expect consistent diagnoses for ADHD, GAD, MDD, OCD, and SP. The Structured Clinical Interview for DSM-5 (SCID) and Mini-International Neuropsychiatric Interview (MINI), which are common tests to screen different psychiatric conditions, were not used for comparison with CliniCom, as this was a retrospective assessment from historical patient data and these tests are not commonly used within Dothan Behavioral Medicine.

On a disorder level, CliniCom appears to have a relatively high level of reliability as evidenced by an overall concordance level of 78% when administered twice in the same patients. Disorders with more persistent symptoms, such as ADHD and MDD, were more consistently diagnosed than others that have a more transient presentation, such as GAD and SP. In patients with current depressive disorder, it is estimated that approximately 40% have a current anxiety disorder (Lecrubier, 1998). This may also be a reason that CliniCom found that more persistent disorders of MDD, ADHD, and OCD (most of these have anxiety-like components) had higher concordance rates. CliniCom was reliable in the diagnosis of five prevalent psychiatric disorders, as patients had approximately 3 disorders each.

Concordance at the subject-set level diagnosis was less reliable. This was due, in part, to the need for all disorders to match in the test-retest evaluation in order for a subject’s diagnosis to be considered concordant. Subjects diagnosed with all five disorders had the highest concordance (78.6%) because the only way to be discordant was for one or more of the disorders to be missed in retesting, whereas subjects diagnosed with fewer disorders could become discordant by adding new disorders in the retest or dropping an original disorder in the retest. While the overall subject-set level concordance was lower than that observed at the disorder level (52.5% versus 78.6%), this was likely due to the difficulty in perfectly matching all comorbidities, especially those including less persistent disorders such as GAD and SP. The more persistent disorders had higher concordance.

Correlations of psychiatric comorbidity have been observed to be highest (correlations exceeding 0.60) in well-known and persistent syndromes such as bipolar disorder, double depression, anxious depression, ADHD, and SP (Kessler et al., 2005). These findings are similar to the subject-set level comorbidity described within the current publication with the diagnoses of MDD, ADHD, and OCD (83.3%, 81.0%, and 68.4% concordance, respectively). The timing between test and retest was approximately two weeks. A shorter time between test-retest may result in less variability in the diagnosis of these disorders, thus likely increasing subject-set level concordance.

A survey completed in 2005 for DSM-5 disorders found that the prevalence of mental illness disorders ranged from anxiety disorders (including GAD, OCD, and SP) at 18.1% to mood disorders (including MDD) at 9.5% to impulse control disorders (including ADHD) at 8.9% (Kessler et al., 2005). The five psychiatric illnesses selected for analysis in this study, while among the most prevalent of illnesses, also represent a range of stability fluctuation (Kessler et al., 2005). ADHD, for example, is a stable disease, which could help explain why this disorder was more consistently diagnosed (Law et al., 2014). Anxiety and social phobia are thought to fluctuate more due to environmental factors; however, additional research is needed to validate this hypothesis. Since the CliniCom as a self-assessment was not completed in a controlled environment, it is unknown if such external factors contributed to the severity of the diagnosis during CliniCom completion. Future research may focus on the impact of environmental factors while completing the CliniCom assessment.
Some limitations of the current study are that only 5 conditions were studied; among other important conditions, Bipolar Disorder (BPD), Schizophrenia, Posttraumatic Stress Disorder (PTSD), and Autism Spectrum Disorder, could be studied in the future. The specificity comparison with control tools should be studied prospectively, as this may improve concordance because the time between CliniCom and control tool assessment could be the same day, instead of up to one month as in this study. With regard to the ADHD subset ADHD-RS could be considered to be used in comparison with CliniCom since continuous performance tests (like QbTest) are not considered diagnostic instruments. A utility study of CliniCom would also be of benefit to show the value of this tool in the specialty of psychiatry. This was a preliminary study using retrospective data for reliability. Based on these results the authors would like to examine CliniCom’s validity and reliability prospectively using other control tools for ADHD and MDD (i.e., ADHD-Rating Scale (ADHD-RS) and Montgomery-Asperg Depression Rating Scale (MDD-RS)).

Fig. 4. Venn diagrams representing the subject-set level concordance for each disorder (Attention Deficit and Hyperactivity Disorder (ADHD), Generalized Anxiety Disorder (GAD), Major Depressive Disorder (MDD), Obsessive Compulsive Disorder (OCD), and Social Phobia (SP)). The overlap represents those subjects having the same diagnosis in the original and retest scenarios.
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Dr. Handal is owner and Medical Director of Harmonex Neuroscience Research, which owns the legal rights of CliniCom™. Ms. Baldwin, MS and Ms. Roesar BS are employees of Harmonex. James LePage, MS, Philip Dayley BS, Joni Kay, BS, Heather Ann Theobald, BS, MPH, Michael Nellamattathil, MS, Scott Drotch, MA, Connor Weir, MS, Neil Tindell, MS, Kevin Tice, BS are medical students who do not have a conflict of interest with Harmonex/CliniCom™.

References


FDA, 2013. FDA Approval Letter for NEBA System.


Table 3

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>No. subjects diagnosed in original test</th>
<th>No. subjects diagnosed in retest</th>
<th>No. subjects diagnosed in both original and retest</th>
<th>Concordance</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD</td>
<td>21</td>
<td>19</td>
<td>17</td>
<td>81.0%</td>
</tr>
<tr>
<td>GAD</td>
<td>17</td>
<td>14</td>
<td>9</td>
<td>52.9%</td>
</tr>
<tr>
<td>MDD</td>
<td>24</td>
<td>24</td>
<td>20</td>
<td>83.3%</td>
</tr>
<tr>
<td>OCD</td>
<td>19</td>
<td>20</td>
<td>13</td>
<td>68.4%</td>
</tr>
<tr>
<td>SP</td>
<td>14</td>
<td>12</td>
<td>6</td>
<td>42.9%</td>
</tr>
</tbody>
</table>

Scale (MADRS). Important to note, is that the data can potentially be put forth into a registry and used to monitor treatment effects from real-world findings.

CliniCom is a reliable online assessment tool that uses proprietary algorithms to determine a patient's type and severity of psychiatric illness. A notable attribute of CliniCom is that the proprietary algorithms can diagnose multiple disorders using a single assessment as compared to the current need of separate questionnaires for each disorder. Clinicians are able to provide care through the information CliniCom gathers from the patient prior to the first clinical visit. Clinicians using CliniCom should rely not only on the initial diagnosis given by the assessment tool, but also their knowledge and experience in the psychiatric field. Years of clinical experience are needed to not only adequately diagnose psychiatric disorders but to instill proper treatment (Aboraya et al., 2005). Nothing replaces clinicians talking and spending time with patients to arrive to the correct diagnoses, but CliniCom can facilitate this process.

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