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# BMJ Open

## A brief intervention in reducing alcohol consumption in China: study protocol for a randomized controlled trial

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3 **A brief intervention in reducing alcohol consumption in China: study protocol for a**  
4 **randomized controlled trial**  
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## Abstract

### Introduction

Alcohol is the 7<sup>th</sup> leading risk factor of Disabled Adjusted Life Years (DALYs) all over the world according to Global Burden of Disease study 2017. As the largest developing country, Chinese people consume a large amount of alcohol, and suffer from the related health risk. Despite China has made great achievement in eradicating absolute poverty, many people are in still relative poverty, which suggests that the adverse health effects caused by alcohol consumption among vulnerable population in China should be paid more attention. The aim of this paper is to provide an overview of alcohol consumption among ethnic population in China, and to test the feasibility and efficacy of small financial incentive with brief advice intervention targeting reduction of harmful drinking behaviors among poor people.

### Methods

This is a three-arm, single-blinded, pragmatic, individual randomized controlled trial with follow-ups at 1,2,3 months after randomization. We aim to enroll 333 daily drinkers in Xichang. All participants receive the EtG test and simple suggestion within 3 months. Additionally, participants in the brief alcohol intervention group receive free three-time counsel and constant multi-media messages about the topic of alcohol consumption for three months. The participants in the incentive group receive brief alcohol intervention cash incentives according to the results of EtG test. The primary outcomes are the self-reported drinking quantity, binge drinking frequency, drinking intensity and the proportion of people who pass the EtG test.

### Ethics and dissemination

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4 This protocol has been approved from the Peking University Health Science Center  
5 Institutional Review Board (IRB00001052-20049). Findings will be published in peer-  
6 reviewed journals and presented at local, national and international conferences to  
7 publicize and explain the research to key audiences.  
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### 10 **Trial registration**

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13 ClinicalTrials.gov registration number NCT04999371, registration date August 05, 2021  
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### 15 **Strengths and limitations of this study**

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18 This study can differentiate potentially at-risk populations, which can have a preventive  
19 effect for those people.  
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22 We use the results of EtG test as the financial incentive indicator, which ensured the  
23 accuracy of the intervention.  
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26 In order to further evaluate effects of alcohol intervention, we also identify change of  
27 individual income and consumption capacity per day as well as alcohol-relevant  
28 variables.  
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31 The finding of this trial may limit the generalizability of our findings to other settings.  
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## Introduction

Alcohol is the 7<sup>th</sup> leading risk factor of Disabled Adjusted Life Years (DALYs) all over the world according to Global Burden of Disease study 2017 <sup>1</sup>. In 2017, 2.84 million deaths and 108.00 million DALYs globally were attributable to alcohol use <sup>1</sup>. Alcohol use is associated with many physical issues, like gastric distress, hypertension, cardiovascular diseases, permanent liver damage, diabetes, and cancer, to name a few<sup>2</sup>. Drinking too much on a single occasion could immediately increase the risk of motor vehicle crashes, drowning, intimate partner violence, unprotected sex, childhood sexual abuse, etc. <sup>2</sup>.

As the largest developing country, Chinese people consume a large amount of alcohol, and suffer from the related health risk. In 2016, the total alcohol per capita consumption was at the level of 6.4 litres among the world's population aged 15 and older. While in China, this amount is 7.2 litres of pure alcohol, 12.5% more than that of the global consumption <sup>3</sup>. The increase in per capita alcohol consumption is observed in China <sup>3</sup>, especially in regions inhabited by minority groups<sup>4</sup>.

For the perspective of decision-making, studies show that low-income groups are more inclined to pay attention to current goals and fail to make optimal decisions because of short-sightedness<sup>5 6</sup>. Despite China has made great achievement in eradicating absolute poverty, many people are in still relative poverty, which suggests that the adverse health effects caused by alcohol consumption among vulnerable population in China should be paid more attention.

Although the effectiveness of brief alcohol interventions on reducing alcohol consumption has been supported by a number of studies<sup>7 8</sup>, studies show that alcoholic drinkers are reluctant to accept interventions<sup>9 10</sup>. A randomized-controlled trail conducted in India indicated that financial incentives may serve as a feasible intervention for participates in low income countries. Financial incentives are external motivators and may increase intervention adherence <sup>11</sup>. Based on previous trials, it seems more effective to offer a financial incentive to reduce alcohol consumption among one of the most vulnerable population in China.

The existing alcohol intervention studies are mainly conducted in developed countries<sup>7 8 12 13</sup>, few studies have focused on alcohol consumption among ethnic minority migrant people

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4 in developing countries. To address this gap, we aim to evaluate the effects of a brief  
5 intervention combined with a small financial incentive on alcohol consumption and health  
6 outcomes among migrated population in Liangshan Prefecture. This study is conducted in  
7 Liangshan Prefecture for two reasons: first, Liangshan is a region located in the  
8 southwestern of Sichuan province and is populated by Yi minority, and the average income  
9 in Liangshan are just about two thirds of the national average income <sup>14</sup>. Second, a study  
10 found that the drinking rate of Yi minority (47.9%) is higher than that of other regions in  
11 China <sup>15</sup>.

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18 The aim of this paper is to provide an overview of alcohol consumption among ethnic  
19 population in China, and to test the feasibility and efficacy of small financial incentive with  
20 brief advice intervention targeting reduction of harmful drinking behaviors among poor  
21 people.  
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## 24 **Methods and Analysis**

### 25 **Study design**

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29 This is a three-arm, single-blinded, pragmatic, individual randomized controlled trial,  
30 which aims to reduce alcohol consumption among residents. Figure 1 shows the  
31 Consolidated Standards of Reporting Trials (CONSORT) flow diagram.  
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### 34 **Recruitment and participants**

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38 Recruitment activities are conducted in building sites and villages (n=8) in Xichang. It is  
39 located in the Liangshan Yi Autonomous Prefecture, in the south of Sichuan, China. We  
40 will use flyers and community posts to invite residents to take a quick test. The test of  
41 Alcohol Use Disorder Identification Test (AUDIT) is utilized to measure if a respondent  
42 meets the criteria. Respondents are informed that the experiment involves a baseline  
43 assessment of alcohol consumption and irregular follow-up to take an alcohol test and fill  
44 in the questionnaire within three months. Eligible participants are workers in poverty aged  
45 between 18 years and 65 years, scores of AUDIT  $\geq 8$ . Besides, employees whose wages are  
46 calculated based on hour wage or piece-rate wage, such as hourly workers at construction  
47 sites, delivery man and so on. They will spend the next three months in Xichang and take  
48 part in our intervention. Importantly, those who have abstinence experience, epilepsy, liver  
49 disease before this trial, and those who are using sedative drugs are excluded.  
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## Randomization and blinding

Randomization occurs at the individual level. Participants within the same recruitment session are individual-randomized in a ratio to the intervention or control group. The randomization sequence is generated using a web-based system ([www.sealedenvelope.com](http://www.sealedenvelope.com)). One investigator who is not involved in participant enrolment implements the allocation sequence and notifies the recruitment staff one day prior to the recruitment session. Because of the nature of the intervention, the recruitment staff delivering the interventions cannot be blinded to participant allocation, but participants are not informed about the treatment in the other group. Outcome assessors and statistical analysts are blinded to the group allocation.

## Sample size

The proportion of people who drink alcohol according to the EtG test in control group is 25%, and that in the brief intervention group is expected to be 10%. According to Eq (1), in order 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).

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

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 group respectively,  $p$  equals to  $(p_1 + p_2)/2$ .

## Intervention

### Brief Alcohol Intervention

The participants in treatment group 1 received free three-time counsel and constant multi-media messages about the topic of alcohol consumption for three months. One-to-one counseling services will be provided via telephone calling, which is based on World Health



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4 Organization (WHO) recommendations. A total of three counsels are conducted, which are  
5 set on the second week, sixth and tenth week after baseline survey.  
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8 Brief intervention counselors are from team of this study and trained by Hongkong  
9 University. All counselors are required to attend a full-day workshop before participant  
10 recruitment. The contents of the workshop include: (1) knowledge of excessive drinking  
11 harms and benefits of controlling drinking; (2) overview of AUDIT; (3) alcohol reduction  
12 advices; (4) a standard procedure of brief intervention.  
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16 An experienced research staff provides supervision and assistance at each brief intervention  
17 session, to ensure the accurate delivery of the intervention. All advisors follow a  
18 standardized process and complete a checklist table.  
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### 21 22 **Incentive group**

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24 The participants in treatment group 2 will receive brief alcohol intervention with cash  
25 incentives according to the results of EtG test. The participants financial incentive will be  
26 conducted by deducting money. Firstly, a certain amount of vouchers with RMB ¥ 490  
27 (≈US\$75.8) was given to the participants, which was equivalent to the reward for passing  
28 seven tests. Then, the voucher would be deducted according to every EtG test result. Finally,  
29 the participants will receive cash according to the vouchers.  
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### 32 33 **Control group**

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35 No information or cash incentives are provided to the participants in the control group, but  
36 it is also necessary to collect the information of the participants in the control group and  
37 perform an alcohol test. Therefore, the project team will provide a certain degree of  
38 compensation for participants in control group (participants of intervention group also will  
39 receive this part of compensation).  
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### 42 43 **Procedures**

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45 Participants are assessed at baseline, 1, 2, 3 months after treatment initiation (Table 1).  
46 Participants are required to take a test four times a week for 1-4 week, twice a week for 5-8  
47 weeks, and once a week for 9-11 weeks. In order to avoid cheating by abstaining from  
48 alcohol only the day before the test, the time of each test was randomly determined by  
49 program team. The baseline questionnaire measures participants' drinking behavior (eg,  
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Daily alcohol consumption, age of starting drinking, whether and the number of attempts to quit or reduce, methods for quitting used in past). At weeks 2, 6 and 10 after the intervention initiation, participants are followed up by trained counsellors with a phone call. The Prime Screen single panel urine test paper is used to conduct the ethyl glucuronide (EtG) test. Participants are informed that they may withdraw from the study at any time without giving a reason.

Table 1 Schedule of baseline and follow-up assessments

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

Sociodemographic characteristics include age, gender, education level, marital status and household income

## Outcomes

We focus on the alcohol use behavior, health status, productivity and income, as well as the 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).
3. Self-reported drinking frequency (drinking days per week).
4. Self-reported drinking intensity (number of drinks per drinking day).

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4 5. The proportion of people who drink alcohol according to the EtG test.  
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6 Secondary outcomes:  
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- 8 1. Health status indicators, including sleep quality, and mental health in the past one month.  
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10 2. Life satisfaction.  
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12 3. Health-care utilization, including emergency/outpatient visits, medical hospitalization,  
13 mean days in hospital in the past one month.  
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15 4. Productivity and income, which are income per day, and working hours per day in the  
16 past one month.  
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18 5. Household expenditure includes the daily expenditure for alcohol, children, parents, and  
19 health care services in the past one month.  
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21 6. Score on the knowledge about the harm of alcohol consumption.  
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## 26 **Statistical analysis**

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28 The sociodemographic characteristics and baseline information including sex, age, and the  
29 indicators listed in the outcome section of the participants will be reported. The differences  
30 of alcohol consumption capacity, sobriety status, health status, health-care utilization, daily  
31 working hours and income, as well as the household expenditure between the control group  
32 and the intervention group will be examined by t tests and chi-square tests to assess balance  
33 between the control and intervention groups.  
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36 The effect of intervention on alcohol consumption behaviors will be analyzed using  
37 multiple linear regression models. Alcohol consumption capacity, drinking frequency,  
38 drinking intensity indicators are considered as dependent variables respectively, and taking  
39 control or intervention group i.d., and controlling for individual fixed effect, baseline level  
40 of the targeted outcome variable and sociodemographic characteristics (age group, sex,  
41 education, marital status, annual household income), time between baseline and follow-up  
42 surveys as independent variables.  
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45 The effect of alcohol using on health, life satisfaction, alcohol-related traffic accident and  
46 harm, health-care utilization, productivity and household expenditure outcomes will be  
47 analyzed using regression models with adjustment. All comparisons will use generalized  
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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/ health-care utilization/ daily working hours/ daily income/ monthly expenditure for alcohol, children's education, parents, and health care 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, we performed "worst case" sensitivity analyses by assuming that 100% of study dropouts remained 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 were two-sided, and p-value < 0.05 was 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 08/05/2021). 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. Findings will be published in peer-reviewed journals and presented at local, national and international conferences to publicize and explain the research to key audiences.

### **Discussion**

In this study, we used brief intervention plus a financial incentive as a model to improve drinking behavior in Liangshan Prefecture, so as to improve their health human capital and

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4 consumption behavior. If the intervention is found to be effective, this will be valuable for  
5 decision-makers and non-government organizations to prioritize education support to  
6 encourage the use of alcohol cessation services, which will ultimately decrease alcohol  
7 drinks.  
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11 There are four innovations of this study. First, this is the first time to conduct brief alcohol  
12 intervention in the minority habitation in China. Second, a small financial incentive is  
13 integrated in brief alcohol intervention to evaluate its effect in behavior change, which is a  
14 crucial part in the path of changing health status and productivity performance. Third, by  
15 assessing the income and expenditure pattern, it is possible to evaluate whether drinking  
16 reduction can make the subjects more productive and rational. Last, we are going to assess  
17 the effectiveness of brief alcohol intervention with a small financial incentive in  
18 community rather than in clinical facilities, which provides scientific evidence and  
19 suggestions for community healthcare workers to carry out the intervention.  
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27 This trial has several strengths. First, this study can differentiate potentially at-risk  
28 populations, which can have a preventive effect for those people. Additionally, we use the  
29 results of EtG test as the financial incentive indicator, which ensured the accuracy of the  
30 intervention. This is much more beneficial to our evaluation. Finally, in order to further  
31 evaluate effects of alcohol intervention, we also identify change of individual income and  
32 consumption capacity per day as well as alcohol-relevant variables.  
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38 This trial also has several potential limitations. First, this study is unable to assess the long-  
39 term effects of the intervention (eg, 12 months) because of budget constraints. Nevertheless,  
40 three consecutive follow-ups survey (at 1,2 and 3 months) allow us to have a basic  
41 understanding of how intervention can change participants' drinking behavior. Second, the  
42 evidence of drinking behavior is based on self-reporting which cannot obtained by research  
43 team directly. Third, as consumption of alcohol in Liangshan Prefecture are relatively high,  
44 which is may limit the generalizability of our findings to other settings.  
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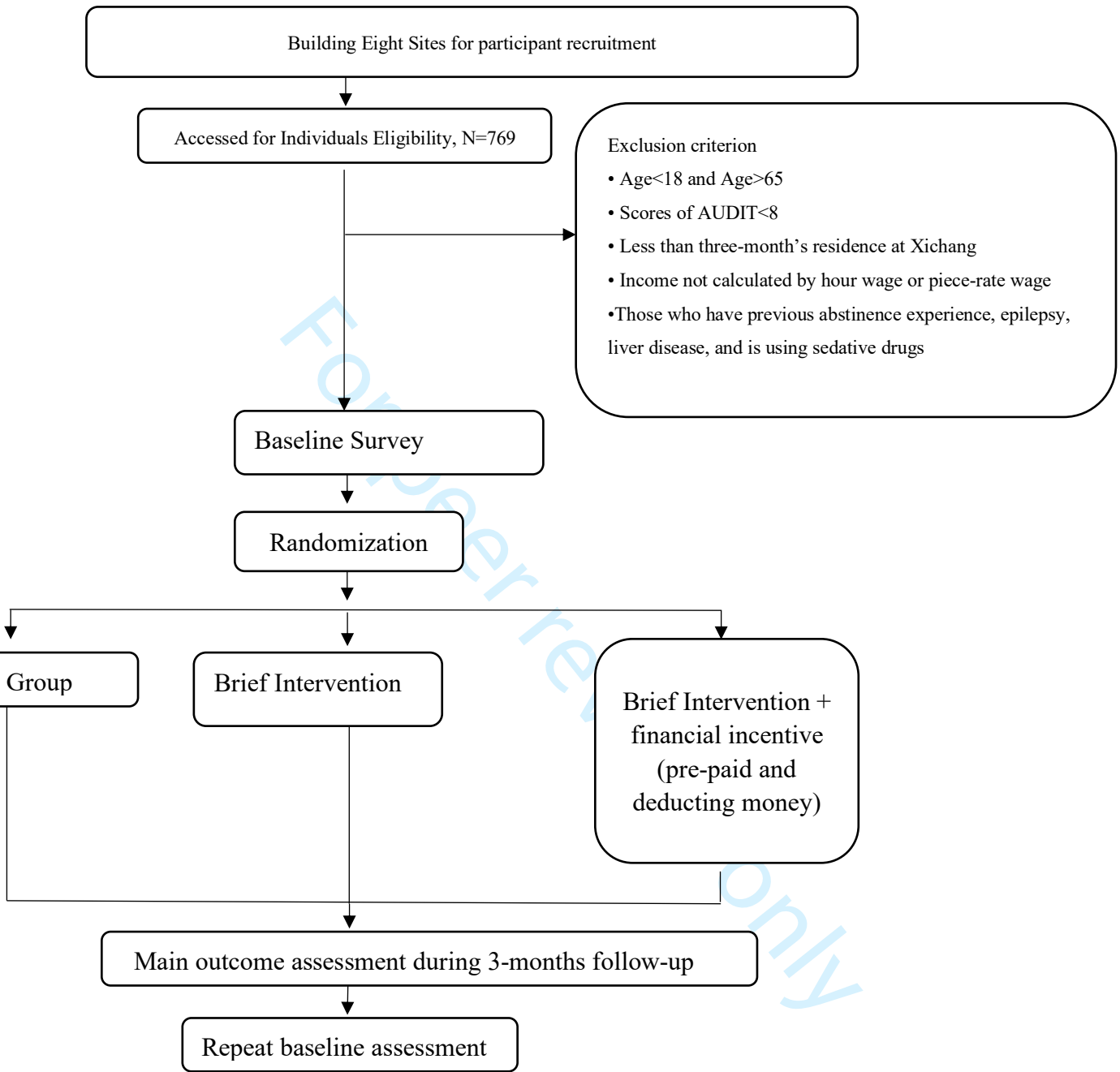
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17 their views and experiences in this study.  
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20  
21 **Authors' contributions:** GL, SS and ZT contributed to the research concept and design,  
22 supervise the work, and offered critical suggestions for revisions. SS, ZT, SJ and  
23 SY participated in conducting the study. They also conducted data analysis and drafted the  
24 manuscript. All authors have read and approved the manuscript.  
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**Figure 1. CONSORT flow diagram**



# BMJ Open

## Using brief intervention with small financial incentives to reduce alcohol consumption in China: study protocol for a randomized controlled trial

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1           **Using brief intervention with small financial incentives to reduce alcohol**  
2           **consumption in China: study protocol for a randomized controlled trial**

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4  
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7  
8 32 **Abstract**

9  
10 33 **Introduction**

11  
12 34 Alcohol is the 7<sup>th</sup> leading risk factor of Disabled Adjusted Life Years (DALYs) all over the  
13  
14 35 world according to Global Burden of Disease study 2017. As the largest developing  
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16 36 country, Chinese people consume a large amount of alcohol, and suffer from the related  
17  
18 37 health risk. Despite China having made great achievement in eradicating absolute poverty,  
19  
20 38 many people are still living in relative poverty, which suggests that the adverse health  
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22 39 effects caused by alcohol consumption among vulnerable populations in China warrant  
23  
24 40 more attention. The aim of this paper is to provide an overview of alcohol consumption  
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26 41 among ethnic populations in China, and to test the feasibility and efficacy of small financial  
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28 42 incentive with brief advice intervention targeting reduction of harmful drinking behaviors.

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30 43 **Methods**

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32 44 This is a three-arm, single-blinded, pragmatic, individual randomized controlled trial with  
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34 45 follow-ups at 1,2,3 months after randomization. We aim to enroll 440 daily drinkers in  
35  
36 46 Xichang and divide them into three groups (brief intervention group, financial incentive  
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38 47 group, control group). All participants receive the urine ethyl glucuronide (EtG) test,  
39  
40 48 which helped us to figure out whether a participant consumed alcohol in the past 80 hours.  
41  
42 49 Additionally, participants in the brief intervention group receive free three-time counsel  
43  
44 50 and multi-media messages about the topic of alcohol consumption each time after  
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46 51 consultation. The participants in the financial incentive group receive brief intervention  
47  
48 52 and cash incentives according to the results of EtG test. The primary outcomes are the self-  
49  
50 53 reported drinking quantity, binge drinking frequency, drinking intensity and the proportion  
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52 54 of people who pass the EtG test.

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54 55 **Ethics and dissemination**

55  
56 56 This protocol has been approved from the Peking University Health Science Center  
57  
58 57 Institutional Review Board (IRB00001052-20049). Findings will be published in peer-

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4 58 reviewed journals and presented at local, national and international conferences to  
5 59 publicize and explain the research to key audiences.  
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## 8 60 **Trial registration**

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10 61 ClinicalTrials.gov registration number NCT04999371, registration date August 05, 2021  
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## 12 62 **Strengths and limitations of this study**

13  
14 63 This trial examines the effectiveness of brief alcohol intervention on alcohol abuse  
15 64 behavior by providing personalized reminder with a financial incentive to reduce alcohol  
16 65 consumption, family consumption and education investment.  
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20 66 A personalized health reminder approach is very short and it also alleviates the failure to  
21 67 correctly interpret information due to limited attention and redundancy neglect.  
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24 68 Using urine ethyl glucuronide (EtG) test as one of the primary outcomes increased  
25 69 scientific rigour and decreases misreporting.  
26  
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28 70 This trial cannot completely disentangle the effect of financial incentive.  
29

30 71 Keywords: Health economic, alcohol disorder, rural China  
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## 74 Introduction

75 Alcohol is the 7<sup>th</sup> leading risk factor of Disabled Adjusted Life Years (DALYs) all over the  
76 world according to Global Burden of Disease study 2017 <sup>1</sup>. In 2017, 2.84 million deaths  
77 and 108.00 million DALYs globally were attributable to alcohol use <sup>1</sup>. Alcohol use is  
78 associated with many physical issues, like gastric distress, hypertension, cardiovascular  
79 diseases, permanent liver damage, diabetes, and cancer, to name a few<sup>2</sup>. Drinking too much  
80 on a single occasion could immediately increase the risk of motor vehicle crashes,  
81 drowning, intimate partner violence, unprotected sex, childhood sexual abuse, etc. <sup>2</sup>.

82 As the largest developing country, Chinese people consume a large amount of alcohol, and  
83 suffer from the related health risk. In 2016, the total alcohol per capita consumption was at  
84 the level of 6.4 litres among the world's population aged 15 and older. While in China, this  
85 amount is 7.2 litres of pure alcohol, 12.5% more than that of the global consumption <sup>3</sup>. An  
86 increase in per capita alcohol consumption is observed in China <sup>3</sup>, especially in regions  
87 inhabited by minority groups<sup>4</sup>.

88 For the perspective of decision-making, studies show that low-income groups are more  
89 inclined to pay attention to current goals and fail to make optimal decisions<sup>5 6</sup>. Despite  
90 China having made great achievement in eradicating absolute poverty, many people are  
91 still living in relative poverty, which suggests that the adverse health effects caused by  
92 alcohol consumption among vulnerable populations in China warrant more attention.

93 Although the effectiveness of brief alcohol interventions on reducing alcohol consumption  
94 has been supported by a number of studies<sup>7 8</sup>, researches show that alcoholic drinkers are  
95 reluctant to accept interventions<sup>9 10</sup>. A randomized-controlled trial conducted in India  
96 indicated that financial incentives may serve as a feasible intervention for participants in  
97 low income countries. Financial incentives are external motivators and may increase  
98 intervention adherence <sup>11</sup>. Based on previous trials, it seems more effective to offer a  
99 financial incentive to reduce alcohol consumption among one of the most vulnerable  
100 population in China.

101 The existing alcohol intervention studies are mainly conducted in developed countries<sup>7 8 12</sup>,  
102 few studies have focused on alcohol consumption among ethnic minority migrant people  
103 in developing countries. To address this gap, we aim to evaluate the effects of a brief

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4 104 intervention combined with a small financial incentive on alcohol consumption and health  
5 105 outcomes among migrated population in Liangshan Prefecture. This study is conducted in  
6 106 Liangshan Prefecture for two reasons: first, Liangshan is a region located in the  
7 107 southwestern of Sichuan province and is populated by Yi minority, and the average income  
8 108 in Liangshan are just about two thirds of the national average income<sup>13</sup>. Second, a study  
9 109 found that the drinking rate of Yi minority (47.9%) is higher than that of other regions in  
10 110 China<sup>14</sup>.

11 111 The aim of this paper is to test the feasibility and efficacy of small financial incentive with  
12 112 brief advice intervention targeting reduction of harmful drinking behaviors among poor  
13 113 people.

## 14 114 **Methods and Analysis**

### 15 115 **Study design**

16 116 This is a three-arm, single-blinded, pragmatic, individual randomized controlled trial,  
17 117 which aims to reduce alcohol consumption among residents. Figure 1 shows the  
18 118 Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

### 19 119 **Recruitment and participants**

20 120 Recruitment activities are conducted in building sites and villages (n=8) in Xichang. It is  
21 121 located in the Liangshan Yi Autonomous Prefecture, in the south of Sichuan, China. We  
22 122 will use flyers and community posts to invite residents to take a quick test. The test of  
23 123 Alcohol Use Disorder Identification Test (AUDIT) is utilized to measure if a respondent  
24 124 meets the criteria. Respondents are informed that the experiment involves a baseline  
25 125 assessment of alcohol consumption and irregular follow-ups to take alcohol tests and fill  
26 126 in the questionnaire within three months. Eligible participants are workers aged between  
27 127 18 years and 65 years, with scores of AUDIT  $\geq 8$ . Besides, employees whose wages are  
28 128 calculated based on hour wage or piece-rate wage, such as hourly workers at construction  
29 129 sites, delivery man and so on. They will spend the next three months in Xichang and take  
30 130 part in our intervention. Importantly, those who have abstinence experience, epilepsy, liver  
31 131 disease before this trial, and those who are using sedative drugs are excluded.

### 32 132 **Randomization and blinding**

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4 133 Randomization occurs at the individual level. Participants within the same recruitment  
5  
6 134 session are individually randomized in a ratio of 1:1:1 to two intervention groups and one  
7  
8 135 control group (brief intervention group, financial incentive group, control group). The  
9  
10 136 randomization sequence is generated using a web-based system  
11  
12 137 (www.sealedenvelope.com). One investigator who is not involved in participant enrolment  
13  
14 138 implements the allocation sequence and notifies the recruitment staff one day prior to the  
15  
16 139 recruitment session. Because of the nature of the intervention, the recruitment staff  
17  
18 140 delivering the interventions cannot be blinded to participant allocation, but participants are  
19  
20 141 not informed about the treatment in the other group. Outcome assessors and statistical  
21  
22 142 analysts are blinded to the group allocation.

### 23 24 25 143 **Sample size**

26  
27 144 The proportion of people who drink alcohol according to the EtG test in control group is  
28  
29 145 25%, and that in the brief intervention group is expected to be 10%. According to Eq (1),  
30  
31 146 in order to achieve a 95% CI ( $\alpha=0.05$ ) and 80% power, the required sample size was  
32  
33 147 calculated to be 100 in the brief intervention group. Assuming a retention rate of 90%  
34  
35 148 during follow-up, the overall sample size of the study should be 333 for the three groups  
36  
37 149 ((100\*3 groups)/90% retention rate). 440 participants are planned to enroll this study.

$$38 \quad 150 \quad N = \frac{[z_{\alpha}\sqrt{2p(1-p)} + z_{\beta}\sqrt{p_1(1-p_1) + p_2(1-p_2)}]^2}{(p_1 - p_2)^2} \quad \text{Eq (1)}$$

39  
40  
41 151 where N is the sample size for one group,  $z_{\alpha}$  and  $z_{\beta}$  are the 5% and 20% percentile of  
42  
43 152 the standard normal distribution respectively,  $p_1$  and  $p_2$  are the proportion of people  
44  
45 153 who drink alcohol in control and brief intervention group respectively,  $p$  equals to  $(p_1 +$   
46  
47 154  $p_2)/2$ .

### 48 155 **Intervention**

#### 49 50 156 **Brief Alcohol Intervention**

51  
52 157 The participants in treatment group 1 received free monthly one-to-one consultation and  
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54 158 multi-media messages via Wechat APP or SMS about the topic of alcohol consumption  
55  
56 159 (including the harms of alcohol consumption, tips to reduce drinking, abstinence cases, etc)

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4 160 each time after consultation. One-to-one counseling services will be provided via telephone  
5 161 calling, which is based on World Health Organization (WHO) recommendations<sup>15</sup>. A total  
6 162 of three counsels are conducted, which are set on the second week, sixth and tenth week  
7 163 after baseline survey.

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11 164 Brief intervention counselors are from team of this study and trained by Hongkong  
12 165 University. All counselors are required to attend a full-day workshop before participant  
13 166 recruitment. The contents of the workshop include: (1) harms of excessive drinking and  
14 167 benefits of controlling drinking; (2) overview of AUDIT; (3) alcohol reduction advice; (4)  
15 168 a standard procedure of brief intervention.

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20 169 An experienced research staff member provides supervision and assistance at each brief  
21 170 intervention session, to ensure the accurate delivery of the intervention. All advisors follow  
22 171 a standardized process and complete a checklist table.

### 23 172 **Incentive group**

24  
25  
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28 173 The participants in treatment group 2 will receive brief alcohol intervention with cash  
29 174 incentives according to the results of EtG test. The participants financial incentive will be  
30 175 conducted by deducting money. Firstly, a voucher of RMB ¥490 ( $\approx$ US\$75.8) was given  
31 176 to the participants in this group, and we would deduct ¥70 once if their urine tests show  
32 177 positive results. Finally, the participants will receive cash equal to the remaining amount  
33 178 of money in the voucher.

### 34 179 **Control group**

35  
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39 180 No information or cash incentives are provided to the participants in the control group, but  
40 181 it is also necessary to collect the information of the participants in the control group and  
41 182 perform an alcohol test. Therefore, the project team will provide a certain degree of  
42 183 compensation for participants in control group (participants of intervention group also will  
43 184 receive this part of compensation).

### 44 185 **Procedures**

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49 186 Participants are assessed at baseline, 1, 2, 3 months after treatment initiation (Table 1).  
50 187 Participants are required to take a test four times a week for weeks 1-4, twice a week for  
51 188 weeks 5-8, and once a week for weeks 9-11. In order to avoid cheating by abstaining from



189 alcohol only the day before the test, the time of each test was randomly determined by  
 190 program team. The baseline questionnaire measures participants' drinking behavior  
 191 including daily alcohol consumption, age of starting drinking, whether and the number of  
 192 attempts to quit or reduce, methods for quitting used in past). At weeks 2, 6 and 10 after  
 193 the intervention initiation, participants are followed up by trained counsellors with a phone  
 194 call. The Prime Screen single panel urine test paper is used to conduct the ethyl glucuronide  
 195 (EtG) test<sup>16</sup>. Participants are informed that they may withdraw from the study at any time  
 196 without giving a reason. The researcher also has access to interim analyses and terminate  
 197 the trial. For the subjects who withdraw from the study, we will collect information on the  
 198 number of interventions, the duration of participating in the program and the reasons for  
 199 withdrawal. For the subjects who go out on the survey day, we will make an appointment  
 200 with them by telephone.

201 Data will be collected via a web-based questionnaire, and the dataset is accessible in real  
 202 time. The online dataset is managed by the project leader with username and password.  
 203 Range checks for data values by a graduate student will be conducted every day after field  
 204 work, and all the unreliable or logistically wrong data will be corrected in time. After the  
 205 end of the project, the data will be managed by the data management specialist in the  
 206 institute where the person in charge is located, and the data will be desensitized. Each use  
 207 needs to be approved by the administrator.

Table 1 Schedule of baseline and follow-up assessments

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

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Sociodemographic characteristics include age, gender, education level, marital status and household income

208

**209 Outcomes**

210 We focus on the alcohol use behavior, health status, productivity and income, as well as  
211 the household expenditure. The detailed outcomes are listed as follows:

212 Primary outcomes:

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

219 Secondary outcomes:

- 220 1. Health status indicators. Specifically, sleep quality measured by Pittsburgh Sleep Quality  
221 index (PSQI) which is widely used to evaluate sleep quality and linked to psychological disorders<sup>17</sup>.  
222 Mental health measured by a short version of the Depression Anxiety Stress Scale (DASS-  
223 21) which are internationally recognized method of assessing the risk of mental health  
224 outcomes<sup>18</sup>.
- 225 2. Life satisfaction, assessed by ONS questionnaire. ONS measures the respondent's life  
226 evaluations, positive emotions and negative emotions on an 11-point scale, where the higher point  
227 indicates the greater extent of life evaluations that the respondent feels<sup>19</sup>.
- 228 3. Health-care utilization, including emergency/outpatient visits, medical hospitalization,  
229 mean days in hospital in the past one month.
- 230 4. Productivity and income, which are income per day, and working hours per day in the  
231 past one month.

232 5. Household expenditure includes the daily expenditure for alcohol, children, parents, and  
233 health care services in the past one month.

234 6. Score on the knowledge about the harm of alcohol consumption.

235

### 236 **Statistical analysis**

237 The sociodemographic characteristics and baseline information including sex, age, and the  
238 indicators listed in the outcome section of the participants will be reported. The differences  
239 in alcohol consumption capacity, sobriety status, health status, health-care utilization, daily  
240 working hours and income, as well as the household expenditure between the control group  
241 and the intervention group will be examined by t tests and chi-square tests to assess  
242 differences between the control and intervention groups.

243 The effect of intervention on alcohol consumption behaviors will be analyzed using  
244 multiple linear regression models. Alcohol consumption capacity, drinking frequency,  
245 drinking intensity indicators are considered as dependent variables respectively, and taking  
246 control or intervention group, baseline level of the targeted outcome variable and  
247 sociodemographic characteristics (age group, sex, education, marital status, annual  
248 household income), time between baseline and follow-up surveys as independent variables.

249 The effect of alcohol using on health, life satisfaction, alcohol-related traffic accident and  
250 harm, health-care utilization, productivity and household expenditure outcomes will be  
251 analyzed with regression models with adjustment. All comparisons will use generalized  
252 estimating equation models (multiple linear models for continuous outcomes or logistic  
253 models for dichotomous outcomes) to adjust for the participant's baseline alcohol  
254 consumption capacity and baseline sociodemographic characteristics (age group, sex,  
255 education, marital status, annual household income), and time between the baseline and  
256 follow-up surveys. Taking health status/ life satisfaction/ frequency of alcohol-related  
257 traffic accident and harm/ health-care utilization/ daily working hours/ daily income/  
258 monthly expenditure for alcohol, children's education, parents, and health care as  
259 dependent variables, alcohol consumption capacity as independent variables, and  
260 controlling for individual fixed effect and all the baseline characteristics listed above.

261 To address the possibility of bias attributable to higher attrition rates among intervention  
262 participants, we performed “worst case” sensitivity analyses by assuming that 100% of  
263 study dropouts remained at the highest level of alcohol consumption. The intervention  
264 effect by subgroups will be assessed, respectively, including age group, sex, education  
265 level, and household income. Statistical analyses will be conducted using Stata V.15.1  
266 (Stata Corp, Texas, USA). The statistical tests were two-sided, and p-value < 0.05 was  
267 considered as statistically significant.

### 268 **Patient and public involvement**

269 No patient involved.

### 270 **Ethics and Dissemination**

271 This study received ethical approval from the Peking University Health Science Center  
272 Institutional Review Board. The trial is registered on ClinicalTrials.gov (registration  
273 number: NCT04999371; Date of registration 08/05/2021). All participants gave their  
274 consent for their own involvement in the study. Authorship will be determined in  
275 accordance with the International Committee of Medical Journal Editors guidelines. If  
276 there are any changes to the protocol, we will report to the Peking University Health  
277 Science Center Institutional Review Board and inform the subjects. Findings will be  
278 published in peer-reviewed journals and presented at local, national and international  
279 conferences to publicize and explain the research to key audiences.

### 280 **Discussion**

281 In this study, we used brief intervention plus a financial incentive as a model to improve  
282 drinking behavior in Liangshan Prefecture, so as to improve residents’ health capital and  
283 consumption behavior. If either of the two interventions are found to be effective, this will  
284 be valuable for decision-makers and non-government organizations to prioritize education  
285 support to encourage the use of alcohol cessation services, which will ultimately decrease  
286 alcohol drinks.

287 There are four innovative aspects to this study. First, this is the first time to conduct brief  
288 alcohol intervention in the minority habitation in China. Second, a small financial incentive  
289 is integrated into brief alcohol intervention to evaluate its effect on behavior change, which

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4 290 is a crucial part in the path of changing health status and productivity performance. Third,  
5 291 by assessing the income and expenditure pattern, it is possible to evaluate whether drinking  
6 292 reduction can make the subjects more productive and rational. Last, we are going to assess  
7 293 the effectiveness of brief alcohol intervention with a small financial incentive in  
8 294 community rather than in clinical facilities, which may strengthen scientific evidence for  
9 295 community health care workers to carry out the intervention.

14 296 This trial has several strengths. First, this is one of the first randomized controlled trials in  
15 297 China to explore the approaches to reduce alcohol consumption. The intervention using in  
16 298 this study deserves extrapolation if improved effective. Additionally, we use the results of  
17 299 EtG test as the financial incentive indicator, which ensured the accuracy of the intervention.  
20 300 This is much more beneficial to our evaluation than using the self-reported alcohol  
21 301 consumption habit. Finally, in order to further evaluate effects of alcohol intervention, we  
22 302 also identify the change of individual income by questionnaire to figure out whether the  
23 303 alcohol consumption affect work efficiency and as a result, income.

28 304 This trial also has several potential limitations. First, this study is unable to assess the long-  
29 305 term effects of the intervention (eg, 12 months) because of budget constraints. Nevertheless,  
30 306 three consecutive follow-ups survey (at 1, 2 and 3 months) allow us to have a basic  
31 307 understanding of how intervention can change participants' drinking behavior. Second, the  
32 308 evidence of drinking behavior is based on self-reporting which cannot obtained by research  
33 309 team directly. Third, as consumption of alcohol in Liangshan Prefecture are relatively high,  
34 310 which is may limit the generalizability of our findings to other settings.

40 311

43 312 **Figure 1. CONSORT flow diagram**

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47 314

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371

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378 **Authors' contributions:** GL, SS and ZT contributed to the research concept and design,  
379 supervise the work, and offered critical suggestions for revisions. SS, ZT, SJ and SY  
380 participated in conducting the study. They also conducted data analysis and drafted the  
381 manuscript. All authors have read and approved the manuscript.

382

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385 **Competing interests statement:** The authors declare no conflict of interest.

386

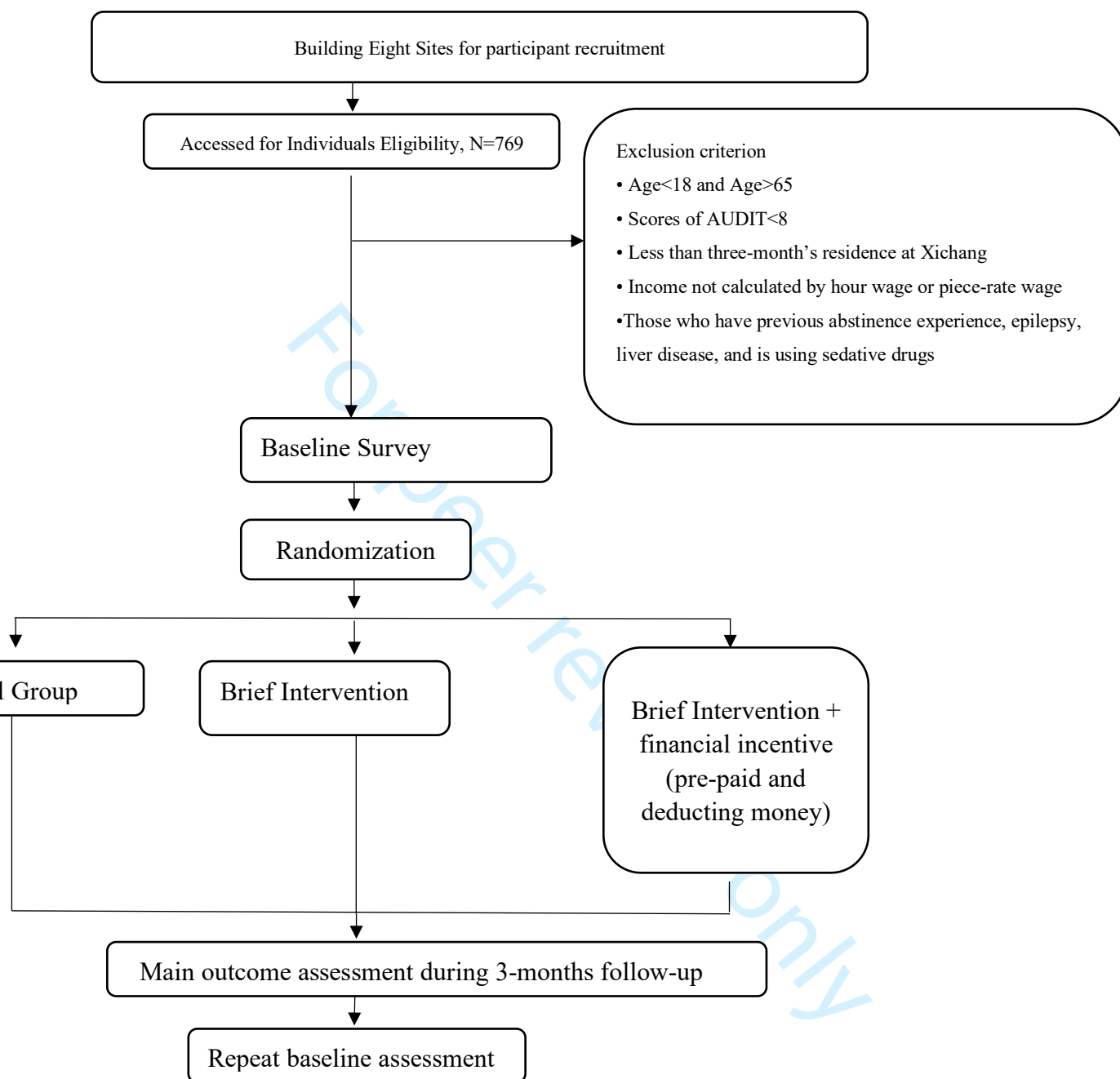


Figure 1. CONSORT flow diagram





SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	Location
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1, line 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 3, line 60
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	
Funding	4	Sources and types of financial, material, and other support	Page 14, line 376
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 14, line 371
	5b	Name and contact information for the trial sponsor	
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 4, line 74-110

	6b	Explanation for choice of comparators	
Objectives	7	Specific objectives or hypotheses	Page 5, line 111-113
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 5, line 114
<b>Methods: Participants, interventions, and outcomes</b>			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 5, line 120-122
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 5, lines 124-131
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 6, line 155
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 7, line 173-178
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 8, line 203-228
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 6, line 143-154
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 6, line 119

### Methods: Assignment of interventions (for controlled trials)

#### Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Page 5, line 136
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 5, line 137
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 5, line 133
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 5, lines 137-142
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	

### Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 7, line 186
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Page 8, line 197-200

1				
2	Data	19	Plans for data entry, coding, security, and storage,	Page 8, line
3	management		including any related processes to promote data	201-207
4			quality (eg, double data entry; range checks for data	
5			values). Reference to where details of data	
6			management procedures can be found, if not in the	
7			protocol	
8				
9				
10	Statistical	20a	Statistical methods for analysing primary and	Page 10, line
11	methods		secondary outcomes. Reference to where other	234-245
12			details of the statistical analysis plan can be found, if	
13			not in the protocol	
14				
15				
16		20b	Methods for any additional analyses (eg, subgroup	Page 10, line
17			and adjusted analyses)	246-257
18				
19		20c	Definition of analysis population relating to protocol	Page 10, line
20			non-adherence (eg, as randomised analysis), and any	258-264
21			statistical methods to handle missing data (eg,	
22			multiple imputation)	
23				
24				
25	<b>Methods: Monitoring</b>			
26	Data monitoring	21a	Composition of data monitoring committee (DMC);	Page 14, line
27			summary of its role and reporting structure; statement	204-207, 382
28			of whether it is independent from the sponsor and	
29			competing interests; and reference to where further	
30			details about its charter can be found, if not in the	
31			protocol. Alternatively, an explanation of why a DMC	
32			is not needed	
33				
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35				
36		21b	Description of any interim analyses and stopping	Page 8, 195-
37			guidelines, including who will have access to these	196
38			interim results and make the final decision to	
39			terminate the trial	
40				
41				
42	Harms	22	Plans for collecting, assessing, reporting, and	INFORMED
43			managing solicited and spontaneously reported	CONSENT
44			adverse events and other unintended effects of trial	FORM, line 45-
45			interventions or trial conduct	50, 85-89
46				
47				
48	Auditing	23	Frequency and procedures for auditing trial conduct, if	
49			any, and whether the process will be independent	
50			from investigators and the sponsor	
51				
52	<b>Ethics and dissemination</b>			
53				
54	Research ethics	24	Plans for seeking research ethics	Page 2, lines 55
55	approval		committee/institutional review board (REC/IRB)	
56			approval	
57				
58				
59				
60				

1			
2	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
3			Page 11, 275-
4			277
5			
6			
7			
8			
9	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
10			INFORMED
11			CONSENT
12			FORM, lines
13			2~24
14			
15		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
16			
17			
18			
19	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
20			INFORMED
21			CONSENT
22			FORM, line 91
23			
24			
25	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
26			Page 14, line
27			385
28	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
29			INFORMED
30			CONSENT
31			FORM, line 94-
32			102
33			
34	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
35			INFORMED
36			CONSENT
37			FORM, line 85-
38			89
39			
40	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
41			INFORMED
42			CONSENT
43			FORM, line 90-
44			1-2
45			
46			
47		31b	Authorship eligibility guidelines and any intended use of professional writers
48			INFORMED
49			CONSENT
50			FORM, line 90-
51			1-2
52			
53		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
54			
55			
56			
57	<b>Appendices</b>		
58	<hr/>		
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60			

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	See INFORMED CONSENT FORM
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	

\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

# BMJ Open

## The effect of a brief intervention with small financial incentives on alcohol consumption in China: study protocol for a randomized controlled trial

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1           **The effect of a brief intervention with small financial incentives on alcohol**  
2           **consumption in China: study protocol for a randomized controlled trial**

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31 Word count: 2933

## 32 **Abstract**

### 33 **Introduction**

34 Alcohol is the 7<sup>th</sup> leading risk factor of Disabled Adjusted Life Years (DALYs) all over the  
35 world according to the Global Burden of Disease study 2017. As the largest developing  
36 country, Chinese people consume a large amount of alcohol, and suffer from related health  
37 risks. Despite China having made a great achievement in eradicating absolute poverty,  
38 many people are still living in relative poverty, which suggests that the adverse health  
39 effects caused by alcohol consumption among vulnerable populations in China warrant  
40 more attention. The aim of this paper is to provide an overview of alcohol consumption  
41 among ethnic populations in China, and to test the feasibility and efficacy of targeting  
42 reduction in harmful drinking behaviors through a small financial incentive with brief  
43 advice intervention.

### 44 **Methods**

45 This is a three-arm, single-blinded, pragmatic, individual randomized controlled trial with  
46 follow-ups at 1,2 and 3 months after randomization. We aim to recruit 440 daily drinkers  
47 living in Xichang and divide them into three groups (brief intervention group, financial  
48 incentive group, control group). All participants receive an urine ethyl glucuronide (EtG)  
49 test, which informed us if a participant consumed alcohol in the past 80 hours. Additionally,  
50 participants in the brief intervention group receive three free counselling sessions alongside  
51 multi-media messages on the topic of alcohol consumption after each session. The  
52 participants in the financial incentive group received the same interventions as well as cash  
53 incentives according to the results of EtG test. The primary outcomes are the self-reported  
54 drinking quantity, binge drinking frequency, drinking intensity and the proportion of  
55 people who pass the EtG test.

### 56 **Ethics and dissemination**

57 This protocol was approved by the Peking University Health Science Center Institutional  
58 Review Board (IRB00001052-20049). Findings will be published in peer-reviewed

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4 59 journals and presented at local, national and international conferences to publicize and  
5 60 explain the research to key audiences.  
6  
7

8 61 **Trial registration**

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10 62 ClinicalTrials.gov registration number NCT04999371, registration date August 05, 2021  
11

12 63 **Strengths and limitations of this study**

13  
14 64 This trial examines the effectiveness of brief alcohol intervention on alcohol abuse  
15 65 behavior by providing a personalized reminder with a financial incentive to reduce alcohol  
16 66 consumption, and increase investment on health and education, etc.  
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20 67 A personalized health reminder approach is very short and it also alleviates the failure to  
21 68 correctly interpret information due to limited attention and redundancy neglect.  
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24 69 Using urine ethyl glucuronide (EtG) test as one of the primary outcomes increased  
25 70 scientific rigour and decreases misreporting.  
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28 71 This trial cannot completely disentangle the effect of financial incentive.  
29

30 72 Keywords: Health economic, alcohol disorder, rural China  
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## 75 Introduction

76 According to Global Burden of Disease study 2017<sup>1</sup>, alcohol is the 7<sup>th</sup> leading risk factor  
77 of Disabled Adjusted Life Years (DALYs) in the world. In 2017, 2.84 million deaths and  
78 108.00 million DALYs globally were attributable to alcohol use<sup>1</sup>. Alcohol use is associated  
79 with many physical issues, like gastric distress, hypertension, cardiovascular diseases,  
80 permanent liver damage, diabetes, and cancer<sup>2-4</sup>. Further, excessive drinking on a single  
81 occasion increases the risk of motor vehicle crashes, drowning, intimate partner violence,  
82 unprotected sex, and childhood sexual abuse.<sup>2,3</sup>.

83 As the largest developing country, Chinese people consume a large amount of alcohol, and  
84 suffer from the health related risk. For instance, in 2016, the total alcohol per capita  
85 consumption among the world's population aged 15 and older was 6.4 litres. However,  
86 in China, this amount was 7.2 litres, implying that alcohol consumption in China was 12.5%  
87 more than global consumption<sup>5</sup>. Moreover, an increase in per capita alcohol consumption  
88 is observed in China<sup>5</sup>, especially in regions inhabited by minority groups<sup>6</sup>.

89 From the perspective of decision-making, studies show that low-income groups are more  
90 inclined to pay attention to current goals and fail to make rational decisions<sup>7 8</sup>. Despite  
91 China having made great achievement in eradicating absolute poverty, many people are  
92 still living in relative poverty, which suggests that the adverse health effects caused by  
93 alcohol consumption among low-income populations in China warrant more attention.

94 Brief alcohol interventions is considered to be an effective way to reduce the amount of  
95 alcohol consumption, and its efficacy has been supported by a number of studies<sup>9-12</sup>.  
96 However, researches show that alcoholic drinkers are reluctant to accept interventions<sup>13 14</sup>.  
97 A randomized-controlled trial conducted in India indicated that financial incentives may  
98 serve as a feasible intervention for participants in low income countries. Financial  
99 incentives are external motivators and may increase intervention adherence<sup>15</sup>. Contingency  
100 management is an approach to reinforce participants' behaviors by delivering a reward only  
101 if the target behavior occurs<sup>16</sup>. It is reported that contingency management is among the  
102 more effective way to help people refrain from substance abuse<sup>17-19</sup>. Based on previous  
103 trials, it seems more effective to offer a financial incentive to reduce alcohol consumption  
104 among ethnic minority migrants.

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3  
4 105 The existing alcohol intervention studies are mainly conducted in developed countries<sup>11 12</sup>  
5 106 <sup>20</sup>, or paying attention to school students<sup>21</sup>, or based on the clinical settings and health care  
6 107 service providers<sup>10 22</sup>. Few studies have focused on alcohol consumption among ethnic  
7 108 minority migrant people in developing countries where residents' education level is  
8 109 generally low and the primary health care system is not well developed<sup>23</sup>. To address this  
9 110 gap, we aim to evaluate the effects of a brief intervention combined with a small financial  
10 111 incentive on alcohol consumption and health outcomes among migrated population in  
11 112 Liangshan Prefecture. This study is conducted in Liangshan Prefecture for two reasons:  
12 113 First, Liangshan is a region located in the southwestern of Sichuan province and is  
13 114 populated by Yi minority, and the average income in Liangshan are just about two thirds  
14 115 of the national average income <sup>24</sup>. Second, a study found that the drinking rate of Yi  
15 116 minority (47.9%) is higher than that of other regions in China <sup>25</sup>.

16  
17 117 The aim of this paper is to test the feasibility and efficacy of small financial incentive with  
18 118 brief advice intervention targeting reduction of harmful drinking behaviors among ethnic  
19 119 minority migrants.

## 20 21 22 23 24 25 26 27 28 29 30 120 **Methods and Analysis**

### 31 32 121 **Study design**

33  
34 122 This is a three-arm, single-blinded, pragmatic, individual randomized controlled trial,  
35 123 which aims to reduce alcohol consumption among residents. Figure 1 shows the  
36 124 Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

### 37 38 39 40 125 **Recruitment and participants**

41  
42 126 Recruitment activities are conducted in building sites and villages (n=8) in Xichang. It is  
43 127 located in the Liangshan Yi Autonomous Prefecture, in the south of Sichuan, China. We  
44 128 will use flyers and community posts to invite residents to take a quick Alcohol Use  
45 129 Disorder Identification Test ( AUDIT ) , which is utilized to measure whether a  
46 130 respondent meets the criteria of an at-risk drinker. Respondents are informed that the  
47 131 experiment involves a baseline assessment of alcohol consumption and irregular follow-  
48 132 ups to take alcohol tests and fill in the questionnaire within three months. Eligible  
49 133 participants are workers aged between 18 years and 65 years, with scores of AUDIT  $\geq 8$ .

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4 134 Besides, employees whose wages are calculated based on hour wage or piece-rate wage  
5 135 will be included in our study, such as hourly workers at construction sites, delivery man  
6 136 and so on. All the eligible participants should be in Xichang in the next three months and  
7 137 are willing to participate in this study. Importantly, those who have abstinence experience,  
8 138 epilepsy, liver disease before this trial, and those who are using sedative drugs are excluded.

### 139 **Randomization and blinding**

140 Randomization occurs at the individual level. Participants within the same recruitment  
141 session are individually randomized in a ratio of 1:1:1 to two intervention groups and one  
142 control group (brief intervention group, financial incentive group, control group). The  
143 randomization process is generated using a web-based system ([www.sealedenvelope.com](http://www.sealedenvelope.com))  
144 by an investigator who is not involved in the participant recruitment. After the  
145 randomization, the investigator will conduct a balancing test to make sure that participants  
146 in the intervention groups and the control group are comparable and notifies the recruitment  
147 staff one day prior to the base-line investigation. Then the recruiting staff inform  
148 participants the results of randomization independently. Because of the nature of the  
149 intervention, the recruitment staff are also responsible for delivering the interventions, and  
150 cannot be blinded to participant allocation, but. Participants are not informed about the  
151 treatment in the other groups. Outcome assessors and statistical analysts are blinded to the  
152 random grouping.

### 153 **Sample size**

154 The proportion of people who drink alcohol according to the EtG test in control group is  
155 25%, and that in the brief intervention group is expected to be 10%. According to Eq (1),  
156 in order to achieve a 95% CI ( $\alpha=0.05$ ) and 80% power, the required sample size was  
157 calculated to be 100 in the brief intervention group. Assuming a retention rate of 90%  
158 during follow-up, the overall sample size of the study should be 333 for the three groups  
159  $((100*3 \text{ groups})/90\% \text{ retention rate})$ . 440 participants are planned to enroll this study.

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

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 group respectively,  $p$  equals to  $(p_1 + p_2)/2$ .

## Intervention

### Brief Alcohol Intervention

The participants in treatment group 1 received free monthly one-to-one consultation and multi-media messages via Wechat APP or SMS about the topic of alcohol consumption (including the harms of alcohol consumption, tips to reduce drinking, abstinence cases, etc) each time after consultation. One-to-one counseling services will be provided via telephone calling, which is based on World Health Organization (WHO) recommendations<sup>26</sup>. A total of three counsels are conducted, which are set on the second week, sixth and tenth week after baseline survey.

Brief intervention counselors are staff of the research team. All counselors are required to attend a full-day workshop according to the scheme and teaching materials provided by Hongkong University. The contents of the workshop include: (1) harms of excessive drinking and benefits of controlling drinking; (2) overview of AUDIT; (3) Personalized alcohol reduction advice; (4) a standard procedure of brief intervention. Counselors guide participants to evaluate their own drinking behaviors, offered them advice, and gave them encouragement.

An experienced research staff member provides supervision and assistance at each brief intervention session, to ensure the accurate delivery of the intervention. All advisors follow a standardized 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 unannounced EtG tests. Participants will receive a text message regarding our incentive treatment strategy promptly after we finish the follow-up random urine test. We describe our monetary incentive as losses based on the

189 theory of framing effect. Firstly, a voucher of RMB ¥ 490 ( $\approx$ US\$77.5) was given to the  
190 participants in this group, and we would deduct ¥70 once if their urine tests show positive  
191 results. Finally, the participants will receive cash equal to the remaining amount of money  
192 in the voucher.

### 193 **Control group**

194 No information or cash incentives are provided to the participants in the control group, but  
195 it is also necessary to collect the information of the participants in the control group and  
196 perform an alcohol test. Therefore, RMB ¥ 20 ( $\approx$ US\$3.2) compensation will be provided  
197 for participants in control group (participants of intervention group also will receive this  
198 part of compensation).

### 199 **Procedures**

200 Participants are assessed at baseline and the end of each month after treatment initiation  
201 (Table 1). Participants are required to take a test four times a week for weeks 1-4, twice a  
202 week for weeks 5-8, and once a week for weeks 9-11. In order to avoid cheating by  
203 abstaining from alcohol only the day before the test, the time of each test was randomly  
204 determined by program team. The baseline questionnaire measures participants' drinking  
205 behavior including daily alcohol consumption, age of starting drinking, whether and the  
206 number of attempts to quit or reduce and methods for quitting used in past. At weeks 2, 6  
207 and 10 after the intervention initiation, participants are followed up by trained counsellors  
208 with a phone call. The Prime Screen single panel urine test paper is used to conduct the  
209 EtG test<sup>27</sup>. Participants are informed that they may withdraw from the study at any time  
210 without giving a reason. The researcher also has access to interim analyses and terminate  
211 the trial. For the subjects who withdraw from the study, we will collect information on the  
212 number of interventions, the duration of participating in the program and the reasons for  
213 withdrawal. For the subjects who go out on the survey day, we will make an appointment  
214 with them by telephone.

215 Data will be collected via a web-based questionnaire, and the dataset is accessible in real  
216 time. The online dataset is managed by the project leader with username and password.  
217 Logical checks will be conducted every day after field work by a graduate student, and all  
218 the unreliable or missing data will be corrected in time. The data will be managed by a data

219 management specialist, and the data will be desensitized. Each use needs to be approved  
 220 by the project leader.

Table 1 Schedule of baseline and follow-up assessments

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

Sociodemographic characteristics include age, gender, education level, marital status and household income

221

## 222 Outcomes

223 We focus on the alcohol use behavior, health status, productivity and income, as well as  
 224 the household expenditure. The detailed outcomes are listed as follows:

225 Primary outcomes:

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

232 Secondary outcomes:



- 233 1. Health status indicators. Specifically, sleep quality measured by Pittsburgh Sleep Quality  
234 index (PSQI) which is widely used to evaluate sleep quality and linked to psychological disorders<sup>28</sup>.  
235 Mental health measured by a short version of the Depression Anxiety Stress Scale (DASS-  
236 21) which are internationally recognized method of assessing the risk of mental health  
237 outcomes<sup>29</sup>.
- 238 2. Life satisfaction, assessed by ONS questionnaire. ONS measures the respondent's life  
239 evaluations, positive emotions and negative emotions on an 11-point scale, where the  
240 higher point indicates the greater extent of life evaluations that the respondent feels<sup>30</sup>.
- 241 3. Health-care utilization, including emergency/outpatient visits, medical hospitalization,  
242 mean days in hospital in the past one month.
- 243 4. Productivity and income, which are income per day, and working hours per day in the  
244 past one month.
- 245 5. Household expenditure includes the daily expenditure for alcohol, children, parents, and  
246 health care services in the past one month.
- 247 6. Score on the knowledge about the harm of alcohol consumption.

248

### 249 **Statistical analysis**

250 The sociodemographic characteristics and baseline information including sex, age, and the  
251 indicators listed in the outcome section of the participants will be reported. The differences  
252 in alcohol consumption capacity, sobriety status, health status, health-care utilization, daily  
253 working hours and income, as well as the household expenditure between the control group  
254 and the intervention group will be examined by t tests and chi-square tests to assess  
255 differences between the control and intervention groups.

256 The effect of intervention on alcohol consumption behaviors will be analyzed using  
257 multiple linear regression models. Alcohol consumption capacity, drinking frequency,  
258 drinking intensity indicators are considered as dependent variables respectively, and taking  
259 control or intervention group, baseline level of the targeted outcome variable and

260 sociodemographic characteristics (age group, sex, education, marital status, annual  
261 household income), time between baseline and follow-up surveys as independent variables.

262 The effect of alcohol consumption on health, life satisfaction, alcohol-related traffic  
263 accident and harm, health-care utilization, productivity and household expenditure  
264 outcomes will be analyzed with regression models with adjustment. All comparisons will  
265 use generalized estimating equation models (multiple linear models for continuous  
266 outcomes or logistic models for dichotomous outcomes) to adjust for the participant's  
267 baseline alcohol consumption capacity and baseline sociodemographic characteristics (age  
268 group, sex, education, marital status, annual household income), and time between the  
269 baseline and follow-up surveys. Taking health status/ life satisfaction/ frequency of  
270 alcohol-related traffic accident and harm/ health-care utilization/ daily working hours/  
271 daily income/ monthly expenditure for alcohol, children's education, parents, and health  
272 care as dependent variables, alcohol consumption capacity as independent variables, and  
273 controlling for individual fixed effect and all the baseline characteristics listed above.

274 To address the possibility of bias attributable to higher attrition rates among intervention  
275 participants, we performed "worst case" sensitivity analyses by assuming that 100% of  
276 study dropouts remained at the highest level of alcohol consumption. The intervention  
277 effect by subgroups will be assessed, respectively, including age group, sex, education  
278 level, and household income. Statistical analyses will be conducted using Stata V.15.1  
279 (Stata Corp, Texas, USA). The statistical tests were two-sided, and p-value < 0.05 was  
280 considered as statistically significant.

### 281 **Patient and public involvement**

282 No patient involved.

### 283 **Ethics and Dissemination**

284 This study received ethical approval from the Peking University Health Science Center  
285 Institutional Review Board. The trial is registered on ClinicalTrials.gov (registration  
286 number: NCT04999371; Date of registration 08/05/2021). All participants gave their  
287 consent for their own involvement in the study. Authorship will be determined in  
288 accordance with the International Committee of Medical Journal Editors guidelines. If

289 there are any changes to the protocol, we will report to the Peking University Health  
290 Science Center Institutional Review Board and inform the subjects. Findings will be  
291 published in peer-reviewed journals and presented at local, national and international  
292 conferences to publicize and explain the research to key audiences.

## 293 **Discussion**

294 This study entails a comparison of a control group with two different intervention arms,  
295 that is, a brief intervention and brief intervention plus financial incentive, to improve  
296 drinking behavior in Liangshan Prefecture, so as to improve residents' health capital and  
297 consumption behavior. If either of the two interventions are found to be effective, this will  
298 be valuable for decision-makers and non-government organizations to prioritize education  
299 support to encourage the use of alcohol cessation services, which will ultimately decrease  
300 alcohol drinks.

301 There are four innovative aspects to this study. First, this is the first time to conduct brief  
302 alcohol intervention in the minority habitation in China. Second, a small financial incentive  
303 is integrated into brief alcohol intervention to evaluate its effect on behavior change, which  
304 is a crucial part in the path of changing health status and productivity performance. Third,  
305 by assessing the income and expenditure pattern, it is possible to evaluate whether drinking  
306 reduction can make the subjects more productive and rational. Last, we are going to assess  
307 the effectiveness of brief alcohol intervention with a small financial incentive in  
308 community rather than in clinical facilities, which may strengthen scientific evidence for  
309 community health care workers to carry out the intervention.

310 This trial has several strengths. First, this is one of the first randomized controlled trials in  
311 China to explore the approaches to reduce alcohol consumption. The intervention using in  
312 this study deserves extrapolation if improved effective. Additionally, we use the results of  
313 EtG test as the financial incentive indicator, which ensured the accuracy of the intervention.  
314 This is much more beneficial to our evaluation than using the self-reported alcohol  
315 consumption habit<sup>19</sup>. Finally, in order to further evaluate effects of alcohol intervention,  
316 we also identify the change of individual income by questionnaire to figure out whether  
317 the alcohol consumption affect work efficiency and as a result, income.

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4 318 This trial also has several potential limitations. First, this study is unable to assess the long-  
5 319 term effects of the intervention (eg, 12 months) because of budget constraints. Nevertheless,  
6  
7 320 three consecutive follow-ups survey (at 1, 2 and 3 months) allow us to have a basic  
8  
9 321 understanding of how intervention can change participants' drinking behavior. Second, the  
10 322 evidence of drinking behavior is based on self-reporting which cannot obtained by research  
11 323 team directly. Third, as consumption of alcohol in Liangshan Prefecture are relatively high,  
12 324 which is may limit the generalizability of our findings to other settings.

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16 325 **Figure 1. CONSORT flow diagram.** This diagram shows all the processes of the three-  
17 326 arm, individual randomized controlled trial, including participants recruitment, baseline  
18 327 survey, randomization, intervention, follow-up survey, and final evaluation.

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## 22 421 **Acknowledgements**

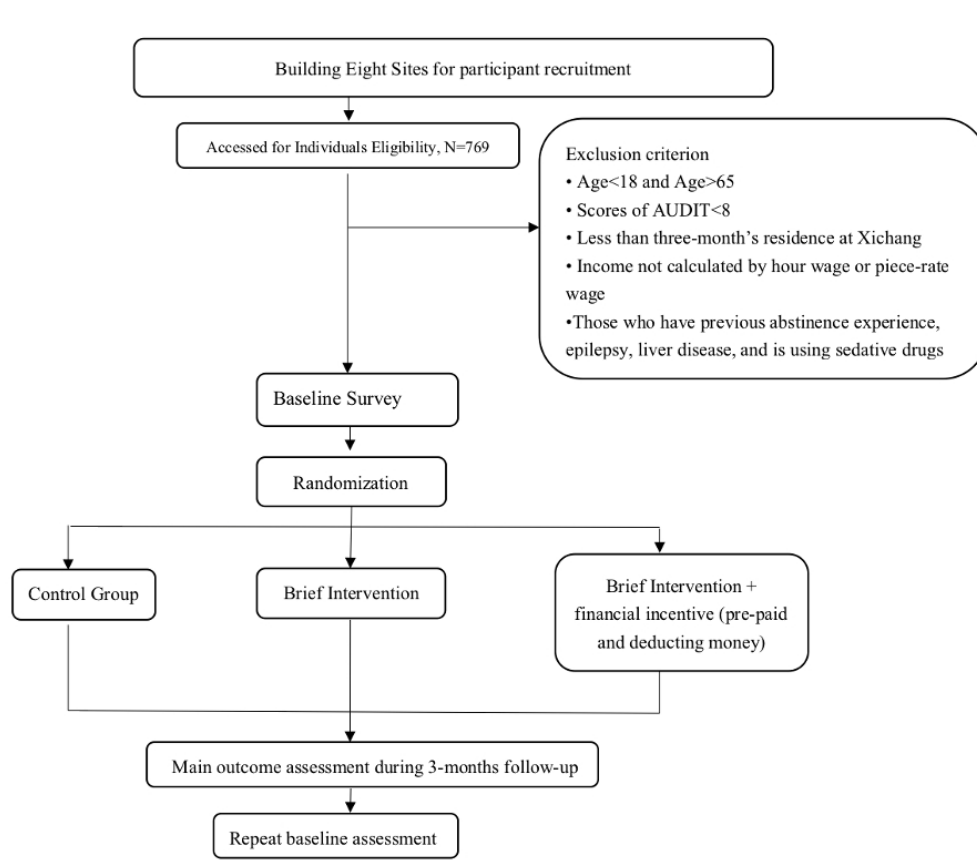
23  
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33 428 **Authors' contributions:** Gordon G. Liu, Shanshan Li and Ziting Wu contributed to the  
34 429 research concept and design, supervise the work, and offered critical suggestions for  
35 430 revisions. Shanshan Li, Ziting Wu, Sun Yu and Sijia Liu participated in conducting the  
36 431 study. Shanshan Li, Ziting Wu and Sijia Liu conducted data analysis and drafted the  
37 432 manuscript. All authors have read and approved the manuscript.  
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43  
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46

47  
48 436 **Competing interests statement:** The authors declare no conflict of interest.  
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This diagram shows all the processes of the three-arm, individual randomized controlled trial, including participants recruitment, baseline survey, randomization, intervention, follow-up survey, and final evaluation.

152x131mm (150 x 150 DPI)



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## INFORMED CONSENT FORM

Dear Subjects,

By reading the informed consent form carefully below, you are agreeing that: (1) you have read and understood all the information, (2) you know your rights, (3) questions about your participation in this study have been answered satisfactorily (if you have any question at any time, you can require researchers to explain), (4) you are aware of the potential risks (if any) and benefits, and (5) you are willing to take part in this research.

The project is led by Professor Gordon Liu who works in the National School of Development (NSD), Peking University and funded by the National Natural Science Foundation of China.

1. Why is this study being conducted?

Under the national policy of "Health China 2030", one of the top priorities is how to effectively promote targeted poverty alleviation. At present, residents in poverty are mainly from bankruptcy through medical bills in Liangshan Yi Autonomous Prefecture. Therefore, this study will intervene in residents' health in Liangshan Prefecture based on big data, and explore whether improving health can break the vicious cycle of "poverty caused by disease and disease caused by poverty" through the method of experimental economics. The data will be used to help formulate policies related to health management in poor areas and promote the goal of poverty eradication.

2. Who will be invited to participate in this study?

Our survey will be conducted in Liangshan Yi Autonomous Prefecture, Sichuan Province. The number of randomly selected households is twenty in each village. They are volunteered to participate in the study. Exceptionally, all households residing in Liangshan Prefecture for at least six months of the year will be included in the study sample.

3. How many people will participate in the study?

Those with drinking habits will be invited to participate in urine testing on a voluntary basis, and no more than 440 subjects are planned to be enrolled in this project with urine testing.

4. What is included in this study?

The study aims to explore intervention methods to promote the health level of local residents through health information interventions in cooperation with local health commission, which could reduce the incidence of diseases, improve the health and productivity of local populations, and provide scientific suggestions to the government to address poverty alleviation due to diseases. The team will design a questionnaire based on the objectives and content of the study and provide standardized training to the village doctors and local university students. The village doctors and researchers will collect data based on the questionnaire in a one-on-one manner, and the researchers will be responsible for urine retention and observation of the subjects. The EtG test strips were used for urine alcohol testing, and the cost of urine testing was borne by the project team. The five-year study is to collect data in every six months, and the content of each follow-up visit will be basically the same except for basic household information.

5. How long will the study last?

The duration of this alcohol consumption study is three months (including baseline research,

1  
2 42 intervention and 7 follow-up visits), and each questionnaire will take approximately 20-60  
3 43 minutes to complete. You may withdraw during the process of the study and your benefits will  
4 44 not be affected in any way.

5  
6 45 6. What are the risks of participating in this study?

7  
8 46 This study mainly involves information intervention and health education, mainly to provide  
9 47 you with information to improve your health and health behavior and to help you learn more  
10 48 about your health, and will not cause you any harm. To ensure that you can fully understand  
11 49 the information content of the intervention, the intervention will be conducted through  
12 50 information platforms, voice or on-site.

13  
14 51 To achieve the goal of this study, we will regularly collect information about your health and  
15 52 other information, which may cause inconvenience to your life if the information is  
16 53 inadvertently disclosed. In order to properly control this risk, all information will only be  
17 54 collected through local village doctors, and the information collected will only be used for  
18 55 research, not for commercial purposes, and the team is committed to not disclose your personal  
19 56 information in any papers and reports.

20  
21 57 7. What are the benefits of participating in this study?

22  
23 58 We will follow up on your health status to fully protect your rights. By participating in this  
24 59 program, you are likely to learn more about health and hygiene information. That can help you  
25 60 change your bad habits, reduce the incidence of disease, and improve your personal health.

26  
27 61 8. Is it mandatory to participate in and complete this study?

28  
29 62 Your participation in this study is completely voluntary. If you do not want to, you can refuse  
30 63 to participate and this will not have any negative impact on you. Even after you have agreed to  
31 64 participate, you may change your mind at any time and tell the investigator to withdraw from  
32 65 the study, and your withdrawal will not affect your access to normal medical services. In  
33 66 principle, after you have withdrawn, the researchers will keep your information in strict  
34 67 confidence and will not use or disclose it further during this period. However, in the following  
35 68 circumstances, the researchers can continue to use information about you even after you have  
36 69 withdrawn from the study or the study has ended. These circumstances include:

37  
38 70 (1) Removal of your information would affect the scientific validity of the study results or the  
39 71 evaluation of the security of the data.

40  
41 72 (2) Providing some limited information for research, teaching, or other activities (this  
42 73 information will not include your name, ID number, or other personal information that  
43 74 identifies you).

44  
45 75 (3) If something happened can affect your decision to continue participating in that research,  
46 76 we will inform you.

47  
48 77 9. About the study cost and compensation

49  
50 78 There is no fee involved in participating in this study, and the team mainly collect data by  
51 79 visiting the household, and minimize disturbance to farmers as much as possible. Additionally,  
52 80 if reasonable costs are incurred due to this study, such as transportation costs incurred by

1  
2 81 farmers in order to cooperate with the research, the project will provide some compensation  
3 82 with advance notice.

4  
5 83 10. Do subjects receive compensation for participating in this study?

6  
7 84 No compensation will be paid for participation in this study.

8  
9 85 11. What happens in case of research-related injuries?

10  
11 86 In the event of an accidental injury resulting from the performance of the study, we provide  
12 87 the necessary medical treatment, cover the appropriate medical expenses and provide  
13 88 appropriate financial compensation in accordance with the relevant laws and regulations of  
14 89 China.

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16  
17 90 12. Will my information be kept confidential?

18  
19 91 If you decide to participate in this study, your participation in the study and your personal  
20 92 information during the study will be confidential. Any information that identifies you will not  
21 93 be disclosed to members outside of the research team without your permission. All study  
22 94 members and study-related parties will keep your identity confidential as required. Your file  
23 95 will be kept securely and will be accessible only to the researcher. To ensure that the research  
24 96 is conducted in accordance with regulations, members of the government administration, school  
25 97 authorities or ethics committee will have access to your personal information at the research  
26 98 unit as required. When the results of this study are published, no personal information about  
27 99 you will be disclosed.

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31 100 Information about you will only be used for research purposes, and when researchers publish  
32 101 public articles or reports, the data will be encrypted and no personal information about you will  
33 102 appear.

34  
35 103 13. Who do I contact if I have any question?

36 104 If you have any questions related to this study, please contact Shanshan Li.

37  
38  
39 105 E-mail: [lishanshan7@pku.edu.cn](mailto:lishanshan7@pku.edu.cn)

40 106 Tel: 010-62757318

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42  
43 107

44  
45 108 If you have questions related to the subject's own rights, you may contact the Biomedical Ethics  
46 109 Committee of Peking University.

47 110 E-mail: [llwyh@bjmu.edu.cn](mailto:llwyh@bjmu.edu.cn)

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2 116 Investigator's Statement  
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4 117 *I have informed the subject of the background, purpose, risks and benefits of the study,*  
5 118 *given him/her sufficient time to read the informed consent form, discuss with others, and*  
6 119 *answered his/her questions about the study; I have informed the subject that he/she could*  
7 120 *contact Dr. Gordon Liu at any time when he/she encountered problems related to the study and*  
8 121 *the Biomedical Ethics Committee of Peking University at any time when he/she encountered*  
9 122 *problems related to his/her rights/rights, and provided accurate contact information; I have*  
10 123 *informed the subject that he/she could withdraw from the study; I have informed the subject*  
11 124 *that he/she would be given a copy of this informed consent form, which contains my signature*  
12 125 *and his/her signatures.*  
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18 127

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20 128 Signature

Date

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23  
24 130 Subject Statement

25  
26 131 *I have been informed of the background, purpose, risks and benefits of the study. I was given*  
27 132 *sufficient time and opportunity to ask questions and I was satisfied with the answers to my*  
28 133 *questions. I was also told who to contact if I had questions, difficulties, concerns, suggestions*  
29 134 *about the study, or if I wanted further information or help with the study. I have read this*  
30 135 *informed consent form and agree to participate in this study. I understand that I may withdraw*  
31 136 *from this study at any time during the study without any reason. I am informed that I will be*  
32 137 *given a copy of this informed consent form containing my signature and that of the researchers.*  
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39  
40 140 Signature

Date

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44 142 Signature of the legal agent

Date

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48 144 Relationship to the subject

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52 146 Subject's signature (10 years old and above)

Date

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STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	Location
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1, line 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 3, line 60
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	
Funding	4	Sources and types of financial, material, and other support	Page 14, line 376
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 14, line 371
	5b	Name and contact information for the trial sponsor	
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 4, line 74-110

	6b	Explanation for choice of comparators	
Objectives	7	Specific objectives or hypotheses	Page 5, line 111-113
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Page 5, line 114
<b>Methods: Participants, interventions, and outcomes</b>			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 5, line 120-122
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 5, lines 124-131
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 6, line 155
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Page 7, line 173-178
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 8, line 203-228
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 6, line 143-154
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 6, line 119

### Methods: Assignment of interventions (for controlled trials)

#### Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Page 5, line 136
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 5, line 137
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 5, line 133
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 5, lines 137-142
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	

### Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 7, line 186
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Page 8, line 197-200

1				
2	Data	19	Plans for data entry, coding, security, and storage,	Page 8, line
3	management		including any related processes to promote data	201-207
4			quality (eg, double data entry; range checks for data	
5			values). Reference to where details of data	
6			management procedures can be found, if not in the	
7			protocol	
8				
9				
10	Statistical	20a	Statistical methods for analysing primary and	Page 10, line
11	methods		secondary outcomes. Reference to where other	234-245
12			details of the statistical analysis plan can be found, if	
13			not in the protocol	
14				
15				
16		20b	Methods for any additional analyses (eg, subgroup	Page 10, line
17			and adjusted analyses)	246-257
18				
19		20c	Definition of analysis population relating to protocol	Page 10, line
20			non-adherence (eg, as randomised analysis), and any	258-264
21			statistical methods to handle missing data (eg,	
22			multiple imputation)	
23				
24				
25	<b>Methods: Monitoring</b>			
26	Data monitoring	21a	Composition of data monitoring committee (DMC);	Page 14, line
27			summary of its role and reporting structure; statement	204-207, 382
28			of whether it is independent from the sponsor and	
29			competing interests; and reference to where further	
30			details about its charter can be found, if not in the	
31			protocol. Alternatively, an explanation of why a DMC	
32			is not needed	
33				
34				
35				
36		21b	Description of any interim analyses and stopping	Page 8, 195-
37			guidelines, including who will have access to these	196
38			interim results and make the final decision to	
39			terminate the trial	
40				
41				
42	Harms	22	Plans for collecting, assessing, reporting, and	INFORMED
43			managing solicited and spontaneously reported	CONSENT
44			adverse events and other unintended effects of trial	FORM, line 45-
45			interventions or trial conduct	50, 85-89
46				
47				
48	Auditing	23	Frequency and procedures for auditing trial conduct, if	
49			any, and whether the process will be independent	
50			from investigators and the sponsor	
51				
52	<b>Ethics and dissemination</b>			
53				
54	Research ethics	24	Plans for seeking research ethics	Page 2, lines 55
55	approval		committee/institutional review board (REC/IRB)	
56			approval	
57				
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1			
2	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
3			Page 11, 275-
4			277
5			
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7			
8			
9	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
10			INFORMED
11			CONSENT
12			FORM, lines
13			2~24
14			
15		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
16			
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18			
19	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
20			INFORMED
21			CONSENT
22			FORM, line 91
23			
24			
25	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
26			Page 14, line
27			385
28	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
29			INFORMED
30			CONSENT
31			FORM, line 94-
32			102
33			
34	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
35			INFORMED
36			CONSENT
37			FORM, line 85-
38			89
39			
40	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
41			INFORMED
42			CONSENT
43			FORM, line 90-
44			1-2
45			
46			
47		31b	Authorship eligibility guidelines and any intended use of professional writers
48			INFORMED
49			CONSENT
50			FORM, line 90-
51			1-2
52			
53		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
54			
55			
56			
57	<b>Appendices</b>		
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Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	See INFORMED CONSENT FORM
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	

\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

# BMJ Open

## The effect of a brief intervention with small financial incentives on alcohol consumption in China: study protocol for a randomized controlled trial

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1           **The effect of a brief intervention with small financial incentives on alcohol**  
2           **consumption in China: study protocol for a randomized controlled trial**

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34 Word count: 2933

## 35 **Abstract**

### 36 **Introduction**

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

### 47 **Methods**

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

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4 59 **Ethics and dissemination**

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6 60 This protocol was approved by the Peking University Health Science Center Institutional  
7 61 Review Board (IRB00001052-20049). Findings will be published in peer-reviewed  
8 62 journals and presented at local, national and international conferences to publicize and  
9 63 explain the research to key audiences.

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13 64 **Trial registration**

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16 65 ClinicalTrials.gov registration number NCT04999371, registration date August 05, 2021

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18 66 **Strengths and limitations of this study**

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20 67 This trial examines the effectiveness of brief alcohol intervention on alcohol abuse  
21 68 behavior by providing a personalized reminder with a financial incentive to reduce alcohol  
22 69 consumption and increase investment in health and education.

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26 70 A personalized health reminder approach is very feasible and it also minimizes the  
27 71 possibility of incorrectly interpreting information due to limited attention and redundancy  
28 72 neglect.

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31 73 Using the urine ethyl glucuronide (EtG) test as one of the primary outcomes increases  
32 74 scientific rigor and decreases participant misreporting.

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35 75 This trial cannot completely disentangle the effect of financial incentives.

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38 76 This study is unable to assess the long-term effects of intervention due to budget constraints.

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40 77 Keywords: Health economic, alcohol disorder, rural China

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## 80 Introduction

81 According to the Global Burden of Disease study 2017<sup>1</sup>, alcohol is the seventh leading risk  
82 factor for disability adjusted life years (DALYs) in the world. In 2017, 2.84 million deaths  
83 and 108.00 million DALYs globally were attributable to alcohol use<sup>1</sup>. Alcohol  
84 consumption is associated with health conditions such as gastric distress, hypertension,  
85 cardiovascular diseases, permanent liver damage, diabetes, and cancer<sup>2-4</sup>. Furthermore,  
86 excessive drinking on a single occasion increases the risk of motor vehicle crashes,  
87 drowning, intimate partner violence, unprotected sex, and childhood sexual abuse.<sup>2 3</sup>.

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

94 From the perspective of decision-making, studies have shown that low-income groups are  
95 more inclined to pay attention to current goals and fail to make rational decisions<sup>7 8</sup>. Despite  
96 China having made outstanding achievements in eradicating absolute poverty, many  
97 people are still living in relative poverty, which suggests that the adverse health effects  
98 caused by alcohol consumption among low-income populations in China warrant more  
99 attention.

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

109 trials, it seems more effective to offer a financial incentive to reduce alcohol consumption  
110 among ethnic minority migrants.

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

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

## 126 **Methods and Analysis**

### 127 **Study design**

128 This is a three-arm, single-blinded, pragmatic, individually randomized controlled trial that  
129 aims to reduce alcohol consumption among residents. Figure 1 shows the Consolidated  
130 Standards of Reporting Trials (CONSORT) flow diagram.

### 131 **Recruitment and participants**

132 Recruitment activities will be conducted in building sites and villages (n=8) in Xichang,  
133 Liangshan Yi Autonomous Prefecture, south of Sichuan, China. Flyers and community  
134 posts will be used to encourage residents to take a quick Alcohol Use Disorder  
135 Identification Test (AUDIT) to determine whether they meet the criteria of an at-risk  
136 drinker. Respondents will be informed that the experiment involves a baseline assessment  
137 of alcohol consumption and irregular follow-ups through three months that require them to



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4 138 take alcohol tests and complete questionnaires. Eligible participants are workers aged  
5 139 between 18 years and 65 years, with scores of AUDIT  $\geq 8$ . Employees whose wages are  
6 140 calculated based on hourly or piece-rate wages will also be included in the study, such as  
7 141 hourly workers at construction sites, delivery men and more. Eligible participants agreeing  
8 142 to partake in this study should remain in Xichang for the next three months. Informed  
9 143 consent will be obtained before starting the trial (see supplementary file 1). Respondents  
10 144 with abstinence experience or a history of epilepsy, liver disease, and sedative drug use  
11 145 will be excluded from the study.

### 146 **Randomization and blinding**

147 Randomization occurs at the individual level. Participants within the same recruitment  
148 session will be individually randomized in a 1:1:1 ratio into two intervention groups and  
149 one control group (brief intervention group, financial incentive group, control group). The  
150 randomization process will be generated using a web-based system  
151 ([www.sealedenvelope.com](http://www.sealedenvelope.com)) by an investigator who is not involved in participant  
152 recruitment. After the randomization, the investigator will conduct a balancing test to  
153 ensure that participants in the intervention groups and the control group are comparable  
154 and they will notify the recruitment staff one day prior to the baseline investigation. The  
155 recruiting staff will then inform the participants of the results of randomization  
156 independently. Due to the nature of the intervention, the recruitment staff are also  
157 responsible for delivering the interventions and thus cannot be blinded from participant  
158 allocation. However, participants will not be informed about the treatment in the other  
159 groups. Outcome assessors and statistical analysts will be blinded to the random grouping.

### 160 **Sample size**

161 The proportion of people who drink alcohol according to the EtG test in the control group  
162 is 25%, and that in the brief intervention group is expected to be 10%. According to Eq (1),  
163 to achieve a 95% CI ( $\alpha=0.05$ ) and 80% power, the required sample size was calculated  
164 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 enroll in this study.

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

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 group 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 multi-media messages via the Wechat APP or SMS on alcohol consumption, including the harms of alcohol consumption, tips to reduce drinking, abstinence cases, etc., each time after consultation. One-to-one counseling services will be provided via phone calls based on World Health Organization (WHO) recommendations<sup>26</sup>. A total of three counsels scheduled for the second, sixth and tenth week after the baseline survey will be conducted.

Brief intervention counselors are staff of the research team. All counselors are required to attend a full-day workshop organized 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) personalized alcohol reduction advice; and (4) a standard procedure of brief intervention. Counselors will guide participants to evaluate their own drinking behaviors, 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 counselors will follow a standardized process and complete a checklist table.

### Incentive group

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

### 200 **Control group**

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

### 206 **Procedures**

207 Participants will be assessed at baseline and at the end of each month after treatment  
208 initiation (Table 1). Participants are required to take a test four times a week for weeks 1-  
209 4, twice a week for weeks 5-8, and once a week for weeks 9-11. To prevent cheating by  
210 abstaining from alcohol only the day before the test, the program team will randomly  
211 determine the time of each test. The baseline questionnaire measures participants' drinking  
212 behavior, including daily alcohol consumption, age at first drink, the number of attempts  
213 at quitting or reducing drinking, and methods for quitting used in the past. At weeks 2, 6  
214 and 10 after the intervention initiation, trained counselors will follow up with participants  
215 via phone calls. The Prime Screen single-panel urine test paper will be used to conduct the  
216 EtG test<sup>27</sup>. Participants will be informed that they may withdraw from the study at any time  
217 without providing a reason. The researcher also has access to interim analyses and right to  
218 terminate the trial at their discretion. For subjects who withdraw from the study,  
219 information on the number of interventions, the duration of participation in the program,  
220 and the reasons for withdrawal (if willing to provide) will be collected. For subjects who

221 are unavailable on survey day, the research team will schedule appointments with them via  
222 telephone.

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

Table 1 Schedule of baseline and follow-up assessments

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

Sociodemographic characteristics include age, gender, education level, marital status and household income

229

## 230 **Outcomes**

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

233 Primary outcomes:

234 1. Self-reported drinking quantity (drinks per week).

235 2. Self-reported binge drinking frequency (number of binges per week), binge drinking is  
236 defined as four or more standard drinks on one occasion.

237 3. Self-reported drinking frequency (drinking days per week).

238 4. Self-reported drinking intensity (number of drinks per drinking day).

239 5. The proportion of people who drink alcohol according to the EtG test.

240 Secondary outcomes:

241 1. Health status indicators. Sleep quality will be measured by the Pittsburgh Sleep Quality  
242 index (PSQI), a widely used instrument for evaluating sleep quality and linking findings to  
243 psychological disorders<sup>28</sup>. Mental health will be assessed by a short version of the  
244 Depression Anxiety Stress Scale (DASS-21), an internationally recognized method of  
245 assessing the risk of mental health outcomes<sup>29</sup>.

246 2. Life satisfaction will be assessed by the ONS questionnaire, which measures the  
247 respondent's life evaluations, positive emotions, and negative emotions on an 11-point  
248 scale. A higher score indicates a greater extent of the respondent's life evaluations<sup>30</sup>.

249 3. Health-care utilization will be determined, including emergency/outpatient visits,  
250 medical hospitalization, mean days in hospital in the past one month.

251 4. Productivity and income, which will be calculated as income per day and working hours  
252 per day in the past one month.

253 5. Household expenditure includes the daily expenditure for alcohol, children, parents, and  
254 health care services in the past one month.

255 6. Score on the knowledge about the harm of alcohol consumption.

256

## 257 **Statistical analysis**

258 The sociodemographic characteristics and baseline information, including sex, age, and the  
259 indicators listed in the outcome section of the participants, will be reported. The differences  
260 in alcohol consumption capacity, sobriety status, health status, health-care utilization, daily

261 working hours and income, and household expenditure between the control and the  
262 intervention groups will be examined using t-tests and chi-square.

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

269 The effect of alcohol consumption on health, life satisfaction, alcohol-related traffic  
270 accident and harm, health-care utilization, productivity, and household expenditure  
271 outcomes will be analyzed with regression models with adjustments. All comparisons will  
272 use generalized estimating equation models (multiple linear models for continuous  
273 outcomes or logistic models for dichotomous outcomes) to adjust for the participant's  
274 baseline alcohol consumption capacity and baseline sociodemographic characteristics (age  
275 group, sex, education, marital status, annual household income), and time between the  
276 baseline and follow-up surveys. Taking health status/ life satisfaction/ frequency of  
277 alcohol-related traffic accident and harm/ health-care utilization/ daily working hours/  
278 daily income/ monthly expenditure for alcohol, children's education, parents, and health  
279 care as dependent variables, alcohol consumption capacity as independent variables, and  
280 controlling for individual fixed effect and all the baseline characteristics listed above.

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

## 288 **Patient and public involvement**

289 No patient involved.

## 290 **Ethics and Dissemination**

291 This study received ethical approval from the Peking University Health Science Center  
292 Institutional Review Board. The trial is registered on ClinicalTrials.gov (registration  
293 number: NCT04999371; Date of registration 08/05/2021). All participants gave their  
294 consent for their own involvement in the study. Authorship will be determined in  
295 accordance with the International Committee of Medical Journal Editors guidelines. If  
296 there are any changes to the protocol, we will report to the Peking University Health  
297 Science Center Institutional Review Board and inform the subjects. Findings will be  
298 published in peer-reviewed journals and presented at local, national and international  
299 conferences to publicize and explain the research to key audiences.

## 300 **Discussion**

301 This study entails a comparison of a control group with two different intervention arms,  
302 a brief intervention and brief intervention plus financial incentive, on improving drinking  
303 behaviors in Liangshan Prefecture to ameliorate residents' health capital and consumption  
304 behavior. The effectiveness of the two interventions will generate valuable information for  
305 decision-makers and non-government organizations and encourage them to prioritize  
306 educational support on alcohol cessation services, which will ultimately decrease alcohol  
307 consumption.

308 There are four innovative aspects to this study. First, this is the first time a brief alcohol  
309 intervention will be conducted in a minority habitation in China. Second, a small financial  
310 incentive will be integrated into the brief alcohol intervention to evaluate its effect on  
311 behavioral changes, which is crucial in changing health status and productivity  
312 performance. Third, by assessing the income and expenditure pattern, the research team is  
313 able to evaluate whether drinking reduction can make the subjects more productive and  
314 rational in decision-making. Last, the effectiveness of brief alcohol intervention with a  
315 small financial incentive will be assessed in the community rather than in clinical facilities,  
316 which will strengthen scientific evidence supporting the incorporation of community health  
317 care workers in carrying out the intervention.

318 This trial has several strengths. First, this is one of the first randomized controlled trials in  
319 China to explore the approaches to reducing alcohol consumption. The use of intervention

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4 320 in this study deserves extrapolation if proved effective. Additionally, the use of EtG test  
5 321 results as the financial incentive indicator will ensure the accuracy of the intervention. This  
6  
7 322 is more beneficial for evaluation than using the self-reported alcohol consumption habit<sup>19</sup>.  
8  
9 323 Finally, in order to further evaluate the effects of the alcohol intervention, the research team  
10 324 will also identify changes in individual income using a questionnaire to determine whether  
11  
12 325 alcohol consumption affects work efficiency and, as a result, income.  
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14 326 This trial also has several potential limitations. First, this study is unable to assess the long-  
15 327 term effects of the intervention (eg, 12 months) due to budget constraints. Nevertheless,  
16 328 three consecutive follow-up surveys (at 1, 2 and 3 months) will allow the development of  
17 329 a basic understanding of how intervention can change participants' drinking behaviors.  
18  
19 330 Second, the evidence of drinking behavior is based on self-reporting which cannot be  
20  
21 331 obtained by the research team directly. Third, the consumption of alcohol in Liangshan  
22 332 Prefecture is relatively high, which may limit the generalizability of study findings to other  
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24 333 settings.  
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28 334 **Figure 1. CONSORT flow diagram.** This diagram shows all the processes of the three-  
29 335 arm, individual randomized controlled trial, including participants recruitment, baseline  
30 336 survey, randomization, intervention, follow-up survey, and final evaluation.  
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## 21 22 430 **Acknowledgements**

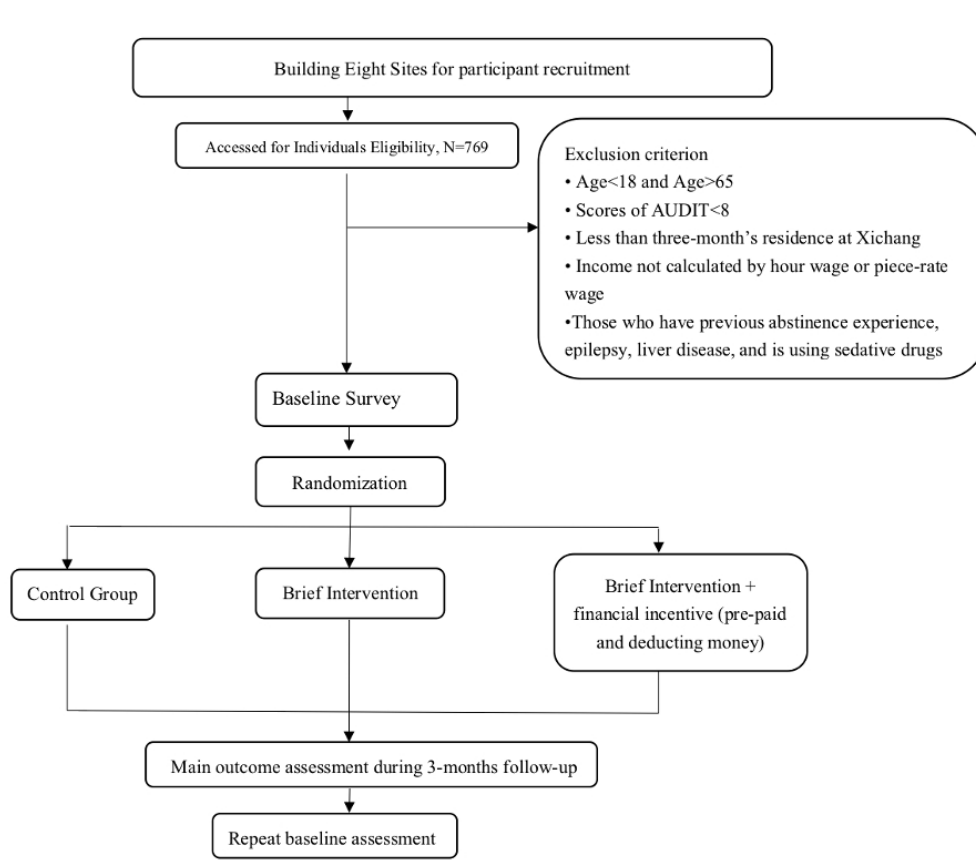
23  
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30  
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32 438 research concept and design, supervise the work, and offered critical suggestions for  
33 439 revisions. Shanshan Li, Ziting Wu, Sun Yu and Sijia Liu participated in conducting the  
34 440 study. Shanshan Li, Ziting Wu and Sijia Liu conducted data analysis and drafted the  
35 441 manuscript. All authors have read and approved the manuscript.  
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46  
47  
48 445 **Competing interests statement:** The authors declare no conflict of interest.  
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This diagram shows all the processes of the three-arm, individual randomized controlled trial, including participants recruitment, baseline survey, randomization, intervention, follow-up survey, and final evaluation.

152x131mm (150 x 150 DPI)

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## INFORMED CONSENT FORM

Dear Subjects,

By reading the informed consent form carefully below, you are agreeing that: (1) you have read and understood all the information, (2) you know your rights, (3) questions about your participation in this study have been answered satisfactorily (if you have any question at any time, you can require researchers to explain), (4) you are aware of the potential risks (if any) and benefits, and (5) you are willing to take part in this research.

The project is led by Professor Gordon Liu who works in the National School of Development (NSD), Peking University and funded by the National Natural Science Foundation of China.

1. Why is this study being conducted?

Under the national policy of "Health China 2030", one of the top priorities is how to effectively promote targeted poverty alleviation. At present, residents in poverty are mainly from bankruptcy through medical bills in Liangshan Yi Autonomous Prefecture. Therefore, this study will intervene in residents' health in Liangshan Prefecture based on big data, and explore whether improving health can break the vicious cycle of "poverty caused by disease and disease caused by poverty" through the method of experimental economics. The data will be used to help formulate policies related to health management in poor areas and promote the goal of poverty eradication.

2. Who will be invited to participate in this study?

Our survey will be conducted in Liangshan Yi Autonomous Prefecture, Sichuan Province. The number of randomly selected households is twenty in each village. They are volunteered to participate in the study. Exceptionally, all households residing in Liangshan Prefecture for at least six months of the year will be included in the study sample.

3. How many people will participate in the study?

Those with drinking habits will be invited to participate in urine testing on a voluntary basis, and no more than 440 subjects are planned to be enrolled in this project with urine testing.

4. What is included in this study?

The study aims to explore intervention methods to promote the health level of local residents through health information interventions in cooperation with local health commission, which could reduce the incidence of diseases, improve the health and productivity of local populations, and provide scientific suggestions to the government to address poverty alleviation due to diseases. The team will design a questionnaire based on the objectives and content of the study and provide standardized training to the village doctors and local university students. The village doctors and researchers will collect data based on the questionnaire in a one-on-one manner, and the researchers will be responsible for urine retention and observation of the subjects. The EtG test strips were used for urine alcohol testing, and the cost of urine testing was borne by the project team. The five-year study is to collect data in every six months, and the content of each follow-up visit will be basically the same except for basic household information.

5. How long will the study last?

The duration of this alcohol consumption study is three months (including baseline research,

42 intervention and 7 follow-up visits), and each questionnaire will take approximately 20-60  
43 minutes to complete. You may withdraw during the process of the study and your benefits will  
44 not be affected in any way.

#### 45 6. What are the risks of participating in this study?

46 This study mainly involves information intervention and health education, mainly to provide  
47 you with information to improve your health and health behavior and to help you learn more  
48 about your health, and will not cause you any harm. To ensure that you can fully understand the  
49 information content of the intervention, the intervention will be conducted through information  
50 platforms, voice or on-site.

51 To achieve the goal of this study, we will regularly collect information about your health and  
52 other information, which may cause inconvenience to your life if the information is  
53 inadvertently disclosed. In order to properly control this risk, all information will only be  
54 collected through local village doctors, and the information collected will only be used for  
55 research, not for commercial purposes, and the team is committed to not disclose your personal  
56 information in any papers and reports.

#### 57 7. What are the benefits of participating in this study?

58 We will follow up on your health status to fully protect your rights. By participating in this  
59 program, you are likely to learn more about health and hygiene information. That can help you  
60 change your bad habits, reduce the incidence of disease, and improve your personal health.

#### 61 8. Is it mandatory to participate in and complete this study?

62 Your participation in this study is completely voluntary. If you do not want to, you can refuse  
63 to participate and this will not have any negative impact on you. Even after you have agreed to  
64 participate, you may change your mind at any time and tell the investigator to withdraw from  
65 the study, and your withdrawal will not affect your access to normal medical services. In  
66 principle, after you have withdrawn, the researchers will keep your information in strict  
67 confidence and will not use or disclose it further during this period. However, in the following  
68 circumstances, the researchers can continue to use information about you even after you have  
69 withdrawn from the study or the study has ended. These circumstances include:

- 70 (1) Removal of your information would affect the scientific validity of the study results or the  
71 evaluation of the security of the data.
- 72 (2) Providing some limited information for research, teaching, or other activities (this  
73 information will not include your name, ID number, or other personal information that  
74 identifies you).
- 75 (3) If something happened can affect your decision to continue participating in that research,  
76 we will inform you.

#### 77 9. About the study cost and compensation

78 There is no fee involved in participating in this study, and the team mainly collect data by  
79 visiting the household, and minimize disturbance to farmers as much as possible. Additionally,  
80 if reasonable costs are incurred due to this study, such as transportation costs incurred by

1  
2 81 farmers in order to cooperate with the research, the project will provide some compensation  
3 82 with advance notice.

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5 83 10. Do subjects receive compensation for participating in this study?

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7 84 No compensation will be paid for participation in this study.

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9 85 11. What happens in case of research-related injuries?

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11 86 In the event of an accidental injury resulting from the performance of the study, we provide  
12 87 the necessary medical treatment, cover the appropriate medical expenses and provide  
13 88 appropriate financial compensation in accordance with the relevant laws and regulations of  
14 89 China.

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17 90 12. Will my information be kept confidential?

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19 91 If you decide to participate in this study, your participation in the study and your personal  
20 92 information during the study will be confidential. Any information that identifies you will not  
21 93 be disclosed to members outside of the research team without your permission. All study  
22 94 members and study-related parties will keep your identity confidential as required. Your file  
23 95 will be kept securely and will be accessible only to the researcher. To ensure that the research  
24 96 is conducted in accordance with regulations, members of the government administration, school  
25 97 authorities or ethics committee will have access to your personal information at the research  
26 98 unit as required. When the results of this study are published, no personal information about  
27 99 you will be disclosed.

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31 100 Information about you will only be used for research purposes, and when researchers publish  
32 101 public articles or reports, the data will be encrypted and no personal information about you will  
33 102 appear.

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35 103 13. Who do I contact if I have any question?

36 104 If you have any questions related to this study, please contact Shanshan Li.

37  
38  
39 105 E-mail: [lishanshan7@pku.edu.cn](mailto:lishanshan7@pku.edu.cn)

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41 106 Tel: 010-62757318

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45  
46 108 If you have questions related to the subject's own rights, you may contact the Biomedical Ethics  
47 109 Committee of Peking University.

48  
49 110 E-mail: [llwyh@bjmu.edu.cn](mailto:llwyh@bjmu.edu.cn)

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51 111 Tel: 010-82805751

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2 116 Investigator's Statement  
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4 117 *I have informed the subject of the background, purpose, risks and benefits of the study,*  
5 118 *given him/her sufficient time to read the informed consent form, discuss with others, and*  
6 119 *answered his/her questions about the study; I have informed the subject that he/she could*  
7 120 *contact Dr. Gordon Liu at any time when he/she encountered problems related to the study and*  
8 121 *the Biomedical Ethics Committee of Peking University at any time when he/she encountered*  
9 122 *problems related to his/her rights/rights, and provided accurate contact information; I have*  
10 123 *informed the subject that he/she could withdraw from the study; I have informed the subject*  
11 124 *that he/she would be given a copy of this informed consent form, which contains my signature*  
12 125 *and his/her signatures.*  
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20 128 Signature Date  
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24 130 Subject Statement  
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26 131 *I have been informed of the background, purpose, risks and benefits of the study. I was given*  
27 132 *sufficient time and opportunity to ask questions and I was satisfied with the answers to my*  
28 133 *questions. I was also told who to contact if I had questions, difficulties, concerns, suggestions*  
29 134 *about the study, or if I wanted further information or help with the study. I have read this*  
30 135 *informed consent form and agree to participate in this study. I understand that I may withdraw*  
31 136 *from this study at any time during the study without any reason. I am informed that I will be*  
32 137 *given a copy of this informed consent form containing my signature and that of the researchers.*  
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40 140 Signature Date  
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44 142 Signature of the legal agent  
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48 144 Relationship to the subject  
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51 146 Subject's signature (10 years old and above)  
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STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	Location
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1, line 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 3, line 60
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	
Funding	4	Sources and types of financial, material, and other support	Page 14, line 376
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 14, line 371
	5b	Name and contact information for the trial sponsor	
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	
<b>Introduction</b>			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 4, line 74-110

1			
2		6b	Explanation for choice of comparators
3			
4	Objectives	7	Specific objectives or hypotheses
5			Page 5, line
6			111-113
7	Trial design	8	Description of trial design including type of trial (eg,
8			parallel group, crossover, factorial, single group),
9			allocation ratio, and framework (eg, superiority,
10			equivalence, noninferiority, exploratory)
11			
12			
13	<b>Methods: Participants, interventions, and outcomes</b>		
14			
15	Study setting	9	Description of study settings (eg, community clinic,
16			academic hospital) and list of countries where data will
17			be collected. Reference to where list of study sites can
18			be obtained
19			
20			
21	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If
22			applicable, eligibility criteria for study centres and
23			individuals who will perform the interventions (eg,
24			surgeons, psychotherapists)
25			
26			
27	Interventions	11a	Interventions for each group with sufficient detail to
28			allow replication, including how and when they will be
29			administered
30			
31		11b	Criteria for discontinuing or modifying allocated
32			interventions for a given trial participant (eg, drug dose
33			change in response to harms, participant request, or
34			improving/worsening disease)
35			
36			
37		11c	Strategies to improve adherence to intervention
38			protocols, and any procedures for monitoring
39			adherence (eg, drug tablet return, laboratory tests)
40			
41		11d	Relevant concomitant care and interventions that are
42			permitted or prohibited during the trial
43			
44	Outcomes	12	Primary, secondary, and other outcomes, including
45			the specific measurement variable (eg, systolic blood
46			pressure), analysis metric (eg, change from baseline,
47			final value, time to event), method of aggregation (eg,
48			median, proportion), and time point for each outcome.
49			Explanation of the clinical relevance of chosen
50			efficacy and harm outcomes is strongly recommended
51			
52			
53	Participant	13	Time schedule of enrolment, interventions (including
54	timeline		any run-ins and washouts), assessments, and visits
55			for participants. A schematic diagram is highly
56			recommended (see Figure)
57			
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Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 6, line 143-154
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 6, line 119

### Methods: Assignment of interventions (for controlled trials)

#### Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Page 5, line 136
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Page 5, line 137
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 5, line 133
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 5, lines 137-142
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	

### Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 7, line 186
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Page 8, line 197-200

1				
2	Data	19	Plans for data entry, coding, security, and storage,	Page 8, line
3	management		including any related processes to promote data	201-207
4			quality (eg, double data entry; range checks for data	
5			values). Reference to where details of data	
6			management procedures can be found, if not in the	
7			protocol	
8				
9				
10	Statistical	20a	Statistical methods for analysing primary and	Page 10, line
11	methods		secondary outcomes. Reference to where other	234-245
12			details of the statistical analysis plan can be found, if	
13			not in the protocol	
14				
15				
16		20b	Methods for any additional analyses (eg, subgroup	Page 10, line
17			and adjusted analyses)	246-257
18				
19		20c	Definition of analysis population relating to protocol	Page 10, line
20			non-adherence (eg, as randomised analysis), and any	258-264
21			statistical methods to handle missing data (eg,	
22			multiple imputation)	
23				
24				
25	<b>Methods: Monitoring</b>			
26	Data monitoring	21a	Composition of data monitoring committee (DMC);	Page 14, line
27			summary of its role and reporting structure; statement	204-207, 382
28			of whether it is independent from the sponsor and	
29			competing interests; and reference to where further	
30			details about its charter can be found, if not in the	
31			protocol. Alternatively, an explanation of why a DMC	
32			is not needed	
33				
34				
35				
36		21b	Description of any interim analyses and stopping	Page 8, 195-
37			guidelines, including who will have access to these	196
38			interim results and make the final decision to	
39			terminate the trial	
40				
41				
42	Harms	22	Plans for collecting, assessing, reporting, and	INFORMED
43			managing solicited and spontaneously reported	CONSENT
44			adverse events and other unintended effects of trial	FORM, line 45-
45			interventions or trial conduct	50, 85-89
46				
47				
48	Auditing	23	Frequency and procedures for auditing trial conduct, if	
49			any, and whether the process will be independent	
50			from investigators and the sponsor	
51				
52	<b>Ethics and dissemination</b>			
53				
54	Research ethics	24	Plans for seeking research ethics	Page 2, lines 55
55	approval		committee/institutional review board (REC/IRB)	
56			approval	
57				
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1			
2	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
3			Page 11, 275-
4			277
5			
6			
7			
8			
9	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
10			INFORMED
11			CONSENT
12			FORM, lines
13			2~24
14			
15		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
16			
17			
18			
19	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
20			INFORMED
21			CONSENT
22			FORM, line 91
23			
24			
25	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
26			Page 14, line
27			385
28	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
29			INFORMED
30			CONSENT
31			FORM, line 94-
32			102
33			
34	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
35			INFORMED
36			CONSENT
37			FORM, line 85-
38			89
39			
40	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
41			INFORMED
42			CONSENT
43			FORM, line 90-
44			1-2
45			
46			
47		31b	Authorship eligibility guidelines and any intended use of professional writers
48			INFORMED
49			CONSENT
50			FORM, line 90-
51			1-2
52			
53		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
54			
55			
56			
57	<b>Appendices</b>		
58	<hr/>		
59			
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2	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
3			See
4			INFORMED
5			CONSENT
6			FORM
7	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable
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13 \*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013  
14 Explanation & Elaboration for important clarification on the items. Amendments to the  
15 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT  
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