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

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Abstract

Introduction

Alcohol is the 7th 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

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

Trial registration

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

Strengths and limitations of this study

This study can differentiate potentially at-risk populations, which can have a preventive effect for those people.

We use the results of EtG test as the financial incentive indicator, which ensured the accuracy of the intervention.

In order to further evaluate effects of alcohol intervention, we also identify change of individual income and consumption capacity per day as well as alcohol-relevant variables.

The finding of this trial may limit the generalizability of our findings to other settings.

Introduction

Alcohol is the 7th leading risk factor of Disabled Adjusted Life Years (DALYs) all over the world according to Global Burden of Disease study 2017 [1]. In 2017, 2.84 million deaths and 108.00 million DALYs globally were attributable to alcohol use [1]. Alcohol use is associated with many physical issues, like gastric distress, hypertension, cardiovascular diseases, permanent liver damage, diabetes, and cancer, to name a few[2]. 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. [2].

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 [3]. The increase in per capita alcohol consumption is observed in China [3], especially in regions inhabited by minority groups[4].

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[5 6]. 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[7 8], studies show that alcoholic drinkers are reluctant to accept interventions[9 10]. 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 [11]. 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[7 8 12 13], few studies have focused on alcohol consumption among ethnic minority migrant people

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

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 and Analysis

Study design

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

Recruitment and participants

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

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). 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).

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

where N is the sample size for one group, z_α and z_β 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

Organization (WHO) recommendations. 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 from team of this study and trained by Hongkong University. All counselors are required to attend a full-day workshop before participant recruitment. The contents of the workshop include: (1) knowledge of excessive drinking harms and benefits of controlling drinking; (2) overview of AUDIT; (3) alcohol reduction advices; (4) a standard procedure of brief intervention.

An experienced research staff 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 treatment group 2 will receive brief alcohol intervention with cash incentives according to the results of EtG test. The participants financial incentive will be conducted by deducting money. Firstly, a certain amount of vouchers with RMB ￥490 (≈US$75.8) was given to the participants, which was equivalent to the reward for passing seven tests. Then, the voucher would be deducted according to every EtG test result. Finally, the participants will receive cash according to the vouchers.

Control group

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

Procedures

Participants are assessed at baseline, 1, 2, 3 months after treatment initiation (Table 1). Participants are required to take a test four times a week for 1-4 week, twice a week for 5-8 weeks, and once a week for 9-11 weeks. In order to avoid cheating by abstaining from alcohol only the day before the test, the time of each test was randomly determined by program team. The baseline questionnaire measures participants' drinking behavior (eg,

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).

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

Secondary outcomes:

1. Health status indicators, including sleep quality, and mental health in the past one month.

2. Life satisfaction.

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

4. Productivity and income, which are income per day, and working hours per day in the past one month.

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

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

Statistical analysis

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

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

The effect of alcohol using on health, life satisfaction, alcohol-related traffic accident and harm, health-care utilization, productivity and household expenditure outcomes will be analyzed using regression models with adjustment. All comparisons will use generalized

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

consumption behavior. If the intervention is found to be effective, this will be valuable for decision-makers and non-government organizations to prioritize education support to encourage the use of alcohol cessation services, which will ultimately decrease alcohol drinks.

There are four innovations of this study. First, this is the first time to conduct brief alcohol intervention in the minority habitation in China. Second, a small financial incentive is integrated in brief alcohol intervention to evaluate its effect in behavior change, which is a crucial part in the path of changing health status and productivity performance. Third, by assessing the income and expenditure pattern, it is possible to evaluate whether drinking reduction can make the subjects more productive and rational. Last, we are going to assess the effectiveness of brief alcohol intervention with a small financial incentive in community rather than in clinical facilities, which provides scientific evidence and suggestions for community healthcare workers to carry out the intervention.

This trial has several strengthens. First, this study can differentiate potentially at-risk populations, which can have a preventive effect for those people. Additionally, we use the results of EtG test as the financial incentive indicator, which ensured the accuracy of the intervention. This is much more beneficial to our evaluation. Finally, in order to further evaluate effects of alcohol intervention, we also identify change of individual income and consumption capacity per day as well as alcohol-relevant variables.

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

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Authors' contributions: GL, SS and ZT contributed to the research concept and design, supervise the work, and offered critical suggestions for revisions. SS, ZT, SJ and SYparticipated in conducing the study. They also conducted data analysis and drafted the manuscript. All authors have read and approved the manuscript.

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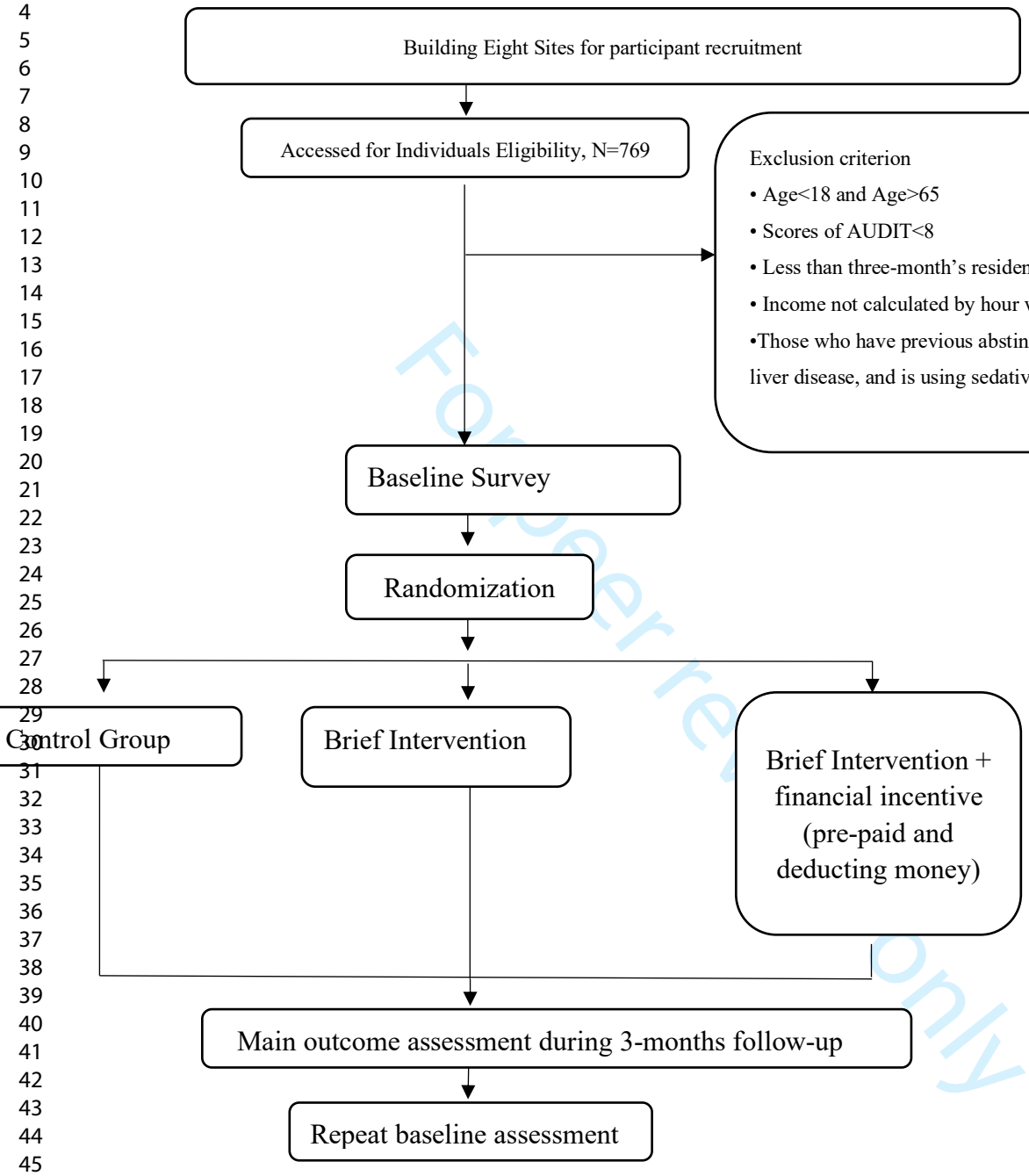

Figure 1. CONSORT flow diagram

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Abstract

Introduction

Alcohol is the 7th 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 having made great achievement in eradicating absolute poverty, many people are still living in relative poverty, which suggests that the adverse health effects caused by alcohol consumption among vulnerable populations in China warrant more attention. The aim of this paper is to provide an overview of alcohol consumption among ethnic populations in China, and to test the feasibility and efficacy of small financial incentive with brief advice intervention targeting reduction of harmful drinking behaviors.

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 440 daily drinkers in Xichang and divide them into three groups (brief intervention group, financial incentive group, control group). All participants receive the urine ethyl glucuronide (EtG) test, which helped us to figure out whether a participant consumed alcohol in the past 80 hous.. Additionally, participants in the brief intervention group receive free three-time counsel and multi-media messages about the topic of alcohol consumption each time after consultation. The participants in the financial incentive group receive brief intervention and 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

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

reviewed journals and presented at local, national and international conferences to publicize and explain the research to key audiences.

Trial registration

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

Strengths and limitations of this study

- This trail examines the effectiveness of brief alcohol intervention on alcohol abuse behavior by providing personalized reminder with a financial incentive to reduce alcohol consumption, family consumption and education investment.
- A personalized health reminder approach is very short and it also alleviates the failure to correctly interpret information due to limited attention and redundancy neglect.
- Using urine ethyl glucuronide (EtG) test as one of the primary outcomes increased scientific rigour and decreases misreporting.
- This trial cannot completely disentangle the effect of financial incentive.

Keywords: Health economic, alcohol disorder, rural China

Introduction

Alcohol is the 7th leading risk factor of Disabled Adjusted Life Years (DALYs) all over the world according to Global Burden of Disease study 2017 [1]. In 2017, 2.84 million deaths and 108.00 million DALYs globally were attributable to alcohol use [1]. Alcohol use is associated with many physical issues, like gastric distress, hypertension, cardiovascular diseases, permanent liver damage, diabetes, and cancer, to name a few[2]. 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. [2].

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intervention combined with a small financial incentive on alcohol consumption and health outcomes among migrated population in Liangshan Prefecture. This study is conducted in Liangshan Prefecture for two reasons: first, Liangshan is a region located in the southwestern of Sichuan province and is populated by Yi minority, and the average income in Liangshan are just about two thirds of the national average income [13]. Second, a study found that the drinking rate of Yi minority (47.9%) is higher than that of other regions in China [14].

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Methods and Analysis

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

Randomization and blinding

Randomization occurs at the individual level. Participants within the same recruitment session are individually randomized in a ratio of 1:1:1 to two intervention groups and one control group (brief intervention group, financial incentive group, control group). The randomization sequence is generated using a web-based system (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.

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

where N is the sample size for one group, z_α and z_β 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[15]. A total of three counsels are conducted, which are set on the second week, sixth and tenth week after baseline survey.

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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 treatment group 2 will receive brief alcohol intervention with cash incentives according to the results of EtG test. The participants financial incentive will be conducted by deducting money. Firstly, a voucher of RMB￥490 (≈US$75.8) was given to the participants in this group, and we would deduct ¥70 once if their urine tests show positive results. Finally, the participants will receive cash equal to the remaining amount of money in the voucher.

Control group

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

Procedures

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

alcohol only the day before the test, the time of each test was randomly determined by program team. The baseline questionnaire measures participants' drinking behavior including 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[16]. Participants are informed that they may withdraw from the study at any time without giving a reason. The researcher also has access to interim analyses and terminate the trial. For the subjects who withdraw from the study, we will collect information on the number of interventions, the duration of participating in the program and the reasons for withdrawal. For the subjects who go out on the survey day, we will make an appointment with them by telephone.

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

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), binge drinking is defined as four or more standard drinks in one occasion.

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

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

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

Secondary outcomes:

1. Health status indicators. Specifically, sleep quality measured by Pittsburgh Sleep Quality index (PSQI) which is widely used to evaluate sleep quality and linked to psychological disorders[17]. Mental health measured by a short version of the Depression Anxiety Stress Scale (DASS-21) which are internationally recognized method of assessing the risk of mental health outcomes[18].

2. Life satisfaction, assessed by ONS questionnaire. ONS measures the respondent's life evaluations, positive emotions and negative emotions on an 11-point scale, where the higher point indicates the greater extent of life evaluations that the respondent feels[19].

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

4. Productivity and income, which are income per day, and working hours per day in the past one month.

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

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

Statistical analysis

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

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

The effect of alcohol using on health, life satisfaction, alcohol-related traffic accident and harm, health-care utilization, productivity and household expenditure outcomes will be analyzed with regression models with adjustment. All comparisons will use generalized 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 at the highest level of alcohol consumption. The intervention effect by subgroups will be assessed, respectively, including age group, sex, education level, and household income. Statistical analyses will be conducted using Stata V.15.1 (Stata Corp, Texas, USA). The statistical tests 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. If there are any changes to the protocol, we will report to the Peking University Health Science Center Institutional Review Board and inform the subjects. Findings will be published in peer-reviewed journals and presented at local, national and international conferences to 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 residents' health capital and consumption behavior. If either of the two interventions are found to be effective, this will be valuable for decision-makers and non-government organizations to prioritize education support to encourage the use of alcohol cessation services, which will ultimately decrease alcohol drinks.

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

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

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

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

Figure 1. CONSORT flow diagram

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

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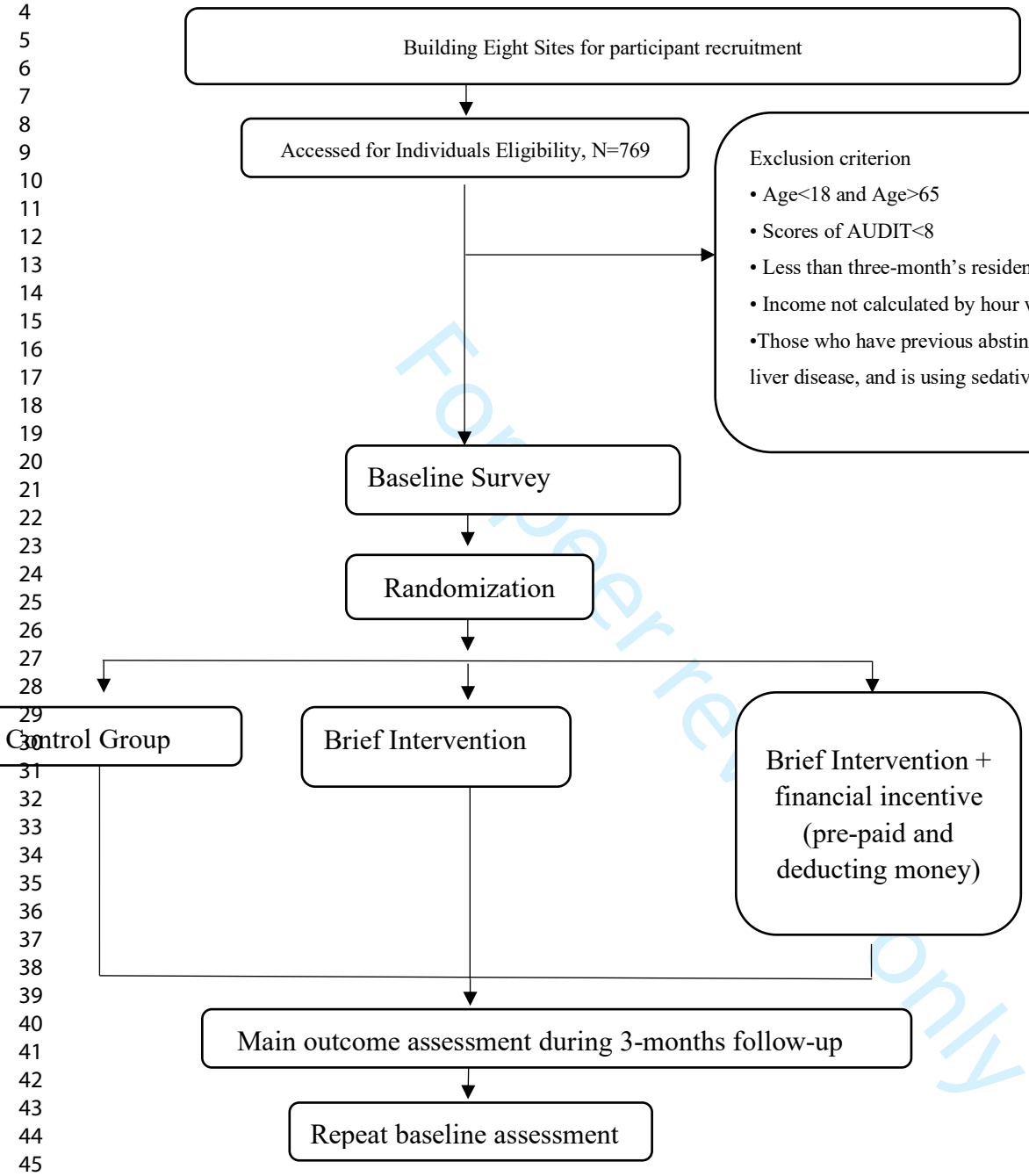

Figure 1. CONSORT flow diagram

SPIRIT
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
Administrative information			
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)	
Introduction			
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
Methods: Participants, interventions, and outcomes			
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

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 8, line 201-207
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 10, line 234-245
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Page 10, line 246-257
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Page 10, line 258-264
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Page 14, line 204-207, 382
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Page 8, 195-196
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	INFORMED CONSENT FORM, line 45-50, 85-89
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 2, lines 55

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)	Page 11, 275-277
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	INFORMED CONSENT FORM, lines 2~24
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
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	INFORMED CONSENT FORM, line 91
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 14, line 385
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	INFORMED CONSENT FORM, line 94-102
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	INFORMED CONSENT FORM, line 85-89
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	INFORMED CONSENT FORM, line 90-1-2
	31b	Authorship eligibility guidelines and any intended use of professional writers	INFORMED CONSENT FORM, line 90-1-2
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			

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" 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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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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Abstract

Introduction

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

Methods

This is a three-arm, single-blinded, pragmatic, individual randomized controlled trial with follow-ups at 1,2 and 3 months after randomization. We aim to recruit 440 daily drinkers living in Xichang and divide them into three groups (brief intervention group, financial incentive group, control group). All participants receive an urine ethyl glucuronide (EtG) test, which informed us if a participant consumed alcohol in the past 80 hours. Additionally, participants in the brief intervention group receive three free counselling sessions alongside multi-media messages on the topic of alcohol consumption after each session. The participants in the financial incentive group received the same interventions as well as 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

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

journals and presented at local, national and international conferences to publicize and explain the research to key audiences.

Trial registration

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

Strengths and limitations of this study

This trial examines the effectiveness of brief alcohol intervention on alcohol abuse behavior by providing a personalized reminder with a financial incentive to reduce alcohol consumption, and increase investment on health and education, etc.

A personalized health reminder approach is very short and it also alleviates the failure to correctly interpret information due to limited attention and redundancy neglect.

Using urine ethyl glucuronide (EtG) test as one of the primary outcomes increased scientific rigour and decreases misreporting.

This trial cannot completely disentangle the effect of financial incentive.

Keywords: Health economic, alcohol disorder, rural China

Introduction

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

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

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

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

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

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

Methods and Analysis

Study design

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

Recruitment and participants

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

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

Randomization and blinding

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

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). 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_α and z_β 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[26]. 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

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

Control group

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

Procedures

Participants are assessed at baseline and the end of each month after treatment initiation (Table 1). Participants are required to take a test four times a week for weeks 1-4, twice a week for weeks 5-8, and once a week for weeks 9-11. In order to avoid cheating by abstaining from alcohol only the day before the test, the time of each test was randomly determined by program team. The baseline questionnaire measures participants' drinking behavior including daily alcohol consumption, age of starting drinking, whether and the number of attempts to quit or reduce and 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 EtG test[27]. Participants are informed that they may withdraw from the study at any time without giving a reason. The researcher also has access to interim analyses and terminate the trial. For the subjects who withdraw from the study, we will collect information on the number of interventions, the duration of participating in the program and the reasons for withdrawal. For the subjects who go out on the survey day, we will make an appointment with them by telephone.

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

management specialist, and the data will be desensitized. Each use needs 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

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), binge drinking is defined as four or more standard drinks in one occasion.

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

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

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

Secondary outcomes:

1. Health status indicators. Specifically, sleep quality measured by Pittsburgh Sleep Quality index (PSQI) which is widely used to evaluate sleep quality and linked to psychological disorders[28]. Mental health measured by a short version of the Depression Anxiety Stress Scale (DASS-21) which are internationally recognized method of assessing the risk of mental health outcomes[29].

2. Life satisfaction, assessed by ONS questionnaire. ONS measures the respondent's life evaluations, positive emotions and negative emotions on an 11-point scale, where the higher point indicates the greater extent of life evaluations that the respondent feels[30].

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

4. Productivity and income, which are income per day, and working hours per day in the past one month.

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

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

Statistical analysis

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

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

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

The effect of alcohol consumption on health, life satisfaction, alcohol-related traffic accident and harm, health-care utilization, productivity and household expenditure outcomes will be analyzed with regression models with adjustment. All comparisons will use generalized 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 at the highest level of alcohol consumption. The intervention effect by subgroups will be assessed, respectively, including age group, sex, education level, and household income. Statistical analyses will be conducted using Stata V.15.1 (Stata Corp, Texas, USA). The statistical tests 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. If

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

Discussion

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

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

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

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

Figure 1. CONSORT flow diagram. 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.

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Authors' contributions: Gordon G. Liu, Shanshan Li and Ziting Wu contributed to the research concept and design, supervise the work, and offered critical suggestions for revisions. Shanshan Li, Ziting Wu, Sun Yu and Sijia Liu participated in conducing the study. Shanshan Li, Ziting Wu and Sijia Liu conducted data analysis and drafted the manuscript. All authors have read and approved the manuscript.

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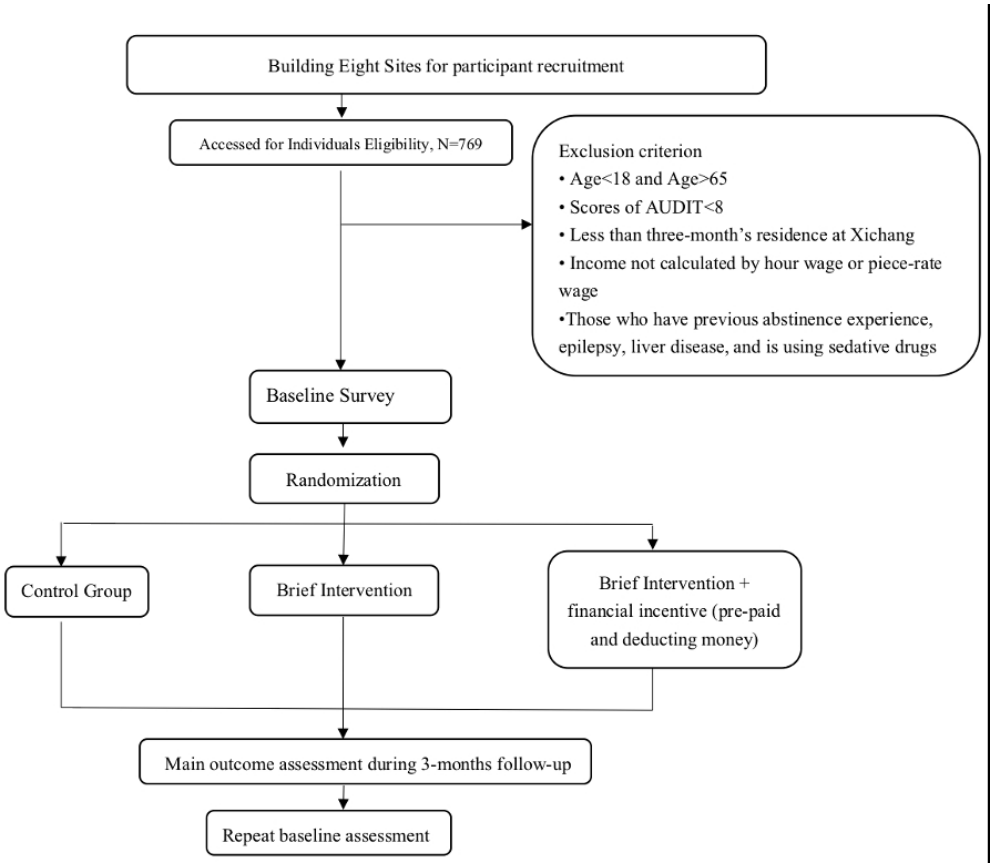
Competing interests statement: The authors declare no conflict of interest.



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)

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 are 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,

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

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

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

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

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

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

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

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

(1) Removal of your information would affect the scientific validity of the study results or the evaluation of the security of the data.

(2) Providing some limited information for research, teaching, or other activities (this information will not include your name, ID number, or other personal information that identifies you).

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

9. About the study cost and compensation

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

farmers in order to cooperate with the research, the project will provide some compensation with advance notice.

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

No compensation will be paid for participation in this study.

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

In the event of an accidental injury resulting from the performance of the study, we provide the necessary medical treatment, cover the appropriate medical expenses and provide appropriate financial compensation in accordance with the relevant laws and regulations of China.

12. Will my information be kept confidential?

If you decide to participate in this study, your participation in the study and your personal information during the study will be confidential. Any information that identifies you will not be disclosed to members outside of the research team without your permission. All study members and study-related parties will keep your identity confidential as required. Your file will be kept securely and will be accessible only to the researcher. To ensure that the research is conducted in accordance with regulations, members of the government administration, school authorities or ethics committee will have access to your personal information at the research unit as required. When the results of this study are published, no personal information about you will be disclosed.

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

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

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

E-mail: lishanshan7@pku.edu.cn

Tel: 010-62757318

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

E-mail: llwyh@bjmu.edu.cn

Tel: 010-82805751

Investigator's Statement

I have informed the subject of the background, purpose, risks and benefits of the study, given him/her sufficient time to read the informed consent form, discuss with others, and answered his/her questions about the study; I have informed the subject that he/she could contact Dr. Gordon Liu at any time when he/she encountered problems related to the study and the Biomedical Ethics Committee of Peking University at any time when he/she encountered problems related to his/her rights/rights, and provided accurate contact information; I have informed the subject that he/she could withdraw from the study; I have informed the subject that he/she would be given a copy of this informed consent form, which contains my signature and his/her signatures.

Signature Date

Subject Statement

I have been informed of the background, purpose, risks and benefits of the study. I was given sufficient time and opportunity to ask questions and I was satisfied with the answers to my questions. I was also told who to contact if I had questions, difficulties, concerns, suggestions about the study, or if I wanted further information or help with the study. I have read this informed consent form and agree to participate in this study. I understand that I may withdraw from this study at any time during the study without any reason. I am informed that I will be given a copy of this informed consent form containing my signature and that of the researchers.

Signature Date

Signature of the legal agent Date

Relationship to the subject

Subject's signature (10 years old and above) Date

SPIRIT

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
Administrative information			
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)	
Introduction			
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
Methods: Participants, interventions, and outcomes			
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

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 8, line 201-207
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 10, line 234-245
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Page 10, line 246-257
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Page 10, line 258-264
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Page 14, line 204-207, 382
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Page 8, 195-196
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	INFORMED CONSENT FORM, line 45-50, 85-89
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 2, lines 55

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)	Page 11, 275-277
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	INFORMED CONSENT FORM, lines 2~24
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
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	INFORMED CONSENT FORM, line 91
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 14, line 385
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	INFORMED CONSENT FORM, line 94-102
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	INFORMED CONSENT FORM, line 85-89
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	INFORMED CONSENT FORM, line 90-1-2
	31b	Authorship eligibility guidelines and any intended use of professional writers	INFORMED CONSENT FORM, line 90-1-2
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			

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" license.

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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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Abstract

Introduction

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

Methods

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

Ethics and dissemination

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

Trial registration

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

Strengths and limitations of this study

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

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

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

This trial cannot completely disentangle the effect of financial incentives.

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

Keywords: Health economic, alcohol disorder, rural China

Introduction

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

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

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

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

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

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

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

Methods and Analysis

Study design

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

Recruitment and participants

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

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

Randomization and blinding

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

Sample size

The proportion of people who drink alcohol according to the EtG test in the control group is 25%, and that in the brief intervention group is expected to be 10%. According to Eq (1), to achieve a 95% CI (alpha=0.05) and 80% power, the required sample size was calculated to be 100 in the brief intervention group. Assuming a retention rate of 90% during follow-

up, the overall sample size of the study should be 333 for the three groups ((100*3 groups)/90% retention rate). Four hundred forty participants are anticipated to 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_α and z_β 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[26]. 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

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

Control group

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

Procedures

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

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

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

Outcomes

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

Primary outcomes:

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

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

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

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

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

Secondary outcomes:

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

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

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

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

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

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

Statistical analysis

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

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

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

The effect of alcohol consumption on health, life satisfaction, alcohol-related traffic accident and harm, health-care utilization, productivity, and household expenditure outcomes will be analyzed with regression models with adjustments. All comparisons will use generalized 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, the research team will perform a "worst-case" sensitivity analysis by assuming that 100% of study dropouts remain at the highest level of alcohol consumption. The intervention effect by subgroups will be assessed, respectively, including age group, sex, education level, and household income. Statistical analyses will be conducted using Stata V.15.1 (Stata Corp, Texas, USA). The statistical tests are two-sided, and a p-value < 0.05 is considered as statistically significant.

Patient and public involvement

No patient involved.

Ethics and Dissemination

This study received ethical approval from the Peking University Health Science Center Institutional Review Board. The trial is registered on ClinicalTrials.gov (registration number: NCT04999371; Date of registration 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. If there are any changes to the protocol, we will report to the Peking University Health Science Center Institutional Review Board and inform the subjects. Findings will be published in peer-reviewed journals and presented at local, national and international conferences to publicize and explain the research to key audiences.

Discussion

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

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

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

in this study deserves extrapolation if proved effective. Additionally, the use of EtG test results as the financial incentive indicator will ensure the accuracy of the intervention. This is more beneficial for evaluation than using the self-reported alcohol consumption habit[19]. Finally, in order to further evaluate the effects of the alcohol intervention, the research team will also identify changes in individual income using a questionnaire to determine whether alcohol consumption affects work efficiency and, as a result, income.

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

Figure 1. CONSORT flow diagram. 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.

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Authors' contributions: Gordon G. Liu, Shanshan Li and Ziting Wu contributed to the research concept and design, supervise the work, and offered critical suggestions for revisions. Shanshan Li, Ziting Wu, Sun Yu and Sijia Liu participated in conducing the study. Shanshan Li, Ziting Wu and Sijia Liu conducted data analysis and drafted the manuscript. All authors have read and approved the manuscript.

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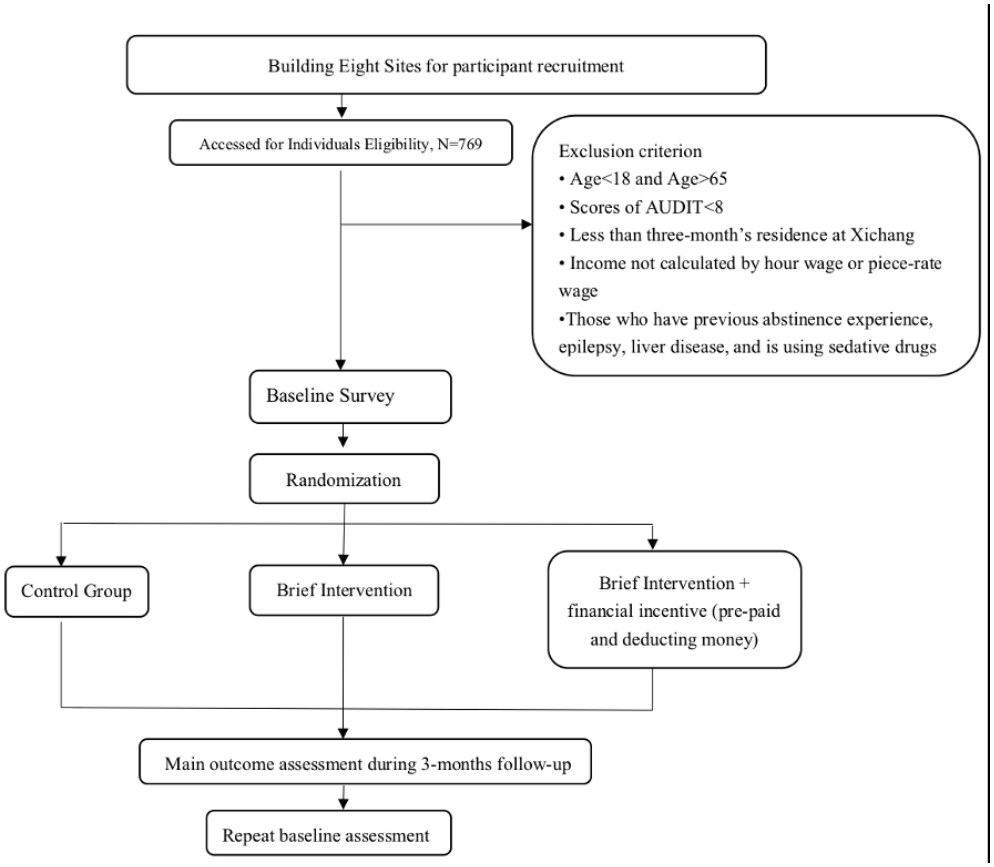

This diagram shows all the processes of the three-arm, individual randomized controlled trial, including participants recruitment, baseline survey, randomization, intervention, follow-up survey, and final evaluation.

152x131mm (150 x 150 DPI)

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 are 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,

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

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

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

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

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

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

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

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

(1) Removal of your information would affect the scientific validity of the study results or the evaluation of the security of the data.

(2) Providing some limited information for research, teaching, or other activities (this information will not include your name, ID number, or other personal information that identifies you).

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

9. About the study cost and compensation

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

farmers in order to cooperate with the research, the project will provide some compensation with advance notice.

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

No compensation will be paid for participation in this study.

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

In the event of an accidental injury resulting from the performance of the study, we provide the necessary medical treatment, cover the appropriate medical expenses and provide appropriate financial compensation in accordance with the relevant laws and regulations of China.

12. Will my information be kept confidential?

If you decide to participate in this study, your participation in the study and your personal information during the study will be confidential. Any information that identifies you will not be disclosed to members outside of the research team without your permission. All study members and study-related parties will keep your identity confidential as required. Your file will be kept securely and will be accessible only to the researcher. To ensure that the research is conducted in accordance with regulations, members of the government administration, school authorities or ethics committee will have access to your personal information at the research unit as required. When the results of this study are published, no personal information about you will be disclosed.

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

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

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

E-mail: lishanshan7@pku.edu.cn

Tel: 010-62757318

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

E-mail: llwyh@bjmu.edu.cn

Tel: 010-82805751

Investigator's Statement

I have informed the subject of the background, purpose, risks and benefits of the study, given him/her sufficient time to read the informed consent form, discuss with others, and answered his/her questions about the study; I have informed the subject that he/she could contact Dr. Gordon Liu at any time when he/she encountered problems related to the study and the Biomedical Ethics Committee of Peking University at any time when he/she encountered problems related to his/her rights/rights, and provided accurate contact information; I have informed the subject that he/she could withdraw from the study; I have informed the subject that he/she would be given a copy of this informed consent form, which contains my signature and his/her signatures.

Signature Date

Subject Statement

I have been informed of the background, purpose, risks and benefits of the study. I was given sufficient time and opportunity to ask questions and I was satisfied with the answers to my questions. I was also told who to contact if I had questions, difficulties, concerns, suggestions about the study, or if I wanted further information or help with the study. I have read this informed consent form and agree to participate in this study. I understand that I may withdraw from this study at any time during the study without any reason. I am informed that I will be given a copy of this informed consent form containing my signature and that of the researchers.

Signature Date

Signature of the legal agent Date

Relationship to the subject

Subject's signature (10 years old and above) Date

SPIRIT

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
Administrative information			
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)	
Introduction			
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
Methods: Participants, interventions, and outcomes			
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

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 8, line 201-207
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Page 10, line 234-245
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Page 10, line 246-257
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Page 10, line 258-264
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Page 14, line 204-207, 382
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Page 8, 195-196
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	INFORMED CONSENT FORM, line 45-50, 85-89
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Page 2, lines 55

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)	Page 11, 275-277
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	INFORMED CONSENT FORM, lines 2~24
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	
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	INFORMED CONSENT FORM, line 91
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 14, line 385
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	INFORMED CONSENT FORM, line 94-102
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	INFORMED CONSENT FORM, line 85-89
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	INFORMED CONSENT FORM, line 90-1-2
	31b	Authorship eligibility guidelines and any intended use of professional writers	INFORMED CONSENT FORM, line 90-1-2
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	
Appendices			

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" license.