Validation of the SAGE-SR: A Self-Report Diagnostic Assessment Based on the DSM-5 and SCID Designed to Improve the Signal-to-Noise-Ratio in Clinical Trials

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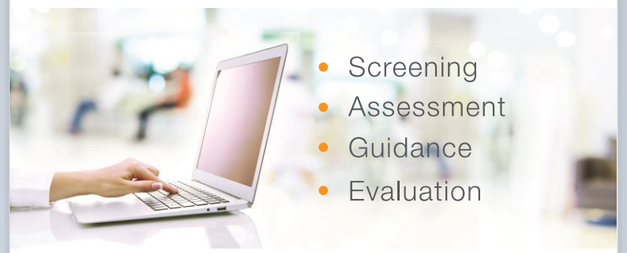
TELESAGE™
Standardized Behavioral Health Diagnoses and Outcomes

SAGE SELF-REPORT

The first comprehensive self-report behavioral health diagnostic assessment compatible with the ICD-10 and DSM-5.



Features include:

- PC, laptop, tablet, and smartphone administration
- Standard internet browsers supported
- Fully adaptive assessment
- Self-report at 5th grade reading level
- Twenty minute average administration time
- 31 diagnoses and episodes
- 65 item Screener
- Over 600 follow-up diagnostic items
- Automatic logic calculations and branching
- Prompts automatically created based on previous responses
- Ability to stop and resume assessment at any time
- Configurable administration modules
- Comprehensive diagnostic reporting including DSM-5 and ICD-10 codes
- Geo-redundant HIPAA-compliant encrypted cloud databases
- Secure real-time remote access to all item and response level data
- Data export to SPSS and SAS
- SMS/text reminders to take the assessment online
- Customizable permission access structure

Background

Accurate characterization of patients entering clinical trials is essential if we are to improve the signal-to-noise-ratio in CNS clinical trials. Patient characterization starts with a diagnostic assessment and an assessment of symptom severity. The Structured Clinical Interview for DSM-5[1] Disorders (SCID) represents the "gold standard" assessment for psychiatric diagnoses[4]. The web-based version of the SCID, the NetSCID-5 Research Version (RV) covers 66 disorders and episodes with an average interview time of 102 minutes[2]. The NetSCID-5 Clinician Version (CV) takes an average time of 64 minutes per interview, and it is an abbreviated version of the RV covering the 39 most common disorders and episodes with an additional 16 screener questions[3] for other disorders. The NetSCID-5 Clinical Trials Version (CT) is the name used for the customized version of the RV that can be used in FDA clinical trials, which require specific diagnostic groups. The NetSCID products are the web-based version of the "gold standard" in behavioral health diagnostics; however, clinicians should receive 8-16 hours of training to achieve high interrater reliability and the study protocol must allow for administration time. The NetSCID would ideally be used for making an official diagnosis once patients have been briefly screened and there is a high probability they will be a participant in any given trial. Another diagnostic instrument, the Mini International Neuropsychiatric Interview (MINI), requires on average 30 minutes for administration[5]. The MINI covers 28 disorders and is widely used in FDA clinical trials, but it is generally not considered as accurate as the SCID[6]. When compared to the NetSCID, the MINI has no report feature, no easy way to electronically navigate back and forth between sections, it does not save data that was previously answered if you change an answer and then change the answer back again, and it does not contain ICD-10 codes. These instruments require a trained clinician for administration. To date, no comprehensive self-report behavioral health diagnostic assessment has been developed with sufficient rigor to use in clinical trials.

Objective

To develop and validate a rigorous self-report diagnostic assessment based on DSM-5 and ICD-10 diagnostic criteria that can be used: to accurately identify any of 31 standard behavioral health diagnoses and mood episodes, to facilitate screening for eligibility to participate in FDA clinical trials, and to generate a searchable database with granular information on symptom severity.

Methods

The item development and validation process included an expert panel, four clinical sites, and a control population. An expert panel iteratively developed items based on the exact individual symptoms, time-frames, and clustering described in the DSM-5 and the Structured Clinical Interview for DSM-5 Disorders (SCID-5). Items were tested using cognitive interviewing (CI) with a total of 50 participants in three rounds. Items that gave rise to any confusion were re-written and re-tested iteratively with CI until all items were clearly understood in the final round of CI. Items were placed into a computer adaptive instrument according to DSM-5 diagnostic logic and a branching pattern was developed to eliminate non-contributory items during each assessment. The resulting SAGE-SR was administered to 44 public sector clinical participants and to 84 non-clinical controls.

Sample Report

Consumer ID: S10019
Assessment Date: 1/10/16

SAGE
SAGE-SR CLINICIAN REPORT

Demographic Information	
Initials	WJS
Age	24
Gender	Male
Race	Caucasian
Ethnicity	Non-Hispanic

Diagnoses to Consider	ICD-10 Code
Persistent Depressive Disorder, Dysthymic	F34.1
Obsessive Compulsive Disorder, Mixed obsessed thoughts and acts	F42.2
Alcohol Abuse, Without dependence	F10.1

Report Key

- Click to expand list
- Click to close list

Recommended Action
- Consider diagnosis and treatment
- Consider further evaluation
- Note minimal symptoms

Symptoms
- Present
- Absent or subthreshold

Depressive Disorders

Screener Items	
I felt sad.	Always
I felt depressed.	Often
I felt hopeless.	Rarely
I enjoyed life.	Sometimes
I had difficulty enjoying things that I used to enjoy	Sometimes
I was interested in my usual activities.	Sometimes

Follow-Up Items	
I ate a normal amount of food for me.	Often
I slept well.	Rarely
I felt physically restless.	Often
I reacted slowly to things that were said or done	Never
I felt tired, even after resting.	Sometimes
I felt physically exhausted.	Rarely
I felt worthless.	Sometimes

Follow-Up Items continued	
I felt guilty.	Sometimes
I had difficulty concentrating.	Never
I had difficulty making even simple decisions.	Sometimes
My thinking was clear.	Often
Regarding your feelings of sadness, depression and difficulty sleeping: have you had at least 2 of these feelings more days than not for at least 2 years?	Yes
Has there ever been a time in the past 2 years when you did NOT have any of these feelings and behaviors for at least 2 months?	No
My sadness, depression and difficulty sleeping interfered with my life.	Often
These feelings occurred when I was drinking or using drugs to get high	Rarely

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Results

We successfully developed and validated 661 items covering the exact symptoms, time frames, and clustering criteria for the 31 most common DSM-5 diagnoses and episodes. The resulting computer adaptive program ran smoothly and was well liked by the majority of study participants. A clinical report was successfully generated after each assessment. For non-clinical controls the assessment took 14 minutes (SD=6.8) to administer. For public sector behavioral health patients, the SAGE-SR took 24 minutes (SD=12.5) to administer.

Conclusion

The SAGE-SR is a brief self-report diagnostic assessment that can be used to efficiently screen large populations. Because the SAGE-SR is a self-report assessment, the same assessment can also be administered by a clinician or lay person with minimal training. The SAGE-SR can be used to generate individual clinical reports, but it also generates a database that can be searched to identify individuals who might be appropriate for participation in specific clinical trials. Because the SAGE-SR database includes a detailed library of symptoms and severity, it can be administered at multiple time points to track response to intervention over time and identify improvement in specific symptom clusters, as well as identify and characterize sub-populations that have a robust response to a clinical intervention. The SAGE-SR could bring efficiency, accuracy, and rigor to clinical trials. With the inclusion of the most appropriate participants for a clinical trial, the signal-to-noise-ratio will be improved.

Citations

[1]American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 5th ed. Arlington, VA: American Psychiatric Publishing; 2013.

[2]Brodey B, First M, Linthicum J, Haman K, Sasiela JW, Ayer D. Validation of the NetSCID: an automated web-based adaptive version of the SCID. Comprehensive Psychiatry. 2016; 66: 67-70.

[3]First MB, Williams JBW, Karg RS, Spitzer RL: Structured Clinical Interview for DSM-5 Disorders, Clinician Version (SCID-5-CV). Arlington, VA, American Psychiatric Association, 2015.

[4]First MB, Williams JBW, Karg RS, Spitzer RL: Structured Clinical Interview for DSM-5—Research Version (SCID-5 for DSM-5, Research Version; SCID-5-RV). Arlington, VA, American Psychiatric Association, 2015.

[5]Sheehan DV, Lecrubier Y, Sheehan KH, et al. The Mini International Neuropsychiatric Interview (MINI): The Development and Validation of a Structured Diagnostic Psychiatric Interview for DSM-IV and ICD-10. J Clinical Psychiatry. 1998; 59 (suppl. 20): 22-33.

[6]Sheehan DV, Lecrubier Y, Sheehan KH, et al. The validity of the Mini International Neuropsychiatric Interview (MINI) according to the SCID-P and its reliability. Eur Psychiatry. 1997; 12:232-241.

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Disclosure: The NetSCID-5 versions and the SAGE-SR are sold by TeleSage for profit. Dr. Benjamin B. Brodey is Chief Executive Officer and Dr. Lisa Zweede is employed by the company as a clinical research specialist.