Research Article

Effectiveness of Stay Strong Treatment of Alcohol-Related Trauma: Results of a Randomised Controlled Trial

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Abstract

Alcohol use is a leading risk factor for global disease burden and causes extensive harm. In the Australian community, First Nations Australians are slightly more likely to abstain from alcohol than non-First Nations Australians, but among those who do drink, a higher proportion drink at risky levels. The Northern Territory has the highest proportion of the Australian population identifying as First Nations people. Brief interventions have been shown to decrease alcohol consumption in a wide array of clinical settings, but little is known regarding the effects of brief interventions in high-risk drinkers with facial trauma. Across the world facial fractures are predominantly driven by falls [1]. However, in the NT, assault related to alcohol intoxication is the most frequent cause of these injuries [2]. The objective of this trial was to test the effectiveness of a brief, culturally adapted intervention (Stay Strong Motivational Care Planning) for high-risk drinkers admitted to a Northern Territory hospital with facial trauma. The study used a two-group parallel, randomised controlled design with a 6-month follow-up period. Facial trauma patients admitted to the maxillofacial unit, aged 12 years or over and scoring 6 or more on the brief screening version of the Alcohol Use Disorder Identification Test (AUDIT-C), were randomly allocated to receive either one session of Motivational Care Planning (MCP), or Treatment as Usual (TAU). The primary outcomes were alcohol use on the AUDIT-C and distress on the Kessler 6; secondary outcomes were alcohol and cannabis dependence on the Substance Dependence Scale. Data were analysed using mixed linear models, to allow reports using intention to treat. A total of 85 participants (54 First Nations and 31 non-First Nations) were recruited between December 2010 and July 2012. Follow up was extended from 6 to 18 months due to challenges in locating and assessing participants post-discharge. From baseline to final assessment, MCP showed significantly greater reductions than TAU in AUDIT-C, alcohol dependence and emotional distress. Cannabis dependence showed a reduction over time, but no differential reduction after MCP. Compared with TAU, MCP was effective at reducing high-risk drinking and distress, and may provide an effective low-intensity treatment for patients with facial trauma.

Introduction

Alcohol use is a leading risk factor for global disease burden [3,4]. In Australia, it remains a significant source of harm to both users and their community through productivity losses, traffic accidents, crime, and health care costs [5,6]. In addition, the rate of total burden of disease attributable to illicit drug use has increased by 35% between 2003 and 2018 of which cannabis use accounted for 10% [7]. First Nations Australians are slightly more likely to abstain from alcohol than non-First Nations Australians, but among those who do drink, a higher proportion drink at risky levels [5]. Most First Nations populations in colonised countries such as Australia experience poorer health outcomes than their non-First Nations counterparts. These disparities are often linked to historical, economic, and social factors including the shaping of health systems by colonial policies and practices [8-11].

The Northern Territory (NT) of Australia has the smallest population of all Australia's states and territories, but the highest proportion of the population identifying as First Nations people (around 30% compared with 3.3% in Australia overall) [5]. It also has the highest proportion of people who engage in life-time risky drinking (24%) and single-occasion risky drinking at least monthly (34%)[5]. Alcohol use was the second largest contributor to total disease burden in 2018 in the NT with injuries more than twice the national rate and hospitalisation for assault 15 times as likely [12,13]. One frequent type of assault-related injury involves facial fractures [13]. They are ubiquitous globally, can be associated with significant disability, and treatment can lead to extensive consumption of hospital resources [14-15]. Across the world facial fractures are predominantly driven by falls [1]. However, in the NT, assault related to alcohol intoxication is the most frequent cause of these injuries [2]. Despite increasing evidence of effectiveness of screening and brief intervention to reduce harmful alcohol consumption in emergency care settings [16], including for those with alcohol related facial trauma [17,18], there remains a scarcity of evidence regarding their effectiveness for Australians First Nations people.

The World Health Organization (WHO) urges action to increase the capacity of health care services to deliver prevention and treatment interventions for hazardous use of alcohol, including screening and brief interventions in all settings [11]. Prioritising the involvement, collaboration and empowerment of First Nations communities and leadership is deemed critical to successful transformation of healthcare [11,19]. The Aboriginal and Islander Mental Health Initiative (AIMhi) in the Northern Territory has conducted foundational work over two decades developing culturally responsive wellbeing interventions through grass roots involvement with First Nations people. The 'Stay Strong Plan' is one such tool which has promising evidence of effectiveness [20]. The tool guides delivery of a brief intervention, 'Motivational Care Planning' (MCP). It adopts an empowering, person-centred, holistic and strengths-based approach which acknowledges and promotes First Nations cultural and family values and self-management [21].

This study aimed to evaluate the effectiveness of MCP for patients hospitalised with alcohol-related facial trauma in Royal Darwin Hospital, the main hospital for the Northern Territory. While some of these patients were expected to come from First Nations communities, the study was open to all who had high-risk drinking.

Methods

Design

A two-group parallel, randomised controlled design with 6-month follow-up was planned. We hypothesised that the brief intervention (Motivational Care Planning) would be superior to usual care in reducing alcohol consumption and psychological distress for high-risk drinkers admitted to hospital with facial trauma. The two treatment conditions were MCP treatment using the Stay Strong Plan, and Treatment as Usual. The trial protocol has been published [22] and was conducted in accordance with the CONSORT statement (http://www.consort-statement.org) for clinical trials.

Consent, ethics, and culturally appropriate approach

The Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research approved this study, which was subsequently registered on the Australian New Zealand Clinical trials registry (ACTRN12611000135910). Informed consent was obtained from all participants by trained First Nations and non-First Nations research officers using pictorial information sheets in plain English. The screening and assessment tools were also adapted to pictorial form allowing ease of understanding in the cross-cultural context. The research team was advised about study procedures from the Menzies Healing and Resilience Indigenous Reference Group which comprised senior First Nations managers, clinicians, and cultural advisors.

Setting and participants

Facial trauma patients admitted to the maxillofacial unit at Royal Darwin Hospital between 08/12/2010 and 04/07/2012 were screened using the Alcohol Use Disorders Identification Test consumption questions (AUDIT-C). This structured screening tool is recommended for assessment and determination of clients at risk from drinking alcohol who may require support [23,24]. Those with an AUDIT-C score of 6 or more who met inclusion criteria were invited to provide written consent to participate. Exclusion

criteria were: inability to provide informed consent, AUDIT-C Score<6, a current diagnosis of mental illness, age less than 12 years, and teenagers (12 to 18 years) without parental consent.

Randomisation

A statistician who was independent of the study team prepared the randomisation code. Blocking was used to ensure an approximate balance in numbers between groups throughout the study. Codes were contained within monitored, sealed envelopes, which were only opened by the allocated member of the study team after the completion of the baseline assessment, to avoid any influence on eligibility assessment.

Blinding

Participants were blinded to treatment condition. The control group participants were assessed for a comparable length of time and given a handout which was similar in appearance to that of the intervention group. Research team members who had delivered the intervention were restricted from conducting follow up assessments. Due to resource constraints linked with delay in follow up, 10% of follow up assessments were conducted by the project manager who was not blinded to intervention assignment.

Treatment conditions

In addition to usual facial trauma care, all participants allocated to the intervention group received one 20 to 30-minute session of Motivational Care Planning (MCP) delivered using the Stay Strong Plan. This intervention incorporates incentives to change through developing discrepancy (**building awareness** in the difference between one's current behaviour and a desired different outcome or behaviour), goal setting, and problem-solving. It is described in detail in the protocol [25-27]. Participants randomised to TAU received usual care, with the addition of a pictorial information sheet about the risks of heavy drinking that was prepared by the research team in consultation with the study's Expert Reference Group. This group combined policy makers and experienced Alcohol and other Drug clinicians from government and non-government settings and First Nations organisations.

Fidelity of the intervention

The interventions were delivered by trained researchers with step-by-step prompts to support fidelity. Review of participant treatment records and regular feedback encouraged researchers to adapt their mode of treatment delivery as needed. These study processes laid groundwork for development of the MCP adherence scale (MCP-AS) [28].

Data collection

Facial trauma patients admitted to the maxillofacial unit at Royal Darwin Hospital between 08/12/2010 and 04/07/2012 were assessed for eligibility through discussion with their medical treatment team. Eligible patients were invited by research staff to participate in the study and screened via face-to-face interview using the AUDIT-C. Those meeting inclusion criteria were assessed at baseline and after 6 months. The original protocol proposed two follow-up points (3 months and 6 months), but the team later predicted challenges with follow up and adapted the protocol to one follow-up point only. In order to minimise dropout, the researchers obtained at least three means of contacting the participants at recruitment (phone numbers and address). Follow up challenges included remote residence and lack of stable accommodation. Follow up protocol was adapted from 6 months to 18 months post-baseline where participants could not be contacted earlier (15% of follow up assessments were completed within 6 months). In addition, a small proportion (<10%) of follow up assessments were conducted via telephone interview rather than entirely face to face assessment as planned in the protocol.

Measures

Primary outcome

The primary outcomes were usual self-assessed alcohol consumption as measured by the AUDIT-C and psychological distress over the previous 4 weeks on the 6-item version of the Kessler distress scale (K6) [29]. The published protocol reported the primary outcome as change in standard drinks consumption per day. This change was to be measured using event-cued recall in a Timeline Followback (TLFB), or the AUDIT-C where the full TLFB could not be obtained [30]. During the study, collection of data on the TLFB proved challenging as participants were usually sharing drinks with groups of varying size, and were often drinking out of makeshift containers. Accurate assessment of periods of consumption and abtinence was not possible. As a result, the AUDIT-C was used to estimate usual alcohol consumption over the previous 12 months. Analyses using the TLFB alcohol consumption, alcohol abstinence days, cannabis use per day, and cannabis abstinence days are not reported given the unreliability of the data.

Secondary outcomes

Secondary outcome measures were the Severity Dependency Scale (SDS) for alcohol and cannabis use (assessing use over the previous 4 weeks) [31].

Demographic information

Data pertaining to age, sex, ethnicity, place of residence, and employment status were collected through clinical record review and baseline interviews.

Sample size and power

The original sample size calculation aimed to detect a minimum difference of 0.5 SD in weekly alcohol consumption (with 80%

power and an alpha of 0.05) leading to an original target baseline sample size of 154. This target sample size allowed for 20% attrition. However, only 85 participants could be recruited, 8 of whom (10.6%) were lost to follow up (Figure 1).
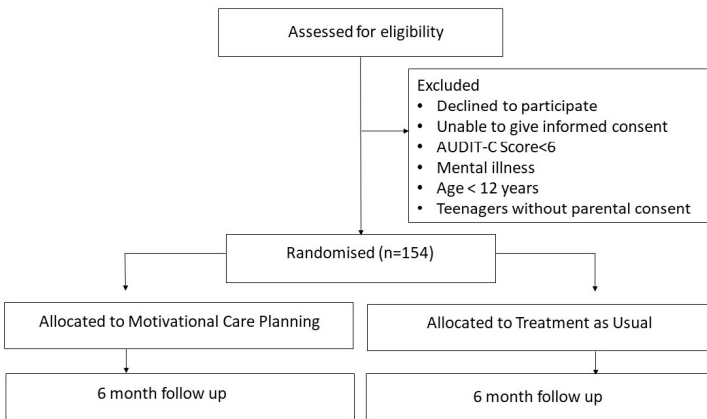

Figure 1: CONSORT Diagram.

Data analysis

All primary and secondary outcomes were assessed at baseline and follow-up. Follow up occurred between 6 and 18 months. Follow up data were pooled for analysis. Baseline descriptive statistics are presented in Table 2.

Primary analysis

The intervention groups were compared on baseline demographics using ANOVAs with Condition and Sex as independent variables. The primary analyses used intention to treat on the full baseline sample (or in the case of dependence on cannabis, on the full sample with baseline scores > 0). Linear mixed models in SPSS version 25 (IBM Corp, Armonk, NY, USA) were conducted on the primary outcomes of alcohol consumption and psychological distress, and the secondary outcome of the severity of alcohol and cannabis dependence. These analyses examined effects of Condition, Time, Sex and their interactions. In each case, the accepted model included random intercepts and used Restricted Maximum Likelihood and Satterthwaite approximation of degrees of freedom. Models that included all three independent variables provided better fit than those omitting one or more.

Results

Participant recruitment and sample characteristics

There were 303 facial trauma patients admitted to the maxillofacial unit between 08/12/2010 and 04/07/2012 at RDH in the NT. Logistical reasons impeded the recruitment of 104 of those patients (short hospital stay, research staff not available after hours, patients unavailable due to investigations, surgery, leaving hospital against medical advice, and physical discomfort). Of the 199 potential recruits approached, 54 First Nations and 31 non-First Nations participants were screened and entered the study (Figure 1). The period for follow-up data collection ranged from 6 to 18 months. No participant in the group formally withdrew from the study and 90% of participants were followed up. Participants were mostly male (88.8%) with mean age approximately 30 years in both allocation groups, 5.8% of whom were underage drinkers (<18 years old) (Table 1). Ethnicity differed significantly between the two groups at baseline ($P = 0.01$) with more First Nations participants in the MCP group. Of the 85 participants, 76 were from seven regions of the NT (45 of whom were from West Arnhem Land), 5 were from interstate regions and 4 did not provide any residential information. Thirty participants (35%) had a cannabis dependence score on the SDS > 0 (16 in MCP and 14 in TAU; χ^2 (1) = 0.01, P = .94). No outcome measures showed differences in baseline levels between conditions (P = .308-.420) or any Condition by Sex interaction (P = .090-.670).

Characteristics	MCP N = 45 N (%)	TAU N = 40 N (%)	Total N = 85 N (%)	*P* value
Gender				
Male	35(77.8)	32 (80)	67 (78.8)	0.81
Age				
≥ 19 years	2 (4.4)	3 (7.5)	5 (5.8)	
20 to 29 years	23 (51.1)	19 (47.5)	42 (49.4)	
30 to 39 years	11 (24.4)	7 (17.5)	18 (21.2)	
40 to 49 years	6 (13.3)	6 (15.0)	12 (14.1)	0.5
50 to 59 years	3 (6.7)	3 (7.5)	6 (7.1)	
≥ 60 years	0 (0.0)	2 (5.0)	2 (2.4)	
Ethnicity				
First Nations	34 (75.5)	20 (50)	54 (63.5)	0.01
Employment*				
Employed	20 (44.4)	19 (47.5)	39 (45.9)	0.2
Age in years (mean, SD)	30.6 (9.7)	32.2 (12.3)	31.4 (11.0)	

Table 1: Baseline demographic characteristics by condition; *Part-time or full-time paid employment.

Analyses of primary and secondary outcomes

Results of the linear mixed models analyses are displayed in Tables 2 and 3. Significant reductions in all outcomes occurred over time, and for all outcomes except cannabis dependence (P = .657), improvements were greater in the MCP condition (P < .001). None of those interactions was significantly modified by Sex.

Outcomes	Condition	Sex	Baseline, mean (SE)	6-18 months, mean (SE)
Primary outcomes				
AUDIT-C	MCP	Female	8.20 (0.52)	2.64 (1.08)
		Male	9.20 (0.28)	6.40 (0.54)
	TAU	Female	7.63 (0.58)	7.61 (1.15)
		Male	9.00 (0.29)	9.14 (0.56)
Kessler 6	MCP	Female	16.20 (1.84)	8.40 (2.07)
		Male	12.00 (0.98)	8.46 (1.05)
	TAU	Female	13.25 (2.05)	13.96 2.23)
		Male	12.44 (1.03)	15.80 (1.09)
Secondary outcomes				
SDS alcohol[1]	MCP	Female	11.00 (1.08)	6.87 (1.05)
		Male	9.03 (0.58)	6.24 (0.53)
	TAU	Female	8.50 (1.21)	8.31 (1.12)
		Male	9.66 (0.60)	12.01 (0.55)
SDS cannabis[2,3]	MCP	Female	11.50 (3.10)	10.50 (3.73)
		Male	9.14 (1.17)	1.90 (1.46)
	TAU	Female	6.67 (2.53)	3.33 (3.05)
		Male	9.82 (1.32)	7.64 (1.59)

Table 2: Estimated means and SDs for primary and secondary outcomes;[1]SDS Alcohol: Severity Dependence Scale for alcohol use; [2]SDS Cannabis: Severity Dependence Scale for cannabis use;[3]Uses sample with a score > 0 at Baseline (n = 30; 16 in MCP and 14 in TAU).

Discussion

This study found improvement in alcohol misuse, emotional distress, and severity of dependence in patients with alcohol-related trauma in response to a brief culturally responsive intervention that was delivered soon after hospitalisation. These benefits were detected 6 -18 months post-baseline without any interim treatment. While significant differential improvements in cannabis dependence were not observed, that was not the primary focus of the intervention, and was only a problem for a minority of participants.

	Primary Outcomes						Secondary Outcomes					
	AUDIT-C			Kessler 6			SDS alcohol[1]			SDS cannabis[2,3]		
	df	F	P	df	F	P	df	F	P	df	F	P
Intercept	1,76.91	828.07	<.001	1,78.38	332.29	<.001	1,78.38	605.96	<.001	1, 25.82	64.28	<.001
Condition	1,76.91	15.09	<.001	1,78.38	3.55	.063	1,78.38	3.36	.071	1, 25.82	0.55	.466
Gender	1,76.91	10.62	0.02	1,78.38	0.32	.574	1,78.38	0.60	.441	1, 25.82	0.22	.646
Time	1,75.10	24.12	<.001	1,74.61	4.44	.039	1,75.73	5.59	.021	1, 25.50	5.13	.032
Condition x Gender	1,76.91	0.17	.667	1,78.38	0.88	.351	1,78.39	6.58	.012	1, 25.82	5.95	.022
Condition x Time	1,75.10	25.48	<.001	1,74.61	19.92	<.001	1,75.73	20.33	<.001	1, 25.50	0.20	.657
Gender x Time	1,75.10	1.03	.313	1,74.61	4.01	.049	1,75.73	3.72	.058	1, 25.50	0.70	.410
Condition x Gender x Time	1,75.10	0.73	.396	1,74.61	0.21	.645	1,75.73	0.36	.551	1, 25.50	1.48	.235

Table 3: Fixed effects from linear mixed models analyses on the primary and secondary outcomes;[1]SDS Alcohol: Severity Dependence Scale for alcohol use; [2]SDS Cannabis: Severity Dependence Scale for cannabis use; [3]Uses sample with a score > 0 at Baseline (n = 30).

The demographic characteristics of the participants were consistent with previous studies involving alcohol-related trauma patients [32-37], except for the high proportion of First Nations patients. High baseline levels of substance misuse, substance dependence and emotional distress were observed in participants of both groups consistent with previous research in this setting [20]. The findings of benefit were consistent with those of previous studies in trauma care settings which found significant effects, even via single sessions [34-36] as well as through multiple sessions of brief interventions [38,39].

Studies involving primary care centres [40-43] and adult patients [44] also found that an intervention of 15-30 minutes that was delivered by health professionals led to a reduction in heavy and harmful alcohol use. Further, the present findings were consistent with the results of studies in different cross-cultural settings in western countries which affirm the positive potential of using emergency trauma admissions as an opportunistic setting for conducting brief interventions addressing alcohol misuse [33-35].

Our findings suggest that Stay Strong planning may offer an effective brief intervention in clinical settings in the NT for addressing alcohol-related harm, as recommended by clinical guidelines [46,47].

Limitations and Strengths

This study focused on facial trauma patients admitted to one hospital setting in Australia. There is thus uncertainty about the generalisability of the findings to other clinical settings. However, many of the demographic characteristics of the participants were consistent with patients recruited from other medical settings [33,48,49].

Given that 17.5% of eligible patients were not recruited, the participants may not be representative of the patient population we studied. In addition, as the randomisation was not stratified, the study did not equalise for First Nations status across conditions. The nature of this patient group meant that it had a majority of young males. As a result, findings for females were based on small subsamples within conditions. Due to resource constraints, 10% of follow-up assessments were conducted by a study team member who was not blinded to intervention assignment. The risk of potential bias in follow up assessments is minimised since all outcomes are self-reported. The study departed from the planned follow-up period due to the complexity of following up remote and itinerant participants post-discharge. The follow up period was thus extended from 6 to a maximum of 18 months. Implementing the approach as standard practice with clinical staff instead of researchers may face challenges such as maintaining treatment fidelity, addressing cross cultural issues, ensuring practitioner support and managing competing service demands [33].

A key strength of this study is that it provides additional research support for this culturally responsive brief intervention [20]. Since the conclusion of data collection, this Stay Strong Motivational Care Planning approach, has been transformed to digital format (the Stay Strong app), with additional evidence of acceptability and effectiveness [50,51]. This study affirms the continued utility of the original hard copy format, still preferred by a proportion of workers in the field. Another strength is the high rate of engagement and follow up that was achieved in a population scattered thousands of kilometres across the remote Northern Territory.

Recommendations

The study introduces a practical and potentially cost-effective approach to integrating brief interventions within the hospital setting (trauma and emergency), with the likelihood of significant benefit for at-risk drinkers with facial trauma in the NT population. Training and guidance for healthcare professionals can support fidelity of delivery of evidence-based brief interventions such as MCP. Future research might seek to replicate these findings in this and other settings and evaluate implementation within consistent frameworks to maximise comparability with other studies.

Conclusions

This study demonstrates that a brief culturally adapted intervention (MCP) was effective at reducing high-risk drinking and emotional distress and may provide a feasible low-intensity treatment for this population.

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