**Components evaluation of a web-based personalised normative feedback intervention for alcohol use among college students: a pragmatic randomised controlled trial with a dismantling design**

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**Abstract**

*Aims*

To evaluate the effects of the two main components of a Personalised Normative Feedback (PNF) (Normative feedback only –NFO; and Consequences feedback only - CFO) compared with the full intervention (PNF) in reducing alcohol use and consequences.

*Design*

Three-arm pragmatic randomised controlled trial with dismantling design and 1-, 3-, and 6-months follow-ups.

*Setting*

Web-based among Brazilian college students.

*Participants*

College students (18-30 years old) who reported alcohol use in the last three months (N=5,476).

*Interventions*

1) full PNF – a) drinking profile; b) normative comparisons; c) practical costs; d) alcohol consequences; e) strategies to decrease risks; 2) NFO – components a, b, and e; or 3) CFO – components c, d, and e.

*Measurements*

The primary outcome was change in AUDIT score; secondary outcomes were the number of alcohol consequences, drinking frequency, and typical/maximum number of drinks. We used Mixed Models with Multiple Imputation and Pattern-Mixture Model to account for attrition. Subgroup analyses considered participant motivation to know more about their drinking (less motivated *vs* motivated).

*Findings*

Dismantled components reduced rather than increased AUDIT score compared to full PNF, with significant effects for NFO at 1 month (b=-0.23 95%CI: -0.46;-0.002) and for CFO at 3-months (b=-0.33 95%CI:-0.62;-0.03). Compared with PNF, NFO reduced the number of alcohol consequences at 1 month (b=-0.16 95%CI:-0.25;-0.06) and drinking frequency at 3 months (b=-0.42 95%CI:-0.79;-0.05), but increased the number of typical drinks at 6 months (b= 0.38, 95%CI:0.04;0.72). CFO reduced drinking frequency at 3 months (b=-0.37 95%CI:-0.73;-0.01). Attrition models confirmed all results, except for the NFO effect on typical drinks and drinking frequency. Subgroup analyses indicated superiority of dismantled components among the students less motivated in knowing more about their drinking.

*Conclusions*

There was no evidence that either the normative or the consequences components of a web-based Personalised Normative Feedback (PNF) intervention to reduce alcohol use and its consequences contributed to intervention effects. There was some evidence of adverse effects of PNF, and these results were driven by 20% of participants who were less motivated in knowing more about their drinking.

**Keywords:** alcohol; college student; personalised normative feedback; intervention components; dismantling design

# Introduction

Alcohol use was responsible for 3 million deaths and 132.6 million disability-adjusted life years (DALYs) worldwide in 2016, and young people (20-39 years) were the most affected, accounting for 13.5% of all deaths (1). Among this age group, college students are particularly at risk of alcohol-related consequences as they consistently show higher alcohol consumption levels than same age non-college peers (2). In Brazil, despite nearly two thirds of college students reporting alcohol use during the last month, approximately only one quarter of higher education institutions offer programs about alcohol or drugs (3).

Perceived and actual social drinking norms (how one thinks others drink and how they actually drink) are associated with alcohol use among college students (4, 5). College students overestimate perceived norms (5, 6), and overestimation of peer group drinking is a predictor of students’ own drinking (7). Social norms interventions, including Personalised Normative Feedback (PNF), provide information about the actual norms aiming to correct misperceptions and reduce alcohol use (8). According to Social Norms Theory, this approach should be effective if interventions could successfully modify perceived norms (9). PNF has been widely evaluated and reviews show small effects in reducing alcohol use among college students (8, 10-12). Despite advances in trials, there are few studies examining PNF’s most effective components or other kinds of mechanistic studies testing the underlying theory (11, 13).

Several studies have shown that changing normative perceptions mediates PNF effects on alcohol use (11, 14-16). Conversely, dismantling studies suggested that PNF effects occur independently of the presence of the normative feedback (17, 18). However, there is substantial methodological heterogeneity in the studies, including how pragmatic are the trials, the use of different populations, and diversity of components studied. On the other hand, one meta-analysis identified that stronger intervention effects were found in studies with more components, and reframing alcohol use in practical costs also elicited changes on alcohol use (11). As far as we are aware, there are no previous trials which have directly compared the effects of the normative and practical costs feedback components of the PNF in the same controlled study.

This study therefore used a dismantling design to evaluate the effects of the absence of the two main components of PNF hypothesised to be the active contributors (Normative feedback only –NFO; and Consequences feedback only - CFO) compared to the full intervention (PNF) in reducing alcohol use and number consequences among Brazilian college students. Formally, the null hypotheses tested are that there are no differences between the effects of the full PNF and the dismantled versions lacking each of the components on AUDIT score and other outcomes investigated. Rejection of the null hypothesis provides evidence in favour of the contribution of the missing component. The performance of the normative feedback component is of particular theoretical interest as it is the defining component of the full intervention.

# Methods

## Design

This study was part of a larger parallel-group pragmatic randomised controlled trial with a 1:1:1:1 allocation ratio designed to evaluate the effectiveness of the PNF compared to a non-intervention control group, and the present dismantling study (Trial Registration: NCT02058355). A previous report (19) showed that the PNF full intervention was effective in reducing the typical number of drinks, but not other outcomes, compared to the control group (assessment only). It also showed that the intervention effects were moderated by participant motivation to know more about their current alcohol use.

## Participants and recruitment

We recruited college students from all Brazilian states to access a website for “self-evaluating their current alcohol use” from September 2015 to October 2016. Participants accessing the website and completing the baseline assessment were screened according to the following inclusion criteria: aged 18 to 30 years and reporting any alcohol use during the previous three months. Participants not meeting the inclusion criteria were thanked for their time and were not randomised.

Recruitment invitations were sent by e-mail and conveyed using the CIEE’s (*Centro de Integração Empresa-Escola* - Education-Business Integration Centre) Facebook page and institutional website. CIEE is a non-profit national organization that intermediate internships opportunities for students. The e-mail invitations took advantage of CIEE’s database of pre-registered college students from which we draw a subsample of 400.000 students who were invited to participate in the study using eight waves of fortnightly invitations. We did not offer any incentives for participating in the study.

## Interventions and comparator

We developed the website PUB - *Pesquisa Universitária sobre Bebidas* (Undergraduate Research on Alcohol) for delivering a PNF intervention immediately after the assessment. Participants were automatically randomised by the website algorithm to receive one out of three interventions: 1) Full PNF intervention; 2) Normative feedback only; or 3) Consequences feedback only. The feedback content and behaviour change techniques (20) included are presented in **Box 1**. The feedback was repeated after each follow-up. Each participant received up to five e-mails reminding them to access the website to complete the follow-up assessment. Researchers and participants were blind to the intervention allocation.

## Measures

Participants were followed-up 1-, 3-, and 6-months after baseline, and all outcomes pertained to the previous three months. The primary outcome was change in Alcohol Use Disorders Identification Test (AUDIT) (21) score (range: 0-40), for which we investigated the differences in means between follow-up and baseline (Cronbach’s αs ranged from 0.81 to 0.86 across the three time points).

Secondary outcomes were the following: a) Number of alcohol consequences (range: 0-7; derived from the AUDIT questions 4 to 10 as the sum of responses after recoding as binary measures due to low prevalence; 0=no or never; 1= all other categories; Cronbach’s αs ranged from 0.82 to 0.86); b) Maximum number of drinks in a single occasion, measured using a box where participant selected an integer value (range: 0-30; Cronbach’s αs ranged from 0.79 to 0.84); c) Frequency of drinking (derived from AUDIT question 1, recoded as: 0= monthly or less, 1= two to four times a month; 2= two or more times a week; Cronbach’s αs ranged from 0.83 to 0.88); and d) Typical number of drinks (derived from AUDIT question 2, recoded as: 0= one or two drinks, 1= three or four drinks; 2= five or more; Cronbach’s αs ranged from 0.83 to 0.86). The re-categorisation of frequency and typical number of drinks were due to the low prevalence of more frequent drinking and higher number of drinks.

The AUDIT-C, questions 1-3 from AUDIT (22), was used to categorise at-risk drinkers (men: ≥4; women: ≥3) and included as a covariate in the analyses. We also collected individual data [sex, age, region, university type (public or private), college year and motivation]. For assessing motivation, students answered the question “How motivated are you to know more about your current alcohol use? - *O quão motivado você está para saber mais sobre o seu consumo de álcool atual?*” using a visual analogue scale ranging from 0 (not motivated at all) to 10 (highly motivated). We further defined two subgroups “less motivated” (score <3) or “motivated” (score ≥3) according to a series of decision tree analyses using the CHAID algorithm on SPSS v23 software. More details are described elsewhere (19).

## Sample size

The sample size calculation was performed using the statistical software GPower version 3.1.9.2 considering a significance level of 5%, 80% observed power, 10% effect size on the primary outcome for the full intervention versus either component for the 6 month period, and an autoregressive correlation of 0.5 between observations of the same respondent. We decided to power the study on a 0.1 effect size based in prior studies (8, 10, 23) and our pilot study, which were found to be in the range 0.08 - 0.29. Using these criteria, we needed 606 participants (PNF=202; NFO=202; and CFO=202). Data from our pilot study showed that only 58 (2.7%) of randomised participants assessed the 6-months follow-up, then we should randomise approximately 22,445 participants if the level of attrition was expected to be similar.

## Analyses

Intervention effects were analysed with Generalised Mixed Models (GMM) with linear or ordered logit distributions (for continuous and ordinal outcomes, respectively). The distributions were initially assessed using graphical presentation, and then considered the best fitting models according to AIC (Akaike Information Criterion) and BIC (Bayesian Information Criterion). Fixed effects were group, time, group*\**time interaction and covariates (sex, age, region, AUDIT-C, and outcome baseline measure). The participant id was used as a random effect and the covariance matrix was set as exchangeable. The covariance matrix choice considered the nature of our data, AIC values, and the covariance matrix of the model (using the postestimation command *estat vce*). After each model, joint effects were assessed using the command *contrast* and the option *overall.* All analyses were performed using Stata v.15 with a minimum significance level of 5%.

Primary analysis considered all available cases at any follow-up (observed cases - N=5,476). We also conducted subgroup analyses considering student’s motivation to receive the feedback [less motivated (N=1,146) *vs.* motivated (N=4,330)], as this variable has been previously identified as a moderator of PNF effectiveness (19). This sub-group analysis should be regarded as exploratory and *post-hoc* as it was not specified in the original trial registration.

We assumed our data are MNAR (missing not at random) (24). Thus, we performed Multiple Imputation (MI) and Pattern-Mixture Models (PMM) to confirm the results from the observed cases analyses. MI produce less biased estimates of the intervention effects than other methods (mean imputation, LOCF, and random imputation) (25). Imputations were performed using the *mi impute chained* command in Stata, with continuous outcomes (AUDIT score, number of alcohol consequences, and maximum number of drinks) imputed using predictive mean matching, whereas ordered data (frequency of drinking and typical number of drinks) imputed using ordered logistic regression. Imputation was performed separately by intervention groups (*by* option) and included sex, age, region, participant id, motivation, and all outcomes (baseline and follow-up data) as auxiliary variables. We imputed 80 datasets (*m=80*) which were considered adequate for our data (26). Data was imputed for 1,016 participants at 1-month (18.6%), 3,387 at 3-months (61.9%), and 3,900 at 6-months (71.2%) follow-ups. Descriptive data of imputed variables by intervention group are shown in **Table S1**.

Although classical implementation of MI assumes data as MAR, its use under MNAR provides reasonable estimates (27, 28). Thus, we also used Pattern-mixture models (PMM) which are considered an excellent tool for MNAR conditions (29). PMM analyses, followed Hedeker and Gibbons (30) and consisted of creating a dummy variable reflecting missing values (0= data at all follow-ups; 1= data at any follow-ups). Variables were then included as a covariate in the GMM models using a three-way interaction term (group\*time\*attrition), which enabled us to assess the intervention effects while accounting for participants’ dropout.

We performed additional Bayesian analyses to distinguish between evidence of no effect and data insufficient to detect an effect. Bayes Factors (BF) values between 0.33 < BF < 3.0 were considered as suggestive of insensitive data (31), also drawing on Jeffreys’ criteria (32). We calculated BF using the default priors on Stata (considered to be fairly uninformative) and by comparing the alternative model (*H1*: with the interaction term group\*time) to the null model (*H0*: without the interaction terms). All Bayesian models considered the same covariates as the frequentist approach, apart from the use of id as a fixed effect. This adjustment was based on the large sample size and degrees of freedom in the models tested. To improve convergence due to missing data, we used the harmonic-mean approximation for computing marginal likelihood (ML) and the directionality of model (supporting *H1* or *H0*) considered the lowest values of the log(ML).

# Results

*Randomisation and follow-up assessment*

We illustrate the flow diagram of participants in **Figure 1**, where 45,061 participants were screened for eligibility and 34,617 randomised across the 3 arms. We obtained follow-up data from 5,476/34,617 (15.8%) participants who provided information at least once during follow-up assessments: 4,460 (12.9%) at 1-month follow-up; 2,089 (6.0%) at 3-months; and 1,576 (4.6%) at 6-months. Overall, follow-up was a little higher among participants randomised to NFO (15.6%) or CFO (16.9%) compared to those allocated to PNF (15.0%) (p<= 0.001). Unobserved participants not involved in any follow-up (n=29,141) were not significantly different regarding sex (p=0.07), but were a little older (p<0.001), and had lower mean AUDIT scores (p=0.04) compared to those who completed any follow-up (observed cases). Motivated participants were also more adherent (p<0.001) (**Table S2**).

Participants’ sociodemographic and educational characteristics at baseline for each intervention arm are shown in **Table 1** while outcome data at baseline and follow-up are shown in **Table 2**.

*Components’ effectiveness evaluation*

Outcome models are presented in **Table 3** for observed cases and attrition analyses. Contrary to our expectations (the full PNF being more effective than the dismantled versions, particularly CFO), both components reduced the AUDIT score compared to the full PNF at one or more follow-up intervals. There were significant effects for NFO at 1-month (b=-0.23 95%CI:-0.46;-0.002, p= 0.048) and for CFO at 3-months (b=-0.33 95%CI:-0.62;-0.03, p=0.03), and which were confirmed on attrition models. Otherwise, there were no significant differences in relation to the primary outcome. Overall contrast tests confirmed that both NFO and CFO reported lower AUDIT scores than PNF over the study period compared to PNF [x2(11, N=5,476)=198.37, p < 0.001]. Bayesian analysis showed that data supported the *H1* (model with the interaction), with strong evidence supporting an overall effect for NFO (BF:18.49) and CFO (BF:10.14), but was insensitive for detecting an specific effect of NFO at 6-months (BF:1.22) and CFO at 1-month (BF:1.18).

Similarly for the secondary outcomes, NFO reduced the number of consequences at 1-month (b=-0.16 95%CI:-0.25;-0.06, p=0.001) and drinking frequency at 3-months (aOR=0.66 95%CI: 0.45;0.95, p=0.03), whereas the CFO reduced drinking frequency at 3-months (aOR=0.69 95%CI: 0.48;0.99, p=0.045) compared to the full PNF. In one instance, however, there was an effect that had been hypothesised, on the number of typical drinks being higher in NFO compared to full PNF at 6-months (aOR=1.46, 95%CI: 1.04;2.05, p=0.03). Overall contrast tests confirmed that groups were different over time on these outcomes – number of consequences [x2(11, N=5,476)=103.18, p < 0.001]; drinking frequency [x2(11, N=5,476)=93.59, p < 0.001]; and typical drinks [x2(11, N=5,476)=134.31, p < 0.001].

The attrition models confirmed all results, except for the one hypothesised component effect (NFO compared with PNF) on typical drinks at 6-months (PMM: p=0.607; MI: p= 0.098), and another that was contrary to that hypothesised (NFO compared with PNF) on drinking frequency at 3-months (MI: p=0.167). Additionally, the three-way interaction terms (group\*time\*attrition) of PMM models (data not shown) showed that intervention effects occurred independently of attrition (data in all follow-ups *vs* data in any follow-up).

For the maximum number of drinks at all follow-ups, and all outcomes at follow-up intervals other than those described in the text, there were no statistically significant differences between the component only and full intervention conditions. Bayesian analysis considering the secondary outcomes showed that data favours the *H1* (model with interaction term) but was insensitive for detecting an overall difference of the CFO effect on the number of typical drinks over time (BF:1.36), in specific at 1-month (BF:1.13). Similarly, data was also considered insensitive for detecting an effect of NFO on the maximum number of drinks over time (BF:2.07), which was observed for all timepoints [1- (BF: 2.25), 3- (BF:1.11), and 6-months (BF:0.54)].

*Subgroup Analysis*

**Table S3** showssample characteristics by motivation. Three-way interaction (group\*time\*motivation) terms suggested that intervention effects were moderated by participants’ motivation (less motivated *vs* motivated) in knowing more about their current alcohol use. Overall contrast tests confirmed that the joint effects were significant for all primary and secondary outcomes (**Table S4**).

Further analyses showed that the observed differences between single components and full intervention groups were largely driven by the less motivated students. Among this group (N=1,146, 20.93%), the full PNF intervention did worse on the primary outcome than NFO at 3-months (b=-0.88 95%CI:-1.66;-0.10, p=0.03), and CFO at 3- (b=-1.19 95%CI:-1.91;-0.47, p=0.001) and 6-months (b=-1.48 95%CI:-2.28;-0.68, p<0.001). The attrition models confirmed CFO effect at 3-months in this sub-group, whereas other differences were less consistent (**Table 4**). Among motivated students, there were no differences on AUDIT score. The only significant difference (CFO *vs* PNF) was observed at 6-months (b=0.40 95%CI: 0.05;0.76, p=0.03), but was not confirmed in any attrition models. Results were similar for the secondary outcomes, i.e. showing significant effects in favour of single components only among those less motivated and no consistent effects among those motivated (**Table S5**).

Among less motivated students, Bayesian analyses supported *H0* but was insensitive for detecting a difference on the overall effects of NFO on the primary outcome (BF: 0.79) and the number of typical drinks (BF: 0.74). Among motivated students, analysis supported *H1* on the primary outcome NFO: (BF: 29.5) and CFO: (BF: 263.5), which strengthen the lack of significant effects among motivated students (BF > 3).

Discussion

The main finding of the present study was that there is no consistent evidence that the absence of either component detracts from the effects of a web-based Personalised Normative Feedback. Contrary to our hypothesis, any significant effects observed at particular timepoints and overall were in the opposite direction, showing that single components were more effective than the full PNF. Post-hoc subgroup analyses suggested that these differences were mainly related to a minority of students who were not very motivated to receive the intervention.

Our findings showing the absence of differences, or even potential for the superiority of the dismantled components compared to the full intervention, appear *prima facie* to be counter-intuitive. The latter possibility was accounted for by the sub-group analysis, and although there is evidence available, the null findings here also replicate prior findings. For instance, a meta-analytic study of psychological treatments indicates that dismantling studies not only fail to show significant differences between full treatments and the dismantled versions, but also that the latter can be superior, which raises the possibility that some components are unnecessary or counter-productive (33). In our study, it is also possible that in some instances adding an extra component (either consequences or normative) produced adverse effects among those less interested.

This study did not support that the absence of normative feedback in particular attenuates the intervention effects (11, 14-16). Conversely, our findings replicate on a larger sample the results from PNF dismantling studies showing that the personalisation component without social norms comparisons outperformed the full PNF intervention (17), and which indicates that PNF effects occur even without the normative component (17, 18). Although social norms interventions show small effects, it could be that findings lack rigour (8, 34), and derive from biased evaluations (8).

The between-group differences observed in this study were mostly driven by a subgroup of participants less motivated to receive the intervention. This finding is complementary to our parallel trial result showing a moderation effect by this variable (19). In this previous report the full PNF effects compared to an assessment-only control group were larger among students who were motivated to receive the intervention, but adverse (increasing AUDIT score) among participants less motivated (19). In the same direction, our present findings suggest that it may be more appropriate to provide less information (not the full PNF) to those less motivated. One could hypothesize that less motivated participants provided with longer intervention or more information would be less attentive to its contents. In this regard, some studies suggested attentiveness to PNF as a key factor in securing its effects (16, 35-37), and it may be the case that the full PNF attentiveness were reduced among the less motivated students. Future studies are needed to evaluate the potential moderating effects of both participant’ motivation and attentiveness on the intervention effects, as well as conditions in which such effects are observed.

Recent evidence from a meta-analysis of individual patient data evaluating the effectiveness and moderators of internet interventions for adult drinkers suggested that future research should identify for whom the interventions work best, the most favourable context, and how the interventions work (38). Such conclusions are similar to those in the present study and from process studies of brief interventions (39, 40) which emphasises the need for more studies on the mechanisms of behaviour change, including for personalised feedback and technology-based interventions (11, 19, 41).

This pragmatic randomised trial is one of the few studies not using any sort of incentives. Incentives are widely used in web-based research (42) and limit valid inferences to conditions where they are not provided (37). Our study provides evidence on the effects of the intervention in a setting where people will not receive incentives should it be disseminated outside research contexts. The attrition rates observed in this study, which reflect our attention to external validity, may compromise internal validity if they introduce attrition bias, and may relate to the lack of incentives. We used different statistical approaches for accounting for attrition, which provided some assurance that attrition bias was not an important threat to valid inference. It is worth noting that one review on this issue did not find differences in effect sizes between studies with retention rates of more than 70% versus those with less than 70% (43).

In a previous PNF comparison with a non-intervention control group we did not identify effects on the primary outcome, but did on the secondary outcomes (19), which lead us to be more cautious about the effects observed there. Other large pragmatic trials also struggled to identify positive effects of normative feedback interventions (44, 45) or to provide evidence supportive of dismantled feedback components (46, 47). As in other studies (8, 10) effect sizes in this study were small, and their practical public health importance deserves to be considered carefully. The one-month follow-up had an overlap with baseline as the outcome assessment referred the last three months, and results of this time point should be considered with caution. Besides, the feedback interventions were provided after each follow-up and this could have had a booster effect, even without finding evidence of such effect previously (19). Additional analyses including the number of feedbacks received as a covariate or as an interaction term (group\*time\*number of feedbacks) did not yield significant results (data available on request).

In conclusion, we found no evidence that either the normative or the consequences components made contributions to web-based PNF alcohol intervention effects. Indeed, there were instances in which single components outperformed the full intervention, with additional analyses identifying that these results were driven by 20% of the students less motivated to receive the intervention. Finding such evidence of adverse effects, this study corroborates previous studies highlighting the relevance of studying moderators of web-based PNF interventions to identify who may benefit from such interventions, as well as studying mediators to better understand how they may do so. Another important issue to be considered in future studies is thus the risks of providing interventions to people who do not want them.**Acknowledgements**

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**Box 1 Behaviour change techniques and feedback components by intervention groups.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Feedback component** | **PNF** | **NFO** | **CFO** | **BCT** |
| Drinking profile (AUDIT risk level, binge drinking frequency, estimated blood alcohol content), and drinks consumed during the last year) | X | X |  | *Feedback and monitoring / Feedback on behaviour* |
| Gender-specific normative comparisons | X | X |  | *Comparison of behaviour / Social comparison* |
| Practical costs (money spent on alcohol and its monetary equivalents in goods, calories consumed, weight gained and time to burn the respective calories) | X |  | X | *Feedback and monitoring / Feedback on behaviour**Natural consequences / Health consequences and Social and environmental consequences* |
| Alcohol-related consequences and potential future consequences | X |  | X | *Natural consequences / Health consequences and Social and environmental consequences* |
| Low risk drinking limits and strategies to avoid risky drinking | X | X | X | *Shaping knowledge / Instruction on how to perform a behaviour* |

BCT: Behaviour Change Technique; PNF: Personalised Normative Feedback full intervention; NFO: Normative feedback only; CFO: Consequences feedback only. Behaviour change techniques according to Michie et al., 2013 (20).

**45,061**

screened for eligibility

**10,112** did not meet inclusion criteria:

* **6,088** aged <18 or >30 years
* **2,242** never used alcohol
* **1,533** no alcohol use in the last 3 months

Data in any follow-up (n=1,725; 15.0%)

Personalized Normative Feedback (Full)

(n=11,529)

Completed 1 month

(n=1,396; 12.1%)

Completed 3 months

(n=649; 5.6%)

Data in all follow-ups (n=235; 2.0%)

Completed 6 months

(n=510; 4.4%)

Data in any follow-up (n=1,800; 15.6%)

Normative Feedback Only

(n=11,554)

Completed 1 month

(n=1,490; 12.9%)

Completed 3 months

(n=688; 6.0%)

Data in all follow-ups (n=289; 2.5%)

Completed 6 months

(n=521; 4.5%)

Data in any follow-up (n=1,951; 16.9%)

Consequences Feedback Only

(n=11,534)

Completed 1 month

(n=1,574; 13.7%)

Completed 3 months

(n=752; 6.5%)

Data in all follow-ups (n=278; 2.4%)

Completed 6 months

(n=545; 4.7%)

**34,617** randomised

Figure 1 Trial flowchart diagram

Table 1 Participants characteristics at baseline by intervention group

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **PNF** | **NFO** | **CFO** | **Total** |
|   | n=1725 | n=1800 | n=1951 | n=5476 |
| Female - n (%) | 902 (52.3) | 911 (50.6) | 1011 (51.8) | 2824 (51.6) |
| Age - mean (SD) | 21.8 (3.0) | 21.7 (2.9) | 21.8 (2.9) | 21.8 (3.0) |
| Institution type - n (%) |  |  |  |  |
| *Private* | 1375 (79.7) | 1432 (79.6) | 1554 (79.7) | 4361 (79.6) |
| *Public* | 350 (20.3) | 368 (20.4) | 397 (20.4) | 1115 (20.4) |
| College Year - mean (SD) | 2.7 (1.5) | 2.8 (1.5) | 2.8 (1.5) | 2.8 (1.5) |
| Motivation to know about own alcohol use - n (%) |  |  |  |  |
| *Less motivated* | 365 (21.2) | 365 (20.3) | 416 (21.3) | 1146 (20.9) |
| *Motivated* | 1360 (78.8) | 1435 (79.7) | 1535 (78.7) | 4330 (79.1) |
| PNF: Personalised Normative Feedback full intervention; NFO: Normative feedback only; CFO: Consequences feedback only |

Table 2 Outcome data by intervention group at baseline, 1 month, 3 months and 6 months

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | **Baseline** | **1 month** | **3 months** | **6 months** |
| Primary Outcome |   | n=5476 | n=4460 | n=2089 | n=1576 |
| **AUDIT Score - mean (SD)** | PNF | 5.4 (4.4) | 5.0 (4.7) | 4.9 (4.7) | 4.9 (4.8) |
|  | NFO | 5.6 (4.3) | 5.0 (4.1) | 5.0 (4.5) | 4.9 (4.3) |
|   | CFO | 5.7 (4.5) | 5.3 (4.5) | 4.9 (4.3) | 5.3 (4.9) |
| Secondary Outcomes |  |  |  |  |  |
| **Number of Consequences - mean (SD)** | PNF | 1.3 (1.6) | 1.2 (1.7) | 1.2 (1.7) | 1.1 (1.7) |
|  | NFO | 1.3 (1.6) | 1.1 (1.6) | 1.2 (1.7) | 1.1 (1.7) |
|  | CFO | 1.3 (1.6) | 1.3 (1.8) | 1.1 (1.6) | 1.2 (1.8) |
| **Maximum Number of Drinks - mean (SD)** | PNF | 6.9 (6.1) | 6.1 (5.8) | 6.1 (6.2) | 6.3 (6.2) |
|  | NFO | 6.8 (6.2) | 6.2 (5.7) | 6.4 (6.2) | 6.1 (5.5) |
|  | CFO | 7.2 (6.2) | 6.7 (6.2) | 6.2 (5.9) | 6.6 (6.3) |
| **Drinking Frequency - n (%)** |  |  |  |  |  |
| *Never, monthly or less* | PNF | 1001 (58.0) | 866 (62.0) | 407 (62.7) | 323 (63.3) |
|  | NFO | 1013 (56.3) | 866 (58.1) | 414 (60.2) | 309 (59.3) |
|  | CFO | 1082 (55.5) | 917 (58.3) | 466 (62.0) | 313 (57.4) |
| *2-4 times/month* | PNF | 548 (31.8) | 399 (28.6) | 186 (28.7) | 144 (28.2) |
|  | NFO | 549 (30.5) | 455 (30.5) | 200 (29.1) | 159 (30.5) |
|  | CFO | 628 (32.2) | 495 (31.5) | 209 (27.8) | 168 (30.8) |
| *2 or more times/week* | PNF | 176 (10.2) | 131 (9.4) | 56 (8.6) | 43 (8.4) |
|  | NFO | 238 (13.2) | 169 (11.3) | 74 (10.8) | 53 (10.2) |
|   | CFO | 241 (12.4) | 162 (10.3) | 77 (10.2) | 64 (11.7) |
| **Typical Drinks - n (%)** |  |  |  |  |  |
| *1 or 2* | PNF | 574 (33.3) | 525 (37.6) | 257 (39.6) | 202 (39.6) |
|  | NFO | 595 (33.1) | 520 (34.9) | 264 (38.4) | 190 (36.5) |
|  | CFO | 584 (29.9) | 534 (33.9) | 286 (38.0) | 187 (34.3) |
| *3 or 4* | PNF | 540 (31.3) | 442 (31.7) | 209 (32.2) | 154 (30.2) |
|  | NFO | 569 (31.6) | 485 (32.6) | 215 (31.3) | 176 (33.8) |
|  | CFO | 635 (32.6) | 470 (29.9) | 233 (31.0) | 174 (31.9) |
| *5 or more* | PNF | 611 (35.4) | 429 (30.7) | 183 (28.2) | 154 (30.2) |
|  | NFO | 636 (35.3) | 485 (32.6) | 209 (30.4) | 155 (29.8) |
|   | CFO | 732 (37.5) | 570 (36.2) | 233 (31.0) | 184 (33.8) |
| PNF: Personalised Normative Feedback full intervention; NFO: Normative feedback only; CFO: Consequences feedback only |

Table 3 Components evaluation of observed cases and attrition models (Pattern-Mixture and Multiple Imputation)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Observed** |  | **PMM** |  | **Multiple Imputation** |  |
|  | **b(95%CI)** |  | **b(95%CI)** |  | **b(95%CI)** |  |
| Primary Outcome |  |  |  |  |  |  |
| **AUDIT score (mean difference)a** |   |   |   |   |   |   |
| Group (ref=PNF) |   |   |   |   |   |   |
| *NFO* | 0.02(-0.15;0.18) |   | 0.02(-0.16;0.19) |   | 0.02(-0.15;0.19) |   |
| *CFO* | 0.04(-0.12;0.20) |   | 0.04(-0.13;0.22) |   | 0.04(-0.12;0.21) |   |
| Time (ref=baseline) |   |   |   |   |   |   |
| *1 month* | -0.38(-0.55;-0.22) | \*\*\* | -0.39(-0.57;-0.21) | \*\*\* | -0.34(-0.51;-0.18) | \*\*\* |
| *3 months* | -0.47(-0.68;-0.25) | \*\*\* | -0.48(-0.74;-0.21) | \*\*\* | -0.20(-0.40;-0.01) | \* |
| *6 months* | -0.60(-0.84;-0.37) | \*\*\* | -0.50(-0.81;-0.19) | \*\*\* | -0.43(-0.61;-0.24) | \*\*\* |
| Group x Time (ref=PNF x baseline) |   |   |   |   |   |   |
| *NFO x 1 month* | -0.23(-0.46;-0.002) | \* | -0.26(-0.51;-0.01) | \* | -0.24(-0.46;-0.01) | \* |
| *NFO x 3 months* | -0.21(-0.51;0.09) |   | -0.26(-0.63;0.11) |   | -0.27(-0.54;0.01) |   |
| *NFO x 6 months* | 0.06(-0.27;0.39) |   | 0.06(-0.39;0.52) |   | 0.07(-0.21;0.34) |   |
| *CFO x 1 month* | -0.10(-0.32;0.13) |   | -0.13(-0.38;0.11) |   | -0.09(-0.31;0.13) |   |
| *CFO x 3 months* | -0.33(-0.62;-0.03) | \* | -0.40(-0.76;-0.04) | \* | -0.38(-0.63;-0.12) | \*\* |
| *CFO x 6 months* | 0.01(-0.31;0.34) |   | -0.23(-0.67;0.21) |   | -0.04(-0.32;0.23) |   |
| Secondary Outcomes |   |   |   |   |   |   |
| **Number of Consequences (mean difference)a** |   |   |   |   |   |
| Group (ref=PNF) |   |   |   |   |   |   |
| *NFO* | 0.01(-0.06;0.08) |   | 0.01(-0.07;0.08) |   | 0.01(-0.06;0.08) |   |
| *CFO* | 0.01(-0.06;0.07) |   | 0.01(-0.06;0.08) |   | 0.01(-0.07;0.08) |   |
| Time (ref=baseline) |   |   |   |   |   |   |
| *1 month* | -0.05(-0.12;0.01) |   | -0.06(-0.13;0.02) |   | -0.06(-0.13;0.01) |   |
| *3 months* | -0.10(-0.19;-0.02) | \* | -0.07(-0.18;0.04) |   | -0.09(-0.17;-0.01) | \* |
| *6 months* | -0.22(-0.32;-0.12) | \*\*\* | -0.19(-0.32;-0.06) | \*\* | -0.17(-0.25;-0.09) | \*\*\* |
| Group x Time (ref=PNF x baseline) |   |   |   |   |   |   |
| *NFO x 1 month* | -0.16(-0.25;-0.06) | \*\*\* | -0.16(-0.27;-0.06) | \*\* | -0.15(-0.24;-0.05) | \*\* |
| *NFO x 3 months* | -0.10(-0.22;0.03) |   | -0.14(-0.30;0.01) |   | -0.07(-0.18;0.05) |   |
| *NFO x 6 months* | 0.00(-0.14;0.14) |   | 0.03(-0.16;0.22) |   | -0.01(-0.13;0.10) |   |
| *CFO x 1 month* | 0.00(-0.09;0.10) |   | -0.01(-0.11;0.10) |   | 0.02(-0.08;0.11) |   |
| *CFO x 3 months* | -0.07(-0.19;0.05) |   | -0.10(-0.25;0.05) |   | -0.06(-0.18;0.05) |   |
| *CFO x 6 months* | 0.07(-0.07;0.21) |   | -0.04(-0.23;0.14) |   | 0.02(-0.09;0.13) |   |
| **Maximum Number of Drinks (mean difference)a** |   |   |   |   |   |
| Group (ref=PNF) |   |   |   |   |   |   |
| *NFO* | -0.02(-0.26;0.23) |   | -0.02(-0.29;0.24) |   | -0.02(-0.30;0.25) |   |
| *CFO* | 0.06(-0.18;0.30) |   | 0.06(-0.20;0.32) |   | 0.08(-0.19;0.34) |   |
| Time (ref=baseline) |   |   |   |   |   |   |
| *1 month* | -0.72(-0.98;-0.47) | \*\*\* | -0.77(-1.04;-0.49) | \*\*\* | -0.65(-0.91;-0.39) | \*\*\* |
| *3 months* | -0.47(-0.80;-0.14) | \*\* | -0.26(-0.65;0.14) |   | -0.37(-0.69;-0.06) | \* |
| *6 months* | -0.79(-1.15;-0.43) | \*\*\* | -0.46(-0.93;0.01) |   | -0.48(-0.80;-0.16) | \*\* |
| Group x Time (ref=PNF x baseline) |   |   |   |   |   |   |
| *NFO x 1 month* | 0.07(-0.28;0.42) |   | 0.12(-0.26;0.51) |   | 0.02(-0.34;0.38) |   |
| *NFO x 3 months* | -0.08(-0.53;0.38) |   | -0.13(-0.69;0.44) |   | 0.09(-0.34;0.52) |   |
| *NFO x 6 months* | 0.28(-0.22;0.79) |   | 0.21(-0.48;0.90) |   | 0.20(-0.25;0.65) |   |
| *CFO x 1 month* | 0.16(-0.19;0.51) |   | 0.20(-0.18;0.58) |   | 0.10(-0.25;0.46) |   |
| *CFO x 3 months* | -0.42(-0.87;0.03) |   | -0.41(-0.95;0.13) |   | -0.39(-0.83;0.06) |   |
| *CFO x 6 months* | 0.09(-0.41;0.59) |   | 0.35(-0.32;1.01) |   | 0.01(-0.43;0.45) |   |
|  | **OR(95%CI)** |  | **OR(95%CI)** |  | **OR(95%CI)** |  |
| **Drinking Frequency b** |   |   |   |   |   |   |
| Group (ref=PNF) |   |   |   |   |   |   |
| *NFO* | 1.06(0.88;1.28) |   | 1.06(0.86;1.30) |   | 1.08(0.90;1.29) |   |
| *CFO* | 1.06(0.88;1.27) |   | 1.06(0.87;1.30) |   | 1.06(0.89;1.27) |   |
| Time (ref=baseline) |   |   |   |   |   |   |
| *1 month* | 0.68(0.55;0.83) | \*\*\* | 0.69(0.56;0.87) | \*\*\* | 0.76(0.64;0.92) | \*\* |
| *3 months* | 0.77(0.59;1.01) |   | 0.72(0.52;1.01) |   | 1.13(0.87;1.46) |   |
| *6 months* | 0.53(0.39;0.70) | \*\*\* | 0.59(0.40;0.88) | \*\* | 0.93(0.69;1.24) |   |
| Group x Time (ref=PNF x baseline) |   |   |   |   |   |   |
| *NFO x 1 month* | 1.04(0.78;1.37) |   | 0.96(0.70;1.30) |   | 1.01(0.78;1.30) |   |
| *NFO x 3 months* | 0.66(0.45;0.95) | \* | 0.63(0.39;0.999) | \* | 0.77(0.52;1.12) |   |
| *NFO x 6 months* | 1.26(0.84;1.89) |   | 1.23(0.70;2.17) |   | 1.06(0.73;1.52) |   |
| *CFO x 1 month* | 0.93(0.71;1.22) |   | 0.83(0.61;1.12) |   | 0.97(0.75;1.24) |   |
| *CFO x 3 months* | 0.69(0.48;0.99) | \* | 0.55(0.35;0.87) | \*\* | 0.70(0.49;0.996) | \* |
| *CFO x 6 months* | 1.47(0.99;2.20) |   | 1.39(0.81;2.39) |   | 1.14(0.76;1.71) |   |
| **Typical Drinksb** |   |   |   |   |   |   |
| Group (ref=PNF) |   |   |   |   |   |   |
| *NFO* | 0.99(0.85;1.16) |   | 1.02(0.86;1.21) |   | 0.97(0.81;1.16) |   |
| *CFO* | 1.08(0.92;1.26) |   | 1.09(0.92;1.28) |   | 1.08(0.91;1.30) |   |
| Time (ref=baseline) |   |   |   |   |   |   |
| *1 month* | 0.65(0.55;0.77) | \*\*\* | 0.65(0.54;0.78) | \*\*\* | 0.73(0.62;0.86) | \*\*\* |
| *3 months* | 0.54(0.43;0.68) | \*\*\* | 0.55(0.41;0.72) | \*\*\* | 0.83(0.68;1.02) |   |
| *6 months* | 0.51(0.40;0.65) | \*\*\* | 0.59(0.43;0.83) | \*\* | 0.73(0.58;0.92) | \*\* |
| Group x Time (ref=PNF x baseline) |   |   |   |   |   |   |
| *NFO x 1 month* | 1.17(0.92;1.48) |   | 1.10(0.85;1.43) |   | 1.12(0.89;1.41) |   |
| *NFO x 3 months* | 1.24(0.91;1.69) |   | 1.03(0.70;1.52) |   | 0.98(0.73;1.32) |   |
| *NFO x 6 months* | 1.46(1.04;2.05) | \* | 1.13(0.70;1.83) |   | 1.33(0.96;1.84) |   |
| *CFO x 1 month* | 1.15(0.91;1.45) |   | 1.18(0.91;1.52) |   | 1.08(0.87;1.36) |   |
| *CFO x 3 months* | 0.90(0.66;1.22) |   | 0.72(0.49;1.05) |   | 0.84(0.64;1.11) |   |
| *CFO x 6 months* | 1.10(0.79;1.55) |   | 0.93(0.58;1.48) |   | 0.97(0.70;1.35) |   |
| a Linear mixed model. b Ordered logit mixed model. All results are adjusted for participant id, sex, age, region, AUDIT-C and baseline data. |
| PNF: Personalised Normative Feedback full intervention; NFO: Normative feedback only; CFO: Consequences feedback only; 95%CI: 95% Confidence Interval; PMM: Pattern-Mixture Model; AUDIT: Alcohol Use Disorders Identification Test. |
| \*p≤0.05; \*\*p≤0.01; \*\*\*p≤0.001 |   |   |   |   |   |   |
| Data for Observed and PMM analyses at baseline (n=5476), 1-month (n=4460), 3-months (n=2089), and 6-months (n=1576).  |   |

Table 4 Subgroup analyses by motivation in components evaluation of observed cases and attrition models (Pattern-Mixture and Multiple Imputation)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Observed** |  | **PMM** |  | **Multiple Imputation** |  |
|  | **b(95%CI)** |  | **b(95%CI)** |  | **b(95%CI)** |  |
| ***Less motivated (n=1146)*** |  |  |  |  |  |  |
| **AUDIT score (mean difference)a** |  |  |  |  |  |  |
| Group (ref=PNF) |  |  |  |  |  |  |
| *NFO* | 0.10(-0.29;0.49) |  | 0.10(-0.31;0.51) |  | 0.10(-0.28;0.49) |  |
| *CFO* | 0.04(-0.34;0.42) |  | 0.05(-0.35;0.44) |  | 0.05(-0.33;0.42) |  |
| Time (ref=baseline) |  |  |  |  |  |  |
| *1 month* | -0.03(-0.44;0.37) |  | -0.05(-0.48;0.39) |  | 0.02(-0.36;0.40) |  |
| *3 months* | 0.31(-0.22;0.85) |  | 0.40(-0.22;1.03) |  | 0.38(-0.12;0.89) |  |
| *6 months* | 1.03(0.46;1.60) | \*\*\* | 0.61(-0.09;1.32) |  | 0.61(0.08;1.13) | \* |
| Group x Time (ref=PNF x baseline) |  |  |  |  |  |  |
| *NFO x 1 month* | -0.51(-1.08;0.06) |  | -0.54(-1.15;0.07) |  | -0.54(-1.07;-0.02) | \* |
| *NFO x 3 months* | -0.88(-1.66;-0.10) | \* | -0.97(-1.91;-0.04) | \* | -0.70(-1.40;0.00) |  |
| *NFO x 6 months* | -0.52(-1.34;0.30) |  | 0.06(-0.96;1.09) |  | -0.17(-0.92;0.59) |  |
| *CFO x 1 month* | -0.13(-0.69;0.43) |  | -0.14(-0.74;0.45) |  | -0.17(-0.70;0.36) |  |
| *CFO x 3 months* | -1.19(-1.91;-0.47) | \*\*\* | -1.17(-2.01;-0.34) | \*\* | -1.02(-1.65;-0.39) | \*\* |
| *CFO x 6 months* | -1.48(-2.28;-0.68) | \*\*\* | -0.77(-1.77;0.22) |   | -1.08(-1.80;-0.37) | \*\* |
| ***Motivated (n=4330)*** |  |  |  |  |  |  |
| **AUDIT score (mean difference)a** |   |   |   |   |   |   |
| Group (ref=PNF) |  |  |  |  |  |  |
| *NFO* | 0.00(-0.18;0.17) |  | -0.01(-0.20;0.19) |  | 0.00(-0.19;0.18) |  |
| *CFO* | 0.04(-0.13;0.22) |  | 0.04(-0.15;0.24) |  | 0.04(-0.14;0.23) |  |
| Time (ref=baseline) |  |  |  |  |  |  |
| *1 month* | -0.47(-0.65;-0.30) | \*\*\* | -0.49(-0.68;-0.29) | \*\*\* | -0.44(-0.62;-0.26) | \*\*\* |
| *3 months* | -0.66(-0.89;-0.43) | \*\*\* | -0.71(-0.99;-0.43) | \*\*\* | -0.36(-0.57;-0.15) | \*\*\* |
| *6 months* | -1.03(-1.28;-0.77) | \*\*\* | -0.85(-1.19;-0.50) | \*\*\* | -0.70(-0.93;-0.47) | \*\*\* |
| Group x Time (ref=PNF x baseline) |  |  |  |  |  |  |
| *NFO x 1 month* | -0.16(-0.40;0.09) |  | -0.18(-0.46;0.09) |  | -0.15(-0.40;0.09) |  |
| *NFO x 3 months* | -0.05(-0.37;0.27) |  | -0.07(-0.47;0.33) |  | -0.15(-0.46;0.16) |  |
| *NFO x 6 months* | 0.24(-0.12;0.60) |  | 0.05(-0.45;0.56) |  | 0.14(-0.18;0.46) |  |
| *CFO x 1 month* | -0.09(-0.33;0.16) |  | -0.13(-0.40;0.14) |  | -0.07(-0.31;0.17) |  |
| *CFO x 3 months* | -0.12(-0.43;0.20) |  | -0.19(-0.59;0.20) |  | -0.20(-0.50;0.10) |  |
| *CFO x 6 months* | 0.40(0.05;0.76) | \* | -0.05(-0.54;0.43) |   | 0.23(-0.09;0.56) |   |
| a Linear mixed model. b Ordered logit mixed model. All results are adjusted for participant id, sex, age, region, AUDIT-C and baseline data. |
| PNF: Personalised Normative Feedback full intervention; NFO: Normative feedback only; CFO: Consequences feedback only; 95%CI: 95% Confidence Interval; PMM: Pattern-Mixture Model; AUDIT: Alcohol Use Disorders Identification Test |
| \*p≤0.05; \*\*p≤0.01; \*\*\*p≤0.001 |  |  |  |  |  |  |
| Data at baseline for less motivated at 1-month (n=887), 3-months (n=391), and , 6-months (n=309); and for motivated at 1-month (n=3573), 3-months (n=1698), and , 6-months (n=1267) |