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Acceptance and Commitment Therapy and nicotine patch for smokers with bipolar disorder: preliminary evaluation of in-person and telephone-delivered treatment

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Abstract

Objectives—People with bipolar disorder are two to three times more likely to smoke and 50% less likely to quit than the general population. New treatments are needed to improve smoking cessation outcomes in this group. The study aim was to develop and pilot test a novel cessation intervention for smokers with bipolar disorder using Acceptance and Commitment Therapy (ACT) combined with nicotine patch.

Methods—The 10-session ACT intervention was initially evaluated as in-person, individual counseling (n = 10), then as telephone-delivered counseling (n = 6). Participants were adult smokers with no more than mild current symptoms of bipolar disorder.

Results—For the in-person protocol, end-of-treatment outcomes were: 80% retention, 40% of participants with carbon monoxide (CO)-verified seven-day point prevalence abstinence (PPA), 90% satisfied with treatment, 8.3 of 10 sessions attended, and 54% increase in acceptance of cravings to smoke (i.e., ACT's theory-based change process) from baseline. The seven-day PPA at one-month follow-up was 30%. For the telephone protocol, end-of-treatment outcomes were: 67% retention, 33% reporting seven-day PPA, 100% satisfied with treatment, 6.7 of 10 treatment calls completed, and 55% increase in acceptance from baseline. At one-month follow up, seven-day PPA was 17%. The proportion of treatment completers who used at least 80% of the nicotine patches was 62.5% for the in-person protocol and 0% for the telephone protocol.

Conclusions—Both in-person and telephone-delivered ACT were feasible. Despite low adherence to nicotine patch, the intervention showed preliminary evidence of facilitating quitting

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and impacting ACT's change mechanism. A randomized, controlled trial of this targeted ACT intervention is now needed.

Keywords

depression; mania; nicotine; smoking cessation; tobacco

Cigarette smoking is two to three times more prevalent among people with bipolar disorder than among people without psychiatric disorders, and quit rates are one-half that of smokers without psychiatric disorders (1). These substantial differences in smoking prevalence and cessation contribute to numerous tobacco-related health disparities, including a 25-year differential in life expectancy (2) and elevated rates of chronic obstructive pulmonary disease, hypertension, and asthma (3). Treatment as usual has failed to address these disparities. New intervention approaches are needed to assist smokers with bipolar disorder to quit successfully.

Very few smoking cessation studies have focused specifically on smokers with bipolar disorder. Extant studies, with sample sizes ranging from five to 60 participants, have tested the safety and efficacy of varenicline (4–6) and bupropion (7). Our prior pilot study ($n = 10$) of an in-person, individual mood management intervention based on cognitive-behavioral therapy (CBT), combined with nicotine patch, is the only study to date of a targeted *behavioral* intervention for smokers with bipolar disorder (8). In that study, we determined that the CBT-based mood management intervention combined with transdermal nicotine patch produced a 20% quit rate at the end of the 12-week treatment period, but the counseling was not uniformly acceptable to participants because it lacked the flexibility needed to address heterogeneous reasons for smoking (8). This finding prompted us to change our treatment model and conduct a new series of pilot feasibility studies.

We hypothesized that smokers with bipolar disorder might find a new treatment based on Acceptance and Commitment Therapy (ACT) both acceptable and effective for two key reasons. First, the accumulating evidence comparing ACT with standard care smoking cessation counseling in multiple modalities (Internet, telephone, and smartphone application) suggests that this treatment approach holds promise for improving cessation outcomes by 50–150% (9–11). Second, ACT targets a unique mechanism of change—acceptance, defined as willingness to experience discomfort or distress in order to make a meaningful life change (12). For smokers with bipolar disorder, *acceptance* of mood symptoms as well as other barriers to cessation in this group (13) may be particularly important for sustained efforts to quit.

In this study, we evaluated an ACT-based cessation program for adults with bipolar disorder to determine its acceptability, efficacy, and impact on its theory-based change mechanism (i.e., acceptance). Two modes of delivery were examined in sequential, single-arm studies: in-person (because of its depth and the ability to observe face-to-face how participants reacted to the new treatment) and telephone (because of its reach and future dissemination potential through tobacco quitlines, as well as our emerging data suggesting that telephone-delivered ACT for smoking cessation in a general population sample was feasible, well-received, and increased the odds of quitting by 50% as compared to standard tobacco

quitline treatment (10)). Recruitment and retention rates were also monitored to inform the feasibility of each modality.

Materials and methods

Participants

Eligibility criteria for the in-person ($n = 10$) and telephone ($n = 6$) protocols were similar. All participants were members of Group Health, a large healthcare system in the Pacific Northwest. Participants met Diagnostic and Statistical Manual for Mental Disorders, 4th edition (DSM-IV) criteria for a diagnosis of bipolar disorder, type I or II, and were: (i) age 18 years or older; (ii) daily smokers, averaging 10 cigarettes per day for the past 90 days, with expired-breath carbon monoxide (CO) level 8 ppm; (iii) motivated to quit in the next 30 days; (iv) taking bipolar disorder maintenance medication(s) and had no psychiatric hospitalizations for at least three months at the time of the screening visit. Exclusion criteria were: (i) alcohol or other substance dependence in the past month; (ii) any medical conditions that would preclude the use of the nicotine patch; (iii) currently receiving treatment (medication or counseling) for smoking cessation; and (iv) current mania or depression, or suicidal ideation.

Assessments

Diagnoses of bipolar disorder and substance use disorder were made using either the Semi-Structured Assessment for the Genetics of Alcoholism [(SSAGA) in-person protocol] (14) or the Mini-International Neuropsychiatric Inventory [(M.I.N.I.) telephone protocol] (15). Severity of nicotine dependence at baseline was measured using the six-item Fagerström Test for Nicotine Dependence (FTND) (16). The 27-item Avoidance and Inflexibility Scale (AIS) (17) was administered at baseline and end of treatment to measure changes in acceptance-based processes of smoking cessation based on ACT's hypothesized mechanism of action—i.e., willingness to experience the physical (nine items), emotional (nine items), and cognitive (nine items) cues that are associated with smoking. The AIS total score is an average of items rated 1 (not at all) to 5 (very much), coded such that higher scores indicate greater acceptance.

Self-report of smoking was assessed using the Smoking Timeline Followback (TLFB) (18). For the in-person protocol, abstinence was biochemically verified using an exhaled carbon monoxide (CO) level of 8 ppm. Assessments of mood were conducted at every visit to evaluate safety and possible clinical deterioration. The clinician-rated, 11-item Young Mania Rating Scale (YMRS) (19) and 10-item Montgomery–Åsberg Depression Rating Scale (MADRS) (20) were used in the in-person protocol. Shorter, self-report measures of depression [Patient Health Questionnaire-9 (PHQ-9)] (21) and mania [Altman Self Rating Mania Scale (ASRM)] (22) were used in the telephone protocol. Nicotine patch adherence was calculated from the self-reported number of doses missed at each weekly study visit during the nicotine replacement therapy (NRT) treatment period. Adherence to the ACT treatment protocol was defined as the number of sessions completed (out of a maximum of 10). Treatment satisfaction was assessed using two forced-choice response items: (i) *Overall, how helpful was the counseling in assisting you to quit smoking?* (range: 1–4,

where 1 = not at all helpful and 4 = extremely helpful; scores of *moderately helpful* or *extremely helpful* were categorized as *helpful* in the analyses); and, (ii) *Would you recommend this counseling to other smokers who were trying to quit?* (range: 1–5, where 1 = definitely would not and 5 = definitely would; responses of *probably would* or *definitely would* were categorized as *would recommend* in the analyses).

Procedures

Recruitment letters were mailed to Group Health members who met basic eligibility criteria based on data in the electronic medical records system. Potential participants were screened for interest and potential eligibility by telephone. Potentially eligible participants based on this preliminary screen then provided informed consent and completed a full screening interview (in-person or by phone, depending on protocol). If eligible, they were enrolled in the study. Participants were each offered a 10-week treatment program which included weekly assessment and counseling sessions. The first 10 study participants were enrolled in the in-person protocol and received face-to-face counseling, and the remaining six participants were enrolled in the telephone protocol and received telephone counseling. Participants were also provided a standard eight-week course of nicotine replacement patches (four weeks at 21 mg, two weeks at 14 mg, and two weeks at 7 mg) starting at Session 3 of the counseling protocol, to allow time for skill acquisition prior to the quit date. Follow-up assessment was collected at end of treatment and one month post-treatment (three months after target quit date). Study procedures were reviewed and approved by the Institutional Review Boards of the Fred Hutchinson Cancer Research Center and Group Health, and are in accordance with the Helsinki Declaration of 1975.

Description of ACT counseling

The treatment manual was an extended, 10-session version of our standard five-session ACT manuals for group and telephone-delivered smoking cessation counseling (10). This higher number of sessions was based on participant preferences assessed in our prior pilot study of CBT-based mood management for smokers with bipolar disorder (8). Each of the 10 sessions was 30 minutes in duration. Content targeted ACT's core processes of acceptance (i.e., willingness to fully engage in all aspects of experience, as opposed to avoiding unpleasant experiences) and commitment (i.e., behavior driven by personal values). Example session activities included practice in mindfulness (i.e., non-judgmentally observing internal experiences, like cravings or anxiety) and cognitive defusion (i.e., getting psychological distance from one's thoughts) as well as identifying personal values guiding quitting (e.g., love of family). In addition to its unique focus on acceptance and values-based behavior change, ACT differs from smoking cessation counseling based on the US Clinical Practice Guidelines (23) in that it relies heavily on experiential in-session exercises and metaphors as a means of helping smokers learn to apply intervention principles to the task of quitting smoking. Treatment was delivered by the first author and a masters-level counselor.

Results

As shown in Table 1, the majority of participants in both protocols were female, Caucasian, and unmarried. Participants smoked, on average, 18 to 20 cigarettes per day and were

moderately to severely nicotine dependent. Consistent with eligibility criteria, participants had minimal symptoms of mania and depression at enrollment.

Design feasibility: recruitment and retention

Across the two protocols, we mailed 390 recruitment letters, completed 89 pre-screens and 21 full screens, and enrolled 16 participants, thereby yielding 4% (16/390) recruitment efficiency. Of the 390 initially contacted by mail, 191 could not be reached by telephone, 112 were not interested, and 71 were not eligible. As shown in Table 2, retention rates through end of treatment were 80% for the in-person protocol and 67% for the telephone protocol.

Treatment acceptability: satisfaction and adherence

Nearly all participants in both protocols (90% for in-person and 100% for telephone) found the intervention helpful, and the same proportion in each protocol reported that they would recommend the treatment to a friend. Session attendance was 8.3 sessions [standard deviation (SD) = 2.2] out of 10 for the in-person protocol and 6.7 (SD = 2.9) out of 10 for the telephone protocol. Over the eight-week treatment period, the proportion of treatment completers who used at least 80% of the nicotine patches was 62.5% (5/8) for the in-person protocol and 0% (0/4) for the telephone protocol. Average patch adherence (i.e., proportion of days the patch was reported to be used out of the possible number of days during the 8 week course) was 72.8% (SD = 32.0) for the in-person protocol and 40.2% (SD = 18.7) for the telephone protocol.

Smoking cessation and progress outcomes: abstinence and smoking reduction

Using the conservative missing = smoking imputation for all cessation outcomes and return to baseline smoking for the reduction outcomes, we found end-of-treatment quit rates (i.e., two months after the target quit date) of 40% (seven-day point prevalence abstinence) and 30% (four-week prolonged abstinence) for the in-person protocol and 33% (seven-day point prevalence abstinence) and 17% (4-week prolonged abstinence) in the telephone protocol. At one-month follow-up (i.e., three months after the target quit date), quit rates were 30% (seven-day point prevalence abstinence) and 10% (four-week prolonged abstinence) for the in-person protocol and 17% (for both seven-day point prevalence and four-week prolonged abstinence) for the telephone protocol. At least half of the participants in both protocols achieved a 50% or greater reduction in the number of cigarettes smoked per day between baseline and end of treatment (50% for the in-person protocol and 67% for the telephone protocol).

ACT's theory-based mechanism of change: acceptance

The amount of change in acceptance was very similar for the in-person (average increase of 54% from baseline in AIS score) and the telephone protocol (average increase of 55% from baseline in AIS score). Using the descriptive anchors that accompany AIS items, average change from baseline to post-treatment in both protocols amounts to a change from *a little* accepting (rating of 2 on the 1–5 scale) to *somewhat* accepting (rating of 3) (see Tables 2 and 3).

Changes in psychiatric symptoms

Changes in psychiatric symptoms during the study were monitored for safety reasons. Examination of change scores on the symptom measures for mania and depression (see Table 3) suggest that, on average, scores did not show a clinically significant change from baseline to end of treatment (i.e., mean increase/decrease of approximately one point). Additionally, none of the reported psychiatric adverse events were determined to be related to the intervention.

Discussion

Results of this pilot feasibility study suggest that: (i) it is feasible to recruit and retain smokers with stable bipolar disorder in a smoking cessation study, and (ii) ACT is highly acceptable to smokers with bipolar disorder, shows promising effects on smoking abstinence, and appears to impact its theory-based mechanism of action for smoking cessation (i.e., acceptance). These findings are consistent with previous work demonstrating ACT's preliminary acceptability and efficacy in broader general population samples of smokers (9–11) as well as among smokers with current depressive symptoms (24). The observed increase in acceptance is similar to our prior work, where a 50% increase in AIS scores from baseline to post-treatment was associated with a 51% increase in the odds of quitting [odds ratios = 1.51, 95% confidence interval: 0.37–6.23; unpublished results from (11)]. Thus, we conclude that that this degree of change in acceptance is clinically meaningful.

Although comparison of quit rates with prior published studies should be considered tentative due to the small sample size of the present study, the observed quit rates at the last follow-up (i.e., 17% in both protocols) appear somewhat lower than in our prior pilot study of telephone delivered ACT for general population smokers (i.e., 31% at six-month follow-up) (10). This may reflect the greater challenge of quitting for smokers with bipolar disorder, compared with the general population. Importantly, our end-of-treatment, seven-day point prevalence abstinence rates (40%) compare favorably to those reported in the limited extant studies on smoking cessation interventions for smokers with bipolar disorder, most of which examined the efficacy of varenicline plus in-person, individual CBT-based standard counseling (with quit rate estimates of 33–48% at end of treatment) (4–6). This similarity in outcomes is noteworthy given that the efficacy of varenicline has exceeded that of the nicotine patch (23). Retention data from the present study (67% and 80% for telephone and in-person, respectively) also compare favorably with prior studies focusing on smokers with bipolar disorder (56–80%) (4–7), and recruitment efficiency data (4% of those contacted about the study) are almost identical to that of our prior studies recruiting a *general population* sample of smokers from the same healthcare organization, using similar methods (25, 26).

Despite less than optimal nicotine replacement therapy adherence, the observed quit rates in each protocol group were encouraging. The reasons for this low adherence are unclear, but we observed a similar pattern in our prior pilot study in this sample (8). Anecdotal evidence from the study therapists who delivered the treatment suggests that continued smoking (e.g., postponed quit dates) contributed to low utilization of nicotine patches during the treatment

period. Future research should explore why smokers with bipolar disorder may be reluctant to use nicotine replacement and how adherence can be enhanced—e.g., integrating techniques from compliance enhancement therapy (CET) (27) into smoking cessation counseling. We previously integrated CET with motivational interviewing for alcohol dependence and achieved high rates of adherence to alcohol pharmacotherapy (79–91%) (28). Additionally, for smokers who demonstrate lower readiness to quit (i.e., those who postpone quit dates one or more times), extended treatment may be needed to reap the full benefit of the medication. Such approaches may further enhance treatment outcomes in this population.

While the results are encouraging, several limitations should be considered. These include the small sample size, lack of a control group, homogeneity of the sample, and lack of long term follow-up. These limitations do not negate our evidence of feasibility, but do limit any conclusions which can be drawn about the true effectiveness of the two intervention protocols. Additionally, comparisons of findings across the two protocols should be made with caution given: (i) the use of different diagnostic and mood assessments, which was necessitated by different modes of administration, and (ii) possible differences in the characteristics of participants (e.g., the higher proportion of telephone participants who had bipolar I disorder: 67% versus 30% for the in-person protocol). Finally, we did not observe an exacerbation of psychiatric symptoms attributable to the intervention, but a larger, controlled trial is needed to conclusively evaluate safety outcomes.

This study has several noteworthy strengths. It is the first study to evaluate ACT for smokers with bipolar disorder and the first study of a targeted, telephone-delivered smoking cessation treatment in this high-risk population. The promising preliminary findings from this study indicate that further evaluation of an ACT-based treatment in a randomized, controlled trial is now warranted and that this intervention can be feasibly delivered either in person or by telephone. These findings are particularly important as it opens the potential for population-level treatment through tobacco quitlines or large health plan sponsors—settings where smokers with bipolar disorder are already being treated and where there is a dearth of research on the efficacy of targeted interventions for this group. These settings are also ideal for conducting future treatment efficacy evaluations, as our recruitment feasibility data suggest that the pool of potentially eligible smokers with bipolar disorder would have to be large in order to conduct an adequately-powered study.

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Table 1

Demographic, smoking, and psychiatric characteristics of participants

Variables	In-person (n = 10)	Telephone (n = 6)
Demographics		
Age, years, mean (SD)	42.1 (16.1)	51.0 (15.4)
Sex, female, n (%)	8 (80)	5 (83)
Race, Caucasian, n (%)	9 (90)	6 (100)
Marital status, married, n (%)	1 (10)	2 (33)
Education, high school, n (%)	2 (20)	3 (50)
Employment, working, n (%)	5 (50)	2 (33)
Income, < \$20,000/year, n (%)	3 (30)	1 (17)
Smoking, mean (SD)		
FTND score	6.1 (2.0)	5.3 (1.4)
Cigarettes/day	20.9 (6.3)	18.5 (6.7)
AIS total score	2.0 (0.5)	1.9 (0.3)
Psychiatric status/symptoms		
Diagnosis, bipolar I disorder, n (%)	3 (30)	4 (67)
Mania severity ^a , mean (SD)	2.2 (3.5)	1.8 (2.1)
Depression severity ^b , mean (SD)	5.3 (4.3)	6.2 (6.1)

SD = standard deviation; FTND = Fagerström Test for Nicotine Dependence (range: 0–10); AIS = Avoidance and Inflexibility Scale (range: 1–5; coded so that higher scores indicate greater acceptance).

^aMania severity rating using Young Mania Rating Scale (scoring range of 0–60) for in-person protocol and Altman Self-Rating Mania Scale (scoring range of 0–20) in telephone protocol.

^bDepression severity rating using Montgomery–Åsberg Depression Rating Scale (scoring range of 0–60) for in-person protocol and Patient Health Questionnaire-9 (scoring range of 0–27) for telephone protocol.

Table 2

Pilot feasibility outcomes

Variables	In-person (n = 10)	Telephone (n = 6)
Design: recruitment and retention		
Recruitment efficiency (no. enrolled/no. contacted)	3% (10/312)	8% (6/78)
Retention, through EOT, n (%)	8 (80)	4 (67)
Treatment acceptability and adherence		
Satisfaction: helpful, n (%)	9 (90)	4 (100) ^b
Satisfaction: would recommend to friend, n (%)	9 (90)	4 (100) ^b
Session attendance, mean (SD)	8.3 (2.2)	6.7 (2.9)
Used 80% of patches, n (%)	4 (40)	0 (0)
Average percent of patches used, mean (SD)	72.8 (32.0)	40.2 (18.7)
Smoking cessation and progress^a, n (%)		
7-day point PPA at EOT	4 (40)	2 (33)
4-week prolonged abstinence at EOT	3 (30)	1 (17)
7-day PPA at one-month follow-up	3 (30)	1 (17)
4-week prolonged abstinence at one-month follow-up	1 (10)	1 (17)
50% reduction in smoking from baseline	5 (50)	4 (67)
Mechanism of change		
AIS total score, mean (SD)	2.8 (0.7)	3.0 (0.8)
AIS change from baseline, mean (SD)	+0.8 (1.1)	+1.0 (0.9)
AIS percent change from baseline	+54%	+55%

SD = standard deviation; EOT = end-of-treatment; PPA = point prevalence abstinence; AIS = Avoidance and Inflexibility Scale (range: 1–5; coded so that higher scores indicate greater acceptance).

^aSmoking abstinence outcomes were carbon monoxide-verified (< 8 ppm) for in-person protocol only.

^bExcluded two participants with missing data.

Table 3

Change in psychiatric symptoms during the treatment period

Variables	In-person (n = 10)	Telephone (n = 6)
Change in mania severity ^a , mean (SD)	−0.1 (1.1)	+0.8 (4.3)
Change in depression severity ^b , mean (SD)	−1.3 (4.0)	−1.2 (9.9)
Psychiatric adverse events ^c , n (%)		
Depression	2 (20)	3 (50)
Mania/hypomania	0 (0)	1 (17)
Suicidal ideation	1 (10)	0 (0)
Serious psychiatric adverse events, n (%)		
Suicide attempt ^d	1 (10)	0 (0)

SD = standard deviation.

^a Mania severity rating using Young Mania Rating Scale (scoring range of 0–60) for in-person protocol and Altman Self-Rating Mania Scale (scoring range of 0–20) in telephone protocol.

^b Depression severity rating using Montgomery–Åsberg Depression Rating Scale (scoring range of 0–60) for in-person protocol and Patient Health Questionnaire-9 (scoring range of 0–27) for telephone protocol.

^c None of these events were classified as being related to treatment.

^d Suicide attempt was classified as *possibly related* due to participant's report that the attempt was triggered by being asked about suicidal ideation on the standardized study assessments. There was no indication, however, of a causal relationship with the study treatment.