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Moderators of the Effectiveness of a Brief Negotiation Intervention for Harmful Alcohol Use in Injured Adults at Northern Zone Referral Hospital in Tanzania

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Research Article

Keywords: Brief Negotiation Intervention, harmful alcohol use, moderation analysis, trauma

Posted Date: November 11th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-11688311/v1

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Additional Declarations: The authors declare no competing interests.

MODERATORS OF THE EFFECTIVENESS OF A BRIEF NEGOTIATION INTERVENTION FOR HARMFUL ALCOHOL USE IN INJURED ADULTS AT NORTHERN ZONE REFERRAL HOSPITAL IN TANZANIA.

Short Title: MODERATORS OF EFFECTIVE BRIEF NEGOTIATION INTERVENTION FOR HARMFUL ALCOHOL USE

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ABSTRACT

Background: Harmful alcohol use is a leading global health risk, with a disproportionately high burden in Africa. A culturally adapted Brief Negotiation Intervention (BNI), “Punguza Pombe Kwa Afya Yako” (PPKAY), was developed in a prior study and demonstrated effectiveness in reducing harmful alcohol use among those who presented with trauma. This study aimed to evaluate BNI's effect on drinking days, drinks consumed, and binge drinking days, and to examine moderators of this effect, among injured adults presenting to Kilimanjaro Christian Medical Center (KCMC) Emergency Medicine Department (EMD).

Methodology: This was a secondary analysis of the Stage 1 cohort (2020-2025) Pragmatic Randomized Adaptive Clinical Trial (PRACT). A total of 584 injured patients with harmful alcohol use were randomized to BNI (PPKAY) (n=413) or Usual Care (n=171). Outcomes were drinking days, drinks consumed, and binge drinking days at 3-month follow-up (Timeline Follow-back), as well as moderators for effective BNI. Mixed-effects zero-inflated negative binomial regression assessed the effect of BNI and nine moderators, with cluster-robust negative binomial regression as a sensitivity analysis.

Results: BNI (PPKAY) significantly reduced all three outcomes at 3 months versus Usual Care: drinking days by 58% (IRR=0.42, $p<0.0001$), drinks consumed by 65% (IRR=0.35, $p=0.0001$), and binge drinking days by 69% (IRR=0.31, $p=0.0028$). Only education moderated these effects (interaction $p=0.024$, 0.018, 0.029). Drinking days fell by 71% (IRR=0.29) with primary education or less, versus a non-significant 28% (IRR=0.72) with secondary education or higher. BNI estimates favored intervention in every subgroup, with non-significant trends toward larger reductions among non-agricultural workers, married or partnered patients, and those with less serious injuries.

Conclusions: PPKAY reduced harmful alcohol use across all three outcomes and in every subgroup examined; education was the only significant modifier, with the largest reductions among patients with primary education or less. PPKAY should be integrated into routine

emergency care for all injured patients, delivered verbally in Kiswahili by trained nurses, with SMS boosters evaluated for patients with secondary education or higher.

Keywords: Brief Negotiation Intervention; harmful alcohol use; moderation analysis, trauma

Background

Harmful alcohol use is one of the leading preventable causes of death and disability worldwide. The World Health Organization (WHO) estimated that alcohol caused 2.6 million deaths in 2019, equal to 4.7% of all deaths globally (1). Injuries are a major part of this burden, accounting for 28%, including road traffic accidents, self-harm and interpersonal violence (1). Globally, about 400 million adults (7%) are living with an alcohol use disorder (AUD), including 209 million (3.7% of adults) with alcohol dependence (1). The harm is concentrated in young people (59.1% aged 15-39 years) and men (76.9% male) (2).

Sub-Saharan Africa presents a paradox as about 58% of people in the WHO African Region do not drink, yet drinkers in the region tend to drink heavily, and the alcohol-attributable death rate in the African Region was 52.2 per 100,000 population, second only to the European Region (52.9 per 100,000) (1,3,4). Tanzania also illustrates this pattern. WHO estimates that 30.1% of Tanzanian adults consume alcohol (39.2% of men and 21.4% of women), and 6.8% have AUD, which is nearly double of the estimated Africa rate of 3.7% (1).

Alcohol is common among injured patients presenting to KCMC, where it's been shown that 30.1% of trauma victims had consumed alcohol (5). Despite the burden of trauma related to alcohol, screening and brief intervention are rarely available in the emergency care (5,6)(7). The PRACT trial has shown that PPKAY reduces binge drinking at 3 months among injured patients at KCMC, but the evidence on which patients benefit most, and which may need more than a single brief encounter, is limited (8).

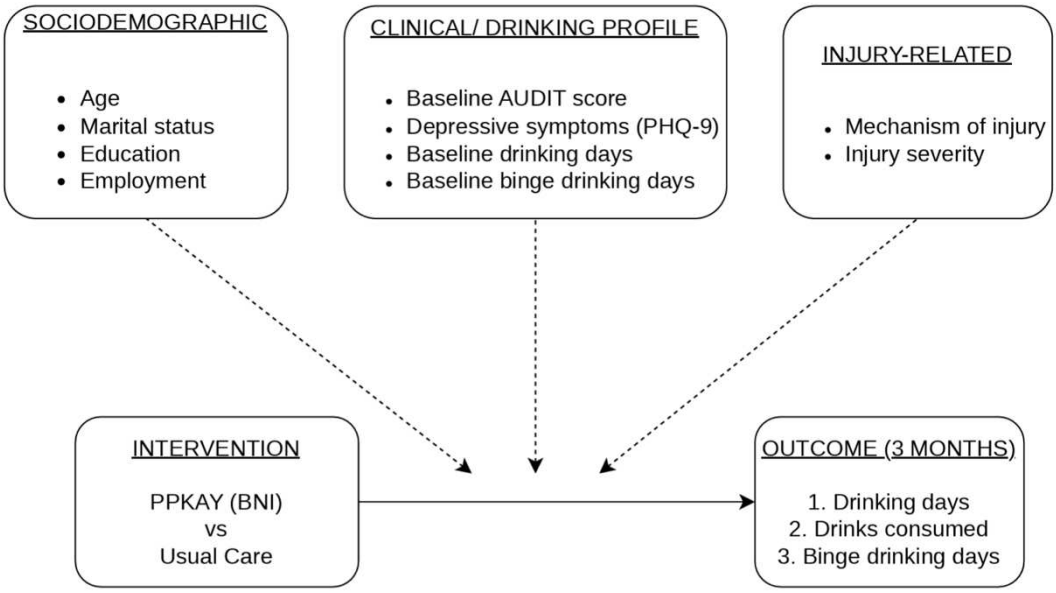
International evidence shows that brief-intervention effects are not uniform, and is affected by factors such as; baseline drinking severity, education, age, and also injury severity (9–12). It is unknown whether these patterns apply in a Tanzanian ED, where the patient population, injury profile and drinking culture differ from the high-income settings in which most evidence was generated. Without this evidence, PPKAY risks being implemented as a uniform intervention when some patient groups may need closer follow-up or more intensive support,

or when others may already be well served by a single brief encounter. This study addresses this practical gap.

Conceptual framework

This secondary analysis draws on three frameworks. First, Teachable Moment theory proposes that an acute health event heightens perceived risk, emotional response and openness to changing one's self-concept, so that drinking may fall in both arms and PPKAY may amplify and sustain this response (13). Second, the AMES model of motivational interviewing describes the patient-centered, non-prescriptive way in which PPKAY works, and suggests that patients with different backgrounds may respond differently to the same conversation (14). Third, the Social-Ecological Model, together with moderation theory (Kenny and Baron, 1986; Brookes *et al.*, 2004), supports the examination of whether intervention effects differ across individual, injury-related and clinical characteristics (15,16).

The framework places PPKAY, compared with Usual Care, as the intervention, drinking days, drinks consumed and binge drinking days at 3 months as the outcomes, and nine baseline patient characteristics as potential moderators: education, employment type, marital status, age, mechanism of injury, injury severity, baseline AUDIT score, depressive symptoms (PHQ-9) and baseline drinking (days and binge days). The framework is adapted from the moderator-diagram convention of Kenny and Baron (15). **Figure 1**



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116 Figure 1: Conceptual framework of the moderating pathways in the PPKAY effectiveness

117 model.

METHODOLOGY

Description of the Data Source

This was a secondary analysis of the PRACT trial (Pragmatic Randomized Adaptive Clinical Trial; ClinicalTrials.gov NCT04535011), a multi-arm randomized trial. The trial protocol has been published (Staton, Minnig, *et al.*, 2022).

Study design

PRACT is a pragmatic, adaptive randomized trial. In Stage 1, the Brief Negotiation Intervention (BNI), known as PPKAY, delivered with a weekly text-message (SMS) booster, was compared with Usual Care, whereas later stages of the study compared booster types and PPKAY without a booster (17). Enrolment began on 12 October 2020, and follow-up data collection continued through March 2025.

Study site

The PRACT trial was conducted at the Emergency Medicine Department (EMD) of Kilimanjaro Christian Medical Centre (KCMC), located in Moshi, Kilimanjaro Region, northern Tanzania. KCMC is a zonal referral and teaching hospital, serving a catchment population of over 15 million people across six regions of northern Tanzania: Kilimanjaro, Tanga, Arusha, Manyara, Dodoma, and Singida, and evaluates over 17,000 emergency patients annually.

Study population and eligibility criteria

The trial enrolled adults aged 18≥years who presented to the EMD within 24 hours of injury and who met at least one alcohol screening criterion (a positive breath alcohol test, an AUDIT score of≥8, or self-reported alcohol use before the injury). Patients were excluded if they didn't consent to the study and if they had a serious psychiatric or cognitive condition that prevented consent. Patients who were intoxicated or critically ill on arrival were re-approached within 24 hours to assess their capacity to consent. **Figure 2.**

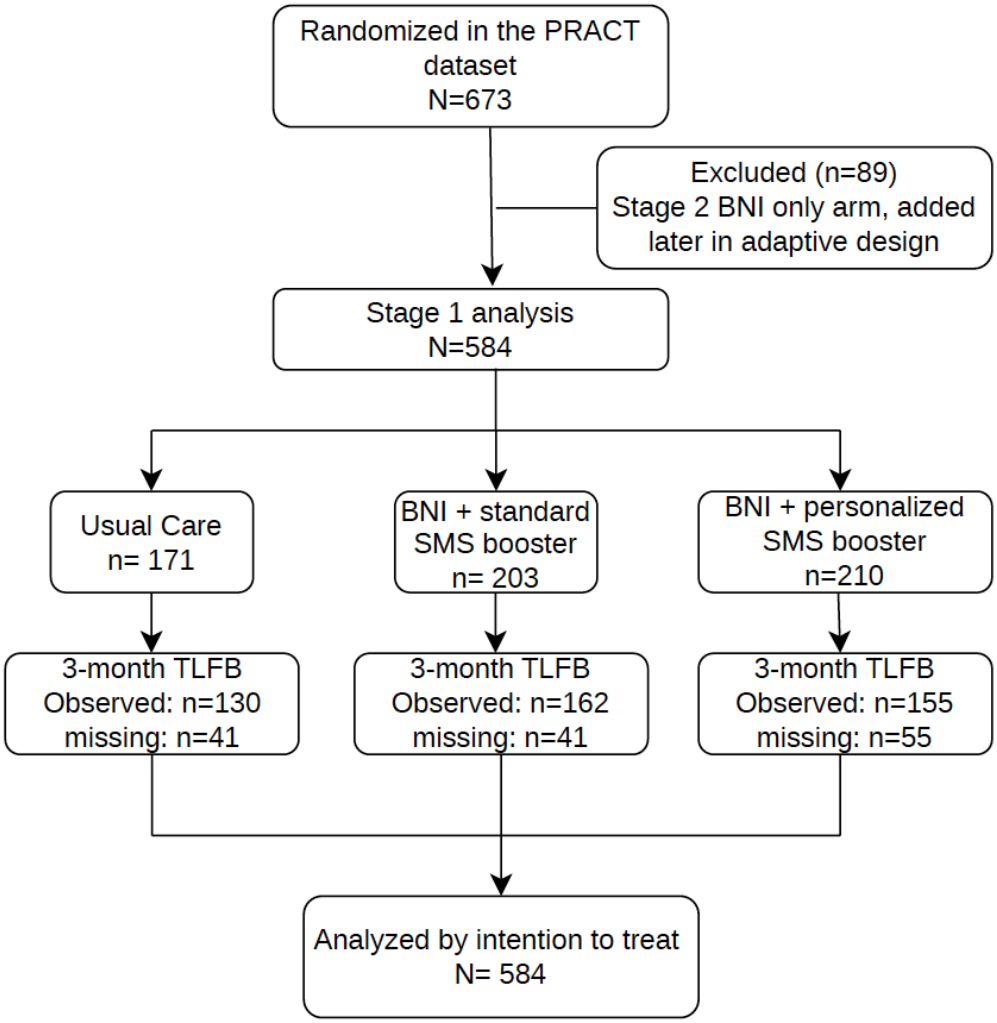


Figure 2: CONSORT flow diagram showing number of adult injured participants analyzed, PRACT trial data from October 2020 to March 2025.

Sample size

Of the 584 participants, 447 (76.5%) had TLFB outcome data at 3 months (Usual Care 130 of 171, 76.0%; BNI 317 of 413, 76.8%). Because the sample is fixed, the precision of every estimate is shown through 95% confidence intervals.

Randomization and allocation concealment

Eligible participants were randomized using a computer-generated sequence with allocation concealment. The allocation ratio was 3:1 in favor of BNI, chosen to maximize exposure to PPKAY and allow comparisons between BNI arms within the adaptive design (17). Nurses delivering PPKAY could not be blinded to allocation, because of the nature of the intervention, but follow-up assessors were not involved in delivering the intervention.

Interventions

PPKAY, the Brief Negotiation Intervention

PPKAY (*Punguza Pombe Kwa Afya Yako*, "Reduce Alcohol for Your Health") is a 15-minute intervention delivered by trained emergency nurses using motivational interviewing techniques (8,17). It was culturally adapted from the brief negotiated interview approach for injured patients in Tanzania using the ADAPT guidance, with Kiswahili language, local drinking contexts and Tanzanian examples (8,18).

The two BNI arms; In the standard-booster arm, participants received generic weekly SMS messages for up to one year after discharge. In the personalized-booster arm, the weekly messages were tailored to the participant's own goal and chosen strategies (8,17).

Usual Care

Participants allocated to Usual Care received standard medical and nursing care for their presenting injury, without any structured alcohol counselling, AUDIT score feedback, goal-setting, or SMS follow-up contact.

Data collection instruments

Trained research assistants collected baseline and follow-up data by structured interview. All instruments were translated into Kiswahili and piloted for comprehension before use. The instruments used were; *Alcohol Use Disorders Identification Test (AUDIT) (19,20)*; *Timeline Followback (TLFB) (21)*; *Patient Health Questionnaire-9 (PHQ-9)* (22); *Breath alcohol test; Sociodemographic and injury questionnaire (*age, sex, education level and years of education,

employment type and status, marital status, mechanism of injury (road traffic injury, fall, blunt force or struck, penetrating trauma, other, burn or drowning) and the participant's rating of injury severity).

Baseline data were collected at enrolment, before randomization. Data were entered directly into Research Electronic Data Capture (REDCap). Participants were followed at 3, 6, 9, 12 and 24 months. Data were collected at two time points relevant to this analysis. At baseline, before the PPKAY session or Usual Care, research assistants administered the AUDIT, PHQ-9, TLFB and sociodemographic questionnaire and recorded the breath alcohol result. The 3-month assessment was done 84 to 98 days after enrolment, by telephone or in person, and repeated the TLFB and PHQ-9. Follow-up assessors were not involved in delivering the intervention and were told not to ask about treatment allocation. Of the 584 participants, 481 attended a 3-month assessment and 447 had complete TLFB outcome data.

Study variables

Outcomes

All three outcomes were derived from the 28-day TLFB at the 3-month assessment, and each was also measured at baseline.

- *Drinking days:* the number of days, out of 28, on which any alcohol was consumed.
- *Drinks consumed:* the total number of standard drinks consumed over the 28 days.
- *Binge drinking days:* the number of days on which the participant consumed four or more standard drinks (women) or five or more (men) (23).

Moderators that influence effectiveness of BNI. Eleven baseline characteristics were examined as potential moderators as shown in table 1.

Table 1: Moderator specifications, reference groups and observed distribution Stage 1, (N = 584)

Moderator Variable	Operationalization	Reference Category	Rationale
Education level	Binary: Primary or less (0) vs Secondary or higher (1)	Primary or less	Health literacy may influence comprehension of PPKAY feedback
Employment type	Binary: Agriculture (0) vs non-agriculture (1)	Agriculture	Occupational context may influence drinking norms and social pressure
Marital status	Binary: Not married (0) vs Married/partnered (1)	Not married	Social support may mediate BNI response
Mechanism of injury	Binary: Non-RTI (0) vs Road traffic injury (1)	Non-RTI	RTI patients may have stronger injury-alcohol attribution, amplifying teachable moment
Injury severity	Binary: Not serious (0) vs Serious/life-threatening (1)	Not serious	Greater severity may heighten motivation to change
Age	Continuous (years)	N/A (per-unit interaction)	Age-related motivation and cognitive engagement may modify BNI response
Sex	Binary: Male (0) vs Female (1)	Male	Sex was identified a priori as a candidate moderator but was excluded from formal testing due to sample size constraints

Education years	Continuous (years of formal education)	N/A (per-unit interaction)	Graded education effect on health literacy and BNI comprehension
Baseline AUDIT score	Continuous (0–40)	N/A (per-unit interaction)	Alcohol severity at baseline may moderate BNI benefit; higher severity may need stepped care
Baseline PHQ-9 score	Continuous (0–27)	N/A (per-unit interaction)	Depressive symptoms may modify capacity to engage with motivational content
Baseline drinking days/binge days	Continuous	N/A (per-unit interaction)	Baseline drinking frequency as a dimension of severity independent of AUDIT

Missing data and multiple imputation

Extent of missing data

TLFB outcome data at 3 months were missing for 137 of 584 participants (23.5%): 41 of 171 in Usual Care (24.0%) and 96 of 413 in the BNI arm (23.2%). All three outcomes were missing together, because they came from the same interview. Baseline TLFB data were missing for 34 participants (5.8%). Among moderators, education level was missing for 60 participants (10.3%) and employment for 22 (3.8%); the others were missing for fewer than 3%. **(Figure 3).**

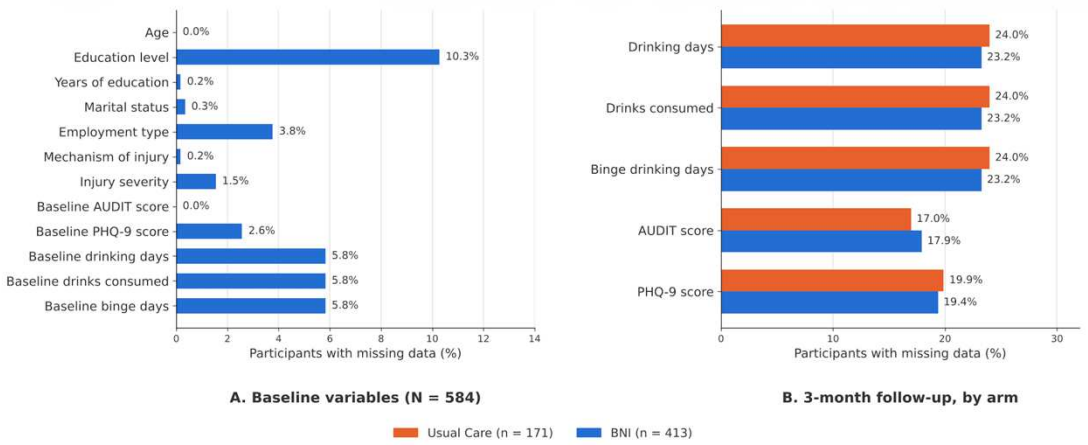


Figure 3: Patterns of missing data in the Stage 1 PRACT dataset. Panel A: baseline variables. Panel B: 3-month follow-up variables, by treatment arm.

Assessment of the missing-at-random assumption

Before multiple imputation, baseline characteristics were compared between participants with and without available 3-month outcome data to explore observed predictors of missingness. Of the 11 statistical comparisons performed, only the baseline AUDIT score differed significantly between the two groups (Wilcoxon rank-sum test, $p = 0.032$). Years of education showed borderline evidence of a difference using Welch's *t*-test ($p = 0.059$), although the corresponding Wilcoxon rank-sum test was not statistically significant ($p = 0.091$). No statistically significant differences were observed for the remaining characteristics, including treatment arm ($p = 0.934$), baseline PHQ-9 score, drinking days, drinks consumed, binge-drinking days, or the categorized baseline measures. **Table 2**

Table 2: Baseline comparison of participants with and without 3-month outcome data

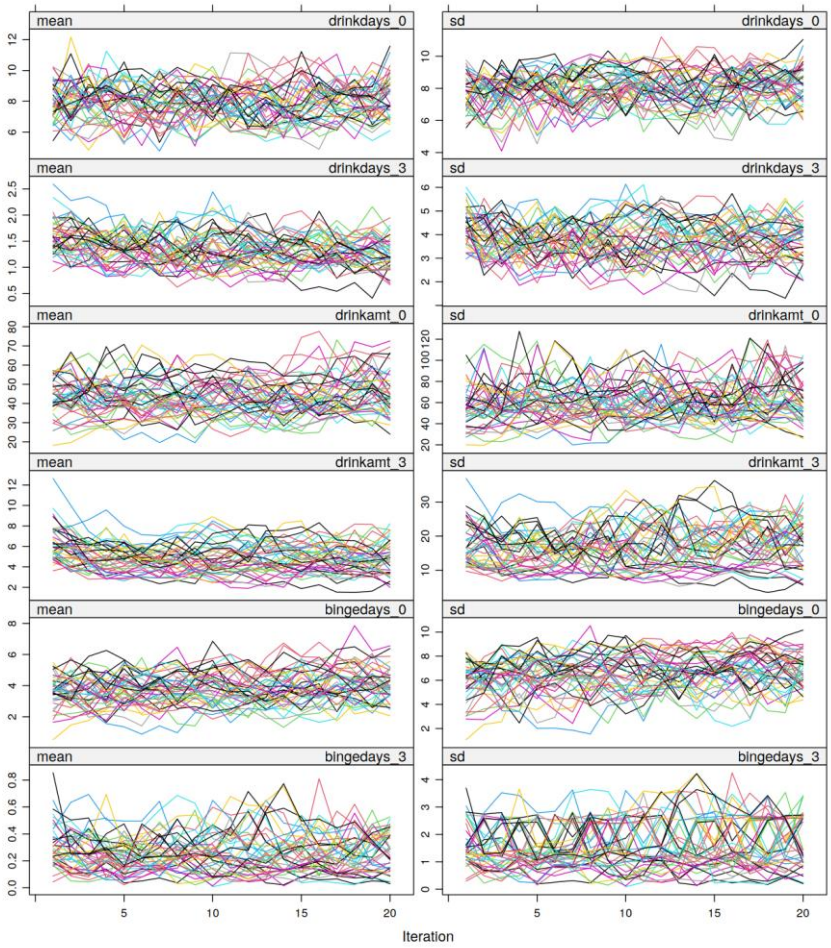
Baseline Characteristics	Test Statistics	P-value
Age	W= 32,071.5	0.401
Years of education	W= 33,303.0	0.091
Baseline AUDIT score	W= 26,923.5	0.032
Baseline PHQ-9 score	W= 27,799.5	0.522
Baseline Drinking days	W= 26,703.0	0.706

Baseline drinks consumed	W= 26,092.0	0.446
Baseline binge drinking days	W= 25,361.5	0.187
Years of education	t(265.2)=1.897	0.059
Treatment arm	$X^2(1) = 0.007$	0.934

Multiple imputation

Missing values were handled by multiple imputation by chained equations MICE (24–26). Forty imputed datasets were created (m = 40), with 20 iterations each and a fixed random seed for reproducibility. Continuous variables, including the outcomes and the AUDIT and PHQ-9 scores at all five assessments (baseline, 3, 6, 9 and 12 months), were imputed by predictive mean matching (24). Unordered categorical variables (marital status, employment status and type, mechanism of injury) were imputed by polytomous logistic regression, and ordered variables (education level, injury severity) by proportional-odds regression.

The predictor set combined an automatic correlation-based selection (minimum correlation 0.15) with a forced set of predictors for every imputed outcome: treatment arm, age, sex, education level and years, marital status, employment status and type, mechanism of injury, injury severity and baseline AUDIT score. Results from the 40 datasets were combined by Rubin's rules (27).



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238 Figure 4 (Panel A): Convergence trace plots of the mean (left) and standard deviation (right)

239 of the imputed drinking days, drinks consumed and binge drinking days at baseline and 3

240 months. Each line is one of the 40 imputations, across 20 iterations.

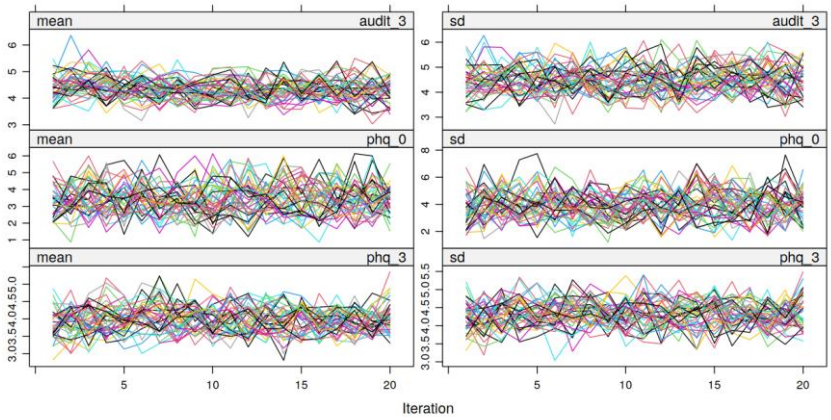


Figure 4 (Panel B): Convergence trace plots for the imputed 3-month AUDIT score and the baseline and 3-month PHQ-9 scores.

Data Analysis

Baseline characteristics were described using counts and percentages for categorical variables and means with standard deviations, or medians with interquartile ranges, for continuous variables. Differences between arms were examined with Wilcoxon rank-sum tests and chi-square or Fisher's exact tests. A linear difference-in-differences model (outcome ~ time × treatment) was fitted in each imputed dataset and pooled by Rubin's rules. The three drinking outcomes were analyzed separately, with $p < 0.05$ taken as the threshold for statistical significance of the treatment effect. The treatment effect is the intention-to-treat effect of allocation to BNI, whatever the participant's later attendance or response to the SMS booster.

For each moderator specification, the interaction between treatment, time and the moderator were added to both model families and refitted in each imputed dataset. In Family B the model was:

$$log(\mu ij) = \beta 0 + \beta 1 \cdot timej + \beta 2 \cdot timej \times modi + \beta 3 \cdot timej \times treati + \beta 4 \cdot timej \times treati \times modi + ui$$

In Family A the model was the full factorial time × treatment × moderator, with cluster-robust standard errors. In both families the three-way term ($\beta 4$ in the equation above) is the moderation parameter of interest. An interaction ratio of 1 means the treatment effect is the same in both groups, and it is *not* the treatment effect of the comparison group itself. To show

who benefits more, the treatment effect within each moderator group was therefore also estimated, as the reference-group effect combined with the interaction term (a linear contrast on the log scale, using the full covariance matrix) and pooled by Rubin's rules. For continuous moderators, which were centered on their means, the treatment term gives the effect at the average moderator value. The analysis used R version 4.3.3.

Ethical Considerations

Ethical clearance for this secondary analysis was obtained from KCMC University, approval number PG 152/2025. Participant informed consent was waived for this secondary analysis, as it involved analysis of an already de-identified patient registry rather than any new contact with participants.

RESULTS

Baseline characteristics of randomized participants by treatment group

A total of 584 participants were included in this analysis (see flow diagram Figure 1). The study population was predominantly male 94.0%. The median age was 33.5 years (IQR: 27-44), with participants distributed relatively evenly across the three age groups, the largest being 29-40 years (34.8%). Just over half (54.8%) of the participants were married or in a partnership, and 53.8% had primary education or less. Most of the participants (71.0%) were engaged in non-agricultural occupations. Road traffic injury was the most common mechanism of injury (60.4%), and the majority of injuries were classified as serious or life-threatening (74.8%).

The median baseline AUDIT score was 12 (IQR: 8-18). Baseline PHQ-9 scores indicated that most participants (72.3%) had minimal depressive symptoms (0-4). Overall, the groups were all balanced at baseline with p >0.005. Baseline characteristics by treatment group are presented in **Table 4**

Table 4: Baseline characteristics of randomized participants by treatment group (N = 584)

Characteristic	Overall N = 584	Usual Care N = 171	BNI N = 413	p-value
Age, years				0.899[1]
Median (IQR)	33.5 (27.0, 44.0)	34.0 (27.0, 42.0)	33.0 (27.0, 44.0)	
Mean (SD)	36.36 (12.44)	36.03 (11.99)	36.50 (12.64)	
Age group, n (%)				0.353[2]
18-28	198 (33.9%)	54 (31.6%)	144 (34.9%)	
29-40	203 (34.8%)	67 (39.2%)	136 (32.9%)	
41+	183 (31.3%)	50 (29.2%)	133 (32.2%)	
Sex, n (%)				0.632[2]
Male	549 (94.0%)	162 (94.7%)	387 (93.7%)	
Female	35 (6.0%)	9 (5.3%)	26 (6.3%)	
Education level, n (%)				0.574[2]
Primary or less	314 (53.8%)	90 (52.6%)	224 (54.2%)	
Secondary or higher	210 (35.9%)	65 (38.0%)	145 (35.1%)	
Missing	*60 (10.3%)*	*16 (9.4%)*	*44 (10.7%)*	

Characteristic	Overall N = 584	Usual Care N = 171	BNI N = 413	p-value
Years of education				0.459[1]
Median (IQR)	7 (7, 11)	7 (7, 11)	7 (7, 11)	
Missing	*1 (0.2%)*	*0 (0.0%)*	*1 (0.2%)*	
Tribe, n (%)				0.923[2]
Chagga	334 (57.2%)	99 (57.9%)	235 (56.9%)	
Pare	66 (11.3%)	20 (11.7%)	46 (11.1%)	
Non-Tanzanian	107 (18.3%)	32 (18.7%)	75 (18.2%)	
Other Tanzanian	77 (13.2%)	20 (11.7%)	57 (13.8%)	
Employment type, n (%)				0.540[2]
Agriculture	147 (25.2%)	45 (26.3%)	102 (24.7%)	
Non-agriculture	415 (71.0%)	116 (67.8%)	299 (72.4%)	
Missing	*22 (3.8%)*	*10 (5.9%)*	*12 (2.9%)*	
Marital status, n (%)				0.858[2]
Married/Partnered	320 (54.8%)	95 (55.6%)	225 (54.5%)	
Not married	262 (44.9%)	76 (44.4%)	186 (45.0%)	
Missing	*2 (0.3%)*	*0 (0.0%)*	*2 (0.5%)*	
Mechanism of injury, n (%)				0.406[2]
RTI	353 (60.4%)	108 (63.2%)	245 (59.3%)	
Non-RTI	230 (39.4%)	63 (36.8%)	167 (40.4%)	
Missing	*1 (0.2%)*	*0 (0.0%)*	*1 (0.3%)*	
Injury severity, n (%)				0.111[2]
Serious	437 (74.8%)	121 (70.7%)	316 (76.5%)	
Not serious	138 (23.6%)	48 (28.1%)	90 (21.8%)	
Missing	*9 (1.6%)*	*2 (1.2%)*	*7 (1.7%)*	
AUDIT score				0.717[1]
Median (IQR)	12 (8, 18)	12 (8, 18)	12 (8, 18)	
Mean (SD)	13.27 (7.37)	13.29 (7.12)	13.26 (7.48)	
AUDIT category, n (%)				0.213[2]
Low risk (<8)	115 (19.7%)	33 (19.3%)	82 (19.8%)	
Hazardous (8-15)	274 (46.9%)	73 (42.7%)	201 (48.7%)	
Harmful (16-19)	83 (14.2%)	36 (21.0%)	47 (11.4%)	
Dependence (20+)	112 (19.2%)	29 (17.0%)	83 (20.1%)	
PHQ-9 score				0.255[1]
Median (IQR)	2 (0, 5)	2 (0, 5)	2 (0, 5)	
Mean (SD)	3.33 (4.08)	3.12 (3.99)	3.42 (4.12)	
Missing	*15 (2.6%)*	*6 (3.5%)*	*9 (2.2%)*	
PHQ-9 category, n (%)				0.573[2]
Minimal (0-4)	422 (72.3%)	123 (71.9%)	299 (72.4%)	
Mild (5-9)	92 (15.7%)	29 (17.0%)	63 (15.3%)	
Moderate (10-14)	40 (6.8%)	8 (4.7%)	32 (7.7%)	
Severe (15+)	15 (2.6%)	5 (2.9%)	10 (2.4%)	
Missing	*15 (2.6%)*	*6 (3.5%)*	*9 (2.2%)*	

Characteristic	Overall N = 584	Usual Care N = 171	BNI N = 413	p-value
Binge drinking days (past 28 days)				0.358[1]
Median (IQR)	0 (0, 3)	0 (0, 3)	0 (0, 4)	
Mean (SD)	3.51 (6.77)	3.31 (6.82)	3.59 (6.75)	
Missing	*34 (5.8%)*	*8 (4.7%)*	*26 (6.3%)*	
Total drinking days (past 28 days)				0.276[1]
Median (IQR)	5 (2, 11)	4 (2, 11)	5 (2, 11)	
Mean (SD)	7.97 (7.88)	7.87 (8.35)	8.01 (7.69)	
Missing	*34 (5.8%)*	*8 (4.7%)*	*26 (6.3%)*	
Drinks consumed (past 28 days)				0.315[1]
Median (IQR)	21 (7, 47)	20 (5, 44)	22 (7, 49)	
Mean (SD)	45.00 (72.51)	43.33 (69.56)	45.70 (73.79)	
Missing	*34 (5.8%)*	*8 (4.7%)*	*26 (6.3%)*	

Continuous variables are reported as median (IQR) and mean (SD); categorical variables as n (%). ¹Wilcoxon rank-sum test (continuous variables). ²Pearson χ^2 test (binary and grouped categorical variables).

Descriptive outcomes at baseline and 3-month follow-up

At baseline, the median number of drinking days, and median number of drinks consumed was higher in the BNI group compared to usual care. The median binge drinking days were equal in both groups. At the 3-month follow-up, lower levels of alcohol consumption were observed in both treatment groups. Among participants with available follow-up data, the mean number of drinking days, the mean number of drinks consumed, and the mean number of binge drinking days were all lower in the BNI group than in the Usual Care group. Outcome variables at baseline and at the 3-month follow-up, stratified by treatment group, are presented in **Table 5**.

Table 5: Outcome variables at baseline and 3-month follow-up by treatment group (N = 584)

Outcome	Baseline BNI N = 413	Baseline Usual Care N = 171	Baseline p-value	3-Month BNI N = 413	3-Month Usual Care N = 171	3-Month p-value
Total drinking days						
Median (IQR)	5.0 (2.0, 11.0)	4.0 (2.0, 11.0)	0.276	0.0 (0.0, 0.0)	0.0 (0.0, 1.0)	**0.007**
Mean (SD)	8.01 (7.69)	7.87 (8.35)		1.18 (3.73)	2.58 (6.29)	
n with data	387	163		317	130	
Drinks consumed						
Median (IQR)	22.5 (7.2, 48.6)	19.8 (5.0, 43.8)	0.315	0.0 (0.0, 0.0)	0.0 (0.0, 3.0)	**0.005**
Mean (SD)	45.70 (73.79)	43.33 (69.56)		5.49 (24.87)	9.44 (25.43)	
n with data	387	163		317	130	
Binge drinking days						
Median (IQR)	0.0 (0.0, 4.0)	0.0 (0.0, 3.0)	0.358	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	**0.014**
Mean (SD)	3.59 (6.75)	3.31 (6.82)		0.37 (2.58)	0.75 (3.08)	
n with data	387	163		317	130	

Continuous variables are reported as median (IQR) and mean (SD) among participants with data at that time point; the row 'n with data' gives the number contributing.

The sex-by-treatment interaction was excluded from the formal moderation analysis because of the small number of women (6.0%).

Effect of BNI on total drinking days

The treatment effect is the incidence rate ratio (IRR) for the time-by-treatment term: the ratio of the change in expected drinking days from baseline to 3 months in the BNI arm to the corresponding change in the Usual Care arm. A value below 1 favors BNI. In the primary analysis (Family B, zero-inflated negative binomial mixed model), BNI was associated with 58% fewer drinking days at 3 months than Usual Care, relative to baseline (IRR=0.42, 95% CI: 0.29-0.61, $p<0.001$). The sensitivity analysis (Family A, negative binomial model with

cluster-robust standard errors) gave a similar estimate (IRR=0.45, 95% CI: 0.27-0.74, p=0.002). The models are unadjusted, so no covariate estimates are reported.

Effect of BNI on drinks consumed

The primary analysis showed that BNI was associated with 65% fewer drinks at 3 months than Usual Care, relative to baseline (IRR=0.35, 95% CI: 0.21-0.60, p<0.001). The sensitivity analysis pointed in the same direction but was smaller and less precise, and its confidence interval included 1 (IRR=0.55, 95% CI: 0.28-1.09, p=0.085).

Effect of BNI on binge drinking days

For binge drinking days, BNI was associated with 69% fewer binge days at 3 months than Usual Care, relative to baseline, in the primary analysis (IRR=0.31, 95% CI: 0.14-0.67, p=0.003). The sensitivity analysis estimated a similar direction and size of effect but with a wide confidence interval that included 1 (IRR=0.46, 95% CI: 0.16-1.33, p=0.152). Binge drinking at follow-up was uncommon: 93.1% of participants with 3-month data (416/447) reported zero binge days, leaving only 31 participants with any binge drinking at 3 months (16 in BNI and 15 in Usual Care). With so few non-zero outcomes the estimates are imprecise, which is reflected in the wide confidence intervals.

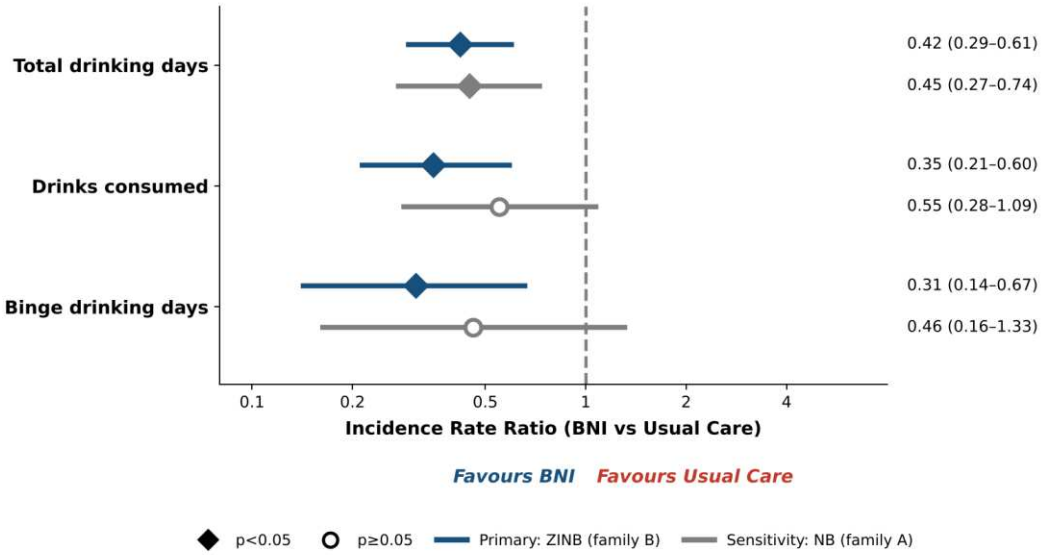


Figure 9: Forest plot showing the effect of BNI on total drinking days, drinks consumed and binge drinking days at 3-month follow-up (ITT/MICE, N=584). IRR<1.0 favours BNI over Usual Care. Diamond = statistically significant (p<0.05); circle = non-significant. Log scale; bars are 95% confidence intervals.

Moderation of total drinking days

For total drinking days, education level was the only moderator with a nominally significant interaction in the primary analysis (IRR=2.47, 95% CI: 1.13-5.42, p=0.024): the BNI effect was weaker in participants with secondary education or higher than in those with primary education or less. This did not survive Bonferroni correction (α=0.0015), and in the sensitivity analysis it was borderline (IRR=3.00, 95% CI: 1.00-8.96, p=0.049). None of the other ten interactions was statistically significant in either model family: employment type (IRR=0.77, p=0.545), marital status (IRR=0.64, p=0.241), mechanism of injury (IRR=1.08, p=0.839), injury severity (IRR=1.78, p=0.158), age (IRR=0.99, p=0.448), education years (IRR=1.09, p=0.123), baseline AUDIT score (IRR=0.99, p=0.760), baseline PHQ-9 score (IRR=1.04, p=0.396), baseline drinking days (IRR=1.02, p=0.499) and baseline binge drinking days (IRR=1.05, p=0.065). Moderation of the effect on total drinking days is presented in **Table 6**.

Table 6: Moderation of BNI effectiveness on total drinking days (N = 584)

Moderator	Primary: Family B (ZINB mixed model)		Sensitivity: Family A (NB, cluster-robust)	
	Interaction IRR (95% CI)	p-value	Interaction IRR (95% CI)	p-value
Education level				
Primary or less	1.00 (ref)		1.00 (ref)	
Secondary or higher	2.47 (1.13-5.42)	**0.024**	3.00 (1.00-8.96)	**0.049**
Employment type				
Agriculture	1.00 (ref)		1.00 (ref)	
Non-agriculture	0.77 (0.32-1.82)	0.545	1.03 (0.31-3.40)	0.961
Marital status				
Not married	1.00 (ref)		1.00 (ref)	
Married or partnered	0.64 (0.30-1.35)	0.241	0.71 (0.24-2.07)	0.525
Mechanism of injury				
Non-RTI	1.00 (ref)		1.00 (ref)	
Road traffic injury	1.08 (0.50-2.35)	0.839	1.15 (0.40-3.29)	0.795
Injury severity				
Not serious	1.00 (ref)		1.00 (ref)	
Serious or life-threatening	1.78 (0.80-3.97)	0.158	1.68 (0.59-4.74)	0.329
Age (per year)	0.99 (0.96-1.02)	0.448	1.00 (0.96-1.04)	0.992
Education years (per year)	1.09 (0.98-1.23)	0.123	1.10 (0.95-1.27)	0.216
Baseline AUDIT score (per point)	0.99 (0.94-1.04)	0.760	1.01 (0.94-1.08)	0.866
Baseline PHQ-9 score (per point)	1.04 (0.95-1.15)	0.396	1.01 (0.90-1.14)	0.838
Baseline drinking days (per day)	1.02 (0.97-1.07)	0.499	1.00 (0.96-1.06)	0.851
Baseline binge days (per day)	1.05 (1.00-1.11)	0.065	1.05 (0.99-1.12)	0.119

Interaction IRR = ratio of the BNI effect (IRR) in the comparison group to the BNI effect in the reference group; for continuous moderators, the ratio per one-unit increases in the moderator (mean-centered). IRR>1 means a weaker BNI effect (smaller reduction) with higher values of the moderator. Reference categories are shown as 1.00 (ref). Pooled over 40 imputed datasets. Bold = p<0.05,

Moderation of drinks consumed

The pattern for drinks consumed was the same. Education level was the only binary moderator with a nominally significant interaction in the primary analysis (IRR=3.74, 95% CI: 1.25-11.19, p=0.018), and the sensitivity analysis gave a larger estimate with a wide interval (IRR=5.69,

95% CI: 1.36-23.87, p=0.017). Neither met the Bonferroni threshold. Education in years showed a weaker version of the same trend (primary analysis IRR=1.15 per year, 95% CI: 0.99-1.35, p=0.075; sensitivity IRR=1.18, p=0.051). All other interactions were non-significant in both families: employment type (IRR=0.75, p=0.634), marital status (IRR=0.51, p=0.209), mechanism of injury (IRR=0.98, p=0.978), injury severity (IRR=2.12, p=0.207), age (IRR=0.98, p=0.331), baseline AUDIT score (IRR=1.02, p=0.604), baseline PHQ-9 score (IRR=1.12, p=0.141), baseline drinking days (IRR=1.00, p=0.931) and baseline binge drinking days (IRR=1.05, p=0.173). Moderation of the effect on drinks consumed is presented in **Table 7**.

Table 7: Moderation of BNI effectiveness on drinks consumed (N = 584)

Moderator	Primary: Family B (ZINB mixed model)		Sensitivity: Family A (NB, cluster-robust)	
	Interaction IRR (95% CI)	p-value	Interaction IRR (95% CI)	p-value
Education level				
Primary or less	1.00 (ref)		1.00 (ref)	
Secondary or higher	3.74 (1.25-11.19)	0.018	5.69 (1.36-23.87)	0.017
Employment type				
Agriculture	1.00 (ref)		1.00 (ref)	
Non-agriculture	0.75 (0.22-2.50)	0.634	0.60 (0.12-3.03)	0.540
Marital status				
Not married	1.00 (ref)		1.00 (ref)	
Married or partnered	0.51 (0.17-1.47)	0.209	0.67 (0.16-2.71)	0.571
Mechanism of injury				
Non-RTI	1.00 (ref)		1.00 (ref)	
Road traffic injury	0.98 (0.33-2.96)	0.978	1.16 (0.29-4.67)	0.836
Injury severity				
Not serious	1.00 (ref)		1.00 (ref)	
Serious or life-threatening	2.12 (0.66-6.86)	0.207	1.56 (0.36-6.86)	0.554
Age (per year)	0.98 (0.94-1.02)	0.331	0.99 (0.95-1.04)	0.770

Moderator	Primary: Family B (ZINB mixed model)		Sensitivity: Family A (NB, cluster-robust)	
	Interaction IRR (95% CI)	p-value	Interaction IRR (95% CI)	p-value
Education years (per year)	1.15 (0.99-1.35)	0.075	1.18 (1.00-1.40)	0.051
Baseline AUDIT score (per point)	1.02 (0.94-1.10)	0.604	1.05 (0.97-1.12)	0.227
Baseline PHQ-9 score (per point)	1.12 (0.96-1.29)	0.141	1.05 (0.89-1.24)	0.580
Baseline drinking days (per day)	1.00 (0.94-1.06)	0.931	1.02 (0.96-1.09)	0.488
Baseline binge days (per day)	1.05 (0.98-1.14)	0.173	1.09 (1.00-1.18)	0.053

Interaction IRR = ratio of the BNI effect (IRR) in the comparison group to the BNI effect in the reference group; for continuous moderators, the ratio per one-unit increases in the moderator (mean-centered). IRR>1 means a weaker BNI effect (smaller reduction) with higher values of the moderator. Reference categories are shown as 1.00 (ref). Pooled over 40 imputed datasets. Bold = p<0.05, nominal; no interaction met the Bonferroni threshold of 0.0015. Abbreviations as in Table 4.5.

Moderation of binge drinking days

For binge drinking days, two interactions were nominally significant in the primary analysis. The interaction for education level was IRR=7.34 (95% CI: 1.23-43.68, p=0.029), and the interaction for education in years was IRR=1.30 per year (95% CI: 1.02-1.67, p=0.034). Both were also nominally significant in the sensitivity analysis (education level IRR=12.28, p=0.031; education years IRR=1.37, p=0.023), and both are in the same direction, with a weaker BNI effect at higher education. Neither survived Bonferroni correction, and the confidence intervals are very wide because only 31 participants had any binge drinking at follow-up. All remaining interactions were non-significant: employment type (IRR=0.25, p=0.229), marital status (IRR=0.88, p=0.871), mechanism of injury (IRR=0.55, p=0.464), injury severity (IRR=2.17, p=0.365), age (IRR=1.00, p=0.990), baseline AUDIT score (IRR=1.03, p=0.560), baseline

PHQ-9 score (IRR=1.06, p=0.584), baseline drinking days (IRR=1.04, p=0.378) and baseline binge drinking days (IRR=1.11, p=0.103). Moderation of the effect on binge drinking days is presented in **Table 8**.

Table 8: Moderation of BNI effectiveness on binge drinking days (N = 584)

Moderator	Primary: Family B (ZINB mixed model)		Sensitivity: Family A (NB, cluster-robust)	
	Interaction IRR (95% CI)	p-value	Interaction IRR (95% CI)	p-value
Education level				
Primary or less	1.00 (ref)		1.00 (ref)	
Secondary or higher	7.34 (1.23-43.68)	**0.029**	12.28 (1.26-119.78)	**0.031**
Employment type				
Agriculture	1.00 (ref)		1.00 (ref)	
Non-agriculture	0.25 (0.03-2.39)	0.229	0.16 (0.01-2.84)	0.213
Marital status				
Not married	1.00 (ref)		1.00 (ref)	
Married or partnered	0.88 (0.18-4.25)	0.871	0.53 (0.07-4.20)	0.546
Mechanism of injury				
Non-RTI	1.00 (ref)		1.00 (ref)	
Road traffic injury	0.55 (0.11-2.71)	0.464	0.76 (0.10-6.12)	0.799
Injury severity				
Not serious	1.00 (ref)		1.00 (ref)	
Serious or life-threatening	2.17 (0.41-11.57)	0.365	1.04 (0.13-8.40)	0.971
Age (per year)	1.00 (0.93-1.07)	0.990	0.99 (0.93-1.06)	0.779
Education years (per year)	1.30 (1.02-1.67)	**0.034**	1.37 (1.04-1.79)	**0.023**
Baseline AUDIT score (per point)	1.03 (0.93-1.14)	0.560	1.04 (0.92-1.18)	0.499
Baseline PHQ-9 score (per point)	1.06 (0.85-1.33)	0.584	1.01 (0.79-1.31)	0.911
Baseline drinking days (per day)	1.04 (0.95-1.14)	0.378	1.04 (0.95-1.14)	0.376
Baseline binge days (per day)	1.11 (0.98-1.25)	0.103	1.13 (0.98-1.30)	0.091

Interaction IRR = ratio of the BNI effect (IRR) in the comparison group to the BNI effect in the reference group; for continuous moderators, the ratio per one-unit increase in the moderator (mean-centered). IRR>1 means a weaker BNI effect (smaller reduction) with higher values of the moderator. Reference categories are shown as 1.00 (ref). Pooled over 40 imputed datasets. Bold = p<0.05, nominal; no interaction met the Bonferroni threshold of 0.0015.

389 Abbreviations as in Table 4.5. Estimates for binge drinking days are imprecise because only

390 31 participants reported any binge drinking at 3 months.

DISCUSSION

To the best of our knowledge, this is the first study to systematically examine moderators of a brief alcohol intervention's effectiveness among injured adults in an African emergency department. Three findings emerged. First, drinking fell substantially in both arms, though PPKAY was associated with greater reductions than Usual Care. Second, women improved as men did, but there were too few of them for a formal comparison. Lastly, education level showed a consistent pattern across all three outcomes, with a larger PPKAY effect among participants with primary education or less.

PPKAY was associated with 58% fewer drinking days at three months than Usual Care (65%), relative to baseline. This is in keeping with the wider evidence on brief interventions in emergency departments. A systematic review of 34 studies found that all reported lower alcohol consumption three months after a brief intervention, although in some studies drinking fell in both the intervention and control groups with no difference between them (28). The same pattern was seen here: drinking days also fell in Usual Care (from a mean of 8.0 to 2.5 days in the imputed data), and BNI participants improved more. One explanation is the “teachable moment”, in which an acute health event increases receptiveness to behavior change (13). However, participants may have been recruited at a time of unusually heavy drinking, so that some of the fall reflects regression to the mean, and repeated assessment can itself reduce reported drinking; a meta-analysis of brief alcohol intervention trials found small reductions from assessment alone, although the evidence from clinical settings, including emergency departments, was uncertain (29). The implication is that the findings support integrating PPKAY into routine emergency care at KCMC, and they add evidence from a region where trials of drinking interventions remain few (30).

For binge drinking days, the primary analysis showed 69% fewer binge days in the BNI arm than in the Usual Care group, relative to baseline. This agrees with the primary PRACT publication, in which binge drinking days at three months were the primary outcome and the intervention arms had 1.2 fewer binge days than Usual Care by difference-in-differences (95%

CI: -2.3 to -0.3 (8). The most likely reason for this imprecision is a floor effect and not an absence of benefit. Binge drinking is an episodic behavior, and about half of participants with baseline data (51.5%) reported no binge days at baseline, which left little room for improvement (23). By three months, 93.1% of participants with data reported none, so only 31 participants (16 BNI, 15 Usual Care) had any binge drinking at follow-up. The result is also notable because PPKAY is a brief, nurse-delivered intervention of about 15 minutes (8). A systematic review of interventions for heavy episodic drinking in sub-Saharan Africa found that only six of 13 trials reported a benefit, and that the interventions with significant effects generally lasted two hours or longer (30). The implication is that the effect of PPKAY on binge drinking should be confirmed in an adequately powered analysis with longer follow-up, and not assumed to be absent.

Women made up only 6.0% of the sample, so sex was not tested as a moderator. Descriptively, both sexes drank less at three months. Mean drinking days fell from 8.2 to 1.7 in men and from 4.1 to 0.6 in women, and the sex difference present at baseline ($p<0.001$) was no longer present at three months ($p=0.385$). These are observed means based on different numbers of participants at each time point; they cannot show whether PPKAY worked differently in women. This matters because sex is the moderator with the strongest outside evidence. An individual participant data meta-analysis of 29 trials and 12,074 participants found that brief interventions reduced binge drinking, drinking frequency, and alcohol-related consequences among women at three months but not among men, although the effects were small (for example, $g=0.09$ for binge drinking (11). Qualitative and survey work among injury patients at KCMC found that sex differences in stigma were most evident when participants discussed women's drinking, and the authors suggested that this may worsen women's already unequal access to health care (31). Women who drink may therefore be less likely to present, to disclose their drinking, or to be enrolled, which would limit both research and clinical delivery. A study that deliberately recruits more women is a priority before PPKAY is targeted by sex.

Education level was the only moderator with a consistent signal. The interaction was nominally significant for all three outcomes in the primary analysis (drinking days IRR=2.47, drinks consumed IRR=3.74, binge drinking days IRR=7.34. Among participants with primary education or less, PPKAY was associated with 71% fewer drinking days (IRR=0.29), 80% fewer drinks (IRR=0.20), and 88% fewer binge drinking days (IRR=0.12) than Usual Care. Among those with secondary education or higher, the estimates were closer to 1, and their confidence intervals included 1 (IRR=0.72, 0.76 and 0.88). The direction agrees with earlier research. In the individual participant data meta-analysis, brief interventions reduced drinking frequency more among adults with less than high school education (g=0.16, six trials), although the authors cautioned that education data were available for only about half of participants (11). A German trial of a computer-based brief intervention found benefit at 12 months only among participants with fewer than 12 years of schooling, and a recent mini-review concluded that people of lower socioeconomic position tend to benefit more from brief interventions, while noting how little research exists (10,32). These studies come from high-income settings, so our result extends the observation to a low-income setting, with the same limits.

Strengths and Limitations

This study drew on a pragmatic randomized controlled trial dataset, designed for causal inference about intervention effectiveness. The parent PRACT trial's concealed allocation, blinded outcome assessment, and intention-to-treat analytic approach together minimized the risk of bias in the estimated treatment effect. Second, missing three-month outcome data were handled by multiple imputation by chained equations with predictive mean matching across 40 imputed datasets, which restored the full intention-to-treat sample and reduced the risk of attrition bias in a complete-case analysis. Third, two model families were compared before the treatment effects were examined. Reporting both models allowed us to say which findings depend on the model.

The study also had limitation. Firstly, all outcomes were self-reported via Timeline Follow back. The risk of social desirability bias, particularly without participant blinding, is acknowledged; the consistency of results across sensitivity analyses somewhat mitigates this concern, though future studies would benefit from incorporating an objective biomarker or negative control outcome to validate self-reported change. Secondly, this was a single-site study at KCMC, limiting generalizability to other settings. Multi-site replication is needed before generalizing these results further.

CONCLUSIONS

In this secondary analysis PPKAY was associated with substantially greater reductions in drinking days, drinks consumed and binge drinking days at three months than Usual Care. Education level showed a consistent, with a larger effect among participants with primary education or less. Taken together, the findings support the integration of PPKAY into routine emergency care for AUDIT-positive injured patients at KCMC EMD and delivered to all eligible patients without subgroup restriction.

We recommend that the education finding as a moderator be tested in a pre-specified moderation analysis, using the later stages of PRACT and, if possible, pooling with other trials, with education measured consistently and with follow-up at 6, 12 and 24 months. We also recommend that the effect of PPKAY on binge drinking be examined in an adequately powered analysis, because only 31 participants had any binge drinking at three months. We also recommend a study that deliberately recruits more women in order to test sex as a moderator.

Acknowledgements: We acknowledge the PRACT trial (Pragmatic Randomized Adaptive Clinical Trial; ClinicalTrials.gov NCT04535011) who's original data was used for this study.

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