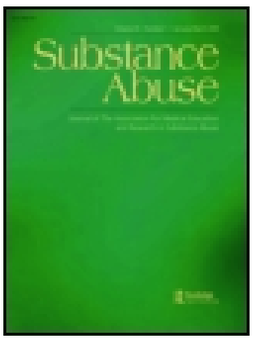

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BRIEF REPORT

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Randomized pilot trial of Web-based cognitive-behavioral therapy adapted for use in office-based buprenorphine maintenance

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ABSTRACT

Background: Despite the clear success of office-based buprenorphine treatment in increasing availability of effective treatment for opioid use disorder, constraints on its effectiveness include high attrition and limited high-quality behavioral care in many areas. Web-based interventions may be a novel strategy for providing evidence-based behavioral care to individuals receiving office-based buprenorphine maintenance. This report describes modification and initial pilot testing of Web-based training in cognitive-behavioral therapy (CBT4CBT) specifically for use with individuals in office-based buprenorphine. *Methods*: Twelve-week randomized pilot trial evaluating effects of CBT4CBT-Buprenophine in retaining participants and reducing drug use with respect to standard office-based buprenorphine alone was carried out. Twenty individuals meeting DSM-5 (*Diagnostic and Statistical Manual of Mental Disorders, 5th Edition*) criteria for current opioid use disorder were randomized to standard buprenorphine treatment or buprenorphine plus access to CBT4CBT-Buprenorphine. *Results*: There were promising findings regarding rates of urine toxicology screens negative for opioids (91% versus 64%; $P = .05$, effect size $d = 0.88$) and all drugs (82% versus 30%; $P = .004$, $d = 1.2$). Individuals randomized to CBT4CBT-Buprenorphine completed a mean of 82.6 (SD = 4.4) days of treatment (of a possible 84) compared with 68.6 (SD = 32.6) for those assigned to standard buprenorphine treatment. *Conclusions*: Although preliminary and limited by the small sample size, this trial suggests the feasibility and promise of validated, Web-based interventions, tailored for this specific patient population, for improving outcomes in office-based buprenorphine.

KEYWORDS
Behavioral interventions; buprenorphine; web-based interventions

Introduction

Opioid use disorder, and with it the risk of overdose and death, remains at epidemic levels in the United States.[1] Providing effective medication-assisted therapy (MAT), such as buprenorphine, greatly improves outcomes, reduces morbidity, and reduces societal costs.[2] Increasing access to buprenorphine treatment in primary care and other nonspecialty settings is an important component of the National Institutes of Health (NIH) strategy to address the epidemic.[3]

Despite buprenorphine's clear successes, some challenges remain: There is a need to improve retention and clinical outcomes in office-based buprenorphine practice. Roughly 50–70% of patients drop out of office-based treatment by 6 months.[4] Attrition from buprenorphine treatment carries higher risk of poor outcome, relapse, and death.[5,6] Moreover, although behavioral counseling is required as part of buprenorphine treatment, competent providers of evidence-based behavioral therapies are not always accessible or affordable in office-based settings.[7,8] Providers of office-based buprenorphine often refer patients out for counseling, but many patients do not follow through on those referrals[9–11] and available counseling is highly variable in fidelity and quality.[7] Finally, many providers see lack of accessible counseling[8,12] as a major barrier to providing buprenorphine. The NIH has called for strategies to improve the treatment infrastructure to support the availability and effectiveness of office-based buprenorphine.[1]

Validated, Web-based interventions are a novel strategy for providing standardized behavioral interventions in a range of settings[13,14] and could be used in office-based buprenorphine treatment. Potential advantages include the ability to access behavioral support at any time, greater confidentiality, minimization of stigma, and lower cost compared with clinician-delivered group or individual therapies.[15] In this report, we describe the adaptation of Web-based cognitive-behavioral therapy (CBT4CBT)[16] for use in office-based buprenorphine treatment as well as a randomized pilot study evaluating its feasibility and efficacy compared with standard buprenorphine care.

Methods

Participants and procedures

Participants were 20 opioid-dependent individuals seeking treatment at a full-service primary care setting associated with a large community-based MAT provider. Study staff

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reviewed the consent form (approved by Western Institutional Review Board [IRB]) in detail with each participant. A true/false test was used to assess each participant's comprehension of the information in the consent form. Following clarification of any incorrect responses, the participants provided written informed consent. Inclusion and exclusion criteria paralleled current practice at Central Medical Unit (CMU), The APT Foundation, and previous large-scale trials of office-based buprenorphine[5,17]: Individuals included were 18 or older and met current DSM-5 (*Diagnostic and Statistical Manual of Mental Disorders, 5th Edition*) criteria for opioid use disorder. Individuals were excluded who had a current unstabilized psychotic disorder; were currently suicidal or homicidal; were pregnant or lactating; or had any other medical or psychiatric condition that would contraindicate outpatient buprenorphine treatment. Individuals with current cocaine, benzodiazepine, or alcohol use disorder were excluded; individuals with nicotine or marijuana use disorders were eligible.

Of 21 individuals seeking buprenorphine treatment at this setting between August and December 2017, 20 were eligible (the single ineligible individual had a benzodiazepine use disorder). Following provision of written informed consent and completion of baseline and screening assessments (urinalysis, demographics, and substance use history, Timeline Follow-Back[18]), participants were randomized to treatment condition (via a computerized randomization program specifying 10 individuals per group). During treatment, participants met weekly with a research assistant for collection of toxicology screens. The primary outcome indicator was percentage of urine toxicology screens negative for all drugs tested (iCup DX Drug Test Cup with Specimen Validity Test [SVT]): amphetamines; barbiturates; benzodiazepines; cocaine; methamphetamine; opiates; oxycodone; tetrahydrocannabinol).

Data were collected weekly by research staff; participants received $10 for each weekly assessment completed. Given that this was a Stage 1/Small Business Technology Transfer Research (STTR) Phase I trial intended to evaluate feasibility and promise of a novel intervention, simple analysis of variance (ANOVA) and chi-square tests were used to evaluate possible baseline differences between groups as well as study outcomes.

Treatments

All participants received standard buprenorphine treatment, which included buprenorphine induction, completion of a buprenorphine contract, weekly meetings with a physician for medical management, and buprenorphine prescriptions. No other psychosocial or behavioral support was provided by the primary care program. After the first month, frequency of medical management visits and weekly assessments could decrease as determined by the physician, depending on patient response.

Adaptation of CBT4CBT for office-based buprenorphine

CBT4CBT is a 7-session (module) system for teaching a range of cognitive and behavioral skills (e.g., decision making, affect tolerance, problem-solving) that has been demonstrated in multiple trials to be effective both as an add-on to standard outpatient treatment (including MAT)[19,20] and, more recently, as a stand-alone treatment[21] with appropriate clinical monitoring. CBT4CBT-Buprenophine consists of a new introductory module covering the basics of buprenorphine treatment, followed by the existing 7-module CBT4CBT drug program. As with the existing modules, the new buprenorphine module includes narration, videos, quizzes, and exercises, in this case intended to familiarize patients with strategies for improving their outcome in buprenorphine maintenance, such as the "5As" (regular Attendance, Adherence to treatment, Abstinence from all other drugs, developing healthy Alternative activities, and Accessing social support).[4] The video portion depicts an initial patient-physician meeting and covers the purpose of a buprenorphine contract, patient responsibilities, strategies for talking to family members about buprenorphine, and common misconceptions about buprenorphine. Participants assigned to this condition were given their unique username and password and were introduced to the program by the research staff following randomization. After completing the introductory buprenorphine module, participants could complete subsequent CBT4CBT modules within the clinic at the time of their meetings with the physician or at home, as they chose.

Results

Of 21 individuals screened, 20 were randomized (1 exclusion due to benzodiazepine use). Nineteen of the 20 individuals randomized initiated treatment; full posttreatment (12-week) data were available from 17 of the 20 participants (85%). As shown in Table 1, the sample was predominantly male and white, most had completed high school, and about half were employed. More women than men were assigned to the CBT4CBT-Buprenorphine condition; otherwise, there were no significant differences between conditions in terms of baseline characteristics.

Table 2 shows that those who were assigned to standard buprenorphine completed a mean of 69 days in the 12-week (84-day) protocol, versus 83 days for those assigned to CBT4CBT-Buprenorphine plus standard treatment. Two participants dropped out of standard buprenorphine maintenance treatment versus 1 in CBT4CBT-Buprenorphine. Table 2 indicates that rates of data availability were high in both conditions (79% of expected urine specimens were submitted) and buprenorphine dose did not differ by condition (mean: 15.0 mg, range: 0–24 mg). Those assigned to CBT4CBT-Buprenorphine submitted more urine samples that were negative for opioids (64% versus 91%; $P = .05$) as well as negative for all drugs tested (30% versus 82%; $P < .004$).

Of those assigned to CBT4CBT-Buprenorphine, all accessed the program at least once; the mean number of modules completed was 4.2 (SD = 2.0) of 8, which is

Table 1. Demographic and baseline substance use by treatment condition.

Characteristic	Standard buprenorphine ($n = 10$)	Standard buprenorphine plus CBT4CBT-Buprenorphine ($n = 10$)	Total ($N = 20$)	F or χ^2	p value
Categorical, *n* (%)					
Female	2 (20)	6 (60)	8 (40)	3.33	.07
Latino	0 (0)	1 (10)	1 (5)	1.05	.31
White/Caucasian	10 (100)	10 (100)	20 (100)	—	
Completed high school	9 (90)	8 (80)	17 (85)	0.39	.53
Married or in permanent relationship	2 (20)	3 (30)	5 (25)	0.27	.61
Employed full or part time	5 (50)	4 (40)	9 (45)	0.20	.65
Has access to a computer and the Internet	9 (90)	10 (100)	19 (95)	1.05	.3
Continuous, mean ± SD					
Age, years	39.6 ± 13.0	41.3 ± 12.0	40.5 ± 12.2	0.092	.76
Age first used opioids	30.6 ± 12.3	24.4 ± 12.1	27.7 ± 12.3	1.196	.29
Days of opioid use/past 28 days	16.3 ± 10.4	11.1 ± 9.3	13.7 ± 10.0	1.384	.25
Days alcohol use/past 28 days	11.2 ± 10.0	6.6 ± 8.5	8.9 ± 9.3	1.227	.28
Days benzodiazepine use/past 28 days	1.7 ± 4.7	0.1 ± 0.3	0.9 ± 3.3	1.158	.30
Days marijuana use/past 28 days	8.6 ± 10.4	3.6 ± 8.8	6.1 ± 9.7	1.355	.26
Baseline buprenorphine dose, mg	10.6 ± 5.7	9.8 ± 4.8	10.2 ± 5.1	0.115	.74

Table 2. Data availability, primary outcomes, and patient satisfaction.

Data/outcome	Standard buprenorphine ($n = 10$)	Standard buprenorphine plus CBT4CBT-Buprenorphine ($n = 10$)	Total ($N = 20$)	F or χ^2	p	Effect size (d)
Data availability and primary outcomes, mean+SD						
Days in treatment (max = 84)	68.6 ± 32.6	82.6 ± 4.4	75.6 ± 23.8	1.81	.19	
Number assessment visits (max = 11)	7.3 ± 3.9	9.1 ± 1.7	8.2 ± 3.1	1.811	.20	
End of treatment buprenorphine dose	15.1 ± 7.7	14.8 ± 5.7	15.0 ± 6.5	.01	.92	
Number urine specimens collected (max = 11)	8.4 ± 3.3	9.3 ± 1.7	8.9 ± 2.6	.516	.48	
Percent of expected urine specimens collected	79.6 ± 20.5	79.2 ± 15.8	79.4 ± 17.6	.003	.96	.
Number of urine specimens free of all illicit drugs	2.3 ± 3.0	7.3 ± 2.8	4.9 ± 3.8	13.60	.01	1.25
% opioid-free urine specimens	63.9 ± 36.6	91.3 ± 20.8	78.3 ± 31.8	4.16	.05	0.88
% urine specimens free of all drugs	29.9 ± 38.1	81.6 ± 29.7	57.1 ± 42.3	11.01	.004	1.21
Evaluation of the CBT4CBT-Buprenorphine program: 1 = Not at all, 2 = A little, 3 = Somewhat, 4 = A great deal, 5 = Extremely						
I learned things I didn't know from the "bup" videos (mean ± SD)		4.2 ± 0.4				
I enjoyed the "bup" videos		4.1 ± 0.6				
I would recommend the "bup" videos to other people		4.4 ± 0.5				
I would feel able to do the examples in my own life after watching homework in program		3.9 ± 0.8				
Doing the homework assignments during the week helped me		4.0 ± 0.9				
The homework gave me tools		4.0 ± 0.9				

consistent with prior research in similar populations.[19,20] Finally, participants were also asked to complete a brief evaluation of the treatment at the posttreatment interview asking about their experience with the CBT4CBT-Buprenorphine module. All questions were rated a mean of 4 or higher on the 5-item Likert-type scale, indicating a high level of satisfaction (Table 2).

Discussion

This pilot study of a modification of an evidence-based, Web-delivered version of cognitive-behavioral therapy specifically for use in office-based buprenorphine indicated high levels of patient satisfaction, good retention, and, even with the small sample size, significant effects on rates of urine toxicology screens that were negative for opioids and for all drugs tested (including stimulants, cannabinoids, and opioids). The role of counseling in office-based buprenorphine maintenance remains controversial, in that several studies have failed to demonstrate additional benefits of counseling added to buprenorphine plus intensive regular visits with a physician (medical management).[4] However, no previous study has evaluated a Web-based intervention specifically designed for individuals enrolled in office-based buprenorphine maintenance, who vary in their acceptance of traditional counseling options.

Although preliminary and limited by the small sample size and some imbalance in baseline characteristics, these results are striking in indicating relatively large effects on drug use as assessed by urine specimens. Retention was high in both conditions; thus, these findings may not generalize to other settings. Results are also consistent with previous studies suggesting that CBT4CBT is well liked by a range of individuals with substance use disorders and may, after a larger randomized trial with adequate power, prove to be an attractive, accessible, and cost-effective means of providing evidence-based treatment and ultimately broadening the availability of MAT in the United States.

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Author contributions

The grant was written by Drs. Shi (Principal Investigator) and Carroll. The CBT4CBT-Buprenorphine module was developed by Dr. Shi, Dr. Carroll, and Ms. Henry. The study was designed and implemented by all authors. Data management and analyses were performed independently. All authors reviewed and approved the manuscript as submitted.

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