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A Randomized Controlled Trial of a Telephone Intervention for Alcohol Misuse with Injured Emergency Department Patients

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Abstract

Objective—This was a randomized controlled trial to test efficacy of a telephone intervention (TBMI) for injured ED patients with alcohol misuse to decrease alcohol use, impaired driving, alcohol-related injuries and alcohol-related negative consequences.

Methods—ED patients screening positive for alcohol misuse were randomized to a three-session telephone brief motivational intervention on alcohol (TBMI) delivered by a counselor trained in motivational interviewing over 6 weeks or a control intervention of a scripted home fire and burn safety education delivered in three calls. Patients were followed for 12 months and assessed for changes in alcohol use, impaired driving, alcohol-related injuries and alcohol-related negative consequences.

None of the authors have any conflicts of interest to report

Authorship Contributions

The study was designed by MJM, JB and RL with funding awarded to MJM. All authors contributed to the conduct of the study. JB provided statistical guidance and analysis of data. MJM developed a manuscript draft that all authors contributed substantially to its revision and approved the final version.

Results—730 ED patients were randomized; 78% received their assigned intervention by telephone and of those, 72% completed 12 months assessments. There were no differential benefits of TBMI intervention versus assessment and a control intervention in all three variables of alcohol use (frequency of binge alcohol use over the prior 30 days, maximum number of drinks at one time in past 30 days, typical alcohol use in past 30 days), alcohol impaired driving, alcohol related injuries and alcohol-related negative consequences.

Conclusions—Despite the potential advantage of delivering a TBMI in not disrupting ED clinical care, our study found no efficacy for it over an assessment and control intervention. Potential etiologies for our finding include that injury itself or alcohol assessments, or the control intervention had active ingredients for alcohol change.

Background and Importance

Alcohol misuse contributes to an estimated 1.8 million deaths globally with half of these due to intentional and unintentional injuries.[1] The emergency department (ED) presents an opportune location to identify injured patients with alcohol misuse. Screening, brief intervention and referral to treatment (SBIRT) for alcohol misuse is recommended to be integrated into the clinical care for injured patients.[2–5] Despite these recommendations, adoption by EDs in the US has been limited with the most often cited barriers being time constraints for ED providers and financial resources.[6,7]

Research on the effectiveness of SBIRT within the ED in addressing alcohol and other substance misuse has been mixed[8,9]. A common approach to ED interventions has been utilizing the principles of motivational interviewing[10], which emphasizes the role of the patient in making changes guided by an interventionist. Most other ED research on this topic has involved interventions delivered face-to-face in the ED with some studies offering additional in-person or telephone follow-up sessions after the ED visit[9,11]. We previously reported on an intervention for alcohol misuse that utilized the ED to identify injured alcohol misusers, but rather than intervening within the ED environment, we delivered a telephone brief motivational intervention within seven days of the patients' ED visit[12,13]. A telephone intervention after ED discharge has the advantage of the patient not being distracted by their medical care, ED utilization time not being extended, and therapist time scheduled more efficiently while still capitalizing on the teaching moment of an ED visit for an injury. In our initial trial, comparing a telephone intervention for alcohol misuse to an assessment only group, we found patients receiving the intervention had decreased drinking and driving behaviors at 3 months[12] and decreased alcohol-related negative consequences at twelve months[13]. However, the intervention group did not decrease their alcohol use more than the assessment-only group.

Goals of This Investigation

The current study was a randomized controlled trial with injured ED patients who screened positive for alcohol misuse. We investigated whether a three-session telephone brief motivational intervention (TBMI) delivered over 6 weeks decreased alcohol use, alcohol-related injuries, and impaired driving during the subsequent twelve months. TBMI was tested against a time-equivalent assessment control intervention also delivered in three

telephone calls. The rationale for the current study was to 1) build upon our previous work to detect a change in alcohol use and attendant alcohol-related consequences between groups; and 2) utilize an assessment control intervention to control for participant-interventionist interaction. We hypothesized that, relative to the assessment control group, those in the TBMI group would have less alcohol use and impaired driving at four months post randomization and this group difference would persist at 12 months, along with distal outcomes of decreased alcohol-related injuries and alcohol-related negative consequences.

Methods

Study Design and Settings

This randomized controlled trial enrolled injured patients who visited two urban EDs located in one northeastern US city from July 2010 until March 2013. To allow for some variability in the ED environment and patient population, one ED is a level one trauma center with ED volume of approximately 105,000 visits per year and the second is an academic community ED with approximately 55,000 patient visits per year. The research protocol was reviewed by the Institutional Review Board for both hospitals and has a Certificate of Confidentiality agreement from NIAAA. The study is registered at clinicaltrials.gov (NCT01326169).

Selection of Participants

Research Assistants (RAs) were assigned to shifts that covered all days of the week and all time periods at both EDs. To create a random sample of patients approached for recruitment, each RA was given a predetermined random sequence for approaching ED patient rooms. The RAs initially reviewed patients' medical records for eligibility including: age ≥ 18 years old, ED visit was for an injury, patient was English speaking and medically stable, not being admitted to the hospital and patient was not incarcerated or intoxicated. If these criteria were met, the RA obtained verbal consent from the patient to be screened for study eligibility, which included: having a telephone and not being homeless. Patients not meeting the eligibility conditions as well as those refusing to participate during the screening process had their reasons documented for later review. The participating patients continued the screening process on a computer tablet that initially confirmed the visit to the ED was for evaluation of an injury that occurred in the last 7 days and then delivered the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) v3.0[14] (see measures section). Patients with an ASSIST score of 11 or greater (moderate or high risk alcohol use) were then asked to consent to the study in which they would receive a telephone intervention on either alcohol use or home fire and burn safety.

Participants electronically completed baseline assessments on alcohol use, injury history, impaired driving and alcohol-related negative consequences (as well as home fire and burn safety behaviors). They were then randomized by the RA opening a sealed envelope directing assignment to one of two conditions: intervention (TBMI for alcohol use) or assessment control (telephone educational intervention on home fire and burn safety). Randomization was stratified by alcohol use severity (ASSIST score 11–26 = moderate risk and ASSIST score 27–39 = high risk). Both interventions involved three telephone calls and participants were scheduled to receive their first assigned call within one week of the ED

visit, with the second and third calls two and six weeks after the first call. In choosing a three-call intervention model we sought to extend the effects of our previous research utilizing two call interventions but still meeting the practical demands of testing a moderate resource intervention that could be disseminated. Participants were not aware of their randomly-assigned condition until the start of the initial phone call. They were told they could receive a telephone intervention about alcohol use or home fire and burn safety; both of these topics were include in the baseline assessments masking which was the intervention of interest. We over-sampled to the TBMI group to allow for training cases that were not used in study analysis. Our final sample size was based on an effect size of 0.29 determined by meta-analysis studies of alcohol brief interventions[15,16] with 80% power to detect an effect, and a 2-tailed alpha of 0.05. Participants received $20 for completion of initial assessments in the ED, $20 for each intervention call, and $40 for completion of subsequent outcome assessments at 4, 8 and 12 months.

Interventions

TBMI is a semi-structured motivational interviewing (MI) based brief intervention for alcohol use, modified from our prior telephone intervention[12,13]. The study team developed the manualized protocol and a total of six interventionists were trained and supervised over the course of the study by a study investigator who is a licensed psychologist and member of the MI Network of Trainers. Those who had not been previously MI trained completed a two-day intensive training session on the principles of MI and all received training for the TBMI protocol. Members of the research team not involved in MI training assessed the interventionists' pilot TBMI interventions using the Motivational Interviewing Treatment Integrity (MITI) global ratings[17]. Global ratings are comprised of therapist Empathy and MI Spirit, an average of Evocation (extent to which clinician conveys understanding that motivation for change and ability to change resides within the client and focuses efforts to elicit and expand on it); Collaboration (treating the patient as an equal partner to work towards shared goals), and Autonomy/Support (extent to which the therapist supports and fosters the client's perception of his/her choice, instead of choosing to control the client's choices)[18]. Interventionists had to achieve ratings of 3 or more on all of the global rating scales on two consecutive pilot participants prior to starting to deliver TBMI to study participants. Throughout the study, supervision of counselors and fidelity to the protocol was achieved through reviews of recorded interventions and weekly group supervision meetings.

The home fire and burn safety (HS) intervention for the control group was developed by the first author as a scripted educational intervention to be approximately time equivalent to TBMI but did not discuss alcohol use. A total of five RAs with no MI training delivered the HS scripted intervention. To discriminate MI utilization between interventions, a random sample of 20% of recordings of telephone calls from both intervention groups throughout the study period was scored by the research team using MITI global ratings.

After each intervention, a second RA called all participants in both groups to complete a post-intervention call assessment of the participants' experience of the intervention using the Participant Rating Form (see measures below).

Methods and Measurements

The primary outcome was past 30 day alcohol use at 12 months and secondary measures included injuries and alcohol-related injuries, alcohol-related negative consequences and impaired driving frequency. Participants completed the initial baseline questionnaire during recruitment in the ED and follow-up questionnaires at 4, 8, and 12 months after recruitment. In addition, based on findings from another study that became available seven months after the study commenced, we wanted to test a reported finding of increased reporting of drinking after a counseling intervention was administered[19]. To do so, participants recruited after that time were queried again about their alcohol use for the 30 days prior to enrollment when contacted by a different RA to complete a post intervention call assessment. All data were collected electronically at baseline with participants completing assessments on a tablet computer connected via the internet to DatStat Illume (Seattle, WA). Follow-up assessments were also completed electronically with participants being sent a unique URL link to the web-based survey. Any participant who did not complete follow-ups using the Internet was called and assessment was conducted by telephone with the RA directly entering the data to DatStat Illume.

Alcohol use—ED patients' study eligibility was determined with the ASSIST v3.0. This substance misuse screening tool developed by the World Health Organization uses eight questions to assess lifetime substance use and substance use within the past three months. It uses scaled multiple choice responses to create individual scores for each substance of use including alcohol. For alcohol use, the ASSIST stratifies these scores into low (<11), moderate (11–26), and high (>27) risk categories, based on past three-month use. Three variables examined alcohol use during the study period and were measured at all assessment points: 1) frequency of binge alcohol use over the prior 30 days was assessed using gender-specific NIAAA guidelines (females 4 or more drinks; males 5 or more drinks), 2) maximum number of drinks at one time in past 30 days, 3) typical alcohol use - measured by participants stating average numbers of drinks on a drinking day in the past 30 days. Assessment of all three alcohol variables were re-administered after the first telephone call to both groups to again measure alcohol use 30 days prior to being recruited in the ED, as has previously been described.

Injuries—Participants' history of injury was collected at the baseline and 12 month assessments for the previous 12 months using the Injury Behavior Checklist (IBC)[20]. Injury occurrence (none, happened once, happened > once) for each of 16 injury types was queried and if the response was once or more, this prompted further questions about alcohol involvement and level of upsetness with the injury. We also collected data on ED-treated injuries by examining patient medical records. An RA, unaware of treatment condition, using an explicit protocol reviewed the patient's medical record and recorded the occurrence of any ED visits for an injury occurring during the 12 months prior and subsequent to study enrollment.

Negative consequences—Alcohol-related negative consequences were measured by the Short Inventory of Alcohol Related Problems (SIP), a 15 item subset of the Drinker Inventory of Consequences (DrInC)[21] that yields an equally valid measure of alcohol-related

consequences for ED patients[22]. The frequency of occurrence of each negative consequence over the past four months was coded as 0 = never; 1 = once/twice; 2 = once/twice a week; 3 = daily/almost daily. The negative consequence score was the sum total of endorsed negative consequences. The SIP was adapted for this study to include an additional question of upsetness for each negative consequence. Responses were coded as 0 = not at all upset; 1 = somewhat upset; 2 = very upset. The summary upsetness score was a ratio of the total upsetness score to the number of endorsed items. The SIP was administered at the baseline and 12-month assessments.

Driving—Participants were asked if they had driven in the prior four months. Those that had were administered the Impaired Driving Scale questions (IDS), a six-item scale that assesses drinking and driving behaviors[12].The IDS was administered at baseline, 4, 8, and 12 months. At the baseline and 12-month assessments participants were also asked if they had a motor vehicle crash (MVC) or a moving traffic violation (e.g. speeding, running a red light, driving while intoxicated) in the prior 12 months.

Intervention process measures—The investigative team refined a Participant Rating Form (PRF)[23] to assess participant experience of the intervention. The PRF was based on questions from prior studies[24–27]. Five of the refined PRF items assessed elements common to MI and most other therapeutic approaches: empathy, collaboration, evocation, acceptance, and developing discrepancy. Three items explicitly focused on alcohol use: decisional balance, giving feedback about how one's drinking compares to others, and developing a new understanding of how drinking affected one's life. Response alternatives were: strongly disagree, disagree, neither agree nor disagree, agree, or strongly agree. In addition to the PRF, participants in both groups were asked to state the topic of the phone discussion with the counselor with available responses: alcohol, home safety, both, or neither.

Data analyses

Data was transferred from the DatStat secure server to Microsoft Excel for preliminary data cleaning. Statistical analyses were conducted using SAS (Version 9.3, Carey, NC). Analysis of data distribution and homogeneity of variance were conducted and informed the selection of appropriate statistical tests. Analyses conducted with participant characteristics and outcome variables are reported with 95% confidence intervals (CIs). Bivariate analyses were conducted between the treatment groups (TBMI versus HS). Appropriate transformations of the data are indicated for each analysis. A sensitivity analysis was conducted to compare outcomes of the total sample randomly assigned to treatment with those randomly assigned who were actually exposed to treatment.

Changes in the primary dependent variables (DVs) of interest were assessed using a mixed effects modeling approach. We used a random intercept with fixed effects of group assignment, time and a time by group interaction in all models. These growth models were used to assess changes in the three alcohol use variables and total impaired driving score after covarying for the baseline values of the DV in each model. Individual responses were nested within time for the growth models. The additional baseline covariates were participant age, which was centered on the randomized group mean with one year

increments from the mean age for ease of interpretation; alcohol severity was entered as a binary variable (baseline ASSIST V 3 scores ≥ 11 < 26 versus ≥ 27), and gender also coded as a binary variable. Alternative approaches to the age variable were also included in the analyses with age being dichotomized into developmentally appropriate alcohol use groups (18–25 years and ≥ 26 years) as a comparison to the approach of centering age. For the growth models the time by group interactions were also entered into the model after the covariates as predictor variables. Absolute fit indices, the Akaike's Information Criteria and the Bayesian Information, are reported to indicate the overall fit of the growth models, and changes in model fit when a time by group interaction was entered into the growth models. For the variables measured at baseline and 12-months only (IBC and SIP), we predicted the effects of group on the 12-month scores after covarying for the baseline scores on these variables and the other previously listed covariates. To address issues of multiple comparisons and the inflation of Type 1 errors that can arise from this, the alpha for rejecting the null hypotheses was set to 0.01 for all outcome analyses.

Across the outcome variables of interest, data were examined for completeness. The growth models adjusted for data that were missing at each follow up, and only data available at the baseline and 12-months were included for the IBC and SIP analyses. Within each measure, missingness for individual items was examined. Individual item data could be missing because of a selected response that was not assigned a numerical value ('I do not know' or 'I refuse to answer) or because no response was given. The number of missing responses within each measure at each time point compared to the number of possible available responses was very small (< 2%); therefore no imputation method was employed. Participants were contacted for follow-up even if we were unsuccessful in contacting them to deliver their assigned intervention within the protocol time period.

Results

Characteristics of study subjects

There were 1,018 ED patients meeting eligibility criteria, with 730 recruited, completing baseline assessments and randomized to TBMI or HS (Figure 1). Of the 397 participants randomized to receive TBMI, 23 participants were for therapist training only either at the beginning of the study or during the trial when a change in staff occurred. These training cases were removed from the dataset for analysis, yielding a sample of 707 (TBMI=374; HS=333). Of these participants 549 (270 TBMI; 279 HS) were classified as exposed to their intended treatment by receiving at least the first intervention call and included in the analysis of all outcome variables. Study participants differed by age, with TBMI participants younger (Mean =31.2, 95%CI: 30.1, 32.4) than the HS group (mean = 34.7, 95% CI: 33.3, 36.2) (see Table 1). Between the group that received at least one call (either TMBI or HS, n = 549) and those assigned to do so but who did not (n = 158), only age was a different baseline characteristic, with those not receiving the call being younger (mean = 29.8, 95% CI: 28.2, 31.4) than those who did receive at least one call (mean = 33.8, 95%CI: 32.7, 34.9).

Intervention process measures results

Of the 707 participants randomized to an intervention, 549 (HS = 84%; TBMI = 72%) received at least one telephone intervention for home safety or alcohol and 511 (72%) completed the 12 months follow up assessment (70% TBMI; 75% HS) (see Figure 1). Of those receiving the first call, 24 (8.6%) of the HS completed only this call; 40 (14.3%) completed two calls in total and 215 (77.1%) completed all three calls. First call only completion was achieved by 33 (12.2%) of the TMBI group, 58 (21.5%) completed two calls and 179 (66.3%) completed all three calls. Consistent with MI theory encouraging participant discussion, the median length of time spent on calls, whether a participant completed one, two, or all three calls, was 40 minutes for the TBMI group but 24 minutes for the HS group. Almost all participants in the TBMI group (98%) reported that the intervention call discussed their alcohol use while 12% in the HS group reported alcohol use was discussed during these assessment control intervention calls. In scoring of the sample of audiotapes using MITI global ratings (TBMI n=52; HS n=50), the TBMI group had higher ratings for Empathy (TBMI: 4.43 95%CI 4.29, 4.57; HS 1.60 95%CI 1.44, 1.76) and Spirit (TBMI: 4.44 95% CI 4.32, 4.55; HS 2.19 95% CI 2.11, 2.28) than those in the HS group.

Main Results

Alcohol Use—At baseline the mean alcohol ASSIST score for the whole sample was 20 (SD = 7.7), and this was not different by assigned treatment group (HS = 19.7 95% CI: 19.9, 20.7; TBMI = 20.3 95% CI: 19.3, 20.1); or by receiving or not receiving the assigned treatment (received call = 20.1 95% CI: 19.8, 20.4; no call =19.9 95% CI: 18.7, 21.1). The remaining reported analyses are on participants who received at least the first intervention call (n = 549). Figure 2 displays the change in the three alcohol use variables across the four time points of assessments. Table 2 shows the unadjusted means and mean differences (with 95%CIs) for the alcohol use and driving variables for both groups.

Impaired Driving and Motor Vehicle Crash data—A summary score for the six impaired driving items from the IDS was calculated. Due to the extreme skewness of each item (with reports of each item in the past 4 months ranging from 0 to > 200) we used Chebyshev's inequality rule and truncated scores to cover 90% of the distribution of scores. Each item score within the IDS was truncated at a maximum of 6. Table 3 shows the bivariate analysis of difference in total IDS score at each of the four assessments. At the baseline assessment 75.6% of the TBMI and 72.8% of the HS reported driving in the past 4 months and were administered the IDS. Although IDS scores decreased over the time-points of assessment compared to baseline, IDS scores were similar between groups at each time point. There were no differences in the proportions of participants who reported driving between the two study groups. At the baseline and 12 month assessments those participants who indicated that they had driven were asked about their MVC and moving traffic violation history over the preceding 12 months. As can be seen in Table 2, the proportion of participants reporting a MVCs or moving traffic violations decreased between baseline and the 12 month assessment for both groups. However, this decrease did not differ between the groups.

Injuries—Scores for each item measuring injuries were summed and are reported in Table 3. Participants in both groups report fewer injuries (total and alcohol-related) at 12 months than at baseline assessment. The mean upsetness score for reported injuries and alcohol-related injuries did not differ between the groups at the baseline or 12-month assessments. Injury data abstracted from the medical record compared the number of injury related ED visits for the 12-month prior (including the injury related ED visit at which the participant was recruited into the study) to the number of injury visits in the 12 months following study recruitment. During the 12 months pre and up to recruitment the median number of ED injury visits for the HS group was 1 (IQR=0), and for the TBMI group also 1 (IQR = 1). In the 12 months following recruitment median number of injury visits was 0 (IQR = 1) for HS and 1 (IQR = 0) for the TBMI group. A logistic regression was conducted on the difference in odds ratio of returning for an injury ED visit in the 12 months post recruitment, after adjusting for the number of injury ED visits in the 12 months up to study recruitment. The adjusted odds of returning for an injury visit were not different between the groups (HS = referent group: AOR: 0.99; 95%CI: 0.67, 1.45).

Negative consequences—Table 3 also shows that at the 12 month assessment the HS group reported fewer negative consequences than the TBMI group, while the TBMI group was more upset by these negative consequences at the 12 month assessment.

Growth Models—Change in the three alcohol use variables and the IDS between 4, 8, and 12-months after covarying for the baseline scores, were modeled. Table 4 indicates the effects of group assignment and time after adjusting for the effects of additional covariates: age, alcohol severity, and gender. The log transformed score of the alcohol and IDS variables were used in these analyses. After adjusting for the effects of the baseline scores and the other covariates in these models, there was no group by time interaction, meaning that the rate of change in these outcome variables did not vary by group. The effect of group in the growth model for most number of drinks in the past 30 days reflects the difference at four-months between HS and TBMI, which has already been presented in the reporting of the unadjusted means. The absolute model fit indices, AIC and BIC, indicate that the predictive fit of the model explaining changes in alcohol did not improve when the group by time effect was included in these models. The alternative age variables (age 18–25 vs. ≥ 26) were also used in these models. There was no difference to the overall model fit or a different effect of group or the group by time interaction when age was entered as a dichotomous variable. Given the difference in mean age between the two groups and the importance of age in alcohol use research, interaction terms of age by group and age by group by time were added to these growth models for comparison. For ease of interpretation these data are not shown in Table 3; but across the three outcome variables change in alcohol use over time was not different between the younger and older participants, and this interaction effect was consistent across the groups.

We also modeled the change in injuries (total and alcohol-related) and alcohol related-negative consequences after baseline values of these variables and other covariates (age, alcohol severity, and gender) had been adjusted for. We also used the log transformed score for each of these outcomes. Table 5 presents the regression weights for each entered variable

with 95% CIs. The change in injuries and alcohol-related injuries are predicted by baseline upsetness for each injury type and by group assignment, and by baseline alcohol severity for alcohol related injuries. The overall predictive model was significant for 12-month injuries ($F(6,419) = 12.2$; $p < 0.001$) and alcohol-related injuries ($F(6,279) = 8.4$; $p < 0.001$). At 12-months for both injuries and alcohol-related injuries the TMBI group reported more than the HS group. Twelve month alcohol-related negative consequences (measured by the SIP), after controlling for baseline SIP scores, age and gender, were predicted by alcohol severity scores, with those in the higher alcohol severity group at baseline reporting more negative consequences at 12-months than those in the lower severity group. Adjusted 12-month SIP scores did not vary by group.

We compared data from re-testing participants at the first post-call assessment with three questions concerning their alcohol in the 30 days prior to recruitment, to their initial responses to these questions for the same time period when answered previously in the ED at enrollment. The mean number of most drinks decreased for the HS group by 1.12 drinks (95%CI: −1.75; −0.44); while it increased for the TBMI group; mean increase = 0.64 (95%CI: 0.27; 1.01 [mean difference between groups = −1.78; 95%CI: −2.81,–0.76]). This was also true for typical number of drinks which decreased on average by 0.94 (95%CI: −1.35; −0.53); drinks for HS, but increased by an average of 0.22 (95%CI: −0.38; 0.82 [mean difference between groups = −1.16; 95%CI: −1.88,–0.43]); drinks for TBMI. For males only, the report of binge drinking frequency decreased for the HS group (mean change = −1.75: [95%CI: −3.03; −0.43]; female mean change = −1.21: [95%CI: −1.63, −0.50]) but increased for male TBMI participants (mean change = 0.89: [95%CI: −0.81; 2.51[mean difference between groups = −2.60; 95%CI: −4.76,–0.44]]; female mean change TBMI = −1.64: [95%CI: −1.93, −1.23] [mean difference between groups = −0.43; 95%CI: 1.79]).

Sensitivity analyses—Of the 707 patients randomized to receive a TBMI or HS call, 158 could not be reached to initiate the protocol (thus providing a self-selected assessment only group). We had baseline data on all of these patients and follow-up assessment data on 67 of these participants. At baseline the only difference was between the assessment only group (i.e. did not receive assigned intervention) and the group that received the HS, with the assessment only group being younger than the HS group. There were no differences between the assessment only group and any of the treatment received groups, or when we compared the assessment only group to a combined HS and TBMI group on change in alcohol use, impaired driving, injuries or alcohol related negative consequences across the time points of data collection. We also conducted moderator analysis by examining the interaction effects of age, gender and baseline alcohol severity with group assignment on changes in alcohol use, impaired driving, negative consequences and injuries over time. There were no differences in the change in these outcome variables over time when these interactions were included in the prediction models.

Limitations

Interpretation of our data has some limitations. We recruited and randomized 75% of eligible ED patients who were approached in the ED. In our limited data of those who were eligible but did not participate, there was no mean difference in their ASSIST scores with

those participating, but these patients may have differed on other variables that could impact treatment effect. Our study was limited to patients at two hospitals and all TBMI counselors were supervised by one investigator. Other locations or training may have resulted in different findings. Our outcome analysis included only those participants who received at least one of the three telephone calls. As presented in Results section, those who did not receive their assigned telephone intervention did not differ in their ASSIST alcohol score but may have differed in other ways that we were not able to detect. Although the participants were blinded to which intervention they were to receive prior to the call, there was a differential rate for receiving the initial call. This may have been due to each intervention having separate research staff and differing efforts attempting to reach participants. Although unlikely, this may contribute to a possible Type II error. In asking patients the discussion topic of the telephone call they just had with the counselor, 12% of those in the HS group said it included alcohol. The HS intervention was a scripted intervention with no discussion of the participant's alcohol use, and the absence of alcohol in the HS intervention was confirmed by the study team who reviewed 20% of these calls. It is unclear if there was some participant perceived contamination (despite separate counselors delivering HS or TBMI). As the HS group was also asked about drinking in the past 30 days at the end of the first alcohol intervention, it may in fact have sensitized them to how alcohol could cause harm to their safety at home. Future investigation should focus on the composition of control groups and inadvertent active ingredients that may be present. We chose to test TBMI with injured patients as a strategy to decrease ED patient injury recidivism that is frequently encountered in ED clinical care. This eliminated many patients for consideration, as approximately 83% of ED visits are not for an acute injury. Injury itself may be enough of a motivator for change for many individuals and TBMI may have a differential effect if delivered to a non-injured ED population.

Discussion

On average participants in both groups improved, with decreased self-reported alcohol consumption and impaired driving at each of the follow-up assessment points following the intervention, relative to prior to the intervention. The greatest improvement was reported at four months post intervention, and this reduction in consumption was maintained through to the 8 month follow up point. While there was some increase in consumption from 8 to 12 months, at 12 months participants remained at lower levels of alcohol consumption and impaired driving in comparison with baseline rates. This pattern was consistent in both the TBMI and HS groups with no between-group differences. Injuries, alcohol-related injuries and negative consequences attributed to drinking also decreased from baseline to 12 month follow-up for both groups with no differential effect between groups. This pattern of observed results that the home fire and burn safety group, our assessment control group fared at least as well as the experimental group and with two variables trending towards better outcomes for the control group, leads us to ask whether neither intervention had any effect or whether both had equal effects or even if there was a negative differential effect of the intervention.

The group of participants who were not successfully contacted for the delivery of their assigned intervention but participated in follow-up assessments offers some potential

insight. Although not being randomized to this condition limits the ability to draw any firm conclusions, there was no difference in measured variables from those in this ad-hoc no intervention but assessed group. This suggests that an ED visit for injury itself may be enough to decrease alcohol use, impaired driving, and injuries for the average participant. An alternative explanation is that subject reactivity to the baseline assessments completed in the ED had an effect on participants' thinking about their alcohol use and its relationship to injury. This assessment effect has been discussed previously as a potential confounder of ED alcohol intervention studies with some research not supporting its impact[9,29,30].

We do have evidence that following the exposure to TBMI, participants experience alcohol as more salient in their lives. After the first telephone intervention session, a sample of participants in both groups was re-administered three questions regarding their alcohol consumption that they had completed during ED enrollment. We found that TBMI participants after their first intervention call reported more pre-ED visit alcohol use than they had previously reported in the ED whereas HS participants did not. This finding replicates results found in an earlier study with court adjudicated adolescents[19] and may indicate that the intervention influences participant's alcohol use recall by encouraging reflection and more self-disclosure about alcohol use and sways self-reported data. As we have only self-reports of alcohol use and no objective measure of drinking, we are unable to test this hypothesis. If the increased saliency of the TBMI is an effect then this may also in part explain differences in self-reported alcohol related injuries and negative consequences between the groups.

Most other successful ED based brief interventions for alcohol have been entirely or at least initially conducted within the ED[9,11]. No comparative study to date has been conducted to determine if treatment fidelity is equivalent between a telephone-based vs. a face-to-face based delivery of an MI intervention, or if certain elements of the MI approach, such as giving feedback, are more successfully implemented using the face-to-face approach to delivery. Fidelity to the relational components of MI, as measured by the MITI, were present in greater degree in the TBMI group, but there may be additional components of a successful MI brief intervention that are were not captured by MITI global ratings alone and were absent from TBMI. Our delivery of a telephone intervention offers practical advantages but may have limited the potential efficacy of the MI-based brief intervention. Others have used the ED to identify ill and injured young adult patients with hazardous alcohol use and deliver a text message intervention for alcohol reduction[31]. There were small reductions in alcohol consumption in this narrowly focused group of patients over a limited 3 month timeline. Further research is needed to identify effective brief interventions for alcohol misuse for injured patients that can overcome the ED's unique barriers to adoption, is translatable to the spectrum of EDs, and efficacious for the diverse ED patient population.

In summary, a telephone intervention for alcohol misuse delivered to injured emergency department patients with alcohol misuse did not decrease alcohol use, impaired driving, injuries, alcohol related injuries or alcohol related negative consequences any more than did assessment and a control intervention on home fire and burn safety.

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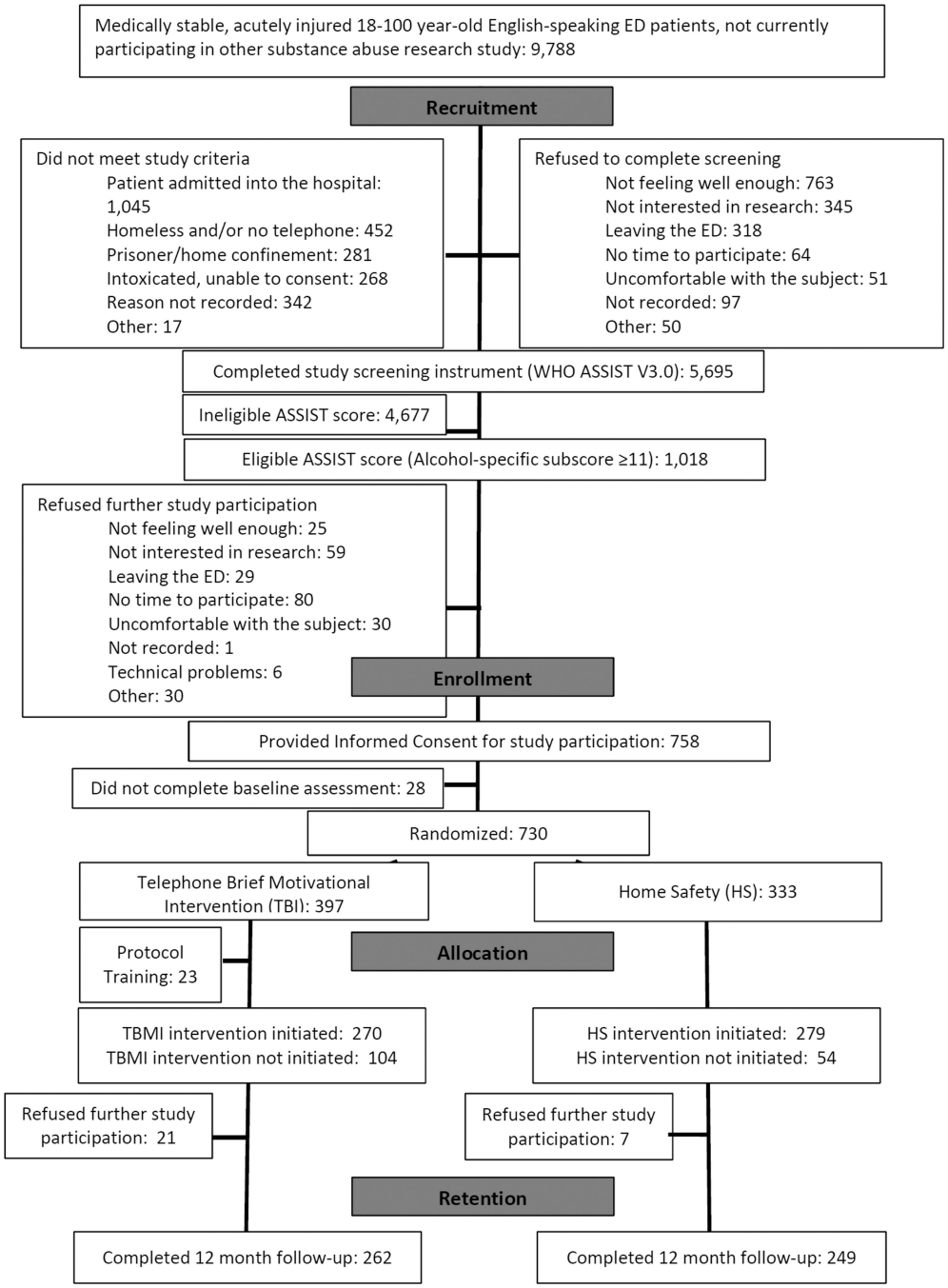

Figure 1.
Diagram of participants' recruitment, enrollment, allocation and retention

Figure 2.
Three Variables of Participant Alcohol Use at Baseline, 4, 8 and 12 Month

Table 1

Demographic characteristics of study sample

Variable	Sample (N=707)	TBMI (n_1 = 374)	HS (n_2 = 333)
Age			
(Mean; SD)	32.9 (12.5)	31.2 (11.4)	34.7 (13.4)
Gender			
% Female	35%	35%	36%
Race			
% White	71%	67%	75%
% Black	22%	25%	19%
% Other	7%	8%	6%
Insurance			
% Yes	66%	63%	68%
Education			
% < High school	22%	24%	20%
% High school	30%	28%	32%
% Some college	48%	48%	48%
Baseline ASSIST (mean; SD)	20.0 (7.7)	20.3 (7.7)	19.7 (7.6)

SD= standard deviation; n_1 = telephone brief motivational interview group (TBMI); n_2 = home safety group (HS)

Table 2

Mean alcohol use variables over time

Outcome	Baseline Mean* (95% CI) (n_1=279) (n_2=270)	4-months Mean* (95% CI) (n_1=247) (n_2 = 238)	8-months Mean* (95% CI) (n_1=236) (n_2 = 220)	12-months Mean* (95% CI) (n_1=230) (n_2= 211)
Alcohol				
Most number of drinks in past 30 days	HS: 8.03 (95%CI:7.29,8.77) TBMI: 8.30 (95%CI:7.49,9.11) Difference: −0.27 (95%CI:−1.38,0.83)	HS: 5.63 (95%CI:4.88,6.38) TBMI: 6.61 (95%CI:5.99,7.23) Difference: −0.98 (95%CI:−1.95, −0.01)	HS: 5.37 (95%CI:4.72,6.02) TBMI: 6.04 (95%CI:5.38,6.70) Difference: −0.67 (95%CI: −1.60,0.26)	HS: 5.94 (95%CI:5.20–6.68) TBMI: 7.05 (95%CI:6.18–7.92) Difference: −1.11 (95%CI:−2.25,0.03)
Typical number of drinks in past 30 days	HS: 5.04 (95%CI:4.54,5.54) TBMI: 5.48 (95%CI:4.86, 6.09) Difference: −0.44 (95%CI: −1.22,0.35)	HS: 3.37 (95%CI:3.91,3.83) TBMI: 3.34 (95%CI:2.92, 3.76) Difference: 0.03 (95%CI: −0.59,0.66)	HS: 3.05 (95%CI:2.60,3.49,) TBMI: 3.79 (95%CI:3.09,4.78) Difference: −0.74 (95%CI:−1.54,0.07)	HS: 3.20 (95%CI:2.82,3.58) TBMI: 3.62 (95%CI:3.10,4.1312.58) Difference: −0.42 (95%CI:−1.05,0.22)
How many days drink 4 or more (female) or 5 or more (male), in past 30 days	HS: 7.09 (95%CI:6.13–8.05) TBMI: 6.40 (95%CI:5.53–7.27) Difference: 0.69 (95%CI:−0.62,1.99)	HS: 3.77 (95%CI:3.06–4.48) TBMI: 3.89 (95%CI:3.15–4.63) Difference: −0.12 (95%CI: −1.15,0.91)	HS: 3.86 (95%CI:3.15–4.57) TBMI: 3.59 (95%CI:2.86−4.32) Difference: 0.27 (95%CI: −0.75,1.30)	HS: 4.35 (95%CI:3.48–5.22) TBMI: 4.76 (95%CI:3.81–5.71) Difference: −0.41 (95%CI:−1.70,0.88)

Unadjusted mean scores n_1 = home safety group (HS); n_2 = telephone brief motivational interview group (TBMI)

Table 3

Mean injuries, negative consequences and upsetness at baseline and 12 months

	Baseline Mean* (95% CI) (n_1=279) (n_2=270)	12-months Mean* (95% CI) (n_1=230) (n_2= 211)
Injury Behavior Checklist		
Injuries	TBMI: 2.75 (95%CI:2.50–3.00) HS: 2.86 (95%CI:2.60–3.12)	TBMI: 1.58 (95%CI:1.35–1.81) HS: 1.38 (95%CI:1.17–1.59)
Alcohol related injuries	TBMI: 1.63 (95%CI:1.41–1.85) HS: 1.73 (95%CI:1.50–1.96)	TBMI: 0.92 (95%CI:0.67–1.17) HS: 0.63 (95%CI:0.43–0.83)
Upsetness at injury	TBMI: 4.84 (95%CI:4.28–5.40) HS: 5.30 (95%CI:4.58–6.02)	TBMI: 3.67 (95%CI:3.20–4.14) HS: 3.70 (95%CI:3.04–4.36)
Upsetness at alcohol related injury	TBMI: 2.03 (95%CI:1.73–2.33) HS: 2.36 (95%CI:1.98–2.74)	TBMI: 1.23 (95%CI:0.89–1.57) HS: 0.91 (95%CI:0.55–1.27)
Short Inventory of Problems		
Negative consequences	TBMI: 8.69 (95%CI:7.80–9.58) HS: 8.78 (95%CI:7.75–9.81)	TBMI: 6.05 (95%CI:5.02–7.08) HS: 4.69 (95%CI:3.89–5.49)
Upsetness at negative consequences	TBMI: 7.79 (95%CI:6.92–8.66) HS: 7.95 (95%CI:6.93–8.97)	TBMI: 6.10 (95%CI:5.01–7.19) HS: 4.73 (95%CI:3.82–5.64)
Driving		
Had a MVC in past 12 month	TBMI: 32% (95%CI:29.0–35.0) HS: 29% (95%CI:26–32)	TBMI: 17% (95%CI:14.0–20.0%) HS: 13% (95%CI:11.0–15.0%)
Had a moving traffic violations in past 12 months	TBMI: 23% (95%CI:20.0–26.0) HS: 24% (95%CI:21–27)	TBMI: 15% (95%CI:12.0–18.0%) HS: 14% (95%CI:11.0–17.0%)

* Unadjusted mean scores n_1 = home safety group; n_2 = telephone brief motivational interview group

Table 4

Hierarchical regression of change in alcohol use and impaired driving over time

	≠Most number drinks		≠Typical number of drinks		≠Binge drinking frequency	
	β	**95%CI**	**β**	**95%CI**	**β**	**95%CI**
Baseline covariates (Step 1)						
≠Baseline DV values	0.43	0.35,0.51	0.21	0.15,0.27	0.37	−0.09,0.07
Age†	−0.01	−0.014,−0.006	−0.07	− 0.15,0.01	−0.01	−0.02,0.01
Alcohol severity	−0.01	−0.17,0.15	−0.35	− 0.47,−0.23	−0.08	−0.26,0.10
Gender	−0.14	−0.26,−0.02	−0.94	−3.02,1.14	−0.09	−0.23,0.05
Group	−0.14±	−0.28,−0.003	−0.75	−3.28,1.78	−0.08	−0.24,0.08
Time	0.03	−0.03,0.09	−0.01	−1.13,1.11	0.04	−0.02,0.10
	AIC 4454.8		*AIC 3927.9*		*AIC 5092.5*	
	BIC 3191.3		*BIC 3962.4*		*BIC 5127.0*	
Step 2						
Group * time	−0.01	−0.09,0.07	0.32	−1.27,1.91	−0.02	−0.12,0.08
	AIC 3148.2		*AIC 11234*		*AIC 3469.3*	
	BIC 4485.4		*BIC 11276.8*		*BIC 3512.2*	
	IDS Summary Score					
	β	95%CI				
Baseline covariates (Step 1)	0.38	0.22,0.54				
≠Baseline DV values	−0.01	−0.05,0.03				
Age†	−0.91	−2.28,0.46				
Alcohol severity	−0.81	−1.87,0.25				
Gender	0.99	−0.46,2.44				
Group	−0.05	−0.91,0.81				
Time						
	AIC 4008.8					
	BIC 4043.3					
Step 2						
Group * time	−0.61	−1.81,0.59				

	≠Most number drinks		≠Typical number of drinks		≠Binge drinking frequency	
	β	95%CI	β	95%CI	β	95%CI
	AIC 6740.9					
	BIC 6780.9					

≠Log score

†Age centered at group mean;

AIC=Akaike's Information Criteria; BIC = Bayesian Information Criteria;

*±At 4-months HS < TMBI

Table 5

Regression of change in IBC injury scores and SIP negative consequences scores

Model	**≠Injury**		**≠Alcohol related injuries**	
	β	**95%CI**	**β**	**95%CI**
Baseline covariates (Step 1)				
≠ Baseline DV values	0.39	0.29,0.49	0.23	0.13,0.33
Age†	−0.01	−0.01,−0.006	−0.001	−0.01,0.003
Alcohol severity	−0.01	−0.15,0.13	0.18	0.04,0.32
Gender	− 0.02	−0.14,0.10	−0.03	−0.15,0.09
	R^2 = 0.13		R^2 = 0.10	
Step 2				
Baseline upsetness	0.12	0.002,0.24	0.21	0.15,0.27
	R^2 = 0.14 ; ΔR^2 =0.01		R^2 = 0.12; ΔR^2 =0.02	
Step 3				
Group	±0.10	0.002,0.20	± 0.14	0.02,0.26
	R^2 = 0.15; ΔR^2 =0.02		R^2 = 0.14; ΔR^2 = 0.02	
Model	Alcohol related negative consequences			
	β	95%CI		
Baseline covariates (Step 1)				
≠ Baseline DV values	0.40	0.24,0.56		
Age†	−0.01	−0.02,−0.004		
Alcohol severity	0.30	0.07,0.54		
Gender	0.16	−0.02,0.34		
	R^2 = 0.19			
Step 2				
Baseline upsetness	−0.18	−0.36,−0.004		
	R^2 = 0.17 ; ΔR^2 =−0.02			
Step 3	0.15	−0.03,0.33		
Group	R^2 = 0.17; ΔR^2 =0.00			

≠Log score;

†Age centered at group mean;

AIC=Akaike's Information Criteria; BIC = Bayesian Information Criteria;

*± HS < TMBI