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Corrected Feedback: A Procedure to Enhance Recall of Informed Consent to Research among Substance Abusing Offenders

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Abstract

This study examined the efficacy of corrected feedback for improving consent recall throughout the course of an ongoing longitudinal study. Participants (N = 135) were randomly assigned to either a corrected feedback or a no-feedback control condition. Participants completed a consent quiz 2-weeks after consenting to the host study and at months 1, 2, and 3. The corrected feedback group received corrections to erroneous responses and the no-feedback control group did not. The feedback group displayed significantly greater recall overall and in specific content areas (i.e., procedures, protections, risks/benefits). Results support the use of corrected feedback for improving consent recall.

Keywords

Informed consent; Research ethics; Corrected feedback; Recall

Research indicates that participants often recall only a portion of consent information following their recruitment into clinical trials. Research participants have been found to be unaware that they are participating in a research study, have poor recall of study information, have inadequate recall of important risks and benefits, lack understanding of randomization procedures and placebo treatments, lack awareness of the ability to withdraw from the research study at any time, and are often confused about the dual roles of clinician and researcher (Appelbaum et al., 1982; Cassileth et al., 1980; Edwards et al., 1998; Levine, 1992; Muss et al., 1979; Robinson & Merav, 1976; Silva & Sorell, 1988; Sugarman et al., 1998; Verheggen & van Wijmen, 1996). In our own program of research with drug-abusing offenders, we similarly found a discouraging lack of understanding and retention of informed consent information (e.g., Festinger, Ratanadilok, Marlowe, Dugosh et al., 2007; Festinger et al., 2009).

Substance abusers in particular may present a number of unique issues when obtaining informed consent because of the direct effects of their substance abuse as well as a wide range of co-morbid conditions (McCrady & Bux, 1999). Acute drug intoxication or withdrawal may impair attention, cognition, or retention of important information (Munro,

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et al., 2000; Saxton et al., 2000; Tapert & Brown, 2000; Victor et al., 1989). Limited educational opportunities, chronic brain changes resulting from long-term drug or alcohol use, poor nutrition, and co-morbid health problems (e.g., AIDS-related dementia) are common in individuals with substance abuse or dependence and may also reduce concentration and limit understanding during the informed consent process (McCrady & Bux, 1999).

Successful strategies for improving understanding and recall of consent information have involved the use of improved and simplified consent forms (e.g., Krynski et al., 1994; Tymchuk et al., 1988; Tymchuk & Ouslander, 1991; Wirshing et al., 1998), the use of consent information summaries (Sorrell, 1991), making post-consent telephone contacts (Aaronson et al., 1996; Dodd & Mood, 1981), and providing procedural orientations (Armstrong et al., 1997; Askew et al., 1990). Other efforts that were generally not successful or showed mixed results included the use of videotape methodologies (*compare* Agre et al., 1994; Fureman et al., 1997 [positive effects] *with*; Westreich et al., 1995; Weston et al., 1997 [no effects]), and the use of highly detailed consent information, which was not associated with improved understanding in either a research or a clinical context (Hopper & Tyler, 1989; Stanley et al., 1998; Taub et al., 1986; Taub et al., 1987).

One strategy that has been most consistently associated with improvements in both *initial understanding* as well as *recall* of informed consent information is the corrected feedback or multiple learning trial approach (Taub et al., 1981; Taub & Baker, 1983; White et al., 1995). This procedure typically involves (1) assessing a participant's knowledge and comprehension of informed consent information following an initial presentation and review of the consent form and (2) providing corrected feedback on incorrect items. This procedure has been evaluated both as a one-time (e.g., Stiles et al., 2001) and as a multiple-trial intervention (e.g., Taub & Baker, 1983).

Taub et al. (1981) examined the extent to which providing elderly patients with feedback on incorrect consent quiz responses improved retention of consent information. A total of 87 elderly adults were divided into two groups. Participants in the experimental group read the consent form and answered multiple-choice questions covering the main points of the consent form. They then received feedback with corrected answers. Participants in the control group read the consent form but did not receive a consent quiz or corrected feedback. All participants were tested two to three weeks later on their recall of the consent information. Results indicated that the use of the corrected feedback procedure significantly improved recall of consent information at all age levels and vocabulary levels. Taub and Baker (1983) used a similar procedure to examine comprehension of consent information in another cohort of elderly participants. Participants in one group were given a single comprehension test and feedback before signing consent documents, while those in the other group were provided with up to three comprehension trials to reach mastery criteria on the quiz. Results indicated that the multi-trial corrected-feedback approach improved comprehension scores at all vocabulary levels.

Carpenter et al. (2000) tested an educational corrected feedback procedure to improve comprehension of consent information among schizophrenic patients. Prior to the intervention, the patients demonstrated significantly poorer comprehension of consent information than a non-patient control group as measured by the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR). Results revealed that the intervention was able to bring schizophrenic patients' scores into the range of the non-patient comparison group. This procedure has also been effective with patients consenting to surgical procedures (White et al., 1995).

Notably, the corrected feedback procedure appears to be one of the only interventions to translate the informed consent into an ongoing process rather than a one-time event. In this respect, ongoing corrected feedback may not only help to remedy problems with the initial informed consent procedure, but may also establish informed consent as a *dynamic, on-going process* that begins when a participant is first approached about entering a study and continues throughout his or her participation. An ongoing consent process may be particularly important for ensuring the recall of certain information, such as the ability to withdraw from the study with out negative recourse, specific side effects that may result from experimental interventions, confidentiality of research data, and how to register complaints in the event of research misconduct. In fact, some of these concerns may not arise until a study is over. This view is clearly endorsed by many research ethics boards and scientific organizations (e.g., Bioethics Interest Group, National Institutes of Health, 1998; Geller et al., 1997; Office of Human Subjects Research, National Institutes of Health, 2000; United States Department of Health and Human Services, 1998). For instance, the NIH Bioethics Interest Group (1998) recommends that: "Investigators should provide information in small increments, repeated over time, and assure that the process lasts as long as is required for the Participant to gain proper appreciation of the study" (p. 3). Similarly, the NIH Office of Human Subjects Research (2000) requires that "depending on the nature, type and duration of the research, ongoing discussion with and education of subjects about the study may continue long after the informed consent document is signed" (p. 1).

Despite highly promising empirical support for the use of corrected feedback in a range of clinical populations, we identified no empirical evaluation of this procedure with substance abusers or with criminal justice-involved populations other than the current line of research. The purpose of the current study was to examine the efficacy of the corrected feedback procedure in improving recall of consent information in a population of drug court clients who were being recruited for participation in a real-world clinical trial. Importantly, the current study seeks to examine the use of corrected feedback to improve recall of consent and study-related information *throughout* the course of a longitudinal study, *after* participants have provided informed consent to participate; in contrast, many other studies of this nature have focused on the initial consent process. Based on the prior literature on this procedure, we hypothesized that clients receiving monthly corrected feedback would recall a significantly larger proportion of the informed consent information over the course of the 4-month study than clients who received the standard consent procedure that did not include ongoing monthly corrected feedback.

Methods

Host Study context

To increase the ecological validity of the study, we appended this informed consent protocol onto an on-going NIDA-funded study. The aim of the host study was to examine the effects of matching drug court clients to different dosages of court hearings before the judge. Because the procedures involved in the host study may have substantial implications for participants' legal rights, it was particularly important to obtain voluntary and knowing consent to participate in the research. The purpose of this study (as described in Marlowe, Festinger, Lee, Dugosh, & Benasutti, 2006) was to prospectively assign high-risk drug court clients to bi-weekly judicial status hearings, and to assign low-risk clients to as-needed hearings, and to compare their outcomes to those of clients attending the standard schedule of status hearings. Specifically, consenting participants were randomly assigned in roughly equal proportions either to be matched or unmatched. Unmatched participants were scheduled to attend status hearings every 4 to 6 weeks, which is the standard practice for this misdemeanor drug court. Matched participants were scheduled either to attend bi-weekly

judicial status hearings or as-needed hearings, depending upon whether they met criteria for APD or had a drug treatment history

Participants

A total of 90 offenders who were admitted to a misdemeanor drug court located in the urban city of Wilmington, Delaware signed up to hear about the parent study between October 26, 2004 and November 15, 2005. All of these individuals ultimately consented to participate in the study. To be eligible for the misdemeanor drug court program and for the host study, offenders had to (1) be at least 18 years of age; (2) be a resident of New Castle County, Delaware; (3) be charged with a misdemeanor drug offense involving possession of cannabis, possession of drug paraphernalia, or possession of hypodermic syringes; and (4) have no history of a violent crime, drug dealing, or drug manufacturing. All individuals admitted to the drug court program received treatment and court monitoring in lieu of incarceration. The drug court program is scheduled to be a minimum of 14 weeks in length and involves a combination of psychosocial treatment, court hearings, regular case management, and weekly urine drug screens. A total of 45 participants were randomly assigned to each of the two study conditions, and the two groups did not differ on baseline demographic or status variables including age, gender, race, and drug problem severity (see Table 1).

Procedures

All potential study participants underwent a comprehensive, manualized informed consent procedure upon entry into the host study. First, the research technician explained the consent process to clients. The research technician then asked clients to read the consent form silently to themselves as the interviewer read it aloud. This procedure avoids clients experiencing embarrassment by having to admit difficulties with reading. The research technician assured clients that they could stop the process at any time to ask for clarification and that there would also be time at the end of the process to discuss the consent form and to ask additional questions. The technician then proceeded to read and subsequently paraphrase each section of the informed consent document according to a standard script. When the technician was finished, clients were given yet another opportunity to ask questions. Subsequently, clients were asked to paraphrase each section of the consent form and offered clarification by the technician until they could correctly paraphrase each section.. Consented clients were then randomly assigned to either the corrected feedback condition or the no-feedback control condition. Importantly, it was necessary to provide all participants with the same high standard of informed consent upon entry into the host study. Unlike many studies conducted in ethics research that often employ sham studies, the current study was conducted in the context of a real-world clinical trial involving a high-risk intervention with a vulnerable population. As such, it would be considered unethical not to clarify misconceptions about the study to participants in one group during their initial informed consent process.

Following the consent process, all participants completed a baseline interview that included the Addiction Severity Index (ASI) (McLellan, Luborsky, O'Brien, & Woody, 1980; McLellan et al., 1992). Within two weeks following the initial assessment (M = 11.63 days, SD = 10.55 days), all clients attended a second appointment at which they completed the baseline consent quiz. During the consent quiz, participants were instructed to answer each question according to their best recollection of how the information was presented to them during the initial consent procedure. Participants in the corrected feedback condition received corrections to erroneous responses and those in the no-feedback control condition did not. Research technicians were trained by the research coordinator to administer the consent quiz and feedback (to the experimental group) in a scripted and highly standardized

manner. The research coordinator conducted multiple role plays of the consent process with the research technicians until they had successfully mastered the process. Following this assessment, clients returned monthly for the next three months to complete a consent quiz. Consequently, clients had the opportunity to complete a total of four possible consent quizzes (i.e., baseline, month 1, month 2, and month 3). Participants received $40 for completing the first baseline assessment, $30 for completing the second baseline assessment, and $25 for completing each monthly quiz.

The study was approved and monitored by the Institutional Review Boards of the Treatment Research Institute and the Delaware State Department of Health and Social Services. We obtained a NIH Confidentiality Certificate for the host study, which shields the research data from a court order or subpoena (42 CFR Part 2a; 42 U.S.C. § 2a(6)).

Measures

Addition Severity Index (ASI)—The ASI (McLellan, Luborsky, O'Brien, & Woody, 1980; McLellan et al., 1992) is a semi-structured interview that assesses current (past 30 days) and lifetime problems in the following domains: legal, medical, drug, alcohol, family/social, employment, and psychiatric. Composite scores are calculated for each ASI domain, and these scores are global indicators of problem severity in that domain (McDermott et al., 1996). The ASI was administered at the first baseline interview and took approximately 45 minutes to complete. ASI composite scores provided a measure of baseline problem severity in order to ensure the equivalence of the two conditions.

Consent Quiz—The consent quiz was modeled after the Understanding Scale of the MacCAT-CR (Appelbaum & Grisso, 2001). The 16-item consent quiz was administered to all participants at their second baseline assessment and at each subsequent assessment. The scale was tailored to assess 16 principal aspects of the host study's consent form including the purpose of the study, the procedures and assessments, remuneration, and human rights protections (e.g., confidentiality, recourse in the event of being harmed, whom to contact with additional questions or concerns). It was developed by translating each of the main elements of the consent form into a scorable question format. This modified version of the scale has been used in a number of previous studies as a measure of consent recall (e.g., Festinger, Ratanadilok, Marlowe, Dugosh, et al., 2007; Festinger, Marlowe, Croft, Dugosh, Arabia, & Benasutti, 2009).

The questions varied in the number of answers that were called for, with the number of necessary responses ranging from one to seven. For example, one question addressing the duration of the study had only one response (i.e., 6 months), whereas another question addressing the schedule of follow-up interviews had seven responses, corresponding to each of the seven follow-up interviews. The questions were delivered in an open-ended manner; therefore, participants did not know the number of responses that were required for each question. The 16-item questionnaire took an average of 12.5 minutes (SD = 2.6) to complete.

Because each item varied in the number of necessary responses, scores for each item were weighted by the number of necessary responses. This weighting was accomplished by calculating the proportion of correct responses provided (out of the total of necessary responses) for each item. For instance, if a person provided one correct response to an item that had two components, he or she received score of .50 for that item. Likewise, if a person provided seven correct responses to an item that had seven components, he or she received a score of 1 for that item. Consent quiz scores were calculated by summing these weighted scores. And scores could range from 0 to 16. In addition, each item could be classified into one of three domains: 1) understanding of protocol (8 items), 2) human subject protections

(6 items), and 3) risks and benefits of participation (2 items). Subscale scores were calculated for each of the three domains listed above by summing the weighted scores for the items within each domain. Understanding of protocol scores could range from 0 to 8, human subject protections scores could range from 0 to 6, and risk and benefits scores could range from 0 to 2.

Data Analysis

Groups were compared on the number of consent quizzes completed using a t-test, and a poisson regression analysis was used to identify baseline status and demographic variables (i.e., age, race, gender, employment status, marital status, history of prior substance abuse treatment, alcohol problem severity, and drug problem severity) that were related to the number of consent quizzes completed. Group differences in the timing of the consent quiz administrations (i.e., the number of days from consent) were examined using a linear mixed effects model (Littell, Milliken, Stroup and Wolfinger, 1996). Mixed effects models are well suited to the analysis of repeated measures data because they allow for the specification of the covariance structure of the repeated measurements and they do not require complete data. The model examined differences in time from consent for quizzes 1 through 4 and included terms for group, administration number, and their interaction. Significant group or group by administration number interaction effects would indicate that time from consent should be included as a covariate in the model as the timing of the consent quizzes varied systematically between the conditions.

The primary analyses examined group differences in recall of the consent information. A series of linear mixed effects models were used to examine differences between the consent as usual and corrected feedback conditions on recall of consent information. The primary model examined differences in total consent quiz scores administrations 1 through 4 and included terms for group, administration number, and their interaction. Models used a maximum likelihood estimation strategy and specified a compound symmetry covariance structure. This approach was repeated for each of the three subscale scores. Analyses were conducted using SAS v. 9.3.

Results

Quiz completion

In the consent as usual group, the sample sizes at administration 1 through 4 were 45, 39, 31, and 13, respectively. Corresponding sample sizes in the feedback group were 45, 41, 32, and 20, respectively. Clients in the consent group completed an average of 2.84 (SD = 1) consent quizzes and clients in the corrected feedback group completed an average of 3.07 consent quizzes ($p = .30$). The number of consent quizzes completed was not related to any demographic or baseline status variables (all p's = .24 to .80). In the consent as usual group, the average number of days from consent for each quiz administration was 18.55 (SD = 19.77), 59.90 (SD = 27.42), 90.10 (SD = 27.42), and 120.23 (SD = 20.15) for administrations 1 through 4, respectively. In the corrected feedback condition, the corresponding average number of days from consent was 22.84 (SD = 27.93), 63.88 (SD = 27.56), 89.06 (SD = 22.25), and 119.90 (SD = 20.76). There was no group [$F(1, 88) = 0.04$, $p = .83$] or group or group by administration number interaction [$F(3, 170) = 1.42$, $p = .24$] for the number of days from consent.

Total scale score

Quiz scores for each group at each assessment number are presented in Table 2. The model examining total scales score revealed a main effect for group, $F(1, 88) = 8.26$, $p < .01$, administration number, $F(3, 170) = 5.06$, $p < .01$, and a group by administration number

interaction, $F(3, 170) = 2.76$, $p < .05$. Specific contrasts indicated that total scale scores were significantly higher in the corrected feedback condition than in the consent as usual condition at the third and forth administrations, but not at the first and second administrations. On average, clients in the corrected feedback condition displayed a 15% increase over time in the percent of correct responses (40% at baseline vs. 55% at the final administration) while clients in the consent as usual displayed a 5% increase over time (37% at baseline vs. 42% at the final administration).

Understanding of protocol score

The model examining the understanding of protocol sub-scale scores indicated a significant effect of group, $F(1, 88) = 5.85$, $p < .05$, and administration number $F(3, 170) = 2.93$, $p < .05$. However, the group by administration number did not reach statistical significance ($p = .33$). Specific contrasts indicated that, overall, scores were significantly higher in the corrected feedback condition ($lsM = 4.00$; $SE = .21$) than in the consent as usual condition ($lsM = 3.24$; $SE = .22$) and scores at the third administration ($lsM = 3.93$; $SE = .20$) were significantly higher than scores at the first ($lsM = 3.41$; $SE = .18$) and second administrations ($lsM = 3.43$; $SE = .18$). On average, clients in the corrected feedback condition displayed a 13% increase over time in the percent of correct responses (45% at baseline vs. 58% at the final administration) while clients in the consent as usual displayed a 9% increase over time (40% at baseline vs. 49% at the final administration).

Human subject protections score

The model examining the human subject protections sub-scale scores indicated significant effects of group $F(1, 88) = 5.52$, $p < .05$ and administration number, $F(1, 170) = 8.59$, $p < .0001$. Collapsing across administration number, scores were significantly higher in the feedback condition ($lsM = 2.69$; $SE = .10$) than in the control condition ($lsM = 2.34$; $SE = .11$). Overall, scores were significantly lower at the first administration ($lsM = 2.10$; $SE = .10$) than at the three subsequent administrations (second: $lsM = 2.50$; $SE = .10$; third: $lsM = 2.70$; $SE = .12$; and fourth: $lsM = 2.77$; $SE = .16$). Finally, there was group by administration interaction trend, $F(3, 1708) = 2.26$, $p < .10$, in which the feedback groups displayed higher scores than the control group at the third and forth administration. On average, clients in the corrected feedback condition displayed a 20% increase over time in the percent of correct responses (35% at baseline vs. 55% at the final administration) while clients in the consent as usual displayed a 5% increase over time (35% at baseline vs. 40% at the final administration).

Risks and benefits score

The model examining risks and benefits sub-scale scores indicated a main effect of group, $F(1, 88) = 4.46$, $p = .04$ and a group by administration number interaction, $F(3, 170) = 2.83$, $p < .05$. Specific contrasts indicated that risks and benefits subscale scores were significantly higher in the corrected feedback condition than in the consent as usual condition at the third and forth administrations. On average, clients in the corrected feedback condition displayed a 15% increase over time in the percent of correct responses (30% at baseline vs. 45% at the final administration) while clients in the consent as usual displayed a 12% decrease over time (32% at baseline vs. 20% at the final administration).

Discussion

The results of this study provide additional support for the efficacy of an ongoing corrected feedback procedure for improving recall of informed consent information. Findings indicated that research participants who received monthly quizzes and corrected feedback on incorrect responses displayed greater recall of consent information overall (i.e., total scale

scores) than participants who did not receive corrected feedback. In addition, the corrected feedback procedure led to significant improvements in participants' correct recall of (1) the nature and purpose of the study, (2) the specific human subject protections afforded to them as research participants and (3) the risks and benefits associated with participation. Importantly, however, these effects were generally modest in size, leading to only a 55% recall of consent information after several repetitions of the corrected feedback procedure.

Consistent with prior research on multiple learning trials and corrected feedback, our procedure resulted in greater recall of potentially important and vital information related to participants' human subject protections. Prior to the present study, the corrected feedback procedure was examined and found to be efficacious in a number of clinical populations including the elderly, medically hospitalized, and schizophrenic patients. However, the current study was the first to examine the utility of this intervention in a doubly vulnerable population of criminally involved substance abusers.

A potential limitation of the study is related to the level or type of knowledge of consent information that we are measuring in the study (Appelbaum and Grisso, 2001; Flory and Emanuel, 2004). Flory and Emanuel (2004) have argued that the improvements observed as a result of the corrective feedback procedure (e.g., Wirshing et al., 1998; Coletti et al., 2003; Stiles et al., 2001; Taub & Baker, 1983; Taub, Kline & Baker, 1981) may reflect rote memorization rather than changes in understanding. For example, simply recalling the elements of a consent document may not necessarily mean a participant appreciates the implications that taking part in the study may have to his or her personal well-being. However, it seems reasonable to assume that accurately recalling consent information is a minimum requirement for engaging in such a decision-making process. If participants do not correctly recall the basic study elements, it is difficult for them to rationally consider the implications of participation to their personal interests.

Moreover, it may be argued that much of the information that is relevant to research participants' human subject protections and risks and benefits *are* simple memorizable facts rather than latent constructs. For example, it may be sufficient for a participant to know that he or she can withdraw from the study at any time without consequence (human subject protection) or that an experimental procedure may cause certain side effects (risks). A procedure that increases the likelihood that this type of information is memorized is likely to improve their overall ethical protections. However, it should be noted that our research technicians were trained to probe participants to gauge whether they understood the concepts behind their responses. For example, "randomization" was considered an acceptable response for the question of how one was assigned to a study condition. If a participant responded to the question with only the word "randomization", the RA probed them to determine whether they truly understood the meaning of randomization.

Another potential limitation of the study is that the open-ended consent quiz used in the study has not been standardized or psychometrically validated. In our review of the literature, we failed to identify a single structured, psychometrically validated consent quiz. In fact, standardization may not be possible because consent quizzes must be tailored to each study. Nevertheless, dozens of versions of consent quizzes are found in the literature (see Flory and Emanuel, 2004 for review). One common limitation of many of these quizzes is that they use of brief, overly simplistic, and leading questions (e.g., true and false, multiple choice) which are likely to overestimate participants' understanding and recall. Furthermore, these instruments often rely on recognition rather than recall of the information. To avoid the shortcomings of these formats and to more accurately assess understanding and recall, we chose to use an open-ended format for our consent quiz that relies on recall rather than recognition. In fact, study participants are likely to rely on recall (rather than recognition)

when they need study related information (e.g., protections, risks, and recourse for adverse events) throughout or following their study participation

A final potential limitation to the study is that the research technicians that administered the consent quiz were not blinded to the different study conditions. It is possible that our failure to blind them to study conditions may have introduced some unintentional bias to the delivery of the informed consent procedures and the scoring of consent quizzes. Future studies should include blinding procedures to prevent the introduction of experimenter bias.

The current study demonstrated the effectiveness of a cognitive-based corrective feedback procedure in improving the recall of consent information in a substance abusing offender population. Clients in the corrected feedback condition recalled approximately 15% more of the consent information at the fourth assessment than they did at baseline; however, they were still only able to recall approximately 55% of the information overall. While the effects of this cognitive intervention have demonstrated statistical significance, its clinical significance is not as apparent as participants who receive corrected feedback still fail to remember 45% of their consent information, on average. We have begun to explore other factors including motivation that may play a role in recall of consent information. In fact, we have demonstrated in a pilot study (Festinger et al., 2009) that increasing motivation to recall consent information through the use of incentives results in higher rates of recall. Future studies are necessary to develop and examine effective cognitive and motivation-based strategies to improve participants' understanding and recall of consent information as to better ensure their human subject protections.

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Table 1

Sample characteristics at baseline (N = 45 per group).

Variable*		Consent as Usual M(SD)/N(%)	Corrected feedback M(SD) N(%)
Age	Years	23.98 (6.39)	24.13 (7.39)
Gender	Male	38 (84%)	35 (78%)
Race	Caucasian	28 (62%)	29 (64%)
	African American	16 (36%)	14 (16%)
Education	Years	12.18 (1.51)	12.04 (1.69)
Employed full time		22 (49%)	24 (53%)
ASI composite	Alcohol	0.09 (0.09)	0.07 (0.08)
	Drug	0.07 (0.09)	0.08 (0.11)
	Employment	0.44 (0.29)	0.42 (0.27)
	Family	0.05 (0.12)	0.05 (0.12)
	Legal	0.19 (0.18)	0.14 (0.14)
	Medical	0.08 (0.15)	0.11 (0.26)
	Psychiatric	0.09 (0.18)	0.09 (0.14)
Marital status	Married	2 (4%)	1 (2%)
	Never married	39 (87%)	42 (93%)
Prior drug treatment		7 (16%)	9 (20%)

* Groups did not differ significantly on any of the variables reported in the table.

Table 2

Quiz scores for each group.

Measure	Group	Quiz 1 M (SD)	Quiz 2 M (SD)	Quiz 3 M (SD)	Quiz 4 M (SD)
Total quiz score (16 items)	Consent as usual	5.94 (2.22)	6.04 (2.15)	6.48 (2.33)	6.70 (3.92)
	Corrected feedback	6.32 (1.98)	6.99 (3.08)	8.49 (3.13)	8.80 (3.00)
Understanding of protocol score (8 items)	Consent as usual	3.20 (1.53)	3.12 (1.63)	3.54 (1.60)	3.93 (2.34)
	Corrected feedback	3.61 (1.43)	3.76 (1.90)	4.72 (1.77)	4.63 (1.58)
Human subject protections score (6 items)	Consent as usual	2.09 (0.76)	2.44 (0.56)	2.49 (0.66)	2.38 (1.25)
	Corrected feedback	2.11 (0.69)	2.55 (1.07)	2.90 (1.35)	3.28 (1.35)
Risks and benefits score (2 items)	Consent as usual	0.64 (0.74)	0.49 (0.60)	0.45 (0.57)	0.38 (0.65)
	Corrected feedback	0.60 (0.62)	0.68 (0.65)	0.88 (0.83)	0.90 (0.85)

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