

# BMJ Open Effect of a brief intervention with small financial incentives on alcohol consumption in China: study protocol for a randomised controlled trial

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**To cite:** Li S, Wu Z, Liu S, *et al.* Effect of a brief intervention with small financial incentives on alcohol consumption in China: study protocol for a randomised controlled trial. *BMJ Open* 2022;**12**:e056550. doi:10.1136/bmjopen-2021-056550

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-056550>).

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Received 20 August 2021  
Accepted 22 April 2022



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## ABSTRACT

**Introduction** Alcohol consumption is the seventh leading risk factor for disability-adjusted life years in the world, according to the Global Burden of Disease Study 2017. As the largest developing country, China has a substantial population of alcohol consumers who suffer from related health risks. Despite having made significant advancements in eradicating absolute poverty, many people still live in relative poverty, which suggests that the adverse health effects caused by alcohol consumption among vulnerable populations in China warrant more attention. This paper aims to provide an overview of alcohol consumption among ethnic populations in China and test the feasibility and efficacy of a brief advice intervention with a small financial incentive in reducing harmful drinking behaviours.

**Methods** This study is a three-arm, single-blinded, pragmatic, individually randomised controlled trial with follow-ups at 1, 2 and 3 months after randomisation. A total of 440 daily drinkers living in Xichang will be recruited and divided into three groups: brief intervention group, financial incentive group and control group. All participants will receive a urine ethyl glucuronide (EtG) test, which detects alcohol consumption in the past 80 hours. Additionally, participants in the brief intervention group will receive three free counselling sessions alongside multimedia messages on the topic of alcohol consumption after each session. The participants in the financial incentive group will receive the same interventions as well as cash incentives according to the results of the EtG test. The primary outcomes are the self-reported drinking quantity, binge drinking frequency, drinking intensity and the proportion of participants who pass the EtG test.

**Ethics and dissemination** This protocol was approved by the Peking University Health Science Center Institutional Review Board (IRB00001052-20049). Findings will be published in peer-reviewed journals and presented at local, national and international conferences to publicise and explain the research to key audiences.

**Trial registration number** NCT04999371.

## INTRODUCTION

According to the Global Burden of Disease Study 2017,<sup>1</sup> alcohol is the seventh leading risk factor for disability-adjusted life years (DALYs) in the world. In 2017, 2.84 million

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This trial examines the effectiveness of brief alcohol intervention on alcohol abuse behaviour by providing a personalised reminder with a financial incentive to reduce alcohol consumption and increase investment in health and education.
- ⇒ A personalised health reminder approach is very feasible and it also minimises the possibility of incorrectly interpreting information due to limited attention and redundancy neglect.
- ⇒ Using the urine ethyl glucuronide test as one of the primary outcomes increases scientific rigour and decreases participant misreporting.
- ⇒ This trial cannot completely disentangle the effect of financial incentives.
- ⇒ This study is unable to assess the long-term effects of intervention due to budget constraints.

deaths and 108.00 million DALYs globally were attributable to alcohol use.<sup>1</sup> Alcohol consumption is associated with health conditions such as gastric distress, hypertension, cardiovascular diseases, permanent liver damage, diabetes and cancer.<sup>2-4</sup> Furthermore, excessive drinking on a single occasion increases the risk of motor vehicle crashes, drowning, intimate partner violence, unprotected sex, and childhood sexual abuse.<sup>2,3</sup>

As the largest developing country, China has a substantial population of alcohol consumers who suffer from related health risks. For instance, in 2016, the total alcohol per capita consumption among the world's population aged 15 and older was 6.4 L. However, this quantity was 7.2 L in China, 12.5% higher than global consumption.<sup>5</sup> An increase in per capita alcohol consumption was also observed in recent years,<sup>5</sup> especially in regions inhabited by minority groups.<sup>6</sup>

From the perspective of decision-making, studies have shown that low-income groups are more inclined to pay attention to current goals and fail to make rational decisions.<sup>7,8</sup>

Despite China having made outstanding achievements in eradicating absolute poverty, many people are still living in relative poverty, which suggests that the adverse health effects caused by alcohol consumption among low-income populations in China warrant more attention.

Brief alcohol intervention is an effective way to reduce the amount of alcohol consumption, and its efficacy has been supported by a number of studies.<sup>9-12</sup> However, research has shown that alcoholic drinkers are reluctant to accept interventions.<sup>13,14</sup> A randomised controlled trial conducted in India indicated that financial incentives may serve as a feasible intervention for participants in low-income countries. Financial incentives are external motivators and may increase intervention adherence.<sup>15</sup> Contingency management is an approach to reinforcing participants' behaviours by delivering a reward only if the target behaviour occurs.<sup>16</sup> Studies have illustrated that contingency management is among the more effective ways to help people refrain from substance abuse.<sup>17-19</sup> Based on previous trials, it seems more effective to offer a financial incentive to reduce alcohol consumption among ethnic minority migrants.

The existing alcohol intervention studies were mainly conducted in developed countries,<sup>11,12,20</sup> centred on school students,<sup>21</sup> or based on clinical settings and health-care service providers.<sup>10,22</sup> Few studies have focused on alcohol consumption among ethnic minority migrant populations in developing countries where residents have low education levels and the primary healthcare system is not well developed.<sup>23</sup> To address this gap, the research team aims to evaluate the effects of a brief intervention combined with a small financial incentive on alcohol consumption and health outcomes among the migrated population in Liangshan Prefecture. This study will be conducted in Liangshan Prefecture for two reasons. First, Liangshan is a region located southwest of Sichuan province, and it is populated by Yi ethnic minority. The average income in Liangshan is approximately two-thirds of the national average income.<sup>24</sup> Second, a previous study found that the drinking rate of Yi minority (47.9%) is higher than that of other regions in China.<sup>25</sup>

The aim of this paper is to test the feasibility and efficacy of small financial incentives with brief advice intervention in the targeted reduction of harmful drinking behaviours among ethnic minority migrants.

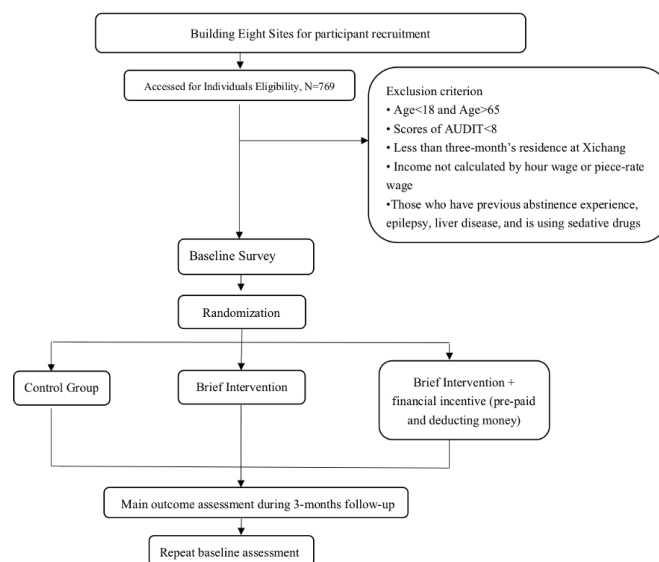
## METHODS AND ANALYSIS

### Study design

This is a three-arm, single-blinded, pragmatic, individually randomised controlled trial that aims to reduce alcohol consumption among residents. **Figure 1** shows the Consolidated Standards of Reporting Trials flow diagram.

### Recruitment and participants

Recruitment activities will be conducted in building sites and villages (n=8) in Xichang, Liangshan Yi Autonomous Prefecture, south of Sichuan, China. Flyers and



**Figure 1** CONSORT flow diagram. This diagram shows all the processes of the three-arm, individual randomised controlled trial, including participants recruitment, baseline survey, randomisation, intervention, follow-up survey and final evaluation. AUDIT, Alcohol Use Disorder Identification Test; CONSORT, Consolidated Standards of Reporting Trials.

community posts will be used to encourage residents to take a quick Alcohol Use Disorder Identification Test (AUDIT) to determine whether they meet the criteria of an at-risk drinker. Respondents will be informed that the experiment involves a baseline assessment of alcohol consumption and irregular follow-ups through 3 months that require them to take alcohol tests and complete questionnaires. Eligible participants are workers aged between 18 years and 65 years, with scores of AUDIT  $\geq 8$ . Employees whose wages are calculated based on hourly or piece-rate wages will also be included in the study, such as hourly workers at construction sites, delivery men and more. Eligible participants agreeing to partake in this study should remain in Xichang for the next 3 months. Informed consent will be obtained before starting the trial (see online supplemental file 1). Respondents with abstinence experience or a history of epilepsy, liver disease and sedative drug use will be excluded from the study.

### Randomisation and blinding

Randomisation occurs at the individual level. Participants within the same recruitment session will be individually randomised in a 1:1:1 ratio into two intervention groups and one control group (brief intervention group, financial incentive group, control group). The randomisation process will be generated using a web-based system ([www.sealedenvelope.com](http://www.sealedenvelope.com)) by an investigator who is not involved in participant recruitment. After the randomisation, the investigator will conduct a balancing test to ensure that participants in the intervention groups and the control group are comparable and they will notify the recruitment staff 1 day prior to the baseline investigation. The recruiting staff will then

inform the participants of the results of randomisation independently. Due to the nature of the intervention, the recruitment staff are also responsible for delivering the interventions and thus cannot be blinded from participant allocation. However, participants will not be informed about the treatment in the other groups. Outcome assessors and statistical analysts will be blinded to the random grouping.

### Sample size

The proportion of people who drink alcohol according to the ethyl glucuronide (EtG) test in the control group is 25%, and that in the brief intervention group is expected to be 10%. According to Eq (1), to achieve a 95% CI ( $\alpha=0.05$ ) and 80% power, the required sample size was calculated to be 100 in the brief intervention group. Assuming a retention rate of 90% during follow-up, the overall sample size of the study should be 333 for the three groups ((100×3 groups)/90% retention rate). Four hundred forty participants are anticipated to enrol in this study.

$$N = \frac{\left[ z_{\alpha} \sqrt{2p(1-p)} + z_{\beta} \sqrt{p_1(1-p_1) + p_2(1-p_2)} \right]^2}{(p_1 - p_2)^2} \text{Eq (1)}$$

where  $N$  is the sample size for one group,  $z_{\alpha}$  and  $z_{\beta}$  are the 5% and 20% percentile of the standard normal distribution, respectively,  $p_1$  and  $p_2$  are the proportion of people who drink alcohol in control and brief intervention groups, respectively,  $p$  equals to  $(p_1 + p_2)/2$ .

### Intervention

#### Brief alcohol intervention

The participants in treatment group 1 will receive free monthly one-to-one consultation and multimedia messages via the WeChat app or SMS on alcohol consumption, including the harms of alcohol consumption, tips to reduce drinking, abstinence cases, and so on, each time after consultation. One-to-one counselling services will be provided via phone calls based on WHO recommendations.<sup>26</sup> A total of three counsels scheduled for the 2nd, 6th and 10th week after the baseline survey will be conducted.

Brief intervention counsellors are staff of the research team. All counsellors are required to attend a full-day workshop organised based on the scheme and teaching materials provided by Hongkong University. The contents of the workshop include: (1) the harms of excessive drinking and the benefits of controlling drinking; (2) an overview of AUDIT; (3) personalised alcohol reduction advice; and (4) a standard procedure of brief intervention. Counsellors will guide participants to evaluate their own drinking behaviours, offer them advice and provide encouragement.

An experienced research staff member will supervise and assist at each brief intervention session to ensure the accurate delivery of the intervention. All counsellors will follow a standardised process and complete a checklist table.

### Incentive group

The participants in one of the treatment groups will receive brief alcohol intervention with cash incentives according to the results of the EtG tests. Participants will receive a text message regarding the incentive treatment strategy promptly after the completion of the follow-up random urine test. The monetary incentive is described as losses based on the theory of framing effect. First, a voucher of RMB ¥ 490 ( $\approx$ US\$77.5) will be given to the participants in this group, and ¥70 will be deducted every time their urine tests show positive results. Finally, the participants will receive cash equivalent to the remaining money in the voucher.

### Control group

No intervention or cash incentives will be provided to the participants in the control group. The general information of the participants in this group will still be collected, and an alcohol test will be performed. Therefore, RMB ¥ 20 ( $\approx$ US\$3.2) compensation will be provided for participants in the control group (participants of the intervention group also will receive this part of the compensation).

### Procedures

Participants will be assessed at baseline and at the end of each month after treatment initiation (table 1). Participants are required to take a test four times a week for weeks 1–4, twice a week for weeks 5–8 and once a week for weeks 9–11. To prevent cheating by abstaining from alcohol only the day before the test, the programme team will randomly determine the time of each test. The baseline questionnaire measures participants' drinking behaviour, including daily alcohol consumption, age at first drink, the number of attempts at quitting or reducing drinking and methods for quitting used in the past. At weeks 2, 6 and 10 after the intervention initiation, trained counsellors will follow-up with participants via phone calls. The Prime Screen single-panel urine test paper will be used to conduct the EtG test.<sup>27</sup> Participants will be informed that they may withdraw from the study at any time without providing a reason. The researcher also has access to interim analyses and right to terminate the trial at their discretion. For subjects who withdraw from the study, information on the number of interventions, the duration of participation in the programme and the reasons for withdrawal (if willing to provide) will be collected. For subjects who are unavailable on survey day, the research team will schedule appointments with them via telephone.

Data will be collected via a web-based questionnaire, and the dataset will be accessible in real time. The project leader will manage the online dataset with a username and password. Logical checks will be conducted daily after fieldwork by a graduate student, and all unreliable or missing data will be corrected in time. A data management specialist will perform data desensitisation to protect the participants' personal information. All personnel

**Table 1** Schedule of baseline and follow-up assessments

Assessment	Baseline	1 Month	2 Month	3 Month
Informed consent	×			
Eligibility screen	×			
Randomisation	×			
Intervention initiation	×			
Sociodemographic characteristics	×			
Self-efficacy of reducing/quitting	×			×
Mental health	×			×
Quality of sleep	×			×
Drinking behaviour	×	×	×	×
Drinking knowledge				
Quit attempts	×	×	×	×
Biochemically validated abstinence (EtG)	×	×	×	×

Sociodemographic characteristics include age, gender, education level, marital status and household income. EtG, ethyl glucuronide.

attempting to access the data need to be approved by the project leader.

### Outcomes

The main focus is on alcohol use behaviour, health status, productivity and income, as well as household expenditure. The detailed outcomes are listed as follows:

Primary outcomes:

1. Self-reported drinking quantity (drinks per week).
2. Self-reported binge drinking frequency (number of binges per week), binge drinking is defined as four or more standard drinks on one occasion.
3. Self-reported drinking frequency (drinking days per week).
4. Self-reported drinking intensity (number of drinks per drinking day).
5. The proportion of people who drink alcohol according to the EtG test.

Secondary outcomes:

1. Health status indicators. Sleep quality will be measured by the Pittsburgh Sleep Quality index, a widely used instrument for evaluating sleep quality and linking findings to psychological disorders.<sup>28</sup> Mental health will be assessed by a short version of the Depression Anxiety Stress Scale-21, an internationally recognised method of assessing the risk of mental health outcomes.<sup>29</sup>
2. Life satisfaction will be assessed by the ONS questionnaire, which measures the respondent's life evaluations, positive emotions and negative emotions on an 11-point scale. A higher score indicates a greater extent of the respondent's life evaluations.<sup>30</sup>
3. Healthcare utilisation will be determined, including emergency/outpatient visits, medical hospitalisation, mean days in hospital in the past 1 month.

4. Productivity and income, which will be calculated as income per day and working hours per day in the past 1 month.
5. Household expenditure includes the daily expenditure for alcohol, children, parents and healthcare services in the past 1 month.
6. Score on the knowledge about the harm of alcohol consumption.

### Statistical analysis

The sociodemographic characteristics and baseline information, including sex, age and the indicators listed in the outcome section of the participants, will be reported. The differences in alcohol consumption capacity, sobriety status, health status, healthcare utilisation, daily working hours and income and household expenditure between the control and the intervention groups will be examined using t-tests and  $\chi^2$  test.

The effect of the intervention on alcohol consumption behaviours will be analysed using multiple linear regression models. Alcohol consumption capacity, drinking frequency and drinking intensity indicators are the dependent variables. Control versus intervention groups, the baseline level of the targeted outcome variable and sociodemographic characteristics (age group, sex, education, marital status, annual household income) and time between baseline and follow-up surveys are independent variables.

The effect of alcohol consumption on health, life satisfaction, alcohol-related traffic accident and harm, healthcare utilisation, productivity and household expenditure outcomes will be analysed with regression models with adjustments. All comparisons will use generalised estimating equation models (multiple linear models for continuous outcomes or logistic models for dichotomous

outcomes) to adjust for the participant's baseline alcohol consumption capacity and baseline sociodemographic characteristics (age group, sex, education, marital status, annual household income), and time between the baseline and follow-up surveys. Taking health status/life satisfaction/frequency of alcohol-related traffic accident and harm/healthcare utilisation/daily working hours/daily income/monthly expenditure for alcohol, children's education, parents and healthcare as dependent variables, alcohol consumption capacity as independent variables and controlling for individual fixed effect and all the baseline characteristics listed above.

To address the possibility of bias attributable to higher attrition rates among intervention participants, the research team will perform a 'worst-case' sensitivity analysis by assuming that 100% of study dropouts remain at the highest level of alcohol consumption. The intervention effect by subgroups will be assessed, respectively, including age group, sex, education level and household income. Statistical analyses will be conducted using Stata V.15.1 (Stata Corp, Texas, USA). The statistical tests are two-sided, and a  $p$  value  $< 0.05$  is considered as statistically significant.

### Patient and public involvement

No patient involved.

### Ethics and dissemination

This study received ethical approval from the Peking University Health Science Center Institutional Review Board. The trial is registered on ClinicalTrials.gov (registration number: NCT04999371; date of registration 5 August 2021). All participants gave their consent for their own involvement in the study. Authorship will be determined in accordance with the International Committee of Medical Journal Editors guidelines. If there are any changes to the protocol, we will report to the Peking University Health Science Center Institutional Review Board and inform the subjects. Findings will be published in peer-reviewed journals and presented at local, national and international conferences to publicise and explain the research to key audiences.

### DISCUSSION

This study entails a comparison of a control group with two different intervention arms, a brief intervention and brief intervention plus financial incentive, on improving drinking behaviours in Liangshan Prefecture to ameliorate residents' health capital and consumption behaviour. The effectiveness of the two interventions will generate valuable information for decision-makers and non-government organisations and encourage them to prioritise educational support on alcohol cessation services, which will ultimately decrease alcohol consumption.

There are four innovative aspects to this study. First, this is the first time a brief alcohol intervention will be conducted in a minority habitation in China. Second, a small financial

incentive will be integrated into the brief alcohol intervention to evaluate its effect on behavioural changes, which is crucial in changing health status and productivity performance. Third, by assessing the income and expenditure pattern, the research team is able to evaluate whether drinking reduction can make the subjects more productive and rational in decision-making. Last, the effectiveness of brief alcohol intervention with a small financial incentive will be assessed in the community rather than in clinical facilities, which will strengthen scientific evidence supporting the incorporation of community healthcare workers in carrying out the intervention.

This trial has several strengths. First, this is one of the first randomised controlled trials in China to explore the approaches to reducing alcohol consumption. The use of intervention in this study deserves extrapolation if proved effective. Additionally, the use of EtG test results as the financial incentive indicator will ensure the accuracy of the intervention. This is more beneficial for evaluation than using the self-reported alcohol consumption habit.<sup>19</sup> Finally, in order to further evaluate the effects of the alcohol intervention, the research team will also identify changes in individual income using a questionnaire to determine whether alcohol consumption affects work efficiency and, as a result, income.

This trial also has several potential limitations. First, this study is unable to assess the long-term effects of the intervention (eg, 12 months) due to budget constraints. Nevertheless, three consecutive follow-up surveys (at 1, 2 and 3 months) will allow the development of a basic understanding of how intervention can change participants' drinking behaviours. Second, the evidence of drinking behaviour is based on self-reporting which cannot be obtained by the research team directly. Third, the consumption of alcohol in Liangshan Prefecture is relatively high, which may limit the generalisability of study findings to other settings.

**Correction notice** The article has been corrected since it was published online. The statement on the equal contributorship for the paper between SL and ZW is reinstated.

**Acknowledgements** The authors are indebted to Erti Guoji from Institute of Science and Technology, National Health Commission of the People's Republic of China for their critical suggestions on conducting the study. The authors would like to thank MPW from Hong Kong University for suggestions on study design. Furthermore, the authors would like to thank Xiaotong Chen and Njoroge Winnie for their working in editing. The authors are grateful to all participants for sharing their views and experiences in this study.

**Contributors** GL, ShanshanL and ZW contributed to the research concept and design, supervise the work and offered critical suggestions for revisions. ShanshanL, ZW, YS and SijiaL participated in conducting the study. ShanshanL, ZW and SijiaL conducted data analysis and drafted the manuscript. All authors have read and approved the manuscript.

**Funding** This work was supported by the National Natural Science Foundation of China, grant number 71833001.

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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