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# A 6-month follow-up of imaginal desensitization plus motivational interviewing in the treatment of pathological gambling

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# Abstract

**BACKGROUND**—Pathological gambling (PG), a disabling disorder experienced by approximately 1% of adults, has few empirically validated treatments. A recent study demonstrated that 6 sessions of imaginal desensitization plus motivational interviewing (IDMI) was effective in achieving abstinence for a majority of individuals with PG. This study sought to examine whether those benefits were maintained 6 months post-treatment.

**METHODS**—Sixty-eight individuals who met DSM-IV criteria for PG were randomly assigned to 6 sessions of IDMI or Gamblers Anonymous (GA) referral over an 8-week period. Participants who failed to respond to GA were offered IDMI after the 8-week acute treatment period. All individuals who responded to IDMI were contacted after 6 months and assessed with measures of gambling severity and psychosocial functioning.

**RESULTS**—Forty-four participants completed 6 sessions of IDMI (25 initially assigned to IDMI and 19 to GA). Thirty-five of the 44 (79.5%) responded during acute treatment, and all 35 were available for a 6-month evaluation. All gambling severity scales maintained statistically significant gains from baseline, although some measures showed significant worsening compared with post-IDMI treatment.

**CONCLUSIONS**—Six sessions of IDMI resulted in statistically significant reductions in PG urges and behavior, which were largely maintained for 6 months.

## Keywords

cognitive-behavioral therapy; impulse control disorder; pathological gambling

# INTRODUCTION

Pathological gambling (PG) is characterized by persistent and recurrent maladaptive patterns of gambling behavior.<sup>1</sup> A chronic and relapsing condition, PG is estimated to affect 0.4% to 1.6% of the US population.<sup>2,3</sup> Financial, legal, marital, and occupational problems are commonly associated with PG.<sup>4</sup>

Despite the personal and social consequences of PG, relatively few randomized controlled clinical trials have evaluated treatments for this disorder. Published studies suggest that

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modifications of cognitive and behavioral interventions may be beneficial for PG.<sup>5,6</sup> Previous studies, however, have suffered from lack of a manualized treatment, small sample sizes (N = 25 to 35), high rates of study discontinuation (52%), lack of psychometrically validated outcome measures, use of waitlist controls, and failure to address therapist adherence and competence.<sup>7,8</sup>

In one of the few studies to address these limitations, Petry and colleagues<sup>9</sup> examined an 8session manualized form of cognitive-behavioral therapy (CBT) wherein 231 participants were randomly assigned to weekly CBT sessions with an individual counselor, to CBT in the form of a workbook, or to referral to Gamblers Anonymous (GA). Although gambling behaviors were reduced to a greater degree among those assigned to individual CBT or the self-help workbook than referral to GA, long-term benefits of treatment were seen on only some measures of gambling severity.

Other research suggests that combining CBT with motivational interviewing techniques may improve long-term response rates in PG by resolving treatment ambivalence and improving retention rates.<sup>10</sup> Another potentially effective modification of CBT, imaginal desensitization, demonstrated significant reduction in gambling behaviors in a small study (N = 20) when compared with traditional aversion therapy.<sup>11</sup> In a larger study (N = 120) by the same group, participants were randomly assigned to aversion therapy, imaginal desensitization, in vivo desensitization, or imaginal relaxation. Those assigned to imaginal desensitization reported better outcomes at 1 month, but study discontinuation rates were high (53%).<sup>12</sup>

Although CBT, motivational interviewing, and imaginal desensitization all have yielded promising results in PG treatment, each intervention has limitations (such as limited outcome data and high rates of treatment discontinuation). As a result, we sought to combine the strengths of the prior treatments into a brief, 6-session manualized treatment of imaginal desensitization plus motivational interviewing (IDMI).<sup>13</sup> When we compared IDMI with the real-world condition of referral to GA, we found IDMI was effective in reducing PG symptoms and a significantly greater percentage of individuals assigned to IDMI (63.6% vs 17.1%) achieved abstinence after 8 weeks of acute treatment.<sup>13</sup>

The goal of this follow-up study was to examine whether the benefits of IDMI were maintained for at least 6 months. Based on the robust acute treatment effect, we hypothesized that the majority of these participants with PG would maintain benefit for at least 6 months following treatment.

# METHODS

#### **Participants**

Men and women age 18 to 75 with a primary diagnosis of PG<sup>1</sup> were recruited by newspaper advertisements and physician referrals for psychosocial treatment. All met DSM-IV criteria for PG as measured by the clinician-administered Structured Clinical Interview for Pathological Gambling (SCI-PG)<sup>14</sup> and had gambled at least 1 time per week for the past 2 months.

Recruits were excluded from participation if they met any of the following criteria: 1) past 3-month substance use disorder; 2) positive urine drug screen; 3) current pharmacotherapy or psychotherapy for PG; 4) previous GA attendance; 5) any clinically significant suicidal ideation; and 6) current use of psychotropic medications.

The University of Minnesota Institutional Review Board approved the study and informed consent. One investigator discussed with recruits potential risks of the study, as well as alternate treatments. Written informed consent was obtained after recruits heard a complete description of the study and were given the opportunity to ask questions about it. The study was carried out in accordance with the Declaration of Helsinki. Data were collected from September 1, 2006, to April 1, 2008.

#### Screening assessment

Participants were evaluated at study entry by the SCI-PG, a reliable and valid diagnostic instrument using DSM-IV PG criteria.<sup>14</sup> A semistructured rater-administered questionnaire (used in previous gambling studies<sup>4</sup>) was used to collect detailed information on demographic and clinical features of PG (such as types of gambling, amount of money lost, triggers to gambling). Psychiatric comorbidity was assessed using the Structured Clinical Interview for DSM-IV (SCID).<sup>15</sup> Other assessments used at screening were also used as primary or secondary measures throughout the study (see Assessments below).

#### Study design

After screening, eligible participants were assigned (using computer-generated randomization with no clinical information) to IDMI or GA referral in a one-to-one fashion.

**Imaginal desensitization plus motivational interviewing**—IDMI treatment was manualized and consisted of 6 1-hour sessions over an 8-week period. It used aspects of previously published CBT manualized treatments,<sup>6,16</sup> with modifications and additions of imaginal desensitization and motivational interviewing. Session 1 consisted of psychoeducation and a motivational enhancement intervention to decrease defensiveness, increase problem awareness, and strengthen commitment to change. Session 2 focused on a functional analysis and behavioral strategies of increasing pleasant activities. Session 3 focused on cognitive strategies of coping with urges to gamble and changing irrational thinking. Imaginal desensitization was introduced in Session 4 and included creating a script and audiotaping 3 gambling scenarios that stimulated urges to gamble. Relaxation training and cognitive skills were included to cope with urges the scenario elicited. Participants in this group were instructed to listen to the tapes 3 times each day for the remainder of the study (they listened to the tapes a mean of  $2.2 \pm 0.8$  times per day). Session 5 included relapse prevention exercises and assertiveness training. Session 6 included family or significant other involvement, education, and therapy.

**Referral to Gamblers Anonymous**—Each participant in this group was given a list of meeting times and locations for GA meetings held throughout the Twin Cities metropolitan area. GA was discussed, and each participant was encouraged to attend and keep an attendance record.

#### Adherence and competence

Two doctoral-level therapists delivered the therapy. They each received didactic training and close supervision of at least 2 cases using the manualized treatment. During the study, ongoing supervision consisted of regular review of therapy notes and case discussion.

Therapist adherence and competence were assessed using IDMI manualized treatment and audiotaping 12 subjects for independent reviewers. The adherence measure was modeled after the Collaborative Study Psychotherapy Rating Scale, a rigorously tested measure of therapist adherence.<sup>17</sup> A competence measure was based on the Cognitive Therapy Scale.<sup>18</sup> Mean adherence scores were  $3.7 \pm 0.5$  (facilitative conditions subscale) and  $2.5 \pm 0.2$  (CBT adherence subscale), based on 7-point Likert scales with 7 = highest amounts of behavior.

Mean total score for competence was  $42.8 \pm 4.3$  (corresponding to a therapist applying a sufficient range of methods with skill and flexibility). Intraclass correlations were .86 (competence) and .92 (adherence).

#### Procedures

After the initial assessment, participants randomly assigned to IDMI were scheduled to begin therapy 1 week later. They were then seen weekly for 6 1-hour sessions. One week after the final therapy session, they returned for evaluation of their PG symptoms. Evaluations were performed by raters blind to initial treatment assignment. Participants assigned to IDMI were informed that they should not attend GA during the entire study period. Those assigned to GA referral also were scheduled to return after 8 weeks for their first follow-up assessment.

Participants initially assigned to IDMI were evaluated 6-months post-therapy. Participants initially assigned to GA referral were entered into the 6 IDMI sessions 1 week after their first 8-week post-GA assessment, and they also were evaluated 6 months post-therapy. No booster sessions of therapy or any other type of treatment was provided during the follow-up period. All ratings were performed by raters blind to initial assignment and to study visit.

#### Assessments

All follow-up evaluations were conducted in person at the same outpatient research facility where participants were seen for the treatment portion of the study. The primary outcome measure was the Yale-Brown Obsessive Compulsive Scale Modified for Pathological Gambling (PG-YBOCS).<sup>19</sup> The PG-YBOCS is a reliable and valid, 10-item, clinician-administered scale that rates gambling symptoms within the last 7 days on a severity scale from 0 to 4 for each item (total scores range from 0 to 40, with higher scores reflecting greater illness severity).

The first 5 items of the PG-YBOCS comprise the gambling urge/thought subscale (time occupied with urges/thoughts; interference and distress due to urges/thoughts; resistance against and control over urges/thoughts). Items 6 to 10 comprise the gambling behavior subscale (time spent gambling and amount of gambling; interference and distress due to gambling; ability to resist and control gambling behavior).

Secondary measures used at each study visit included:

**Gambling Symptom Assessment Scale(G-SAS).**<sup>20</sup>—Patients completed the G-SAS at each study visit. The G-SAS is a 12-item, reliable and valid, self-rated scale assessing gambling urges, thoughts, and behaviors during the previous 7 days. Each item is rated 0 to 4 with a possible total score of 48. Higher scores reflect greater severity of PG symptoms.

**Clinical Global Impression—Severity scales (CGI).**<sup>21</sup>—The CGI consists of a reliable and valid 7-item Likert scale used to assess severity in clinical symptoms. The CGI severity scale was used at each visit and ranges from 1 = "not ill at all" to 7 = "among the most extremely ill." The CGI was used to refer specifically to gambling severity, not overall psychopathology.

**Sheehan Disability Scale (SDS).**<sup>22</sup>—The SDS is a 3-item, reliable and valid, self-report scale that assesses functioning in 3 areas of life: work, social or leisure activities, and home and family life. Scores on the SDS range from 0 to 30.

Hamilton Anxiety Rating Scale (HAM-A).<sup>23</sup>—The HAM-A is a reliable and valid, clinician-administered, 14-item scale that provides an overall measure of global anxiety.

**Hamilton Depression Rating Scale (HAM-D).**<sup>24</sup>—The HAM-D is a valid and reliable, 17-item, clinician-administered rating scale assessing severity of depressive symptoms.

**Quality of Life Inventory (QOLI).**<sup>25</sup>—The QOLI is a 16-item self-administered rating scale that assesses life domains such as health, work, recreation, friendships, love relationships, home, self-esteem, and standard of living. The QOLI has demonstrated excellent reliability and validity in nationwide normative studies and in studies of pathological gambling.<sup>26</sup>

This study was registered at clinicaltrials.gov under number NCT00337753 and entitled, "Cognitive Behavioral Therapy for Pathological Gambling" and can be located at http://www.clinicaltrials.gov/ct2/show/NCT00337753?term=cognitive+pathological&rank=2.

#### Data analysis

The primary outcome measure was the PG-YBOCS total score. "Treatment response" was defined as a 35% reduction in PG-YBOCS total score having been continuous for at least 1 month at the final assessment.<sup>27</sup> This definition was found to correlate with clinically significant changes in PG.<sup>27</sup>

Only participants who were "responders" (n = 35) were analyzed to see if they maintained improvement. The 6-month follow-up assessment was evaluated in 2 ways. First, the differences between baseline and 6-month follow-up measures were examined, pooling both treatment groups. A paired *t* test to test the null hypothesis of no change allowed for an assessment of whether participants were reporting improved symptoms at month 6 compared with baseline.

Second, the difference between the post-IDMI treatment and the 6-month follow-up measure was examined, pooling both treatment groups. The baseline measure, zero-centered, was used as a covariate in an analysis of covariance model, where the intercept was used to test the null hypothesis of no change. This allowed for an assessment of whether improvement after IDMI was maintained for 6 months.

## RESULTS

#### Participant characteristics

Demographics and clinical characteristics at baseline are presented in TABLE 1. There were no statistically significant imbalances regarding age, gender, marital status, education, or gambling severity between treatment groups. Results of the acute treatment portion of the study have been published.<sup>13</sup>

Participants reported onset of PG at 39.0 ( $\pm$  14.1) years [range 16 to 70], with a lag time of 9.59 ( $\pm$  12.0) years [range 0 to 45 years] from starting to gamble and meeting PG criteria. They spent a mean of 12.5 ( $\pm$  4.2) hours each week gambling. They had a mean gross yearly income of \$48,068 ( $\pm$  \$31,338) and reported mean gambling losses of \$23,871 ( $\pm$  \$22,271) in the past year (ie, they lost 49.7% of their gross income to gambling). Most (94.1%; n = 64) identified nonstrategic forms of gambling (such as slot machines, pull tabs, lottery, bingo) as their primary type of gaming. Although many had multiple triggers to gamble, the most common were having money (33.8%; n = 23), loneliness (29.4%; n = 20), stress (19.1%; n = 13), and advertisements (10.3%; n = 7).

Although past-3-month substance use disorders were excluded, enrolled individuals reported clinically important current comorbidities: 19 (27.9%) reported a mood disorder (such as major depressive disorder, dysthymia, depressive disorder not otherwise specified), 7 (10.3%) had another impulse control disorder (including compulsive buying, compulsive sexual behavior, or kleptomania), 5 (7.4%) had an anxiety disorder (such as social phobia, obsessive-compulsive disorder, panic disorder), and 4 (5.9%) had an eating disorder (such as binge eating disorder and bulimia nervosa). Comorbidities did not differ between treatment groups, and no particular comorbidity was associated with 6-month treatment response.

With response defined as a 35% reduction in total PG-YBOCS score,<sup>27</sup> 22 of 33 participants (66.7%) initially assigned to IDMI and 7 of 35 (20.0%) initially assigned to 8 weeks of GA achieved treatment response. Among the 28 participants who did not respond to initial GA, 13 became responders after undergoing IDMI during the next 8 weeks. Thus, 35 participants responded to 6 sessions of IDMI and were evaluated at 6 months to see if gains were maintained.

#### Six-month follow-up

For the 35 participants who reported significant responses on the primary and secondary measures after IDMI (either initially or after referral to GA), all scales maintained statistically significant gains from baseline at 6-month follow-up (TABLE 2). Two scales, however, showed some indication of retreating from post-IDMI levels: the primary outcome measure PG-YBOCS total score (*t* test = 2.06; df = 33; P = .0471) and the PG-YBOCS behavior subscale (*t* test = 2.54; df = 33; P = .0158) (TABLE 2).

In addition, 28 of the 35 responders (80.0%) achieved abstinence in the acute period. At 6-month follow-up, 27 of 35 (77.1%) were still reporting abstinence.

An analysis of variables (sex, age, gambling severity at baseline [PG-YBOCS total score], psychosocial dysfunction [SDS score at baseline], any psychiatric comorbidity, and current nicotine use) to predict who remained abstinent at the 6-month follow-up found that current nicotine use was significantly associated with inability to maintain abstinence (parameter estimate = -1.27; SE = 0.81; Wald  $\chi^2 = 2.47$ ; P = .032).

# DISCUSSION

Follow-up data suggest that 8 weeks of manualized IDMI resulted in acute benefit across a spectrum of illness-specific and global outcome measures that was largely maintained for 6 months after treatment. Although 2 of 3 measures showed notable loss of improvement from the final IDMI treatment to 6-month follow-up, the participants maintained statistically significant improvement compared with baseline PG severity.

One reason for the longer-term effectiveness of IDMI may be that this treatment allows individuals to elicit their urges throughout the day and provides, via audiotapes, immediate cognitive restructuring to control the urges. One theory for IDMI's effectiveness holds that impairments in prefrontally-mediated cognitive functions appear to underlie decision making and inhibitory control.<sup>28</sup> These impairments may increase the risk for making decisions that are impulsive, focused on short-terms gains, and lack inhibitory control. IDMI allows the individual to experience the urge and immediately increases inhibitory control by focusing on decisions that consider both short- and long-term consequences of behavior.

Although participants were not instructed to continue using the audiotapes, most reported using them during the 6-month follow-up period. In fact, they cited the use of audiotapes as the primary reason for their improvement.

These results indicate that although 6 sessions were beneficial for 6 months, a longer evaluation period may have resulted in greater loss of improvement. Therefore, intermittent IDMI booster sessions after acute treatment may help maintain therapeutic benefits for a longer period.

The findings from this study also suggest that continued daily use of tobacco was associated with a greater likelihood of relapse to gambling. Given the elevated rates of tobacco use among pathological gamblers,<sup>29,30</sup> and its association with increased severity of gambling symptoms,<sup>31</sup> this finding may have significant treatment implications. Research in alcohol dependence is somewhat mixed<sup>32,33</sup> but suggests that recovering alcoholics who are encouraged to quit smoking may be twice as likely to remain abstinent from alcohol.<sup>34</sup>

One possible explanation for smoking's effects on gambling outcomes may be that experiences of reward or pleasure are influencing behavioral decision-making. Preclinical data suggest that tobacco use may enhance dopamine response to reinforcers by facilitating burst firing of dopamine neurons, thereby increasing gambling- related reinforcement.<sup>35</sup> Although additional research is needed to clarify this relationship, treatment strategies simultaneously addressing tobacco use and gambling may be particularly helpful in maintaining improvement in pathological gamblers.

Although the results of this study are encouraging, several limitations should be noted. First, PG is a chronic disease that may require long-term therapy. Although this study followed individuals for 6 months after therapy, it did not assess treatment effects beyond 6 months, and longer-term effects thus require further evaluation. Second, it is unclear how many sessions of IDMI are optimal for PG. Most participants continued to use the audiotaped desensitization sessions fairly often during the 6-month follow-up period. A longer course of therapy or a more regimented use of desensitization tapes after therapy ends might result in continued and even greater reductions in gambling symptoms. Finally, this study did not include pharmacotherapy. Effective pharmacologic treatments for PG are emerging<sup>36</sup> and should be considered in conjunction with psychotherapies.

Despite these limitations, the study has multiple strengths, including the large sample of treatment-seeking pathological gamblers and the use of both self-report and clinician-administered measures with strong psychometric properties and established norms.

## CONCLUSIONS

This study suggests that IDMI may be a beneficial treatment for PG, with positive results maintained 6 months after only 6 therapy sessions. As effective treatments for PG emerge, it becomes increasingly important that physicians and mental health care providers screen for PG to provide timely treatment. Future research also should investigate potential factors that may contribute to relapse in PG after successful psychosocial treatment and identify treatment modifications for individuals with risk factors for relapse.

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# TABLE 1

| at baseline |
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| Variable   | IDMI group<br>(n = 33) | GA referral (n = 35) | Statistical test   | đf | P value |
|--|------------------------|----------------------|--------------------|----|---------|
| Age, y, mean (SD)  | 49.55 (13.23)          | 48.51 (12.63)        | <i>t</i> =.32      | 66 | .7499   |
| Sex, male, n (%)   | 20 (60.6)              | 22 (62.9)            | $\chi^{2} = .0042$ | 1  | .9483   |
| White, n (%)   | 32 (97.0)              | 32 (91.4)            | $\chi^{2} = .7104$ | 1  | .3993   |
| Married, n (%)   | 12 (36.4)              | 11 (31.4)            | $\chi^{2} = .6821$ | 1  | .4089   |
| Education, 12 y, n (%)                                     | 22 (66.7)              | 21 (60)              | $\chi^{2} = .0001$ | 1  | .9929   |
| Percentage of income lost during past 12 months, mean (SD) | 56.5% (38.66)          | 66.8% (97.26)        | t =44              | 66 | .6642   |
| Age gambling became a problem, y, mean (SD)                | 38.28 (14.10)          | 37.89 (13.02)        | <i>t</i> = .11     | 66 | 6806.   |
| Current alcohol or drug use disorder, n (%)                | 1 (3.0)                | 3 (8.5)              | $\chi^{2} = .7104$ | 1  | .3993   |
| Current psychiatric comorbidity, n (%)                     | 20 (60.6)              | 22 (62.9)            | $\chi^2 = .1196$   | 1  | .7295   |
| Current nicotine use, n (%)                                | 11 (33.3)              | 16 (45.7)            | $\chi^{2} = .8294$ | 1  | .3624   |

GA: Gamblers Anonymous; IDMI: imaginal desensitization plus motivational interviewing.

# TABLE 2

Six-month follow-up of pathological gambling participants (n = 35) who completed IDMI and responded to treatment

| V ariable <sup>d</sup>              | Baseline      | Post-IDMI<br>treatment | 6 months<br>following<br>IDMI | Assessment<br>compared v  | of month (<br>vith baselin | , e               | Assessme<br>compared | ent of mont<br>with post-I | h 6<br>DMI               |
|-------------------------------------|---------------|------------------------|-------------------------------|---------------------------|----------------------------|-------------------|----------------------|----------------------------|--------------------------|
|                                     |               |                        |                               | ,                         |                            | Effect            | 1                    |                            |                          |
|                                     |               |                        |                               | $\operatorname{Test}^{b}$ | P value                    | size <sup>c</sup> | $Test^d$             | P value                    | Effect size <sup>e</sup> |
| PG-YBOCS total score                | 19.63 (4.88)  | 5.63 (5.22)            | 7.66 (6.54)                   | t = -9.56  df = 33        | <.0001                     | -11.97            | t = 2.06 df = 39     | .0471                      | +2.03                    |
| PG-YBOCS urge/thought subscale      | 9.54 (3.06)   | 3.74 (2.88)            | 4.31 (3.33)                   | $t = -6.87 \ df = 33$     | <.0001                     | -5.23             | t = .93  df = 39     | .3616                      | +0.57                    |
| PG-YBOCS behavior subscale          | 10.09 (3.71)  | 1.89 (3.08)            | 3.43 (4.06)                   | $t = -8.39 \ df = 33$     | <.0001                     | -6.66             | t = 2.54  df = 39    | .0158                      | +1.54                    |
| Gambling Symptom Assessment Scale   | 29.29 (7.56)  | 15.00 (7.70)           | 18.63 (11.28)                 | $t = -4.12 \ df = 33$     | .0004                      | -10.67            | t = 1.65 df = 22     | .1136                      | +3.62                    |
| Clinical Global Impression-Severity | 4.79 (0.66)   | 1.92 (0.97)            | 2.21 (1.18)                   | t = -10.14 df = 33        | <.0001                     | -2.58             | $t = 1.20 \ df = 22$ | .2410                      | +0.29                    |
| Hamilton Depression Rating Scale    | 7.13 (5.67)   | 3.17 (3.64)            | 3.67 (3.75)                   | t = -2.72  df = 22        | .0123                      | -3.46             | t = 0.50  df = 22    | .6244                      | +0.50                    |
| Hamilton Anxiety Rating Scale       | 5.50 (4.39)   | 2.92 (3.27)            | 3.38 (3.03)                   | t = -2.18  df = 22        | .0394                      | -2.13             | $t = 0.60 \ df = 22$ | .5574                      | +0.46                    |
| Sheehan Disability Scale            | 13.96 (7.87)  | 2.88 (3.98)            | 5.63 (7.57)                   | $t = -4.89 \ df = 22$     | <.0001                     | -8.33             | t = 1.98  df = 22    | .0600                      | +2.75                    |
| Quality of Life Inventory           | 30.58 (14.23) | 39.96 (13.92)          | 38.25 (15.26)                 | t = 2.47 df = 22          | .0214                      | +7.67             | t = -0.74  df = 22   | .4659                      | -1.71                    |
|                                     |               |                        |                               |                           |                            |                   |                      |                            |                          |

ANOVA: analysis of variance; IDMI: imaginal desensitization plus motivational interviewing; PG-YBOCS: Pathological Gambling Modification of the Yale-Brown Obsessive Compulsive Scale.

<sup>*a*</sup> All variables are mean ( $\pm$  SD).

 $b_t$  test of null hypothesis of no change from baseline to month 6.

 $^{\mathcal{C}}$ Effect size is mean change from baseline to month 6.

 $d_{\rm ANOVA},$  with zero-centered baseline, with test for non-zero intercept.

 $^e$ Effect size is the magnitude of change, reflected by the intercept of the ANOVA. Treatment response defined as 35% reduction in PG-YBOCS total score from baseline.