One-year efficacy and incremental cost-effectiveness of contingency management for cigarette smokers with depression

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ABSTRACT

Introduction: Contingency management (CM) is efficacious for smoking cessation. To date, the number of cost-effectiveness evaluations of behavioral and pharmacological smoking cessation treatments far outnumbers the ones on CM. This study estimated one-year efficacy and incremental cost-effectiveness (ICE) of adding CM in relation to abstinence outcomes for a cognitive-behavioral therapy (CBT)+behavioral activation (BA) treatment. **Methods:** The study sample comprised 120 smokers with depression [% females: 70.8%; mean age: 51.67(*SD* = 9.59)] enrolled in an 8-week randomized controlled clinical trial. Clinical effectiveness variables were point prevalence abstinence, continuous abstinence, longest duration of abstinence (LDA), and Beck-Depression Inventory-II (BDI-II) scores at one-year follow-up. Cost-effectiveness analyses were based on resource utilization, unit costs per patient, and incremental cost per additional LDA week at one year. **Results:** There was a significant effect of time by treatment group interaction, which indicated superior effects of CBT+BA+CM across time. Point-prevalence abstinence [53.3% (32/60)] was superior in participants receiving CBT+BA+CM compared to those in CBT+BA [23.3% (14/60)], but both groups were equally likely to present sustained reductions in depression. The average cost per patient was €208.85(US$236.57) for CBT+BA and €410.64(US$465.14) for CBT+BA+CM, $p<.001$. The incremental cost of using CM to enhance one-year abstinence by one extra LDA week was 18€(US$20.39) [95%CI: 17.75-18.25]. **Conclusions:** Behavioral treatments addressing both smoking and depression are efficacious for sustaining high quit rates at one year. Adding CM to CBT+BA for smoking cessation is highly cost-effective, with an estimated net benefit of €4,704 (US$5,344.80).

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KEYWORDS: Cost-effectiveness; acceptability curve; contingency management; smoking cessation; depression

IMPLICATIONS

Informing on the cost-effectiveness of CM might expedite the translation of research findings into clinical practice. Findings suggested that CM is feasible and highly cost-effective, confirming that its implementation is worthwhile. At a CM cost per patient of €410.64 (US$465.14), the net benefit equals €4,704 (US$5,344.80), although even starting from a minimum investment of €20 (US$22.72) was cost-effective.

INTRODUCTION

Curtailing the high prevalence of cigarette smoking has been a public health focus for more than 40 years worldwide [1]. Of concern is that the prevalence of smoking in depressed individuals is still more than double that observed in those without depression (39.9% vs. 19.5%) [2]. Consequently, developing effective smoking cessation treatments tailored to this population is now listed as one of the top priority areas in the tobacco research field for the next ten years [3].

There is an accruing evidence-base for the incremental efficacy of contingency management (CM), a reinforcement-based intervention, over standard cessation treatments across a variety of substances, including smoking [4–5]. CM offers reinforcers early in treatment for objectively verified therapy goals (i.e., abstinence, retention, or completion of non-drug related activities), commonly in the form of vouchers (but also sometimes actual cash, checks, or equivalent gift cards), over periods that range between weeks to months [6,7]. However, since CM real-world implementation requires frequent monitoring to precisely capture recent cigarette use and significant costs to cover the incentives, its use has raised widespread concern as to whether it is worth implementing [8-10].

In the economic arena, the number of cost-effectiveness evaluations of pharmacological and other behavioral smoking cessation treatments [11-14] far outnumbers the ones on CM [15-16]. The few cost-effectiveness analyses of CM that have been carried out show that it substantially enhances smoking abstinence over other pharmacological or behavioral treatments [15-16]. CM costs range between US$281-US$445.73 and it produces associated net benefits of around US$2,166, which increase markedly as the amount invested rises [17]. Despite previous research efforts, results are limited

by the lack of long-term follow-ups and the inability to conclude upon comparative efficacy with active non-CM interventions 18. Subgroups with comorbidities, such as those with depression, require more intensive interventions and for these groups cost per quit could be higher than the estimates provided in non-comorbid samples [19]. Thus, analyses are critical to demonstrate that CM is worth the incremental costs [20-21].

Against this background, this study examined the one-year cost-effectiveness of adding CM to cognitive behavioral treatment (CBT) + behavioral activation (BA) for quitting smoking in depressed smokers. Specific objectives of this study were to provide: 1) one-year depression and abstinence outcomes by treatment condition; 2) the incremental cost effectiveness (ICE) and the incremental net benefit (INB) of using CBT+BA+CM relative to CBT+BA only.

METHODS

Study design and procedure

This cost-effectiveness study builds on a previous six-month randomized controlled clinical trial (RCT) 22 comprising 120 depressed smokers receiving CBT+BA or the same treatment combined with CM.

A total of 120 participants [CBT+BA = 60, CBT+BA+CM =60], the majority of whom were females (70.8%) initiated the treatment (Figure 1 illustrates the patient flow-chart). Mean age was 51.67 (SD = 9.59), average cigarettes smoked per day was 21.81 (SD =7.58), and mean nicotine dependence, as measured by the Fagerström Test for Nicotine Dependence (FTND) [23], was 6.52 (SD =1.83). A total of 75% of patients met the criteria for major depression diagnosis and the mean depression score, as measured by the Beck-Depression Inventory-II (BDI-II) 24, was 28.30 (SD =9.31). No significant differences were observed in any of the baseline measures (all p values >.05).

The study conformed to the Code of Ethics of the World Medical Association (Declaration of Helsinki) and written informed consent from participants was collected prior to the beginning of the study. The clinical trial research was registered in the ClinicalTrials.gov database (NCT03163056) and approval from the research ethics committee of the local community was also obtained (nº124/15).

Treatment interventions

Interventions under evaluation were eight weeks of CBT+BA and CBT+BA+CM, which were delivered by both master's and doctoral level psychologists. A detailed description of treatment interventions has been provided elsewhere [see González-Roz et al. study [25]]. In brief, all patients were trained in BA strategies from the first treatment session. The primary CBT treatment components included: psychoeducation on cigarette use, nicotine fading (i.e., a 30% weekly reduction of nicotine consumption from the first to the fourth week and abstinence from 48 hours prior to the fifth session onwards), stimulus control, relaxation, role-playing in alternative behaviors, development of an individualized preventive relapse plan through training in coping skills, and enhancement of social support.

In addition to the above, patients receiving CM were provided vouchers upon objective verification of smoking abstinence (i.e., CO ≤4ppm and cotinine levels ≤80 ng/ml). Feedback on the biochemical analyses and the corresponding vouchers was given to patients by therapists at the end of each therapy session. In consistency with the life areas each patient valued the most, and with the aim of facilitating goal-directed activities, vouchers offered access to a wide range of services and activities (e.g., access to gym centers, beauty and spa facilities, restaurants, and outdoor activities such as hiking or canoeing, amongst others). The CM schedule was implemented following the

guidelines posed by Petry [26]. It consisted of an increasing magnitude of reinforcement that began at 10€ [US$ 11.35), with a maximum attainable of €175 [US$198.65] during the entire 8-week treatment. The first voucher was given contingently upon submission of the first negative urine test at the fifth session (i.e., the first after the quit date). During the follow-up phase (1-3- and 12-month follow-ups), patients earned vouchers upon submission of nicotine-free urine samples. Patients could earn €45 [US$51.08], €50 [US$56.76], and €55 [US$62.43] worth of vouchers in those time frames. Reinforcers were redeemed from the therapists immediately after the session ended.

Outcome variables

Smoking abstinence and depression outcomes

Smoking abstinence was assessed as point-prevalence at one-year follow-up after treatment termination following gold-standard guidelines for reporting cessation outcomes in RCT studies [27]. Point-prevalence was determined by self-report of 7 days and verified by carbon monoxide (≤4ppm) and cotinine-free urine samples (≤80ng/ml). Continuous abstinence was defined as not having smoked at all since first quitting. For completeness, longest duration of abstinence at one year (LDA) (i.e., the longest span of consecutive weeks that patients remained continuously abstinent throughout the entire study period, from quit-day to 12-month follow-up) was also provided. LDA was used as the primary outcome for the cost-effectiveness analyses. This decision was based on the following rationales: (1) LDA is the most widely used variable in RCT trials of CM [28-31], so researchers and health professionals can easily compare CM costs across trials, and more specifically, decide on which reinforcer magnitudes should be used with different profiles of patients (comorbid vs. non comorbid) and contexts (community, hospitals, etc.); (2) LDA is amongst the best markers of long-term cessation outcomes[32],

and; (3) LDA in weeks conforms to the escalating nature (i.e., extending consecutive days of continuous abstinence) of the incentives used in this study.

Lifetime depression (i.e., past and current episodes) was diagnosed using the Structural Clinical Interview for DSM-IV-TR (SCID-Clinical Version)[33] at the baseline assessment. Severity of depressive symptoms was also assessed using the BDI-II[24] and interpreted as per the guidelines of its validation study.

Cost-effectiveness of treatment interventions

Costs were calculated for each participant based on the resources used and considering actual unit costs during the entire treatment study period (2015-2019). Costs were estimated in euros (€) and provided in US dollars as well. Intervention costs included counseling, biochemical testing (i.e., CO and cotinine), equipment (rent of treatment facilities), overhead costs (water, power), miscellaneous resources (a laptop, paper and office supplies, telephone line charges, and cleaning materials), and incentive costs for participants in the CM condition (i.e., the cash value of the received vouchers). Unit counseling cost was calculated as the average per participant expense of counseling sessions (i.e., time spent by the therapist and the co-therapist on both therapy sessions and biochemical testing multiplied by their salary per hour). Unit biochemical testing costs included the expenditures derived from analytical measurements (i.e., mouthpieces, urine containers, urine waste disposal containers, chemistry analyzer for cotinine analysis, disposable cuvettes). Details on costs [€/US$] per unit are provided in Supplemental Table 1.

Data analysis

Descriptive and bivariate analyses were carried out to examine significant differences in baseline characteristics and treatment outcomes across treatments. Both chi-square and *t*-tests were conducted, as appropriate.

A set of logistic regressions for repeated measurements obtained by generalized estimated equations (GEE) was conducted to assess the predictive capability of treatment condition on point-prevalence abstinence and depression across time (i.e., post-treatment, 1-6- and 12-month follow-ups). The first GEE assessed the effects of treatment condition, time, and their interaction on abstinence after controlling for relevant covariates (i.e., baseline depression, time, group, and their interactions). The second GEE estimated main and interaction effects of time and treatment condition on depression including abstinence as a longitudinal covariate. Effects were interpreted by odds ratio comparing primary outcomes for CBT+BA and CBT+BA+CM.

Cost-effectiveness analyses of CBT+BA and CBT+BA+CM were conducted following standardized methodologies recommended for economic evaluations of behavioral interventions [34]. The incremental cost-effectiveness ratio (ICER) was calculated for 12-month LDA. Bootstrapping (with 5,000 replicates) was implemented to calculate confidence intervals for each of the ICERs. The incremental net benefit (INB) was also considered, to inform on the incremental costs that society is willing to pay for an extra unit of effectiveness (lengthening one-year treatment effects by one extra LDA week).

Lastly, a receiving operating characteristic (ROC) curve analysis was performed to analyze the association between the magnitude of incentives (i.e., monetary cost) used and abstinence using different cut-offs. The accuracy of costs in predicting treatment response was evaluated by means of the area under the curve, for which ROC

values above .70 stand as acceptable [35]. The Youden Index procedure[36] [(Y): Y = sensitivity + specificity -1] was used to identify optimal cut-offs for maximizing sensitivity and specificity.

All analyses were conducted using the SPSS (version 25) and SAS software packages (version 9.4).

RESULTS

Smoking and depression outcomes

The overall point-prevalence rate at 12-month follow-up was 38.3% (46/120). CBT+BA+CM (53.3%; 32/60) was more effective in facilitating one-year abstinence compared to CBT+BA (23.3%; 14/60). Continuous abstinence ranged from 0-418 days [CBT+BA=97.14(*SD* =160.70) vs. CBT+BA+CM=187.28(*SD* =182.35), *p* = .013]. Weeks of LDA [25.94 (*SD* =24.27) vs. 13.97 (*SD* =20.61), *p* = .004, *d* = .53] were also superior in patients allocated to CBT+BA+CM. The adjusted GEE model showed a significant effect of time by group interaction [β=.149, 95%CI: .035, .262, *p*= .010] (see Table 1). This indicated that the odds of a favorable response in terms of point-prevalence were 1.16 [standard error (SE) = .067, *p* = .010] times higher in CBT+BA+CM than in CBT+BA.

In regard to BDI-II scores, there was a main effect of abstinence [β=10.54, 95%CI: 8.87-12.22, *p*< .0001] and time [β=.327, 95%CI: -2.04-.76, *p*< .0001] that did not differ significantly by treatment arm at 12-month follow-up [CBT+BA=15.23 (*SD* =14.07) vs CBT+BA+CM=11.33(*SD* =9.17), *p* =.107].

Cost-effectiveness of interventions

Average costs per patient and treatment condition for the 8-week treatment and 12 months of follow-up visits are shown in Table 2. Considering all patients, the mean cost attributed to the 8-week treatment period was estimated at €109.49/US$124.02 (*SD* =1.51), whereas the incremental costs of including biochemical testing (CO and cotinine analyses) were €65.69/US$74.30(*SD* =1.38). Compared to CBT+BA, total costs of CBT+BA+CM [€410.64(US$465.14); *SD*= 131.35] were greater than CBT+BA [€208.85(US$236.57); *SD*= 1.18], giving an incremental cost of CM over CBT+BA of €201.79(US$228.57).

The ICER for extending 12-month LDA by one week was €18 (US$20.39) (95%CI: 17.75-18.25). If it is considered that €30 (US$33.98) extends the LDA by 1 week, CBT+BA+CM would be 96% likely to be cost-effective; whereas at €170(US$192.56), the cost-effectiveness increase would be .03%. Moreover, if the threshold value to extend the LDA by 1 week were above €170, no change in cost-effectiveness would be evinced.

Figure 2 shows decision makers' WTP to lengthen LDA by one week. CM represents a cost-effective intervention starting from a minimum investment of €20 (US$22.66) (INB: €38/ US$43.06). As WTP increased, CM net benefit also increased. At 12-month actual cost of CM (i.e., €410.64/ US$465.14), the net benefit is estimated at being €4,704 (US$5344.80). Of note is that the area under the ROC for CM was .95 (95% CI: .89, .99). This signifies, as indicated by the Youden Index criterion, that the optimum cost per patient that maximized the proportion of patients correctly classified as abstinent was €272.50 (US$308.75) (Sensitivity: 81.3%; Specificity 100%).

DISCUSSION

This study informs on the efficacy and incremental costs and returns on investment from adding CM to a CBT+BA treatment for smoking cessation at one-year follow-up for patients with depression. Results showed that an adjunctive CM intervention in addition to a CBT+BA protocol was significantly more efficacious and cost-effective than CBT+BA alone. Although the addition of CM was on average €201.79 (US$228.57) more expensive than CBT, it promoted significantly superior one-year abstinence outcomes: higher 7-day point prevalence abstinence and LDA.

The long-term abstinence rates found herein (38.3%) are higher than those of other pharmacological and/or behavioral therapies, which report up to 25% one-year abstinence [37]. However, even though both treatments brought about significant reductions in smoking, CBT+BA+CM was found to be superior compared to CBT+BA only.

While the underlying mechanisms involved in long-term CM effectiveness have not been closely examined, several variables such as the magnitude of incentives [38] (i.e., the objective value or the economic value), and the opportunity cost arising from cigarette smoking[39] (i.e., losses beyond vouchers, such as hindered health or personal relationships) have been proposed as candidates. In this study, vouchers were provided beyond treatment termination at one, three, and twelve months, offering patients a wide range of substance-free sources of reinforcement that might have boosted the effects of BA by reducing the personal and economic costs of engaging in different activities each week [40,41]. This, however, is speculative, and since no evidence on activity involvement was provided, conclusions in this regard should necessarily be tempered.

Relatedly, although CM was not directly aimed at reinforcing attendance, a higher proportion of patients in CBT+BA+CM attended the last follow-up assessment,

which suggests more sustained, or even larger, abstinence effects would have been expected if longer term follow-ups had been conducted (particularly considering the relationship between therapist contact and abstinence effects shown in the CM literature[42]). This pattern of results also confirms the benefits of delivering vouchers beyond treatment termination. Achieving high smoking abstinence rates using a low-magnitude CM schedule is relevant since one of the main barriers that arise when implementing CM in real-world contexts is its associated costs [43]. In the interest of allocating resources efficiently, it is highly advisable to use lower cost schedules to save money for providing vouchers during follow-ups.

Another relevant smoking-related outcome pertains to longitudinal depression changes. Across conditions, patients showed similar sustained depression improvements, thus challenging a long-held assumption that depression worsens during cessation attempts [44]. More broadly, the inclusion of a CBT+BA protocol for addressing both smoking and depression might have accounted for both the abstinence and depression outcomes observed. This rationale is supported by studies documenting a bidirectional relationship between abstinence and depression [45,46], which suggest beneficial abstinence effects of incorporating mood-management strategies early in treatment. BA aims to increase patients' non-smoking alternative activities in different life areas (e.g., education, relaxation, enjoyment), which serve as competitors to the rewarding effects of cigarette smoking [19,47]. Additionally, because engaging with positive and rewarding non-smoking alternatives decreases patterns of avoidance, BA might have also promoted positive effects through training in self-regulation skills to deal with negative emotions [48].

Irrespective of abstinence rates, both interventions were highly cost-effective with an ICER well below the threshold used in Europe for judging smoking cessation

therapies as such (i.e., cost-effectiveness ratio lower than three times the gross domestic product: GDP) [49] and also well below the ICER indicated in most of the individual studies [US$382-US$1,286] involving smokers with mental health disorders [11,50.] Of relevance is that the present study indicates that spending €272.50 (US$308.75) maximized the proportion of abstinent patients, whereas increasing the value of vouchers did not lead to improved sensitivity. Also, the associated costs and efficacies of treatments are the core elements that governments consider for funding smoking cessation treatments [51]. This brings us to prior reports that instigated the current investment on tobacco pharmacotherapies in Europe. These works clearly stated that the mean cost ascribable to smoking-related illness (i.e., an average of US$ 34,401 per year) would have been offset by pharmacotherapy such as bupropion (at an average cost of US$170) in the Spanish National Health System [52]. Findings however do not seem to be encouraging, as subsidizing pharmacological treatment (varenicline, bupropion or nicotine) resulted in 15.4% (118/767) abstinent participants at one-year [53]. Even at a lower cost, CM is expected to be highly cost-effective, with rises in investment leading to greater effectiveness in terms of abstinence outcomes. This clearly adds to the active debate [17,54] on the minimum amount that should be allocated to vouchers to produce a meaningful impact. Importantly, cost-effectiveness extends to diverse populations, such as those with depression, at a minimal cost. This is true even when the number of sessions and schedules of reinforcement are augmented. To extend the effects of CM, a range of WTP values could be considered by policymakers.

Several limitations are acknowledged. In the first place, this study was conducted at a single facility, a University Clinical Research Unit. Therefore, estimated treatment costs such as therapists' salaries cannot be entirely generalized to other treatment settings (e.g., primary healthcare centers). However, even if salaries were

more than triple the costs estimated in this study, intervention expenses would still be far below the maximum threshold recommended in Europe for healthcare interventions [55]. Secondly, the cost-effectiveness analyses focused on abstinence outcomes and there might be other direct and indirect benefits that were not included. These pertain to quality of life (QALY) and number of medical visits or hospital admissions. Third, the time horizon of this study was one year and the question of whether CM effects remain after incentives are withdrawn requires further consideration.

Despite the abovementioned limitations, this study has several implications for tobacco control. Developing effective smoking cessation treatments for this difficult-to-treat population is a key priority, and this study provides an economic evidence base to suggest that investing small additional amounts of money using CM may result in greater benefits in the long-term, in line with research showing a positive return on investment in cessation services (i.e., enhanced quality of life and health care cost savings) [55-57]. Moreover, CBT+BA and CBT+BA+CM not only engendered smoking abstinence but also served to ameliorate depressive symptomatology at one year. It is concerning that healthcare settings do not systematically offer smoking cessation treatments to this population due to the idea that abstinence may worsen depression [58]. We hope these findings can help guide clinicians and policymakers to develop and implement interventions for smoking cessation in the broader community.

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DECLARATIONS OF INTEREST

The authors report no conflict of interest.

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