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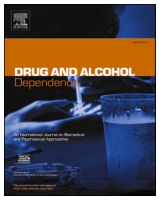

Booster effects and mechanisms of web-based personalised normative feedback alcohol intervention for college students: A pragmatic randomised controlled trial

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ABSTRACT

Background: To evaluate the effects of booster and no booster versions of web-based alcohol Personalised Normative Feedback (PNF) and whether descriptive norms mediated and/or participant motivation moderated the effectiveness of the intervention in real world conditions (i.e. no financial incentives).
Methods: Pragmatic randomised controlled trial with 1-, 3-, and 6-month assessments. Brazilian college students reporting alcohol use in the last 12 months (N=931) were recruited from May/2020 to December/2022 and allocated to 1) No booster/single PNF(S-PNF); 2) Booster/multiple PNF(M-PNF); or 3) Assessment-only control. We applied Helmert coding [1: Any intervention (S-PNF or M-PNF) vs. Control; and 2: S-PNF vs. M-PNF]. Primary outcomes: typical number of drinks/week and maximum number of drinks/week; secondary outcomes: drinking frequency and number of consequences. Three-months assessment was the primary interval. Descriptive norms were tested as mediator. Interest, importance, and readiness to change were examined as moderators.
Results: Compared to control, any intervention did not influence primary outcomes at 3-months or 6-months, but did at 1-month, when reduced typical drinking (IRR:0.77, 95%CI:0.66;0.90) and maximum number of drinks (IRR:0.69, 95%CI:0.58;0.82). There was an intervention effect on the consequences at 3-months. No differences were observed between S-PNF and M-PNF. No mediation effects were found at 3-months. At 6-months, there was an indirect effect on typical drinking through norms at 3-months (b=-0.82, 95%CI:-2.03;-0.12) and effects on maximum drinks through norms at 1-month (b=-0.54, 95%CI:-1.65;-0.02). No support for moderation was found.
Conclusions: Intervention reduced alcohol drinking at 1 month only and was not effective thereafter. Mechanisms of effect remain unclear.

1. Introduction

College drinking has significant public health impact and can affect students, their families and college communities (National Institute on Alcohol Abuse and Alcoholism, 2022). Effective interventions for young people are needed to minimise alcohol-attributable health loss (Alcohol Collaborators, 2022). Digital and internet-delivered interventions to reduce drinking are efficacious in different populations (Kaner et al., 2017; Riper et al., 2018). Web-based Personalised Normative Feedback (PNF) appears an effective individual-level strategy among college students (National Institute on Alcohol Abuse and Alcoholism, 2019). It is understood to correct drinking norms perception (Foxcroft et al., 2015), with evidence of reductions in alcohol consumption up to 3 months (Dotson et al., 2015; Foxcroft et al., 2015; Hennessy et al., 2019; Saxton et al., 2021).

Most studies, however, have used incentives to enhance participation and retention rates (Bedendo et al., 2018), limiting real-world evaluation of PNF effects (Bedendo and Noto, 2016). Incentives risk selection bias and limit generalisation (Neighbors et al., 2018). Consequently, study designs for real-world public health settings are needed (Dempsey

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et al., 2018), particularly as PNF effect sizes are small (Dotson et al., 2015; Hennessy et al., 2019). Studies which do not use incentives may be less likely to show intervention effects (Kypri et al., 2014).

Boosters (i.e., additional intervention content subsequent to initial delivery) have long been suggested as one way to strengthen and extend the effects of computerised interventions (Braitman and Henson, 2016; Braitman and Lau-Barraco, 2018). There is some evidence supporting the provision of biannual presentation of PNF (Neighbors et al., 2010), as well as email boosters to improve intervention effects in college population (Braitman and Henson, 2016; Braitman and Lau-Barraco, 2018, 2020). Those studies, however, were limited to a single institution, did not evaluate effects at less than 6 months. They also delayed boosters in different ways, and used financial incentives. Consequently, whether booster sessions may improve the longevity of any PNF effects is unclear (Saxton et al., 2021).

Another gap in knowledge regarding PNF is on possible mechanisms of effect (Dallery et al., 2015; Dempsey et al., 2018; Labrie et al., 2013). Change in descriptive norms (i.e., perceptions of quantity and frequency of peer alcohol use) has been most studied among college students. It is still unclear, however, to what extent changes in norms drive subsequent drinking behaviour modification (Reid and Carey, 2015). Moreover, most studies do not measure the evaluated mediator before the outcome (Dallery et al., 2015), which is a major issue for secure inference (Domhardt et al., 2021; Kazdin, 2007).

Motivation has been suggested as an important domain associated with positive outcomes for digital alcohol interventions among college students, just as it is understood to be highly relevant to alcohol intervention effects in all populations (Berman et al., 2019). There is some evidence that interest in receiving the intervention, moderates the effects of PNF (Bedendo et al., 2019, 2020). More broadly, studies have underscored the relevance of importance and readiness to change for our understanding of reducing drinking (Bertholet et al., 2012; Gaume et al., 2017, 2022, 2014; Merrill et al., 2015). It should be noted, however, that financial incentives complicate appreciation of the effects of web-based interventions which rely on participants' interest or other aspects of motivation (Bedendo and Noto, 2016; Neighbors et al., 2018). For this reason, evaluations of intervention effects and motivational variables as possible moderators are preferable without the use of incentives for research participation. Additionally, studies which assess moderators and mediators within such a framework, will provide evidence of whether and how they operate together in real world conditions.

The present study aimed to compare the effects of a web-based PNF alcohol intervention provided in a no booster/single (S-PNF) or booster/multiple sessions (M-PNF) versions on alcohol use and related consequences after 1, 3 and 6 months in real world conditions. Secondly, we aimed to evaluate whether the effects of the interventions were mediated by descriptive norms and moderated by participant interest, importance and readiness to change. Formally, we tested the following hypotheses: in comparison with an assessment-only control condition, both interventions will be able to reduce alcohol drinking (hypothesis 1 [H1]) and M-PNF will show superior effects compared to S-PNF (hypothesis 2 [H2]). Compared to control, changes in descriptive norms at one month will mediate intervention effects on drinking at 3 months (hypothesis 3 [H3]) and motivational variables (interest, importance, or readiness to change) at baseline will moderate the intervention effects (hypothesis 4 [H4]).

2. Methods

2.1. Design

A 3-group, web-based, pragmatic randomised controlled trial with assessments at baseline, after one month, three months and six months (Trial Registration: NCT04499456). The primary interval was designated as 3 months after baseline. This study was approved by the Research Ethics Committee of the Federal University of São Paulo (CAAE: 80424317.0.0000.5505).

2.2. Recruitment and procedures

College students were recruited from all Brazilian regions via email, social media (Twitter, Facebook, Instagram and WhatsApp) and data collection took place between May 2020 to April 2022. The inclusion criteria were a) 18 years or older; b) college student; c) reported alcohol use in the last 12 months. Up to five email reminders to complete follow-up assessments were sent, and participants did not receive any incentives for participating in the study.

After providing informed consent, participants accessed a screening questionnaire assessing the inclusion criteria. Those meeting the inclusion criteria were given access to the baseline questionnaire. After completing it, participants were randomised by the website algorithm to one out of three groups (Control, S-PNF or M-PNF) with an allocation ratio of 1:1:1 (Fig. 1). Researchers and participants were blind to intervention allocation.

2.3. Interventions and comparator

The PNF provided sex-specific information on 1) alcohol consumption profile (AUDIT-C; binge drinking and estimated blood alcohol concentration); 2) normative information on alcohol use; 3) alcohol-related consequences; 4) practical costs of alcohol consumption (money spent and calories ingested); 5) strategies to avoid or reduce alcohol problems. Normative information was extracted from a national survey on alcohol and drugs among Brazilian university students (Andrade et al., 2010) and our previous study (Bedendo et al., 2019, 2020). Participants allocated to no booster S-PNF intervention received this immediately after the baseline assessment only. The intervention was hosted at www.quantobebo.com.br and a mock version of the PNF is available from https://tinyurl.com/pub-feedback. The booster version (M-PNF) intervention content was the same as for S-PNF, except that it was provided after every completed assessment (i.e. also after 1 month and 3 months). The control group completed only the assessment and students were thanked for participation. All participants received PNF after the final assessment (at 6-months).

2.4. Measures

Socioeconomic and educational data collected were sex, age, region, family income, type of institution (private or public), and course year.

2.5. Outcomes

All outcome measures referred to the past 30 days. The primary outcomes were the typical number of drinks per week and the maximum number of drinks per week, both extracted from the *Daily Drinking Questionnaire Revised* (DDQ-R) (Collins et al., 1985). Participants responded for each day of the week how many drinks they usually consume and how many drinks they had on the week where they drank most. A score of drinks per week was calculated by summing responses for each day of the week (ranged: 0–140). Cronbach's alphas (α) were 0.89 for the number of typical drinks and 0.85 for the maximum number of drinks.

The secondary outcomes were drinking frequency and alcohol-related consequences. Drinking frequency was extracted from DDQ-R as the typical number of days with alcohol use (range 0–7; α: 0.90). The number of alcohol-related consequences was measured using an adapted version of the *Short Inventory of Problems – Revised* (SIP-R) (Kiluk et al., 2013) using yes/no responses (instead of frequency of occurrence) to reduce the amount of time to complete assessment given the naturalistic online setting. A score was calculated by summing the number of reported consequences (α=0.90).

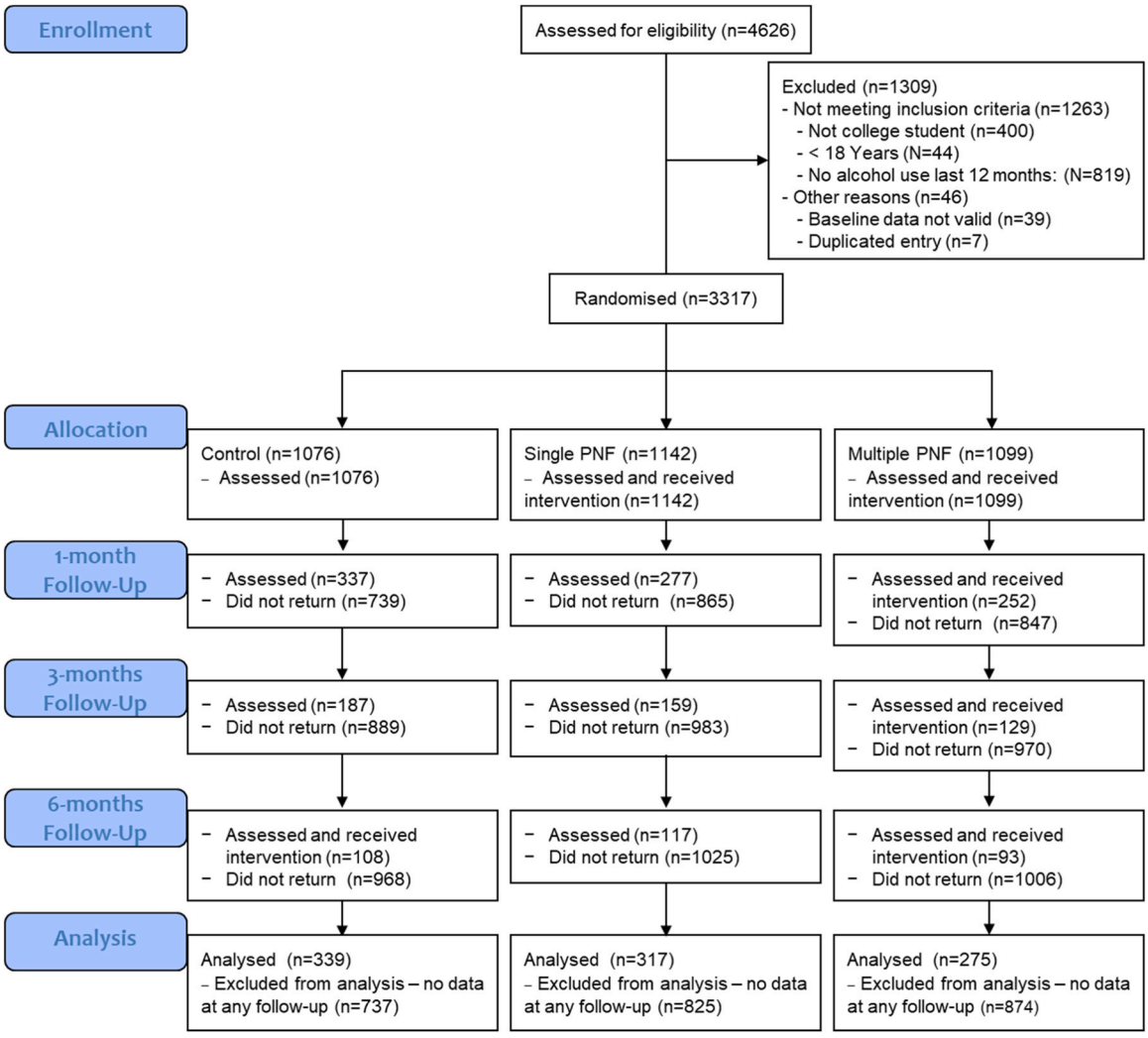

Fig. 1. CONSORT flowchart.

2.6. Mediator

Descriptive norms were measured with the *Drinking Norms Rating Form* (Baer et al., 1991). Participants were asked "*How many drinks do you think a typical college student drinks in a typical week?*" Responses for each week day were summed to compute the final score (range: 0–140; α=0.90).

2.7. Moderators

We assessed distinct aspects of motivation as moderators. We used two readiness rulers (LaBrie et al., 2005) as follows: "*How important is it for you to change your current alcohol use?* " and "*How ready are you to change your current alcohol use?*". In addition, *interest* was measured using the following question: "*How interested are you to know more about your current alcohol use?*".

2.8. Statistical analyses

Pearson's Chi-squared test and Wilcoxon Rank sum test were used to compare those who returned or not during follow-ups. To evaluate intervention effectiveness (H1), we used Generalised Mixed Models using group, time, group*time interaction, sex, age, income, institution type (public or private), and outcome measure at baseline as fixed factors and participant id as random factor. Models were fitted using a zero-inflated negative binomial distribution. Model quality was assessed using residual diagnostics using *DHARMa* package (Hartig, 2022). Analyses considered data from any participant with at least one of the follow-up measurements (N=931).

3. Mediation, moderation, and moderated mediation analyses

Considering the limited evidence regarding temporality and generalisation of the mediation models previously evaluated, we used a stepwise approach to test hypothesis 3 and 4. First, we performed a simple mediation test (H3). Then, we conducted moderation analyses (H4). Primary analyses used the moderator at baseline, mediator at 1 month and outcomes at 3 months. Secondary analyses additionally tested the mediator at 1 or 3 months and outcomes at 1 or 6 months. Additional details on the models, including the theoretical models, are provided in the Supplementary File. Models were tested under the Conditional Process Analysis with multicategorical antecedent assumptions by applying Helmert coding to group variable [Control vs. either PNF intervention; S-PNF vs. M-PNF] (Hayes, 2022). All models were covariated by sex, age, income, institution type, mediator at baseline and outcome measures at baseline. Confidence intervals were calculated using bootstrap with 5000 replications.

3.1. Sensitivity analyses

Data were checked for missing at random assumption [*VIM* package (Kowarik and Templ, 2016)] and multiple imputation to address missing data was confirmed appropriate. We only imputed data on the outcomes and mediator for participants with at least one follow-up assessment (N=931). Imputation was performed using the predictive mean matching method [*mice* package (van Buuren and Groothuis-Oudshoorn, 2011)], 100 datasets and 20 iterations, which showed to be sufficient according to Fraction of Missing Information values and tests using the *howManyImputations* package (von Hippel, 2020). The amount of data imputed varied depending on the outcome, but data was imputed to a maximum of 32 (3.4%) participants at 1-month, 278 (30%) at 3-month and 658 (70.1%) at 6-month. Supplementary Table 1 describes the non-imputed and imputed data.

All data were analysed using R (version 4.2.1) (R Core Team, 2022) and R Studio (v2022.2.1.461) (RStudio Team, 2022) and using a 5% significance level.

3.2. Sample size calculation

Sample size calculation was performed in the G*Power software v 3.1.9.2, with 10% effect size, significance level of 5% and observed power of 95%, totalising a minimum sample of 264 participants (n=88 per group). Based on our previous study (Bedendo et al., 2020), we assumed a 10% response rate at 6 months, requiring an initial sample of at least 2640 randomised students.

4. Results

4.1. Sample characteristics

A total of 3317 students were randomised and 866 (26.1%) were assessed at 1 month, 475 (14.3%) at 3 and 318 (9.6%) at 6 months. 931 (28.1%) completed at least one of the follow-up assessments (Fig. 1). Baseline characteristics are reported in Table 1.

Supplementary Table 2 presents participants' characteristics by attrition status [at least one follow-up (N=931) or having no follow-up (N=2386)]. Attrition was significantly higher among students in the M-PNF group (p= 0.003), at younger ages (p<0.001), in those from private institutions (p<0.001), reporting higher levels of alcohol use (median typical drinks, p<0.001; median maximum drink, p<0.001; median drinking frequency, p=0.003, more severe alcohol use [AUDIT risk; (p=0.009)], and lower readiness to change (p=0.037).

4.2. Intervention effectiveness (H1 and H2)

Intervention effects on primary and secondary outcomes are presented in Table 2**.** Compared to control, participants randomised to any intervention (S-PNF or M-PNF) reported a smaller typical number of drinks consumed per week at 1 month [IRR: 0.77, 95% Confidence Interval (CI): 0.66 – 0.90, p<0.001] and at 3 months (IRR: 0.77, 95%CI: 0.63 – 0.94, p=0.01). Maximum number of drinks per week at 1 month was also significantly smaller [IRR: 0.69, 95CI: 0.58 – 0.82, p<0.001]. However, sensitivity analysis only confirmed the effects at 1-month (Supplementary Table 3). There were no significant effects on the primary outcomes when the two interventions were compared directly (S-PNF vs M-PNF).

On the secondary outcomes, receiving any intervention was related to a smaller number of consequences reported at 3-months (IRR: 0.79, 95%CI: 0.65 – 0.97, p=0.023), as compared to control. This effect was confirmed in sensitivity analysis. Again we found no evidence that M-PNF yielded better effects compared to S-PNF.

Table 1
Sample characteristics at baseline.

	Control (N=339)	S-PNF (N=317)	M-PNF (N=275)	Total (N=931)
Sex				
- Male	120 (35.4%)	99 (31.2%)	94 (34.2%)	313 (33.6%)
Age (year)				
- M(DP)	24.6 (7.7)	24.6 (7.3)	23.9 (6.6)	24.4 (7.2)
Institution				
- Public	157 (47.7%)	151 (49.8%)	120 (45.6%)	428 (47.8%)
- Private	172 (52.3%)	152 (50.2%)	143 (54.4%)	467 (52.2%)
- missing	10	14	12	36
Typical number of drinks per week				
- Median (Q1, Q3)	4 (2, 12)	5 (2, 12)	5 (2, 12)	5 (2, 12)
Maximum number of drinks per week				
- Median (Q1, Q3)	8.0 (3.0, 16.0)	7.0 (3.0, 17.0)	6.0 (3.0, 16.0)	7.0 (3.0, 16.0)
Drinking frequency (days/week)				
- Median (Q1, Q3)	2.0 (1.0, 3.0)	2.0 (1.0, 3.0)	2.0 (1.0, 3.0)	2.0 (1.0, 3.0)
Number of consequences				
- Median (Q1, Q3)	1.0 (0.0, 3.0)	1.0 (0.0, 3.0)	1.0 (0.0, 3.0)	1.0 (0.0, 3.0)
- missing	8	13	11	32
Descriptive Norms (drinks/week)				
- Median (Q1, Q3)	18.0 (11.0, 30.0)	20.0 (12.0, 34.0)	20.0 (12.0, 31.0)	19.0 (12.0, 32.0)
- missing	4	5	3	12
Interest				
- Median (Q1, Q3)	7.0 (5.0, 10.0)	7.0 (6.0, 10.0)	8.0 (6.0, 10.0)	7.0 (5.0, 10.0)
- missing	4	7	5	16
Readiness				
- Median (Q1, Q3)	5.0 (3.0, 7.0)	5.0 (3.0, 8.0)	5.0 (2.0, 7.0)	5.0 (2.5, 8.0)
- missing	4	7	5	16
Importance				
- Median (Q1, Q3)	4.0 (1.0, 6.0)	4.0 (2.0, 7.0)	3.0 (0.0, 6.0)	4.0 (1.0, 6.0)
- missing	4	7	5	16

Missing described only when applicable. PNF: Personalised normative feedback.

4.3. Simple mediation (H3)

Table 3 presents simple mediation models evaluating whether the intervention effects on the outcomes at 3 months were mediated by descriptive norms at 1 month. These analyses showed no significant indirect effects on primary or secondary outcomes. There was evidence of a significant *a1 path* for all models (Table 3), meaning that participants receiving any of the interventions (*S-PNF* or *M-PNF*) reported lower descriptive norms after 1 month compared to the control group. When comparing S-PNF *vs* M-PNF, both interventions yielded similar effects on the mediator (non-significant *a2 path*). Sensitivity analysis confirmed all results (Supplementary Table 4). Secondary simple mediation models are shown in Supplementary Table 5. Two indirect effects emerged as significant from the analyses. Compared to control, descriptive norms at 3 months mediated the effects of any intervention (*S-PNF or M-MPF*) on the number of typical drinks after 6 months (***Indirect Effect D1:*** b=-0.82, 95%CI: −2.03;-0.12). Similarly, descriptive norms at 1 month mediated the interventions effects on the maximum number of drinks after 6 months (***Indirect Effect D1:*** b=-0.54, 95%CI: −1.65;-0.02). Both indirect effects were confirmed in sensitivity analysis (Supplementary Table 6).

Table 2
Intervention effects after 1, 3 and 6 months on primary and secondary outcomes.

	Typical number of drinks per week			Maximum number of drinks per week			Drinking frequency			Number of consequences		
	IRR	*IC95%*	*p*	*IRR*	*IC95%*	*p*	*IRR*	*IC95%*	*p*	*IRR*	*IC95%*	*p*
Group (ref = Control)												
Any PNF	1.05	0.92 – 1.21	0.449	1.01	0.89 – 1.16	0.847	1.04	0.94 – 1.15	0.458	0.88	0.76 – 1.02	0.098
Group (ref = S-PNF)												
M-PNF	1.00	0.84 – 1.18	0.963	0.98	0.83 – 1.16	0.832	1.00	0.89 – 1.13	0.988	0.90	0.75 – 1.09	0.288
Time (ref = Baseline)												
Time [1 month]	**0.77**	**0.72 – 0.84**	**<0.001**	**0.77**	**0.70 – 0.83**	**<0.001**	**0.88**	**0.82 – 0.95**	**0.001**	**0.87**	**0.80 – 0.95**	**0.001**
Time [3 months]	**0.83**	**0.75 – 0.91**	**<0.001**	**0.87**	**0.78 – 0.96**	**0.007**	0.92	0.84 – 1.00	0.062	**0.84**	**0.76 – 0.93**	**0.001**
Time [6 months]	**0.87**	**0.78 – 0.98**	**0.017**	0.94	0.84 – 1.06	0.327	**0.88**	**0.80 – 0.98**	**0.017**	**0.83**	**0.74 – 0.94**	**0.002**
Group*Time (ref = Control*Baseline)												
Any PNF [1 month]	**0.77**	**0.66 – 0.90**	**0.001**	**0.69**	**0.58 – 0.82**	**<0.001**	0.87	0.75 – 1.01	0.075	0.89	0.75 – 1.05	0.151
Any PNF [3 months]	**0.77**	**0.63 – 0.94**	**0.010**	0.86	0.70 – 1.07	0.173	0.92	0.77 – 1.10	0.375	**0.79**	**0.65 – 0.97**	**0.023**
Any PNF [6 months]	0.87	0.69 – 1.09	0.228	0.82	0.64 – 1.05	0.116	0.94	0.76 – 1.17	0.597	0.89	0.70 – 1.13	0.327
Group*Time (ref = S-PNF*Baseline)												
M-PNF [1 month]	0.89	0.73 – 1.08	0.227	0.92	0.74 – 1.14	0.454	0.91	0.75 – 1.10	0.321	1.01	0.82 – 1.26	0.898
M-PNF [3 months]	0.89	0.70 – 1.14	0.350	1.04	0.80 – 1.34	0.790	1.07	0.86 – 1.35	0.541	1.12	0.86 – 1.45	0.398
M-PNF [6 months]	1.13	0.86 – 1.50	0.380	0.98	0.73 – 1.32	0.916	1.14	0.88 – 1.48	0.308	0.88	0.65 – 1.18	0.383

S-PNF: Personalised Normative Feedback presented only at baseline; M-PNF: Personalised Normative Feedback presented on all follow-up. Any PNF (either S-PNF or M-PNF).
Generalised linear mixed models using zero-inflated negative binomial model. All models were covariated by age, sex, income, and outcome measure at baseline. Participant id was used as random factor. Significant effects are highlighted in bold.

4.4. Simple moderation (H4)

Table 4 shows the primary moderation analysis for outcomes measured at 3 months. We found support that *importance* moderated the effects of M-PNF compared to S-PNF (*b5 path*) on the typical number of drinks (b=-1.07, 95%CI: −2.22; −0.32). The secondary models (outcomes at 1 or 6 months) also showed that *interest* moderated M-PNF effects on the number of consequences at 6 months, compared to S-PNF (b=-0.26, 95%CI: −0.57; −0.01; Supplementary Table 7). However, sensitivity analysis did not confirm any of the effects (Supplementary Table 8). With no consistent evidence supporting moderation, we did not examine conditional effects.

4.5. Moderated mediation (H4)

To fully address H4 we also performed moderated mediation analysis as the simple moderation models did not account for mediator effects. Primary models are presented in Table 5**.** None of the primary models supported a moderated mediation of the indirect effects (non-significant Index of Moderated Mediation; Table 5).

The secondary models showed a moderated mediation effect (*Interest* IMM D2*:* Mediator at 3 months and outcomes at 6 months: b=-0.27, 95% CI: −0.72; −0.04; Supplementary Table 9). The effects were not confirmed on sensitivity analysis (Supplementary Table 10).

We also found significant moderation effects of a paths (*a5* path) and direct effects (c'4 and c'5 paths) on both primary (Table 5) and secondary models (Supplementary Table 9), but none of the effects were confirmed on sensitivity analyses (Supplementary Table 10). Therefore, we did not further examine individual paths.

5. Discussion

This pragmatic trial evaluated the effects of a web-based PNF intervention, with or without boosters, and possible mechanisms of change. Hypothesis 1 was only partly confirmed, with evidence supporting effects on both primary outcomes at 1 month, and one secondary outcome at 3 months. Hypotheses 2, 3 and 4 were not confirmed with no evidence supporting the effects of boosters (H2), mediation of effects (H3) or moderation effects (H4) at three months.

The PNF interventions tested in this study thus yielded only short-term effects; after one month on typical and maximum number of drinks, and on consequences after 3 months. The results corroborated our previous trial showing that PNF was effective in reducing reported drinking, and that these effects were robust in the short-term (Bedendo et al., 2019). On the other hand, our previous study showed no significant effects on consequences. Direct comparisons on this outcome are limited as the studies used different scales to assess alcohol-related consequences. Nonetheless, other evidence suggests that the PNF can also reduce alcohol harms (Dotson et al., 2015).

Contrary to our expectations, we found no evidence that boosters improved the magnitude or longevity of PNF effects. Findings on the effectiveness of boosters are, however, mixed. Some studies are supportive of personalised normative boosters (Braitman and Henson, 2016; Neighbors et al., 2010), whilst others demonstrate that alcohol norms booster emails are not effective (Carey et al., 2018). The conflicting evidence may be explained by differences in booster characteristics. They may differ in frequency, delivery timeframe (immediate or delayed presentation at each assessment), content (identical to the initial intervention or a simpler variation of it), delivery mechanism (embedded into the web-based intervention or as an email), and level of personalisation. In our study, boosters involving a replication of the original intervention content were offered immediately after every assessment. This may have had implications for how well participants read and paid attention to the booster contents provided. Our consistent pattern of findings of no booster effects, therefore, are specific to this type of booster and contingent upon examination of study limitations in this pragmatic trial design. We had limited statistical power to study the effects of boosters due to attrition attenuating the number of boosters received and with later assessment. Post hoc analysis testing missing pattern (fully adherent vs partial adherent) did not yield further insights. We should also bear in mind that the effects of boosters are likely to be limited if they do not provide novel intervention content when the effects of the initial intervention are small.

Our mediation hypothesis was not supported; however, we found some indications that mediation effects occurred on later follow-up assessments (i.e., indirect effects of any PNF on typical number of drinks after 6 months through descriptive norms at 3 months). This is broadly in line with various studies showing that mediation effects of descriptive norms are observed after 5 or 6 months (Larimer et al., 2022; Lewis et al., 2007, 2014), but are not at shorter follow-ups (Patrick et al., 2014). This is an interesting pattern, deserving of further scrutiny. In our study, all *a1 paths* were significant indicating that receiving any

Table 3
Simple mediation models testing whether descriptive norms at 1 month mediated the intervention effects on outcomes at 3 months.

	Primary Model		
	Mediator at 1 month Outcome at 3 months		
	B	L95CI	U95CI
Primary Outcome			
Typical number of drinks per week			
a1: *Any PNF (ref = Control)* -> Norms	**-4.08**	**-6.63**	**-1.31**
a2: *M-PNF (ref = S-PNF)* -> Norms	-0.51	-3.70	2.74
b: Norms -> Outcome	0.04	-0.08	0.18
c'1: Direct Effect 1: *Any PNF (ref = Control)*	-1.80	-4.07	0.18
c'2: Direct Effect 2: *M-PNF (ref = S-PNF)*	-0.29	-2.47	2.46
c1: Total Effect 1: *Any PNF (ref = Control)*	**-1.98**	**-3.98**	**-0.21**
c2: Total Effect 2: *M-PNF (ref = S-PNF)*	-0.31	-2.49	2.38
Indirect Effect 1: *Any PNF (ref = Control)*	-0.17	-0.93	0.29
Indirect Effect 2: *M-PNF (ref = S-PNF)*	-0.02	-0.58	0.12
Maximum number of drinks per week			
a1: *Any PNF (ref = Control)* -> Norms	**-4.08**	**-6.79**	**-1.35**
a2: *M-PNF (ref = S-PNF)* -> Norms	-0.47	-3.71	2.55
b1: Norms -> Outcome	0.10	-0.10	0.29
c'1: Direct Effect 1: *Any PNF (ref = Control)*	-2.43	-6.25	0.62
c'2: Direct Effect 2: *M-PNF (ref = S-PNF)*	0.33	-2.77	4.01
c1: Total Effect 1: *Any PNF (ref = Control)*	**-2.83**	**-6.21**	**-0.12**
c2: Total Effect 2: *M-PNF (ref = S-PNF)*	0.28	-2.86	3.92
Indirect Effect 1: *Any PNF (ref = Control)*	-0.40	-1.68	0.30
Indirect Effect 2: *M-PNF (ref = S-PNF)*	-0.05	-0.80	0.24
Secondary Outcomes			
Drinking frequency			
a1: *Any PNF (ref = Control)* -> Norms	**-4.07**	**-6.69**	**-1.36**
a2: *M-PNF (ref = S-PNF)* -> Norms	-0.53	-3.86	2.60
b: Norms -> Outcome	0.003	-0.01	0.02
c'1: Direct Effect 1: *Any PNF (ref = Control)*	-0.17	-0.46	0.13
c'2: Direct Effect 2: *M-PNF (ref = S-PNF)*	0.08	-0.22	0.38
c1: Total Effect 1: *Any PNF (ref = Control)*	-0.18	-0.46	0.10
c2: Total Effect 2: *M-PNF (ref = S-PNF)*	0.07	-0.22	0.38
Indirect Effect 1: *Any PNF (ref = Control)*	-0.01	-0.09	0.04
Indirect Effect 2: *M-PNF (ref = S-PNF)*	-0.001	-0.05	0.02
Number of consequences			
a1: *Any PNF (ref = Control)* -> Norms	**-4.10**	**-6.83**	**-1.43**
a2: *M-PNF (ref = S-PNF)* -> Norms	-0.45	-3.70	2.74
b1: Norms -> Outcome	-0.01	-0.03	0.02
c'1: Direct Effect 1: *Any PNF (ref = Control)*	**-0.54**	**-1.06**	**-0.06**
c'2: Direct Effect 2: *M-PNF (ref = S-PNF)*	0.13	-0.36	0.68
c1: Total Effect 1: *Any PNF (ref = Control)*	**-0.52**	**-1.00**	**-0.06**
c2: Total Effect 2: *M-PNF (ref = S-PNF)*	0.13	-0.37	0.68
Indirect Effect 1: *Any PNF (ref = Control)*	0.02	-0.10	0.14
Indirect Effect 2: *M-PNF (ref = S-PNF)*	0.002	-0.04	0.07

S-PNF: Personalised Normative Feedback presented only at baseline; M-PNF: Personalised Normative Feedback presented on all follow-up. Any PNF (either S-PNF or M-PNF).
All models were covariated by age, sex, income, and outcome measure at baseline. Significant effects are highlighted in bold.

intervention was related to a change in descriptive norms as expected. This change in descriptive norms, however, did not translate into change in reported drinking (*b path*). Our sensitivity analysis showed a significant indirect effect. This suggests that our main analyses lacked power and further research is needed, in line with our findings on boosters.

We found no consistent evidence supporting moderation on any of the paths tested (either from simple moderation or moderated mediation models). We also did not replicate the findings of our previous study showing preliminary evidence that interest moderates some PNF effects (Bedendo et al., 2019, 2020). The differences may have resulted from a different approach than used in the earlier study, which dichotomised participant's interest while the present study used a continuous variable, suggesting the merits of post-hoc exploratory analyses. The lack of findings on readiness to change are in line with at least one moderator evaluation of college alcohol intervention effects (Grossbard et al., 2016). The consistency of our moderator findings across three different measures of motivational variables is noteworthy. In addition, other

Table 4
Moderation analysis using moderator at baseline and outcomes at 3 months.

	Primary Model Outcome at 3 Months					
	Interest		Readiness		Importance	
	B	95%CI	B	95%CI	B	95%CI
Primary Outcome						
Typical number of drinks per week						
b1: Any PNF (ref = Control) -> Outcome	**-4.41**	**-9.25; −0.46**	0.05	-3.76; 4.50	-0.42	-2.99; 2.50
b2: M-PNF (ref = S-PNF) -> Outcome	0.23	-6.10; 5.25	2.52	-3.14; 11.40	3.92	-0.10; 10.35
b3: Moderator -> Outcome	0.24	-0.04; 0.52	**-0.32**	**-0.69; −0.04**	-0.11	-0.62; 0.24
b4: Any PNF (ref = Control) * Moderator -> Outcome	0.35	-0.24; 1.07	-0.37	-1.17; 0.23	-0.39	-1.18; 0.23
b5: M-PNF (ref = S-PNF) * Moderator -> Outcome	-0.05	-0.88; 1.08	-0.47	-1.70; 0.33	**-1.07**	**-2.22; −0.32**
Maximum number of drinks per week						
b1: Any PNF (ref = Control) -> Outcome	**-7.29**	**-14.26; −1.69**	-0.66	-6.55; 5.70	-0.77	-4.68; 3.43
b2: M-PNF (ref = S-PNF) -> Outcome	3.36	-4.89; 10.57	1.89	-5.11; 12.48	4.42	-0.69; 12.24
b3: Moderator -> Outcome	**0.42**	**0.02; 0.90**	-0.38	-0.90; 0.05	0.07	-0.40; 0.53
b4: Any PNF (ref = Control) * Moderator -> Outcome	0.65	-0.31; 1.62	-0.39	-1.55; 0.52	-0.49	-1.75; 0.50
b5: M-PNF (ref = S-PNF) * Moderator -> Outcome	-0.37	-1.58; 1.11	-0.16	-1.58; 0.79	-0.98	-2.34; 0.02
Secondary Outcomes						
Drinking frequency						
b1: Any PNF (ref = Control) -> Outcome	-0.03	-0.75; 0.69	-0.11	-0.66; 0.42	0.06	-0.34; 0.45
b2: M-PNF (ref = S-PNF) -> Outcome	-0.01	-0.94; 1.08	0.10	-0.50; 0.78	0.19	-0.26; 0.69
b3: Moderator -> Outcome	0.02	-0.03; 0.07	**-0.05**	**-0.09; −0.01**	-0.03	-0.07; 0.02
b4: Any PNF (ref = Control) * Moderator -> Outcome	-0.02	-0.11; 0.08	-0.01	-0.10; 0.08	-0.06	-0.15; 0.03
b5: M-PNF (ref = S-PNF) * Moderator -> Outcome	0.01	-0.13; 0.14	0.004	-0.09; 0.09	-0.03	-0.12; 0.06
Number of Consequences						
b1: Any PNF (ref = Control) -> Outcome	-0.62	-1.80; 0.38	-0.33	-1.21; 0.53	-0.03	-0.64; 0.55
b2: M-PNF (ref = S-PNF) -> Outcome	-0.58	-1.69; 0.46	-0.54	-1.42; 0.37	-0.40	-1.09; 0.30
b3: Moderator -> Outcome	-0.02	-0.08; 0.05	-0.05	-0.13; 0.02	-0.01	-0.09; 0.07
b4: Any PNF (ref = Control) * Moderator -> Outcome	0.02	-0.13; 0.17	-0.03	-0.18; 0.11	-0.12	-0.27; 0.02
b5: M-PNF (ref = S-PNF) * Moderator -> Outcome	0.10	-0.07; 0.29	0.15	-0.01; 0.30	0.15	-0.02; 0.32

S-PNF: Personalised Normative Feedback presented only at baseline; M-PNF: Personalised Normative Feedback presented on all follow-up. Any PNF (either S-PNF or M-PNF).
Moderators (interest, readiness, and important) assessed at baseline. All models

were covariated by age, sex, income, and outcome measure at baseline. Significant effects are highlighted in bold.

moderators, not tested here, may have been at play. For example, participants' sex or alcohol problems severity have been shown to moderate effects, at least in some contexts (Baumann et al., 2018; Baumann et al., 2018; Voogt et al., 2013). We did not test these moderators since they were not pre-registered and since there were already many analyses, but further studies might consider these. Such analyses could be conducted separately for each moderator or by combining these, also with the readiness measures presented here, since recent research showed that participants' profiles based on several dimensions (e.g., gender, severity, readiness, mental health) have significantly moderated effects of brief alcohol intervention (Frohlich et al., 2022; Gaume et al., 2023).

5.1. Strengths and limitations

The pragmatic nature of this study, without using any financial incentives for participation enabled us to explore how PNF performs in the context of real-world implementation. The pragmatic trial design is a major study strength, and the context also imposes study limitations. The recruited study population is highly appropriate, but attrition is the main limitation of this study, and is a well-known issue with evaluation studies of web-based interventions. The effects of attrition were studied carefully in analyses performed using multiple imputation models, and only consistent results throughout the models were deemed robust. We suggest this approach is appropriately conservative. The attrition analyses showed that the study population from whom we obtained outcome data were distinct from the randomised population in various ways. This means it is appropriate to attach an important caveat to the conclusions we draw. We chose not to erect barriers to study participation in the form of study procedures, the effects of which were examined in the AMADEUS trials (Bendtsen et al., 2015; McCambridge et al., 2013). Note seemingly small biases are particularly relevant to consider carefully in contexts such as this where intervention effects are themselves small. Trial recruitment occurred during different phases of the COVID-19 pandemic, which affected Brazil, and the associated restrictions may have had impacts on follow-up. Additional analyses (not shown) examined the intervention effects when covaried by 1) time when participants completed the questionnaires; or 2) pandemic-related variables [a) whether the student was in isolation/quarantined when first accessed the intervention; b) whether their alcohol use changed during the isolation/quarantine (increased, decreased, no change)] and confirmed the effects deemed as consistent. One final study limitation should be borne in mind. Due to the nationwide data collection, more proximal referent groups (e.g., same campus peers) may have yielded more pronounced normative feedback effects than the approach we used.

6. Conclusions

PNF compared to an assessment-only control group reduced reported drinking after 1 month. There was no strong evidence that the effects of the intervention were mediated by descriptive norms, or evidence of moderation by motivation, or evidence supportive of the effects of the boosters used in this study. Real-world evidence of mechanisms of change of web-based PNF, information that is pivotal for intervention optimisation, is lacking in this study. Nonetheless, we suggest that we have demonstrated proof of concept, that it is possible to conduct large pragmatic trials which do examine mediators and moderators of effectiveness. On the basis of this study we suggest much larger sample sizes, optimisation of attrition prevention with particular reference to minimising between-group differences, rigorous analyses of missing data and caution in drawing inferences are needed for further study of PNF intervention among college students. This proposal does not imply that tightly controlled efficacy and mechanisms studies should not be

Table 5
Moderated mediation models with descriptive norms (mediator) at 1 month and outcomes at 3 months.

	Primary Model (Mediator at 1 month outcome at 3 months)					
	Interest		Readiness		Importance	
	B	95%CI	B	95%CI	B	95%CI
Primary Outcome						
Typical number of drinks per week						
a1: *Any PNF (ref = Control)* -> Norms	-0.89	-7.66; 6.87	**-6.20**	**-11.06; −1.36**	-3.89	-7.67; 0.03
a2: *M-PNF (ref = S-PNF)* -> Norms	1.89	-8.34; 13.24	-1.57	-7.41; 4.55	0.13	-4.61; 4.65
a3: Moderator -> Norms	-0.40	-1.04; 0.15	-0.10	-0.54; 0.32	-0.17	-0.64; 0.29
a4: *Any PNF (ref = Control)* * Moderator -> Norms	-0.44	-1.44; 0.44	0.42	-0.48; 1.37	-0.05	-0.90; 0.80
a5: *M-PNF (ref = S-PNF)* * Moderator -> Norms	-0.34	-1.81; 0.96	0.21	-0.95; 1.30	-0.20	-1.26; 0.71
b1: Norms -> Outcome	0.05	-0.08; 0.19	0.04	-0.08; 0.16	0.04	-0.08; 0.18
c'1: *Any PNF (ref = Control)* -> Outcome	**-4.67**	**-10.07; −0.52**	-0.41	-3.97; 3.36	-0.64	-3.00; 2.07
c'2: *M-PNF (ref = S-PNF)* -> Outcome	-0.70	-8.63; 5.23	2.88	-2.98; 10.36	3.74	-0.08; 8.97
c'3: Moderator -> Outcome	**0.30**	**0.01; 0.69**	**-0.38**	**-0.77; −0.07**	-0.11	-0.58; 0.24
c'4: *Any PNF (ref = Control)* * Moderator -> Outcome	0.39	-0.24; 1.18	-0.28	-0.93; 0.28	-0.33	-1.04; 0.24
c'5: *M-PNF (ref = S-PNF)* * Moderator -> Outcome	0.03	-0.89; 1.20	-0.59	-1.73; 0.28	**-1.10**	**-2.16; −0.31**
IMM 1: *Any PNF (ref = Control)*	-0.02	-0.20; 0.03	0.02	-0.03; 0.16	-0.002	-0.09; 0.05
IMM 2: *M-PNF (ref = S-PNF)*	-0.02	-0.24; 0.05	0.01	-0.04; 0.16	-0.01	-0.15; 0.03
Maximum number of drinks per week						
a1: *Any PNF (ref = Control)* -> Norms	-0.83	-7.86; 6.99	**-6.12**	**-10.84; −1.27**	-3.59	-7.59; 0.35
a2: *M-PNF (ref = S-PNF)* -> Norms	0.79	-10.17; 12.05	-1.89	-8.15; 4.36	-0.29	-5.24; 4.36
a3: Moderator -> Norms	-0.31	-0.93; 0.27	-0.17	-0.59; 0.27	-0.10	-0.60; 0.34
a4: *Any PNF (ref = Control)* * Moderator -> Norms	-0.45	-1.44; 0.45	0.40	-0.49; 1.33	-0.12	-0.98; 0.73
a5: *M-PNF (ref = S-PNF)* * Moderator -> Norms	-0.17	-1.68; 1.24	0.28	-0.89; 1.50	-0.08	-1.10; 0.89
b1: Norms -> Outcome	0.11	-0.10; 0.31	0.10	-0.09; 0.29	0.09	-0.10; 0.29
c'1: *Any PNF (ref = Control)* -> Outcome	**-7.74**	**-14.82; −2.29**	-0.94	-6.51; 4.12	-0.90	-4.66; 2.65

(*continued on next page*)

Table 5 (*continued*)

	Primary Model (Mediator at 1 month outcome at 3 months)					
	Interest		Readiness		Importance	
	B	95%CI	B	95%CI	B	95%CI
c'2: *M-PNF (ref = S-PNF)* -> Outcome	1.68	-9.54; 9.58	2.41	-4.61; 11.64	4.17	-0.60; 10.69
c'3: Moderator -> Outcome	**0.53**	**0.07; 1.12**	**-0.45**	**-1.02; −0.02**	0.05	-0.47; 0.49
c'4: *Any PNF (ref = Control)* * Moderator -> Outcome	0.74	-0.16; 1.75	-0.30	-1.34; 0.58	-0.42	-1.66; 0.58
c'5: *M-PNF (ref = S-PNF)* * Moderator -> Outcome	-0.23	-1.47; 1.43	-0.37	-1.77; 0.67	**-1.07**	**-2.40; −0.03**
IMM 1: *Any PNF (ref = Control)*	-0.05	-0.37; 0.04	0.04	-0.04; 0.28	-0.01	-0.23; 0.07
IMM 2: *M-PNF (ref = S-PNF)*	-0.02	-0.32; 0.14	0.03	-0.07; 0.34	-0.01	-0.19; 0.11
Secondary Outcomes						
Drinking frequency						
a1: *Any PNF (ref = Control)* -> Norms	-0.84	-8.29; 6.74	**-5.67**	**-10.78; −0.78**	-3.36	-7.53; 0.65
a2: *M-PNF (ref = S-PNF)* -> Norms	0.39	-11.45; 12.69	-1.70	-8.33; 4.44	-0.20	-5.31; 4.63
a3: Moderator -> Norms	-0.34	-1.00; 0.27	-0.18	-0.61; 0.26	-0.09	-0.55; 0.32
a4: *Any PNF (ref = Control)* * Moderator -> Norms	-0.45	-1.40; 0.52	0.32	-0.62; 1.29	-0.18	-1.06; 0.73
a5: *M-PNF (ref = S-PNF)* * Moderator -> Norms	-0.13	-1.71; 1.39	0.22	-0.90; 1.38	-0.11	-1.17; 0.87
b1: Norms -> Outcome	0.003	-0.01; 0.02	0.003	-0.01; 0.02	0.003	-0.01; 0.02
c'1: *Any PNF (ref = Control)* -> Outcome	-0.04	-0.76; 0.66	-0.15	-0.70; 0.36	0.04	-0.35; 0.44
c'2: *M-PNF (ref = S-PNF)* -> Outcome	-0.05	-1.02; 1.06	0.13	-0.46; 0.82	0.18	-0.27; 0.67
c'3: Moderator -> Outcome	0.02	-0.03; 0.07	**-0.05**	**-0.09; −0.01**	-0.03	-0.07; 0.01
c'4: *Any PNF (ref = Control)* * Moderator -> Outcome	-0.02	-0.12; 0.08	-0.004	-0.09; 0.09	-0.06	-0.15; 0.03
c'5: *M-PNF (ref = S-PNF)* * Moderator -> Outcome	0.02	-0.12; 0.14	-0.01	-0.11; 0.09	-0.03	-0.12; 0.06
IMM 1: *Any PNF (ref = Control)*	-0.001	-0.02; 0.004	0.001	-0.004; 0.01	-0.001	-0.01; 0.004
IMM 2: *M-PNF (ref = S-PNF)*	0.000	-0.02; 0.01	0.001	-0.005; 0.02	0.000	-0.01; 0.005
Number of consequences						
a1: *Any PNF (ref = Control)* -> Norms	-0.57	-7.76; 7.53	**-5.44**	**-10.65; −0.51**	-3.10	-7.16; 1.00
a2: *M-PNF (ref = S-PNF)* -> Norms	0.09	-12.55; 12.02	-1.91	-8.69; 4.64	-0.38	-5.49; 4.65
a3: Moderator -> Norms	-0.29	-0.90; 0.25	-0.23	-0.68; 0.20	-0.13	-0.56; 0.28
a4: *Any PNF (ref = Control)* * Moderator -> Norms	-0.49	-1.49; 0.45	0.27	-0.67; 1.27	-0.24	-1.13; 0.61
a5: *M-PNF (ref = S-PNF)* * Moderator -> Norms	-0.07	-1.63; 1.52	0.28	-0.92; 1.42	-0.05	-1.06; 0.91
b1: Norms -> Outcome	-0.004	-0.03; 0.02	-0.01	-0.03; 0.02	-0.01	-0.03; 0.02
c'1: *Any PNF (ref = Control)* -> Outcome	-0.58	-1.80; 0.48	-0.46	-1.32; 0.38	-0.11	-0.72; 0.47
c'2: *M-PNF (ref = S-PNF)* -> Outcome	-0.49	-1.59; 0.56	-0.43	-1.29; 0.50	-0.38	-1.03; 0.33
c'3: Moderator -> Outcome	-0.02	-0.09; 0.04	-0.06	-0.15; 0.01	-0.02	-0.10; 0.06
c'4: *Any PNF (ref = Control)* * Moderator -> Outcome	0.01	-0.17; 0.17	-0.02	-0.16; 0.11	-0.11	-0.26; 0.03
c'5: *M-PNF (ref = S-PNF)* * Moderator -> Outcome	0.09	-0.08; 0.26	0.12	-0.04; 0.29	0.14	-0.05; 0.32
IMM 1: *Any PNF (ref = Control)*	0.002	-0.01; 0.04	-0.001	-0.03; 0.01	0.001	-0.01; 0.03
IMM 2: *M-PNF (ref = S-PNF)*	0.000	-0.02; 0.03	-0.002	-0.03; 0.01	0.000	-0.01; 0.02

S-PNF: Personalised Normative Feedback presented only at baseline; M-PNF: Personalised Normative Feedback presented on all follow-up. Any PNF (either S-PNF or M-PNF).

IMM 1: Index of Moderated Mediation comparing Control vs Any PNF intervention. IMM 2: Index of Moderated Mediation comparing Single PNF vs Multiple PNF].

Moderators (interest, readiness, and important) assessed at baseline, mediator (descriptive norms) at 1 month and outcome at 3 months. All models were covariated by age, sex, income, and outcome measure at baseline.

undertaken. Finally, we suggest it is appropriate that such studies make internal or external comparisons with other population-level interventions which may have larger effects.

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CRediT authorship contribution statement

Andre Bedendo: Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Ana Regina Noto:** Writing – review & editing, Conceptualization. **Maria Lucia Oliveira Souza-Formigoni:** Writing – review & editing, Funding acquisition, Conceptualization. **Jacques Gaume:** Writing – review & editing, Methodology, Conceptualization. **Jim McCambridge:** Writing – review & editing, Methodology, Conceptualization.

Declaration of Competing Interest

We have no conflicts of interest to disclose.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.drugalcdep.2024.111337.

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