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How adolescents with substance use disorder spend research payments

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Abstract

There is concern that research reimbursements to adolescents may increase substance use. However, these concerns have not been examined empirically. Participants were 70 adolescents (13-19 years) with at least one non-nicotine substance use disorder (SUD) enrolled in a 12-week clinical trial of atomoxetine/placebo for attention/deficit-hyperactivity disorder (ADHD). Adolescent participants received cash reimbursement after each study visit (maximum possible = \$425 over 12 weeks). Participants reported each week how they spent the previous reimbursement. Results were tallied, and correlates of spending a payment on substances were examined. Results showed that 26 of 70 subjects reported spending at least one research payment on alcohol or drugs, and 25 of 70 subjects reported spending at least one payment on tobacco. Comparing those who did and did not spend a research payment on alcohol/drugs, those who did had more frequent baseline alcohol/drug use but did not differ in demographics (age, gender) or other clinical characteristics (ADHD severity, diagnosis of conduct disorder, number of SUD diagnoses, number of treatment sessions attended, or pre/post change in number of days used substances in the past 28 days). Comparing those who did and did not spend a payment on tobacco, those who did were slightly older and had more frequent baseline tobacco use. In conclusion, a significant proportion of subjects used at least a portion of one research payment to buy alcohol, drugs or tobacco. However, there was little indication that research payments increased substance use.

Keywords

adolescent; research payment; ethics; human subjects

1. Background

Monetary reimbursement for clinical research participation is considered ethical in adults with substance use disorder (SUD), even though some studies show that a small number of participants spend research reimbursements on substances (Anderson and Dubois, 2007;

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Conflict of Interest. All the authors declare that they have no conflicts of interest.

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Festinger et al., 2005; Festinger et al., 2008; Rothfleisch et al., 1999). This concern is heightened for adolescents with SUD participating in research (Moolchan and Mermelstein, 2002; Brody and Waldron, 2000). For this reason, adolescent research subjects with SUD frequently receive non-cash reimbursements due to concerns that they might use research payments to buy substances (Brody and Waldron, 2000; Weise et al., 2002).

These concerns have not been examined empirically. Empirical data are important because there are a number of advantages to monetary reimbursement over non-cash payments. These include allowing access to research for subjects who might not otherwise be able to participate (Wendler et al., 2002), providing fair compensation for time and effort spent (Wendler et al., 2002), and improving recruitment and retention of research subjects (Festinger et al., 2005; Festinger et al., 2008).

To address this research gap, we conducted secondary analyses to determine how adolescents spent their research payments in a 12-week study of atomoxetine/placebo + motivational interviewing/cognitive behavioral therapy (MI/CBT) for attention-deficit/hyperactivity disorder (ADHD) (n = 70).

2. Methods

2.1 Participants

Participants were 70 adolescents randomized to a 12-week study of atomoxetine/placebo for ADHD. The main inclusion criteria were: 1) age 13-19 years; 2) diagnosis of ADHD using the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) (American Psychiatric Association, 1994) criteria; and 3) a DSM-IV diagnosis of at least one non-nicotine SUD.

The main exclusion criteria were: 1) mental illness or SUD that could not be managed as an outpatient or without concurrent psychotropic medication and 2) medical contraindication to taking atomoxetine.

All participants were offered 12 sessions of manual-standardized, individual MI/CBT for SUD (Riggs et al., 2007).

2.2 Measures

Subjects were asked in a weekly face-to-face confidential interview, "How did you spend the payment from the prior research visit?" The question was open-ended and subjects were allowed to report as many purchases as they made. If spending on substances was not reported, subjects were asked, "Did you spend any of the payment on alcohol, drugs, or tobacco?" If subjects answered yes, they were asked which substances were purchased.

Baseline DSM-IV psychiatric and substance use disorder diagnoses were made by Kiddie-Schedule for Affective Disorders and Schizophrenia (KSADS) interview (Ambrosini, 2000). Baseline number of days used substances in the last 28 days was assessed with a confidential Timeline Followback Interview (Sobell et al., 1996). Baseline ADHD severity was assessed with the DSM-IV ADHD checklist (American Psychiatric Association, 1994) which yields a score ranging from 0 (no ADHD symptoms) to 54 (maximum ADHD symptoms).

2.3 Procedures

Prior to beginning the study, Institutional Review Board approval was first obtained from the Colorado Multiple Institutional Review Board. Written, informed consent was obtained from a parent/guardian of all minor children, and written assent was obtained from all minors. Both

adolescents and their parent/guardian were informed in the assent/consent process that the adolescent would be asked questions “about you, your ADHD, and your drug/alcohol use every week.”

To maximize truthful self-report, adolescents and their parent/guardian were told orally and in writing at the time of consent/assent that “the information you provide about your drug/alcohol use ... is confidential and will not be shared with parent/guardian(s).” Researchers also received a Federal Certificate of Confidentiality for this study, which protected the researchers from being forced to release confidential subject information even under a court of law or lawful subpoena. Participants were informed about this Certificate during the informed consent process.

Participation in research assessments and medication follow-up visits was reimbursed each week by payment in cash at baseline (\$50), weekly post-randomization visits (\$20 plus an additional \$5 for returning medication bottles for pill counts), and the week 12 study completion visit (\$50). Subjects could also earn an additional \$10 for each qualified study referral (maximum of 5 study referrals). The total possible payment amount was \$425. All research subjects were reimbursed directly. No reimbursement was ever made to a parent or guardian. The amount of reimbursement was about \$10 per hour, which is a standard wage for workers in jobs frequently held by Colorado teens (e.g., fast food worker, movie theater attendant, supermarket bagger) (Colorado Department of Labor and Employment, 2005).

2.4 Analyses

Available data regarding purchases are presented for all participants regardless of whether or not they completed the week 12 study visit. Bivariate analyses, including Pearson chi-square analyses and independent t-tests (or Mann-Whitney U tests, if data were not normally distributed), were used to compare those who did and did not purchase alcohol/drugs or tobacco with respect to baseline demographic variables (age, gender, and court mandated status), clinical characteristics (ADHD severity, conduct disorder, nicotine dependence, number of MI/CBT sessions completed, number of SUD diagnoses, and number of days used tobacco and non-tobacco substances in the past 28 days), and outcome variables (mean number of MI/CBT sessions completed and mean pre/post change in days used non-tobacco or tobacco substances in the past 28 days). Variables that were significant ($p \leq 0.05$) in the bivariate analyses were entered into a multivariate logistic regression model to determine their combined association with spending money on tobacco or not. Because only one variable was significantly related to spending research payments on alcohol/drugs, a multiple logistic regression was not completed for this variable. For these analyses, subjects who reported purchasing alcohol or drugs were combined because only 9 subjects reported spending a research payment on alcohol and 8 of these 9 also reported spending at least a portion of a payment on illicit drugs. In a study completers analysis ($n = 65$), an independent t-test (or non-parametric equivalent) was used to compare those who did and did not purchase tobacco or alcohol/drugs on pre/post change in past 28 day tobacco or non-tobacco substance use. Finally, Wilcoxon signed ranks tests were used to assess pre/post change in the number of days used tobacco and non-tobacco substances in the past 28 days for study completers ($n = 65$).

3. Results

Sixty-five (92.9%) of the subjects completed the study. In general, the sample was predominantly male (78.6%) and the average age was 16.1 years ($SD = 1.6$). Table 1 indicates the current baseline substance use disorder diagnoses for the sample. The average amount of money received during the study was \$313.64 ($SD = 57.79$, minimum = \$90, maximum = \$375, median = \$330). Overall, the pre/post change in the number of days used non-nicotine substances in the past 28 days for the sample of study completers ($n = 65$) was -4.63 days (SD

= 9.76; $Z = -3.59$, $p = 0.0005$). The pre/post change in the number of days used tobacco in the past 28 days for the sample of completers ($n = 65$) was -2.03 days ($SD = 7.22$; $Z = -2.17$; $p = 0.030$).

A total of 26 of 70 subjects (37.1%) reported spending research payments on alcohol or non-tobacco drugs at least one time during the 12-week study. For those reporting at least one purchase on alcohol or drugs, the mean number of times research money was spent on alcohol/drugs was 3.46 ($SD = 2.70$). Nine participants reported purchasing alcohol, and 8 of these 9 also purchased drugs. All 25 subjects who purchased illicit drugs reported purchasing marijuana and no other drugs. Those who reported spending at least one research payment on alcohol or drugs had a greater number of baseline days of alcohol or non-tobacco drug use in the past 28 days (22.9 days, $SD = 7.0$), compared to those who did not report spending any research payments on alcohol or drugs (14.7 days, $SD = 10.3$; $U = 308.50$, $p = 0.001$). There was no difference between those who did and did not use research payments to purchase alcohol or drugs in baseline demographic (age, gender, or court mandated status) or clinical characteristics (ADHD severity, conduct disorder, nicotine dependence, number of SUD diagnoses, or past 28 day nicotine use). There was also no difference between groups in the mean number of MI/CBT sessions attended or in the mean pre/post change in the number of days used at least one non-tobacco substance in the past 28 days (-2.42 days, $SD = 9.85$, for those who bought alcohol/drugs compared to -5.93 days, $SD = 9.60$, for those who did not buy alcohol/drugs; $t_{63} = 1.41$, $p = 0.164$).

A total of 25 subjects (35.7%) reported spending research money on tobacco. Of these, 11 also spent at least one research payment on alcohol or drugs. For those reporting at least one purchase on tobacco, the mean number of times research money was spent on tobacco was 2.56 ($SD = 2.52$). Those who reported spending at least one research payment on tobacco had a greater number of baseline days of tobacco use in the past 28 days (23.48 days, $SD = 7.97$) compared to those who did not report spending any research payments on tobacco (9.91 days, $SD = 11.36$; $U = 201.50$, $p = 0.0005$). They were also more likely to have DSM-IV nicotine dependence (88% versus 40%; $\chi^2_1 = 15.12$, $p = 0.0005$) and to be slightly older (mean age = 16.56 years, $SD = 1.58$ compared to 15.82 years, $SD = 1.51$, $t_{68} = -1.92$, $p = 0.059$). There were no other differences between those who did and did not use research payments to purchase tobacco in baseline demographic (gender or court mandated status) or clinical characteristics (ADHD severity, conduct disorder, number of SUD diagnoses, or past 28 day non-tobacco substance use). There was no difference between groups in the mean number of MI/CBT sessions attended or in the mean pre/post change in the number of days used tobacco in the past 28 days (-2.0 days, $SD = 7.55$, for those who purchased tobacco compared to -2.1 days, $SD = 7.12$, for those who did not; $U = 475.50$, $p = 0.915$). A multivariate logistic regression revealed that one additional day of tobacco use at baseline increased the odds of spending at least one research payment on tobacco by 12%, controlling for participant's age and baseline diagnosis of nicotine dependence ($B = 0.11$, $SE = 0.06$; $OR = 1.12$, $p = 0.049$; 95% CI: 1.00 to 1.25). Age and diagnosis of nicotine dependence were not significant in the multiple logistic regression.

4. Discussion

Data from this preliminary report indicate that a significant proportion of adolescent research participants with SUD used at least a portion of one research payment to buy alcohol, drugs, or tobacco. Those who spent their payments on alcohol/drugs had more severe baseline alcohol/drug use. Those who spent their payments on tobacco were more likely to have baseline nicotine dependence, more frequent baseline tobacco use, and were slightly older.

Although a significant proportion of adolescent research participants in this study used at least a portion of one research payment to buy alcohol, drugs, or tobacco, these findings do not necessarily mean that adolescents with SUD should not receive cash reimbursement. First, all participants had a current SUD at baseline and, therefore, were obtaining and using illegal substances before the study began. Moreover, because tobacco and non-tobacco substance use decreased for those who did and did not use a research payment to buy substances, there is little indication that research payments increased substance use.

Limitations of this study include the reliance on self-report and the lack of different payment schedules. Therefore, trials are needed that use different payment schedules and compare how money is spent. A baseline assessment of the amount of money spent on substances would also allow for a pre/post comparison of how much money was spent on obtaining substances. Finally, because all participants in this study attended a research-based substance treatment (MI/CBT), the results may not generalize to research that does not include treatment.

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Table 1

Current baseline DSM-IV substance use disorder diagnoses (total n = 70)

Diagnosis	Number (%)
Cannabis use disorder	67 (95.7%)
Nicotine dependence	40 (57.1%)
Alcohol use disorder	20 (28.6%)
Cocaine use disorder	2 (2.9%)
Amphetamine use disorder	1 (1.4%)
Hallucinogen use disorder	1 (1.4%)