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Preventing Mania: A Preliminary Examination of the GOALS Program

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There is strong evidence of a relationship between goal dysregulation and mania. Building on these findings, we examined the feasibility of developing a mania prevention treatment program designed to improve goal regulation skills for those with bipolar disorder. Here, we describe the process of developing a manual, delivering the intervention to a series of cases, and then conducting a small open uncontrolled trial. All participants met diagnostic criteria for bipolar I disorder based on the Structured Clinical Interview for DSM-IV and were not currently experiencing episodes of depression or mania. Ten participants (8 female, mean age = 46.7 years) were enrolled in the GOALS program and completed an average of 13.2 weekly sessions. Participants were administered the Bech-Rafaelson Mania Scale (BRMS) and the Modified Hamilton Rating Scale for Depression at baseline and termination. Some participants completed self-report scales including the Altman Self-Rating Mania Scale, the Beck Depression Inventory, and the Willingly Approached Set of Statistically Unrealistic Pursuits at baseline and termination. In addition, participants were administered a consumer satisfaction questionnaire at termination. At termination, all 10 participants found the program highly relevant and helpful. Most importantly, even though levels of mania were low initially, mean levels of manic symptoms on the BRMS decreased

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significantly from baseline to termination, and all 10 participants were within a healthy range (BRMS <7) at termination. Although the lack of control group or follow-up data limits this study, preliminary evidence suggests that it is feasible to identify treatment targets by drawing from the basic research literature in bipolar disorder. Findings await replication and more careful testing within a randomized controlled trial.

BIPOLAR DISORDER, DEFINED BY a single lifetime episode of mania, is a debilitating mental illness affecting close to 3,000,000 adults in the United States alone. A recent prospective study tracing the course of bipolar disorder for over 12 years suggested that clients experienced symptoms during more than 47% of the weeks assessed (Judd et al., 2002). As many as 50% of bipolar disorder clients attempt suicide (Jamison, 2000), and people with untreated bipolar disorder are 2.5 times more likely than the general population to die from any cause within a year (Swann, 2005). Thus, there is a critical need for new approaches to reduce the relapse rates, disability, and mortality associated with bipolar disorder

Treatment guidelines are uniform in recommending pharmacological treatments as the primary intervention for bipolar disorder (Bauer et al., 1999). Substantial evidence exists, however, that at least half of persons with bipolar disorder will relapse within 1 year when treated with pharmacological treatments alone, even when blood serum levels are used to verify medication adherence (Keller, Lavori, Coryell, Endicott, & Mueller, 1993). Several adjunctive psychological treatments have been developed for bipolar disorder, including Family-Focused Therapy (FFT; Miklowitz, George,

Richards, Simoneau, & Suddath, 2003), Interpersonal and Social Rhythm Therapy (IPSRT; Frank et al., 2005), Cognitive Therapy (CT; Lam, Hayward, Watkins, Wright, & Sham, 2005), and psychoeducation (Colom et al., 2003). Each of these has been successful in reducing relapse rates. Indeed, in a meta-analysis of five randomized controlled trials, Scott et al. (2006) found that psychosocial treatments yielded lower rates of relapse with an odds ratio of .31. Significant improvements in rates of hospitalization (Colom et al., 2003) and psychosocial functioning (Ball et al., 2006; Perry et al., 1999) have been noted as well. The recent Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD) trial demonstrated that IPSRT, FFT, and CT each yielded faster recovery from depression than pharmacological treatment alone (Miklowitz et al., 2007). Hence, psychosocial treatments have been helpful adjuncts in the treatment of bipolar disorder (Johnson & Leahy, 2004).

Despite promising gains, recent trials indicate that relapse rates remain high after treatment, particularly for mania. Indeed, studies have suggested that mania is not reduced in FFT (Miklowitz et al., 2000), and although 1-year findings were positive in one trial (Lam, Wright, et al., 2005), outcomes with CT have not been positive over longer 2-year follow-up periods (Lam, Hayward, et al., 2005; Scott et al., 2006). Two studies suggest that CT has not reduced rates of manic relapse or levels of manic symptoms in comparison to psychoeducation (Parikh, 2007; Zaretsky, 2003). In her review of psychosocial treatment trials, Scott (2006) concluded that "the effect on depression is more marked than the benefit in reducing manic relapses" (p. 49).

Two programs have clearly influenced mania relapse: psychoeducation (Colom et al., 2003; Perry et al., 1999) and disease management programs that combine psychoeducation with service delivery innovations to improve access to care (Bauer, 2001; Simon, Ludman, Unutzer, & Bauer, 2002). Both programs place a major focus on improving medication adherence (Colom et al., 2005). Hence, it is not clear that any psychological treatments diminish mania symptoms through psychological mechanisms. Moreover, even with psychoeducational efforts, there is still room for improvement, because rates of manic relapse in the 2 years after psychoeducation remain as high as 60% (Colom et al., 2003). Noting the gaps in available psychological interventions for mania, Scott and colleagues (2006) called for treatments that build on the risk factors involved in manic relapse. The GOALS program focuses on such risk factors, drawing from basic findings described next.

Extensive literature suggests that the psychosocial triggers and clinical symptoms of bipolar and unipolar depression are quite comparable (for reviews, see Cuellar, Johnson, & Winters, 2005, and Johnson and Kizer, 2002). Variables that predict bipolar depression, though, have not consistently predicted mania (Johnson, Meyer, Winett, & Small, 2000; Johnson, Winett, Meyer, Greenhouse, & Miller, 1999; Lozano & Johnson, 2001; Yang, Phillips, Licht, and Hooley, 2004). This pattern of findings may help explain why treatments that focus on negative cognitive styles, expressed emotion, or interpersonal stress are more helpful for reducing depressive symptoms than for reducing manic symptoms. Clearly, there is a need for more specific models of the predictors of mania. Goal dysregulation theory provides one such model (although other models are available as well; cf. Ehlers, Frank, & Kupfer, 1988).

GOAL DYSREGULATION MODEL OF MANIA

Several investigators have proposed that manic symptoms are tied to a biologically based system, variously referred to as the behavioral facilitation system, behavioral activation system, and behavioral approach system (BAS; Depue & Iacono, 1989; Fowles, 1993; Gray, 1994). This system is believed to regulate emotion, cognition, and behavior before and after goal attainment. In the context of goal pursuit, BAS changes that correspond closely to manic symptoms are mood change, inflated self-esteem, increased talkativeness, flight of ideas, increased goal-directed activity, and excessive involvement in pleasurable activities. This overlap led Depue & Iacono (1989) to hypothesize that mania may be the outcome of excessively high BAS activity.

Neurobiological models of bipolar disorder are congruent with this idea (Depue & Zald, 1993; Hestenes, 1992; Swerdlow & Koob, 1987), in that they emphasize dysregulation of brain regions involved in the pursuit of reward, such as the ventral tegmental dopamine-secreting neurons projecting to the nucleus accumbens. In keeping with these models, persons with bipolar disorder and those at risk for bipolar disorder both endorse significantly higher BAS levels than do healthy controls (Alloy et al., 2006; B. Meyer, Johnson, & Carver, 1999; B. Meyer et al., 2001; T. Meyer & Hofmann, 2005; see Jones, Tai, Evershed, Knowles, & Bentall, 2006 for a nonreplication in one sample). Importantly, BAS levels appear to be stably high, rather than just a state-dependent feature of the disorder (B. Meyer, Johnson, & Winters, 2001). Moreover, BAS scores predicted

increases in manic symptoms over 6 months in a bipolar I sample (B. Meyer et al., 2001), as well as hypomanic symptoms over a 1-week period in a nondiagnosed community sample (T. Meyer & Hofmann, 2005).

One would expect that heightened BAS would influence the pursuit of goals in myriad ways. Indeed, several aspects of goal regulation appear to be dysregulated in bipolar disorder: People with bipolar disorder demonstrate greater emotional reactivity to successes and rewards, heightened emphasis on goals, increased confidence after successes, and excessive goal engagement after success. We briefly review findings in these domains.

Evidence for Goal Dysregulation in Mania

Several laboratory studies suggest that people at risk for mania display elevated reactivity to rewardrelevant stimuli (see Johnson, Gruber, & Eisner, 2007, for a review), using measures ranging from self-report scales to startle modulation after viewing positive pictures (Sutton & Johnson, 2002). The greater sensitivity to reward stimuli appears to generalize to greater frustration when goals are thwarted (Harmon-Jones et al., 2002), which helps link reward sensitivity conceptually to the irritable symptoms of mania. Most importantly, after life events involving reward and success, people with bipolar disorder and those with bipolar spectrum disorder demonstrate increased manic symptoms (Alloy et al., 2006; Johnson et al., 2008; Johnson, Sandrow, et al., 2000).

Perhaps related to reward reactivity, people with bipolar disorder emphasize goals—even during remission—more than do people without bipolar disorder (Lam, Wright, & Smith, 2002; Scott, Stanton, Garland, & Ferrier, 2000; Spielberger, Parker, & Becker, 1963). Persons with bipolar disorder also demonstrate significantly higher ambitions for extrinsically motivated goals, such as popular fame and wealth, than persons with major depressive disorder or those with no mood disorder (Johnson, Eisner, & Carver, 2008). Across every study, high levels of ambition do not appear to be explained by mood state. In sum, people with bipolar disorder express stable and unrealistically high goals and life ambitions across multiple measures.

Although goals might be stably present, whether or not people think they can reach those high goals seems to fluctuate with mood state. Even during remission, people who are vulnerable to bipolar disorder display higher confidence than those without bipolar disorder (Eckblad & Chapman, 1986; B. Meyer, Beevers, & Johnson, 2004; T. Meyer & Krumm-Merabet, 2003). More impor-

tantly, though, confidence appears particularly high after success (Stern & Berrenberg, 1979) or positive mood inductions (Mansell & Lam, 2006). Persons at risk for bipolar disorder endorse high scores on a brief self-report scale measuring dramatic upward shifts in confidence based on small successes (e.g., "When I have a small financial success, it makes me believe I could become a millionaire"; Eisner, Johnson, & Carver, 2008). Heightened confidence appears to predict relapse into manic episodes. That is, Lam, Wright, et al. (2005) found that persons with bipolar disorder who endorsed overly positive views of self were more likely to relapse over a 6month period. In sum, unrealistically high confidence, particularly after success or positive mood inductions, appears to be a feature of bipolar disorder.

Once persons with bipolar disorder become confident, there is evidence that they also increase their pursuit of and engagement in difficult goals. Specifically, after giving people initial success feedback, we gave participants a choice of difficulty levels for an upcoming eye-hand task. People at high risk for mania chose a more difficult task for themselves than did those at low risk (Johnson, Ruggero, & Carver, 2005). Among people with bipolar disorder, a brief self-report measure of increased goal engagement significantly predicted increases in manic symptoms over the next 4 months, controlling for baseline mania (Lozano & Johnson, 2001).

A recent review of these processes of goal dysregulation in mania (Johnson, 2005) described how mania might unfold after an initial success (see Fig. 1). High reward responsivity alone does not seem to trigger episode onset, as this trait appears to be present throughout the life course. However, confidence about goals seems to increase with successes and positive moods. Judgments about the likelihood of success seem relatively normative for people vulnerable to mania, until an initial success occurs. With an initial success (or mood increase), people

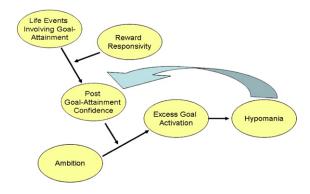


FIGURE I A cognitive-behavioral model of reward sensitivity.

with bipolar disorder seem to develop unrealistically high confidence, which fuels excessive goal engagement. Heightened goal engagement, spurred by shifts in confidence, may be one way in which an initial positive experience spirals into manic symptoms. Hence, the reward sensitivity model provides four treatment targets: reward responses (reactivity after positive events), high goal-setting, shifts in confidence, and goal engagement.

In this paper, we report on the process of developing a manual designed to address these clinical targets and gathering pilot data on 10 persons treated using this manual. We then report on a small open (uncontrolled) trial of whether this intervention designed to improve goal regulation could help prevent inter-episode manic symptoms among persons with bipolar I disorder.

Method

DEVELOPMENT OF THE GOALS MANUAL

With preventing manic symptoms as our primary goal, we developed a treatment manual focused on helping people with bipolar disorder develop new skills for regulating goals. Developing this intervention involved several steps. First, S. Johnson conducted interviews with more than 10 people with bipolar I disorder who have done well in regulating their illness and who have achieved remarkable interpersonal and occupational success, as well as symptom stability, despite serious episodes of mania in their history. She interviewed them about their views of symptom triggers and strategies for preventing symptoms. Strategies often paralleled those reported in empirical surveys (Lam, Hayward, et al., 2005), including processes used to monitor and regulate positive affect, goal setting, goal engagement, and confidence.

Drawing on goal dysregulation research as well as the above clinical interviews, S. Johnson developed a preliminary draft of the treatment manual. Several clinicians with expertise in bipolar disorder and clients with bipolar disorder reviewed the manual to provide feedback about the focus, clarity, and feasibility. Although reviewers were very positive, two consumers expressed concerns that the interventions focusing on high goal-setting were too optimistic, saying that ambitiousness was a core facet of self. Strategies were changed, such that the module now helps people weigh the costs of goals and the reliance on high goals for self-esteem, without attempting to change all facets of these high goals.

DESCRIPTION OF THE GOALS MANUAL

The program focuses only on mania prevention. We do not directly address depression, anxiety, suicid-

ality, substance abuse, or occupational rehabilitation. Where such issues appear primary, we refer clients to other treatments with an invitation to return to our program when ready. Interventions are available to address depressive symptoms (Lam, Hayward, et al., 2005), family discord (Miklowitz et al., 2003), and other aspects of mania. We also do not address many of the known triggers of mania, such as treatment adherence (Scott & Pope, 2002) or sleep disruption (Frank, 2005) beyond a brief mention of these factors in the introductory psychoeducation module. By keeping our focus narrow, we hoped that the treatment would be brief enough to be feasible.

The manual is modularized. The first module focuses on psychoeducation, covering symptoms and course of bipolar disorder, the biological basis, and treatment options. This module is not particularly related to goal regulation. We included it because every established treatment for bipolar disorder includes psychoeducation, and also because of the compelling evidence that psychoeducation bolsters medication adherence and thereby treatment adherence. Our psychoeducation module is parallel to those offered in every other psychological treatment.

The remaining four modules specifically target goal-regulation variables shown to relate to the course of mania: (a) emotional reactivity to positive stimuli, (b) high goal-setting, (c) increases in confidence after success, and (d) goal pacing. Each module follows the same steps: assessment of the client's status on the risk factor, motivational interviewing strategies to enhance a person's motivation to change in this domain, and then specific cognitive-behavioral strategies to address these concerns.

Motivational interviewing. MI, also called Motivational Enhancement Therapy (Miller, Zweben, DiClemente, Rychtarik, & Mattson, 1999), is an empirically supported treatment approach originally developed for the treatment of substance abuse. MI is predicated on the idea that a core goal of clinical interventions is to increase the client's motivation for, and commitment to, change (Miller et al., 1999). The person's readiness to change is evaluated, and based on this evaluation, specific therapeutic targets and specific intervention processes to enhance motivation for change are implemented. Like addictions, certain aspects of the bipolar disorder syndrome are exciting and rewarding for clients. Indeed, change in every one of our treatment targets could involve some costs for a person. For example, denial of the bipolar disorder diagnosis can protect self-image; emotional sensitivity is related to periods of highly, activated positive affect; high goal-setting can help a person feel that their life has special meaning; bursts of confidence can feel inspiring; and zealous pursuit of goals can provide an exciting sense of progress. By enhancing motivation, we hope to provide a more solid therapeutic rapport as we move toward cognitive-behavioral change.

For each given module, the therapist describes a target domain, and the therapist and client jointly review the evidence that the domain is relevant for a person, using scores on objective indices, material from the lifechart, as well as a clinical assessment of the domain. If a domain appears relevant, the client and therapist review the pros and cons of that area—for example, noting the positive aspects of setting highly ambitious goals, as well as the costs of setting such goals. Only once the client perceives a cost for that domain do the client and therapist begin to work on cognitive-behavioral strategies.

Cognitive-behavioral strategies. For each intervention module, the therapist and client design specific strategies, then gather data on whether those strategies appear to work. For the module on reactivity to successes, the therapist and client generate a worksheet of potential strategies to generate calm after small successes and challenges. All participants are taught progressive muscle relaxation, but then asked to compare this strategy with their own self-calming strategies. Clients report many different options, including walking, listening to calm music, rocking, or cooking. Clients choose a favorite strategy, then complete daily monitoring forms to gather data on how well this strategy works to enhance calmness after small successes and challenges. Working together, the client and therapist help refine strategies based on these data. When monitoring data suggest that a potentially good strategy has been identified, the client and therapist test the strategy in session after a standardized positive mood induction.

For the high goal-setting module, the client and therapist review objective and subjective data on the person's life goals. Intriguingly, although all clients we have seen have reported high goals (e.g., becoming the CEO of a fortune-500 business), most were unaware that the goals were higher than those held by other people. The therapist and the client work to assess the costs of goals, and to design a checklist to determine whether a goal is too ambitious or costly. Many clients reported that they had difficulty accepting limits to their goals, that they had made major financial and interpersonal sacrifices to achieve goals, and that they had often felt quite sad about their difficulty achieving these highly ambitious goals. Cognitive strategies are used to challenge the belief that a person is worthless if he or she does not accomplish highly

elevated goals. Participants are also encouraged to consider smaller goals within a given domain that might be more attainable and can be more easily monitored for success. For example, although a person might want to become a nationally respected programmer, a first step might be to enhance one aspect of programming skill.

For the confidence module, the client and therapist first gather data, reviewing the person's life chart of fluctuations in symptoms, the daily monitoring data, and in-session mood ratings, to evaluate the degree to which confidence changes with mood states. By this point in the manual, the client and therapist will have completed an insession mood induction, and confidence scores from that exercise are reviewed carefully. This helps to build the idea that confidence can often shift for the person with bipolar disorder, such that confidence may reflect more about the person's mood than their abilities. Although each client has been able to identify fluctuations in confidence, few had thought about the idea that these shifts might suggest that confidence was not a good barometer of whether to move forward on goals. Most, instead, reported that they relished moments of high confidence and used those times to surge forward without considering consequences. The therapist and the client work to develop a list of ways to test whether confidence has become too high, for example, by examining a past record of success or failure, and garnering interpersonal feedback about a given goal. The therapist and the client create homework to review how well the worksheet performs, noting whether the client is able to internalize and use feedback that confidence is too high.

For the goal pacing module, the therapist and client develop a list of potential goal-pacing strategies, such as working on only one goal at a time (to protect against hyperactivation), ceasing work on a goal until the client is calm and able to think about other non-goal-relevant topics, protecting sleep, and goal scheduling. Clients frequently have strategies they have used, such as taking a day to be in the house, taking an hour to meditate, or limiting the number of hours dedicated to a given goal. The therapist and client review different strategies and choose the strategies that appear most likely to be helpful. Daily monitoring data are used to test how these strategies work, and strategies are refined as needed.

In sum, throughout treatment, the client and the therapist generate potential cognitive and behavioral strategies. Daily monitoring data are used to provide feedback on how well a given strategy works. Refinements to strategies are made as needed.

MANUAL DEVELOPMENT CASES

After developing and refining the manual, our team tested the efficacy of the GOALS intervention with a small group of participants. Our primary goal in this pilot study was to gain a clearer understanding of for whom this intervention worked best, as well as for whom the intervention was unsuccessful.

Eleven persons were enrolled as pilot cases for the purpose of aiding in manual refinement. All potential participants completed written informed consent procedures. Formal data were not gathered on those persons, but clinical outcomes were carefully monitored. Two psychologists and four clinical psychology doctoral students treated clients using the manual, with weekly meetings to review goals, progress, and issues. Consumer reactions and input were gathered, and the clinicians conducted another workshop to edit the manual. Among changes, consumers requested more time to discuss the meaning and losses associated with the disorder. They also felt that the material on emotional reactivity was important to teach early. Finally, they had specific suggestions on refining questionnaires.

From that clinical experience, we identified two variables that appear to predict poorer outcomes. Although outcomes appeared highly positive for most participants, they were not satisfactory for two persons. We discussed these cases intensively, and both cases were characterized by recent and severe substance abuse (heroin abuse and alcohol abuse that had both led to legal problems within the past 6 months). We also reviewed one case in which gains were less specific to key treatment targets. This was the single person we entered into the trial who had bipolar II disorder. At each stage, we felt that her basic motivation for changing mania was weak, which is consistent with the diagnostic criteria for hypomania, which specify that it causes no significant impairment. Drawing on this experience, we decided to limit program participation to those with bipolar I disorder and to exclude participants who meet diagnostic criteria for alcohol or substance abuse/dependence in the past 6 months.

After the manual was revised, we conducted a small open trial to assess whether the GOALS program led to significant decreases in inter-episodic manic symptoms. The open trial was shaped by the experiences with our initial pilot cases.

PARTICIPANTS

Fliers were distributed to local clinics and community outreach programs (e.g., bipolar disorder support groups) describing a research trial for a new mania prevention program. In addition, clients who contacted our training clinic at the University

of Miami Psychological Services Center (PSC) and requested treatment for bipolar disorder were referred to our team. We briefly explained the treatment program to potential clients and, if interested, we scheduled an assessment session. As above, all potential participants completed written informed consent procedures, and the study was approved by the local Institutional Review Board.

We screened a total of 23 participants. All assessments were completed by a person other than the treatment provider. For the initial assessment, potential participants were administered the Structured Clinical Interview for DSM-IV (SCID). If they met criteria for bipolar I disorder, and did not meet exclusionary criteria (see below), they were asked if they were interested in joining the treatment program and to complete baseline measures.

INCLUSION/EXCLUSION CRITERIA

Inclusion criteria were bipolar I disorder as diagnosed by the SCID; ages 18 and older; receiving stable and appropriate pharmacological treatment for bipolar disorder; able to read and communicate in English with sufficient skill to understand the intervention and assessment procedures. Exclusion criteria were current episode of mania or depression as diagnosed by the SCID; significant current suicidal ideation; dementia and other neurocognitive disorders; alcohol or substance abuse/dependence in the 6 months before intake; currently enrolled in psychotherapy focused on mania prevention. Thirteen participants were ruled out of the study based on exclusion criteria, including the following: not meeting diagnostic criteria for bipolar I disorder (5); not willing to receive psychiatric care (2); meeting criteria for current substance abuse (2); meeting criteria for a current major depressive episode (4).

MEASURES

To measure changes in key variables, participants were administered the Bech-Rafaelson Mania Scale, the Altman Self-Rating Mania Scale, the Modified Hamilton Rating Scale for Depression, the Beck Depression Inventory, and the Willingly Approached Set of Statistically Unrealistic Pursuits at baseline and termination. In addition, participants were administered a demographics and treatment history form at baseline, and a Consumer Satisfaction Questionnaire at treatment termination. Participants were given the opportunity to complete self-report measures at home and return them; unfortunately several did not return these forms.

Demographics and treatment history. All participants completed a form concerning personal background information, including age, gender,

ethnicity, marital status, and treatment history. This information was used to assess potential confounding variables.

Bech-Rafaelson Mania Scale (BRMS; Bech, Bolwig, Kramp, & Rafaelsen, 1979). Severity of current mania was assessed using the BRMS. Within our team, standardized probes and anchors have been developed to rate each of the 11 items on a scale of 0 (not present) to 4 (severe). The BRMS is widely used to assess manic symptoms and has demonstrated high interrater reliability on our team (interclass correlation=.92; Johnson, Winett, Meyer, Greenhouse, & Miller, 1999). The BRMS has been shown repeatedly across 20 years of research to demonstrate high sensitivity to small changes in symptoms and to provide valid data within treatment outcome studies (Bech, 2002).

Modified Hamilton Rating Scale for Depression (MHRSD; Miller, Bishop, Norman, & Maddever, 1985). This 17-item clinician-administered scale assesses current depressive symptoms. The MHRSD is a modified version of the original HRSD and correlates highly with it (r=.84). In addition, high interrater reliability has been observed, with an intraclass correlation of .93. Validity for the measure is indicated by correlations with SCID diagnoses of current depression, as well as correlations with other indices related to depression (Johnson et al., 2000).

Beck Depression Inventory-Short Form (BDI-SF; Beck & Beck, 1972). The BDI-SF is a 13-item measure designed to capture severity of depressive symptoms. The measure is widely used and has excellent psychometric characteristics, including robust correlations with interview-based measures of depression (Luty & O'Gara, 2006) as well as a correlation of .96 with the longer, original version of the BDI (Love, Grabach, & Clarke, 2004).

Altman Self-Rating Mania Scale (ASRM; Altman, Hedeker, Peterson, & Davis, 1997). The ASRM is a brief, 5-item self-report scale that assesses current mania. Test-retest reliability and concurrent validity were both adequate, with high sensitivity and specificity for scores greater than 5 (both >85%).

The Willingly Approached Set of Statistically Unlikely Pursuits (WASSUP; Johnson & Carver, 2006). The WASSUP has seven subscales: popular fame (e.g., "you will appear regularly on TV"), idealized relations with friends (e.g., "everyone you know will love you"), having a positive impact on world well-being (e.g., "you will create world peace"), political influence (e.g., "you will be important in political circles"), idealized relations with family (e.g., "your relationship will be more

romantic than Romeo and Juliet"), financial success (e.g., "you will have 20 million dollars or more"), and a subscale with items reflecting creativity ("you will create a great work of art, music, or poetry") and self-actualization ("you will self-actualize or reach Nirvana"). The subscales have demonstrated factor analytic support and strong internal consistency (Johnson & Carver, 2006). Scales relevant to overly ambitious extrinsic goals have been found to be correlated with risk of mania in three samples (Gruber & Johnson, in press; Johnson & Carver, 2006) and to differentiate those with bipolar disorder from those with depression or no mood disorder (Eisner et al., 2008).

Consumer Satisfaction Questionnaire. We developed a brief consumer satisfaction questionnaire to assess how helpful (Helpful) the therapy was, as well as how relevant (Relevance) each of the modules was for a given participant. Possible responses range from 1 (strongly disagree) to 7 (strongly agree), and mean scores on the two subscales were assessed. This 18-item measure demonstrated good reliability ($\alpha = .94$).

Results

Here we describe outcomes for 10 participants (8 female; 6 Caucasian, 4 Hispanic; mean age=46.7 years). Among this group, the age of onset for depression (Mdn=30.0) was higher than the age of onset for mania (Mdn=24.0). The median numbers of lifetime depressive and manic episodes were comparable (5.5 and 6.0, respectively). At baseline, all participants were receiving mood-stabilizing medication and agreed to continue in that treatment (Mdn number of psychiatric medications taken=2.0). Three were receiving lithium, three were receiving lamotrigine, and the remaining participants were receiving another mood-stabilizing medication.

Participants each had a severe psychiatric history. The mean number of hospitalizations was 2.0, the mean number of episodes was 6.0, and eight participants had experienced manic episodes in the past year. Most had participated in psychoeducational programs in the past. Nonetheless, all participants completed the program. Classes of medication treatment remained stable during the study and no participants discontinued psychiatric care during the treatment program.

Participants completed an average of 13.2 weekly sessions (range = 8 to 20, Mdn = 15). At baseline, the mean level of manic symptoms on the BRMS was 5.20 (range = 0 to 13), and the mean level of depressive symptoms on the MHRSD was 4.60

(range = 0 to 9). That is, all persons were below thresholds for manic (BRMS < 16) and depressive episodes (MHRSD < 17) at treatment entry.

At termination, participants found the program both relevant (M = 6.44/7.00) and helpful (M = 6.31/7.00). Scores for each specific module were highly positive as well. In addition, the more detailed open-ended ratings of the program were highly positive across the board.

Even though levels of mania were low initially, mean levels of manic symptoms (BRMS) decreased significantly from baseline (M=5.20; SD=5.05) to termination (M=1.90; SD=1.52) among the 10 participants completing both assessments, t(9) =2.43, p < .05, d = 0.88. All 10 participants were within a healthy range (BRMS<7.0) of manic symptoms at the end of treatment. Mean ratings of unrealistic ambitions for the nine participants who provided data—as measured by the WASSUP—were decreased from baseline (M=53.33; SD=12.84) to termination (M=48.00; SD=10.07), t(8)=3.94,p < .01, d = 0.48. Depressive symptoms, as measured by the MHRSD, did not decrease by treatment termination, t(9) = -0.58, p > .05. In addition, for the small number of participants who completed self-report measures, symptoms of depression on the BDI, t(5) = .81, p > .05, and mania on the ASRM, t(4) = .81, p > .05, did not decrease by treatment termination, although our data for these scales were limited to only six and five participants, respectively.

Neither treatment duration nor level of therapist experience was related to outcomes. That is, number of treatments sessions (range = 8 to 20), controlling for manic symptoms at baseline, was not significantly related to manic symptoms at termination, but there was a large effect size for this variable (partial r = .52, p = .29). Persons attending less than 12 sessions did not appear to be helped as much by the intervention. Hence, we plan to offer a minimum of 12 sessions to future clients.

Discussion

The current paper describes a translational research program, designed to identify key psychological aspects of mania and then develop treatment interventions to target those psychological processes. Despite an array of medication treatments, current research suggests that people with bipolar disorder experience symptoms more than 47% of the time (Judd et al., 2002). Psychological treatments can help to supplement medications in reducing symptoms, thereby reducing the high rates of hospitalization, job loss, and interpersonal costs associated with this illness. We believe that the GOALS program may fill a niche in providing hope

for those suffering from mania. Long-term, we imagine that our intervention, if validated, will be offered along with other validated treatment modules designed to address other common syndromes and concerns among people with bipolar disorder.

Before gathering data on the GOALS program, the intervention was offered to 11 participants. That experience suggested some important limitations to the treatment, including difficulties addressing the concerns of those with severe substance abuse, as well as a poor fit of the treatment for those with bipolar II disorder. Revisions were made to the manual, and an open trial was conducted for participants who met criteria for bipolar I disorder but did not meet criteria for current substance abuse.

In this small sample, consumer satisfaction ratings were uniformly high. Most importantly, participation in the program was related to significant decreases in manic symptoms and reductions in ambitious goal-setting, even though our sample was relatively well at study entry. These preliminary findings and large effect sizes are promising despite the small sample.

Consistent with the idea that the intervention should be tailored to participants' needs, there was a wide range of treatment duration, ranging from 8 to 20 sessions. Some participants were already well-versed in the material covered within certain modules, such as psychoeducation or goal pacing, whereas other participants needed longer to process relevant content. Early evidence suggests that providing at least 12 sessions was helpful for outcomes.

Current findings must be considered highly preliminary. It will be important to gather data for a larger number of participants over a longer period of time to see if mania effects are sustained. The effects of the treatment on confidence, goal engagement, and other core psychological targets remain untested. More fundamentally, data comparing improvements during the GOALS program to a control treatment are needed. Without such data, it remains possible that any group of clients with bipolar disorder willing to take part in an intensive study would be likely to see gains in their symptoms over time. The absence of a control group also meant that raters were aware that participants were taking part in the GOALS program and could have been biased in their evaluations. Because we did not conduct follow-up after treatment termination, we were unable to examine whether the current program reduced rates of manic relapse; this remains a vital goal for future research. That is, our current data are best viewed as a case series, and it remains an open question how the GOALS program would compare to a control group in a more rigorous and long-term trial.

Finally, our program was not designed to address depression, and it did not have effects on depression. Hence, it will be important to consider how to integrate this program with established depression treatments. Clinically, it seems that our emphasis on detecting high goals and moderating goal engagement could work well with empirically supported cognitive therapy interventions for bipolar depression (Miklowitz et al., 2007), which might target unrealistically harsh self-evaluations when persons fail to achieve highly intense goals.

It also should be acknowledged that strategies used in the GOALS program overlap somewhat with those recommended in other treatment manuals for bipolar disorder. Like each of the empirically supported treatments for bipolar disorder, the GOALS program incorporates psychoeducation regarding symptoms, as well as opportunities to consider the costs of the disorder (Colom et al., 2003; Frank et al., 2005; Lam et al., 2002; Miklowitz et al., 2003). For example, one cognitive therapy manual provides strategies for considering whether clients are overly confident (Newman, Leahy, Beck, Reilly-Harrington, & Gyulai, 2002), and another provides strategies for reducing stimulation and protecting sleep (Lam, Jones, Hayward, & Bright, 1999). The Interpersonal and Social Rhythm Therapy manual suggests reducing variation in daily routines, which is likely to put brakes on overly zealous goal engagement (Frank, 2005). Although these other manuals provide some suggestions toward better goal regulation, the current program is unique in its focus on goal regulation and the breadth of strategies provided on this front. Of course, in this focused approach, we also fail to cover many of the innovative content developed in other manuals; there is a need for more research comparing the different approaches (Miklowitz et al., 2007).

In sum, it appears feasible to develop clinical intervention strategies based on basic research on the correlates of mania. Persons who have received the intervention so far appear to have had significant decreases in mania symptoms, suggesting the need for a randomized controlled trial with longer-term follow-up. If future findings are positive, it would provide support for the idea that translational research can be used to develop novel treatment approaches within bipolar disorder.

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