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RESEARCH

Effectiveness of screening and brief alcohol intervention in primary care (SIPS trial): pragmatic cluster randomised controlled trial

OPEN ACCESS

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Abstract

Objective To evaluate the effectiveness of different brief intervention strategies at reducing hazardous or harmful drinking in primary care. The hypothesis was that more intensive intervention would result in a greater reduction in hazardous or harmful drinking.

Design Pragmatic cluster randomised controlled trial.

Setting Primary care practices in the north east and south east of England and in London.

Participants 3562 patients aged 18 or more routinely presenting in primary care, of whom 2991 (84.0%) were eligible to enter the trial: 900 (30.1%) screened positive for hazardous or harmful drinking and 756 (84.0%) received a brief intervention. The sample was predominantly male (62%) and white (92%), and 34% were current smokers.

Interventions Practices were randomised to three interventions, each of which built on the previous one: a patient information leaflet control group, five minutes of structured brief advice, and 20 minutes of brief lifestyle counselling. Delivery of the patient leaflet and brief advice occurred directly after screening and brief lifestyle counselling in a subsequent consultation.

Main outcome measures The primary outcome was patients' self reported hazardous or harmful drinking status as measured by the alcohol use disorders identification test (AUDIT) at six months. A negative AUDIT result (score <8) indicated non-hazardous or non-harmful drinking. Secondary outcomes were a negative AUDIT result at 12 months, experience of alcohol related problems (alcohol problems questionnaire), health utility (EQ-5D), service utilisation, and patients' motivation to change drinking behaviour (readiness to change) as measured by a modified readiness ruler.

Results Patient follow-up rates were 83% at six months (n=644) and 79% at 12 months (n=617). At both time points an intention to treat analysis found no significant differences in AUDIT negative status between the three interventions. Compared with the patient information

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PaT plot of procedures
Results of interaction tests
Mean alcohol problems questionnaire (APQ) score by intervention group

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leaflet group, the odds ratio of having a negative AUDIT result for brief advice was 0.85 (95% confidence interval 0.52 to 1.39) and for brief lifestyle counselling was 0.78 (0.48 to 1.25). A per protocol analysis confirmed these findings.

Conclusions All patients received simple feedback on their screening outcome. Beyond this input, however, evidence that brief advice or brief lifestyle counselling provided important additional benefit in reducing hazardous or harmful drinking compared with the patient information leaflet was lacking.

Trial registration Current Controlled Trials ISRCTN06145674.

Introduction

International studies have shown that 20-30% of patients who routinely present in primary care are hazardous or harmful drinkers.[1] Hazardous drinking is a repeated pattern of drinking that increases the risk of physical or psychological problems,[2] whereas harmful drinking is defined by the presence of these problems.[3] Several meta-analyses have shown that screening using short questionnaires followed by brief intervention (comprising simple advice or psychological counselling) significantly reduces alcohol consumption in primary care populations.[4-8] A Cochrane Collaboration systematic review of 29 primary care trials reported that brief intervention in patients was associated with a statistically significant reduced alcohol consumption of 38 g a week (95% confidence interval 23 g to 54 g) at one year compared with controls typically receiving assessment only, treatment as usual, or written information.[8] Given that a standard drink unit in the United Kingdom contains 8 g of ethanol,[9] this is equivalent to a reduction of 4 or 5 units a week. Nevertheless, brief alcohol intervention is rarely delivered in practice[10] and this gap in implementation has been ascribed to several limitations in the current evidence.

Brief intervention trials have been criticised for being efficacy studies (optimising internal validity) rather than pragmatic trials.[11] Most trials have also focused on middle aged male drinkers, with other groups under-represented.[8 12] Moreover, the optimal intensity of brief intervention is currently unclear. One study[8] reported no significant additional benefit of longer interventions compared with brief ones. However, although three systematic reviews found a benefit of motivational interviewing compared with no input (controls) in reducing alcohol consumption, their conclusions on its impact compared with other active interventions, including giving advice, differed.[13-15] Thus the present trial occurred in a context where brief intervention was widely regarded as being effective at reducing hazardous and harmful drinking. Nevertheless, the necessary length or modality input of brief intervention has yet to be determined. We carried out a pragmatic trial of the effectiveness of three different brief intervention strategies at reducing hazardous and harmful drinking in primary care. This study was one of three trials in the Screening and Intervention Programme for Sensible drinking (SIPS) study. The two linked trials were based in emergency departments[16] and probation offices.[17]

Methods

Details of this trial protocol have been published.[18] The trial incorporated cluster randomisation of practices to avoid the risk of contamination between the trial arms. The overall trial had a 2×2×2×3 nested factorial design encompassing geographical area (north east and south east of England and London), screening approach (universal screening of all patients versus targeted screening focused on presentations where alcohol was most likely to be relevant), screening tool (either the fast alcohol screening test[19] or a modified single alcohol screening questionnaire),[20] and three interventions (patient information leaflet, five minutes of brief advice, and 20 minutes of brief lifestyle counselling). Targeted screening focused on presentations linked to mental health, gastrointestinal problems, hypertension, minor injuries, and new patient registrations. The screening results are reported in detail elsewhere.[21] This paper focuses on patient level outcomes after brief alcohol intervention rather than trial process measures.

Settings

We initially recruited 24 practices across London and the south east and north east of England, plus five standby sites in case of dropouts. All practices delivered the full range of general medical services and covered a range of urban and rural areas, socially deprived and affluent communities, and culturally diverse populations. Recruitment spanned 15 months from May 2008 to July 2009. Fifteen practices completed their target recruitment of 31 patients but nine practices (six in London and three in the north east) only partially recruited this target (three patient information leaflet, one brief advice, and five brief lifestyle counselling). Thus we subsequently utilised the five standby practices. In addition, five practices that had completed the full recruitment agreed to be reallocated to a more intensive intervention than their original allocation. Thus we included 34 practice clusters in the final analysis.

Inclusion and exclusion criteria

We included patients who screened positive for an alcohol use disorder and who were alert and oriented, aged 18 or more, resident within 20 miles of the practice, and able to understand English sufficiently to complete study questionnaires. We excluded patients already involved in an alcohol research study or who were specifically seeking help for alcohol problems and those who were severely injured or unwell, had a serious mental health problem, were grossly intoxicated, or had no fixed abode.

Randomisation

A secure remote randomisation service carried out randomisation. Twenty four allocations were initially generated for each of the possible factorial combinations of screening approach, screening tool, and intervention. Randomisation was stratified by geographical area (north versus south). The standby and reallocated practices were subsequently randomly allocated in a similar manner.

Consent

Primary care staff initially established verbal consent with patients to check eligibility for the trial. At this stage they collected basic personal information and screened the patient using the fast alcohol screening test[19] or modified single alcohol screening questionnaire.[20] Patients who screened positive were then invited to provide written consent for the trial. All consenting patients entered the intervention part of the trial.

Interventions

Immediately after the screening process (in the same consultation), trial participants received a short assessment of their drinking behaviour, and brief intervention was delivered according to the intervention to which the practice had been randomised. All intervention materials are available from the study website (www.sips.iop.kcl.ac.uk/pil.php).

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Patient information leaflet—Patients received simple feedback on their screening outcome and a patient information leaflet that had been developed by the Department of Health in England called *How much is too much?* (www.sips.iop.kcl.ac.uk/pil.php). This 16 page leaflet describes the effects of alcohol on health and wellbeing and shows the number of units contained in popular alcoholic drinks to help the reader understand how much they are drinking. The back page lists two internet help sites plus details of a national Drinkline number. The only modification to this leaflet was the addition of an adhesive label on the back page with contact details of local alcohol treatment agencies relevant to the practice setting.

Brief advice—Patients received feedback on screening and the patient information leaflet plus five minutes of structured brief advice from practice staff based on the *How much is too much?* brief intervention programme.[22] In addition to providing specific details about the health and social consequences of hazardous and harmful drinking, patients were shown a sex specific graph, which indicated that their drinking exceeded that of most of the population, and a list of benefits that would result from reduced drinking. Thereafter patients were taken through a menu of techniques to help reduce drinking and asked to consider a personal target for an achievable reduction in drinking.

Brief lifestyle counselling—Patients received feedback on screening plus the patient information leaflet and structured brief advice in the initial consultation. They were then asked to make an appointment for a follow-up consultation within two weeks for a 20 minute session of brief lifestyle counselling.[22] The counselling was based on a condensed form of motivational interviewing called health behaviour change.[23] The patients first described their typical drinking day and then rated the importance of changing their drinking and their confidence about changing their drinking on a 10 point scale (where a higher number indicated greater importance or confidence and vice versa). The practitioner then worked with these ratings to establish why they were at the current level and how they might be increased to a higher point, before eliciting both pros and cons of drinking and finally working through a six step plan to help reduce drinking levels.

Training and support

Implementation of the protocol in this pragmatic trial varied across practices according to their size, level of interest, and available resources. Practice based training was delivered to 195 people (including all participating clinicians) in designated team meetings. The training included general information on alcohol epidemiology and UK standard drinks, an introduction to the trial protocol, demonstration of the relevant screening and brief intervention approaches, and role play to practise delivery. Research associates delivered training in the patient information leaflet and brief advice group. An alcohol health worker who was experienced in alcohol counselling delivered the training in brief lifestyle counselling. In this group brief lifestyle counselling was practised with trained actors and tape recorded. The competency of counselling was checked using the behaviour change counselling index.[24] Only practitioners who reached a required standard (agreed by inter-rater consensus between three independent clinical assessors) were approved to deliver brief lifestyle counselling in the trial.

Implementation

A mixture of general practitioners and practice care nurses delivered 95% of screening and brief intervention activity in this trial. A graphical summary of the trial procedures has been provided to clarify the sequence and timing of screening, assessment, brief intervention, and follow-up activity (see supplementary diagram 1, PaT plot). Seventy per cent of target patient recruitment occurred within six months, with the remaining 30% over nine months. Owing to this slow recruitment, research staff who had delivered training in study procedures supported screening and brief intervention delivery in 10 practices and recruited 152 patients, which was 5% of the total number of trial participants.

Measures

Baseline

The primary outcome was drinking status at six months as measured by the alcohol use disorders identification test (AUDIT, score range 0-40),[25] which has been validated for use as an outcome measure in primary care.[26] A score of ≥8 on this test indicates hazardous or harmful drinking or the likelihood of dependent drinking, with a sensitivity of 92% and specificity of 94%.[25] Since brief interventions aim to reduce hazardous or harmful drinking, the primary outcome measure was negative status on the test (proportion of participants scoring <8) at six months.

Participants also completed the EuroQol to measure quality of life,[27] a short service use questionnaire,[28] and a modified readiness ruler with one question (and four response categories) to measure patients' motivation or "readiness to change" their drinking behaviour.[29] The use of such readiness to change measures has been recommended in clinical practice to help tailor brief interventions and also predict subsequent drinking outcomes.[30]

Follow-up

At six and 12 months after randomisation researchers who were blinded to the allocated intervention contacted the participants by telephone or post. Researchers administered the same instruments as at baseline plus the alcohol problems questionnaire.[31] A short patient satisfaction questionnaire[32] was also administered at 12 months.

Financial incentives

Each practice received £3000 to cover staff time and disruption. Payments were staged and occurred after training, on completion of participant recruitment, and at the end of data collection. Modelled on smoking cessation payments in the Quality and Outcomes Framework,[33] screening and brief intervention was incentivised as £1 per patient screened (€1.26 or $1.85, all conversions at 2008 exchange rates), £8 per brief advice, and £32 per brief lifestyle counselling. Each patient participant received a £10 voucher shortly after completing the baseline assessment and at each follow-up interview.

Sample size calculation

A comprehensive meta-analysis[4] suggested a clinically important difference in negative status on AUDIT between brief intervention and controls of 13% (5% reduction in controls and 18% in brief intervention recipients). Detecting this difference at the 5% significance level with 80% power (with a two sided test), required 109 patients per group (total 327). Assuming a loss to follow-up of 25%, the sample size was inflated to 145 per group (total 435). To account for potential cluster effects we used an intraclass correlation coefficient of 0.04 based on our experience of primary care trials.[34] Assuming a cluster size of 31 patients per practice, this inflated the calculation by a

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factor of 1.7. Hence we required 248 patients per group (total 744), with an expectation that at least 558 would be followed up at six months.

Statistical analysis

Analysis was by intention to treat, with patients analysed in the group to which they had been randomised. We used logistic regression to analyse the primary outcome, negative status on AUDIT at six months. Included in the model were screening approach, screening tool, and intervention, and the model was adjusted for age, sex, and baseline AUDIT score. To take account of the cluster study design we used the Huber-White-sandwich estimator, robust standard errors method. As a factorial study, interaction effects were considered. To the model we individually added three two-way interactions, screening approach*tool, screening approach*intervention, and screening tool*intervention and compared the result with a model without interactions. If the interaction was found to be significant we included it in the final model.

Data were presented as odds ratios and corresponding 95% confidence intervals. We carried out secondary analyses using appropriate methods for the outcomes (linear, logistic, or ordinal regression) controlling for the same covariates as the primary outcome and adjusting for the clustered nature of the study. Intervention efficacy was also explored in a per protocol analysis.

To assess the impact of missing data on the primary outcome, we carried out multiple imputation using the ICE procedure in STATA. We tested several models for the prediction; the final model used AUDIT negative status at six months as the dependent variable, baseline AUDIT score, screening approach, screening tool, intervention, sex, and age. A series of 10 imputations was done. We combined these using the MIcombine command in STATA. The imputation confirmed the initial analysis where only those actually followed up were included.

Results

Of 3562 presenting patients, 2991 (84.0%) were eligible for screening; 900 (30.1%) of these patients were identified as hazardous or harmful drinkers. Overall, 756 (84.0%) consented to participate in the trial; consent rates were similar between the three interventions (fig 1⇓). All participants received a patient information leaflet, whereas 99% (n=250) of those allocated to the other two interventions received brief advice. However, just 57% (n=143) of relevant patients returned and received the brief lifestyle counselling intervention.

At six months the follow-up rates were 85% (patient information leaflet 85% (n=212), brief advice 86% (n=215), and brief lifestyle counselling 85% (n=217)) and at 12 months 82% (patient information leaflet 79% (n=197), brief advice 83% (n=209), brief lifestyle counselling 83% (n=211)). Follow-up rates between the interventions did not differ significantly. However, those followed up at six months had lower mean baseline AUDIT scores than those not followed up: 12.4 (SE 0.25) *v* 14.3 (SE 0.66).

The average age of participants was 45 years, 62% (n=756) of participants were men, 92% (n=755) were white, 34% (n=253) had attained higher degree level, and 34% (n=258) were smokers (table 1⇓). At baseline 82% (n=611) of participants were identified as hazardous or harmful drinkers by the AUDIT, with an average score of 12.7 (SD 6.4). Reported readiness to change varied across the three interventions, although 62% (n=465) of patients reported never or only sometimes thinking about drinking less.

Primary outcome

The proportions of patients with a negative AUDIT status increased at six months in all three interventions (fig 2⇓). The differences between the interventions were not, however, significant (table 2⇓). None of the interactions tested were significant (see supplementary table S1) so the model without interactions was used to estimate the differences between interventions. The odds ratios of having a negative AUDIT status for brief advice compared with the patient information leaflet was 0.85 (95% confidence interval 0.52 to 1.39) and for brief lifestyle counselling compared with the patient information leaflet was 0.78 (0.48 to 1.25). The primary outcome was not affected by missing data (table 3⇓).

Secondary analyses

At 12 months there were no statistically significant differences between the three interventions in the proportions of patients with a negative AUDIT result (table 2). Compared with the patient information leaflet intervention, at 12 months the odds ratio of having a negative AUDIT result was 0.91 (0.53 to 1.56) for brief advice and 0.99 (0.60 to 1.62) for brief lifestyle counselling. A per protocol analysis, including just those who received their allocated treatment, and an analysis combining the more intensive interventions (brief advice plus brief lifestyle counselling versus patient information leaflet) also indicated no significant differences between the interventions at six or 12 months.

In addition, there were no statistically significant differences in mean AUDIT score by intervention or over time (table 4⇓). At six months, the mean difference between brief advice and the patient information leaflet was 0.06 (−0.70 to 0.83) and between brief lifestyle counselling and the patient information leaflet was −0.38 (−1.51 to 0.75). At 12 months these mean differences were larger but not statistically significant. Compared with the patient information leaflet, the mean difference for brief advice was −0.20 (−0.83 to 0.43) and for brief lifestyle counselling was −0.25 (−1.19 to 0.68). The estimates were derived from models without interactions.

At six months there were differences in reported readiness to change (table 5⇓), with 32% (n=65) of patients in the patient information leaflet group reporting “trying to cut down” compared with 34% (n=69) receiving brief advice and 45% (n=93) receiving brief lifestyle counselling. The expected ordered odds for brief lifestyle counselling compared with the patient information leaflet increased by 1.74 (95% confidence interval 1.27 to 2.39, P=0.001) with a shift to the next higher category—that is, a greater readiness to change. For brief advice compared with the patient information leaflet, the expected ordered odds increased by 1.37 (0.95 to 1.98, P=0.095). A similar finding occurred at 12 months, with 32% (n=61) of those in the patient information leaflet group trying to cut down compared with 37% (n=74) receiving brief advice and 48% (n=95) receiving brief lifestyle counselling. For brief lifestyle counselling compared with the patient information leaflet, the expected ordered odds increased by 1.86 (1.31 to 2.65, P=0.001). For brief advice compared with the patient information leaflet, the expected ordered odds increased by 1.24 (0.83 to 1.87, P=0.293).

Participants who received brief lifestyle counselling also reported greater satisfaction than those who received the patient information leaflet (table 6⇓) based on general communication

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(mean difference 0.13, 95% confidence interval 0.01 to 0.26) and the interpersonal manner of the clinician delivering the intervention (mean difference 0.10, 0.002 to 0.19). These differences were not observed between brief advice and the patient information leaflet interventions.

Interaction with earlier screening activity

At six months there was a significant interaction between brief intervention and earlier screening approach, therefore the results are presented as six separate groups (see supplementary table 2). Each group was compared with the reference group of patient information leaflet/universal screening. At the initial follow-up point, patients in the brief lifestyle counselling/universal screening group (mean difference −0.78, 95% confidence interval −1.53 to −0.03) and the patient information leaflet/targeted screening group (mean difference −0.77, −1.42 to −0.12) had significantly lower scores on the alcohol problems questionnaire. But the other four combinations of brief intervention and screening approach did not differ significantly. Furthermore, outcomes measured by the alcohol problems questionnaire at 12 months did not differ significantly (see supplementary table S2).

Discussion

All patients in this trial received feedback on their hazardous or harmful drinking status immediately after the screening process. At two follow-up points, however, brief advice and brief lifestyle counselling did not provide a statistically significant additional benefit in reducing hazardous or harmful drinking compared with the provision of a patient information leaflet. Brief lifestyle counselling significantly increased patients' motivation to reduce their drinking through a positive shift in readiness to change compared with those receiving the patient information leaflet. Moreover, these patients also reported greater satisfaction with the brief intervention process than those in the patient information leaflet group. However, no significant differences between the brief interventions were found for alcohol related problems or health related quality of life. This study therefore does not support the additional delivery of five minutes of brief advice or 20 minutes of brief lifestyle counselling over and above the delivery of feedback on screening plus a patient information leaflet.

Strengths and weaknesses of the study

This trial was a large pragmatic multicentre evaluation of screening and brief intervention in typical primary care conditions. Cluster randomisation avoided the potential problems of contamination between the trial arms and thus subversion of the study protocol. Five practices delivered more than one brief intervention but only after they had successfully completed recruitment for the intervention to which they had been originally allocated. These reallocated practices subsequently delivered a more intensive brief intervention approach after training in the new procedure.

Other methodological strengths of the study were the use of remote randomisation procedures and validated outcome measures of clinical relevance. Rates of eligibility and patient consent to the trial (84%) were higher than in most previous similar studies,[35] which adds weight to the generalisability of the research. Furthermore, the study achieved its expected sample size, and patient follow-up rates were higher than anticipated (>80%) with no differential loss to follow-up between the three interventions.

In terms of potential weaknesses, since direct monitoring of the consultations would have undermined the pragmatic nature of the study, it was difficult to ascertain the extent to which the interventions were delivered as intended. Moreover, trial staff delivered screening and brief intervention to a small proportion of patients (5%) owing to flagging recruitment. It is possible that the lack of intervention differences may have been due to unsuccessful implementation of the brief intervention protocols by the primary care clinicians. These clinicians often give advice and lifestyle counselling in other areas of practice and there may have been unconscious use of these skills with patients who were not intended to receive them in this trial. The issue of intervention fidelity will be explored in an indepth qualitative (interview based) process study with clinicians from this trial, which occurred after patient follow-up was completed.

Only 57% of patients in the brief lifestyle counselling group actually received the intervention, which could have reduced its potential impact. But, as this was a pragmatic study this level of return to a subsequent counselling session probably reflects what would happen in usual practice. A further issue of pragmatism was our attempt to make baseline assessment as short as possible. We were aware that extensive questioning about alcohol could have acted as an intervention in its own right. Hence we used the 10 item AUDIT (alcohol use disorders identification test) questionnaire to provide our primary outcome measure.[26] Although this tool did not allow detailed measurement of actual consumption levels (in terms of standard drink units daily or weekly), it captured wider aspects of alcohol related risk and harm through items on drinking quantity, frequency, intensity, and negative behavioural consequences.

Relevance of the findings to the discipline

Numerous systematic reviews and meta-analyses have now shown benefits of screening and brief alcohol intervention in primary care compared with a range of control conditions (typically assessment only, treatment as usual, or written information). However, a consistent finding in this discipline is significantly reduced alcohol consumption in both intervention and controls groups.[36-38] One explanation for reduced drinking in both intervention and control groups is regression to the mean, in which extreme measures of behaviour tend to shift to less extreme positions from one time point to another.[39] We cannot fully discount this explanation for our findings. However, we think it unlikely since levels of drinking in this trial, as shown by mean AUDIT scores, were not particularly extreme. Indeed, some patients were close to the threshold for hazardous drinking. In addition, the changes over time in our control condition were similar to mean effect sizes reported for brief intervention.[8 37] An alternative explanation is that our control condition, consisting of simple feedback and written information about alcohol, may have contained active factors of behaviour change.[40] Indeed two controlled trials have reported significant clinical effects of screening[41] and assessment alone[42] on drinking behaviour. Consequently, it is likely that the cumulative impact of screening, assessment, simple feedback, and the delivery of written information may have overwhelmed the additional input of five minutes of structured brief advice both in terms of elapsed time and the number of distinct behaviour change techniques used.[43]

To conclusively demonstrate that providing feedback plus a patient information leaflet led to reduced rates of hazardous and harmful drinking, our trial would ideally have had an additional no intervention arm. However, in view of the extensive evidence supporting brief intervention effectiveness at the time of the

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trial, our control condition was considered to be the minimal ethically acceptable input after screening activity.

Implications for clinicians, service commissioners, and policymakers

The high levels of consent to this trial and the high rates of screening and immediate delivery of brief intervention indicate that routinely presenting patients in primary care are willing to receive feedback, written information, and advice about their drinking behaviour. In addition, the high levels of patient satisfaction after brief intervention in all three conditions support the acceptability of this type of input. However, the significant patient attrition in the brief lifestyle counselling group suggests that there may be a benefit of delivering brief intervention directly after screening rather than delaying until a subsequent occasion. In emergency care, it has been recommended that the time between screening and brief intervention is minimised and ideally occurs on the same day.[44] Indeed it is likely that the process of identifying and quantifying alcohol related risk or harm may be a "teachable moment" where patients have a heightened receptivity to the idea of reducing their drinking.[44]

Nevertheless, in patients who returned to a subsequent consultation for brief lifestyle counselling, there were significant positive changes in motivation to reduce drinking and in patient satisfaction levels. Consequently, it is possible that whereas most hazardous and harmful drinkers in primary care require minimal input after screening, there may be a group of patients who would value and benefit from additional support. Hence a stepped care approach might be helpful in this area. Here the least intensive (less costly) intervention is used with most patients who present with alcohol related risk or harm, and further intervention is reserved for patients who do not respond or who ask for more support to help reduce their drinking behaviour. A previous study found that a stepped care alcohol intervention was more cost effective than a minimal intervention in primary care.[34] This approach was also recommended in recent National Institute for Health and Clinical Excellence guidelines on the prevention of alcohol problems in adults and young people.[45]

Finally, given the extensive published evidence on the effectiveness of screening and brief intervention in reducing hazardous and harmful drinking, the case for its wider implementation in primary care is strong. Regarding the necessary level of input, our findings confirm the conclusion of a Cochrane Collaboration systematic review that longer (more intensive) brief interventions add no significant additional benefit over shorter input in primary care.[8] However, this review contained just one trial, based in Finland, which directly compared three differing intensities of brief intervention. Equivalent outcomes were reported for women[46] and men[47] who received simple feedback compared with three or seven brief intervention sessions. However, this finding was attributed to a failure to successfully implement the more intensive brief interventions in routine practice rather than the merit of simple feedback in itself. The current study strongly suggests that screening followed by simple feedback and written information may be the most appropriate strategy to reduce hazardous and harmful drinking in primary care.

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Contributors: All of the authors contributed to the design and development of this trial protocol. CD was the chief investigator of SIPS and EK was deputy chief investigator and lead for the primary care trial. Expertise on clinical aspects of the research was provided for primary care by PC and JM, for nursing practice by TP and for psychiatry CD and EG. Statistical input was provided by SC, VD and MB. Health economics input was provided by CG and SP. Trial conduct and delivery expertise was provided by PD, DNB and KP. Alcohol and policy expertise was provided by AO and DS. Brief intervention expertise was provided by CD, EK, NH and JS. EK wrote the first draft of the paper and all authors contributed to successive drafts. All authors read and approved the final manuscript.

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Ethical approval: This study received multicentre ethical approval (06/MRE02/90) plus local agreement from all relevant local research ethics committees. Research governance approval was granted by all relevant primary care trusts. The research was done in accordance with the Helsinki declaration.

Data sharing: No additional data available.

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What is already known on this topic

Around 20-30% of patients who routinely present in primary care are hazardous or harmful drinkers

Brief alcohol intervention in primary care can significantly reduce hazardous and harmful drinking

However, the optimal intensity of brief intervention input is currently not clear

What this study adds

Brief advice and brief lifestyle counselling did not provide a statistically significant benefit in reducing hazardous or harmful drinking compared with a patient information leaflet

Screening followed by simple feedback and written information may be the most appropriate strategy to reduce hazardous and harmful drinking in primary care

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Tables

Table 1| Personal and baseline variables by intervention allocation. Values are numbers (percentages) unless stated otherwise

Characteristics	Patient information leaflet	Brief advice	Brief lifestyle counselling	Total
Per cluster:	n=14	n=11	n=19	n=44
Median (interquartile range) No of patients	13.5 (2-32)	31 (3-34)	6 (1-47)	12 (1-47)
Median (interquartile range) age (years)	47.4 (36.0-60.8)	40.2 (31.7-53.6)	42.5 (32.0-67.7)	43.4 (31.7-67.7)
Median (interquartile range) % male	61.8 (0-100)	70.0 (33-75)	55.3 (33-100)	61.8 (0-100)
Median (interquartile range) AUDIT score	11.8 (8.3-16.1)	13.0 (9.4-15.5)	13.0 (8.5-24.0)	12.5 (8.3-24.0)
Patients:	n=251	n=251	n=254	n=756
Mean (SD) age (years)	n=251, 48.2 (17.0)	n=251, 40.4 (16.4)	n=253, 44.9 (14.8)	n=755, 44.5 (16.4)
Mean (SD) EQ-5D*	n=243, 0.78 (0.27)	n=247, 0.84 (0.24)	n=246, 0.81 (0.26)	n=736, 0.81 (0.26)
Mean (SD) AUDIT score	n=245, 12.3 (6.4)	n=245, 12.6 (5.9)	n=244, 13.1 (6.9)	n=734, 12.7 (6.4)
Men	163/251 (64.9)	155/251 (61.8)	152/254 (59.8)	470/756 (62.2)
White	215/251 (86)	239/251 (95)	238/253 (94)	697/755 (91.7)
Education after age 16	118/250 (47)	159/251 (63)	137/251 (55)	414/752 (55.1)
Degree or equivalent professional qualification	63/249 (25)	111/250 (44)	79/249 (32)	253/748 (33.8)
Single	60/251 (24)	98/250 (39)	69/252 (27)	227/753 (30.1)
Smokers	83/251 (33)	93/251 (37)	82/253 (32)	258/755 (34.2)
Readiness to change:	n=250	n=248	n=247	n=745
Never think about drinking less	66 (26.4)	67 (27.0)	64 (25.9)	197 (26.4)
Sometimes think about drinking less	89 (35.6)	100 (40.3)	79 (32.0)	268 (36.0)
Have decided to drink less	26 (10.4)	34 (13.7)	36 (14.6)	96 (12.9)
Already trying to cut down	69 (27.6)	47 (19.0)	68 (27.5)	184 (24.7)

AUDIT=alcohol use disorders identification test.

*Measure of health utility.

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Table 2| Proportions of participants with negative alcohol use disorders identification test result at baseline and six and 12 month follow-up. Values are numbers (percentages) unless stated otherwise

Time point	Patient information leaflet	Brief advice	Brief lifestyle counselling	Odds ratio* (95% CI), P value		ICC (SE)
				Brief advice/patient information leaflet	Brief lifestyle counselling/patient information leaflet	
Baseline	50/247 (20)	51/249 (20)	37/249 (15)	—	—	0.02 (0.02)
6 months	72/202 (36)	61/208 (29)	59/205 (29)	0.85 (0.52 to 1.39), 0.51	0.78 (0.48 to 1.25), 0.30	0.03 (0.02)
12 months	74/190 (39)	72/205 (35)	72/203 (36)	0.91 (0.53 to 1.56), 0.73	0.99 (0.60 to 1.62), 0.96	0.04 (0.02)

ICC=intraclass correlation coefficient.

*Odds ratio from logistic regression models adjusting for screening approach, screening tool, age, sex, and baseline alcohol use disorders identification test score.

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Table 3| Summary of sensitivity of primary outcome results to missing data (status from alcohol use disorders identification test at six months)

	Odds ratio (95% CI), P value	
Analysis	**Brief advice/patient information leaflet**	**Brief lifestyle counselling/patient information leaflet**
Complete case	0.85 (0.52 to 1.39), 0.51	0.78 (0.48 to 1.25), 0.30
Multiple imputation estimate	0.89 (0.53 to 1.50), 0.66	0.78 (0.50 to 1.22), 0.28
Per protocol analysis	0.85 (0.52 to 1.38), 0.51	0.93 (0.50 to 1.72), 0.81

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Table 4| **Alcohol use disorders identification test (AUDIT) scores by condition and over time**

	Mean (SE) AUDIT score			Mean difference (95% CI), P value	
Follow-up	Patient information leaflet	Brief advice	Brief lifestyle counselling	Brief advice/patient information leaflet	Brief lifestyle counselling/patient information leaflet
6 months	n=202, 11.36 (0.31)	n=208, 11.43 (0.23)	n=205, 10.98 (0.49)	0.06 (–0.70 to 0.83), 0.87	–0.38 (–1.51 to 0.75), 0.50
12 months	n=195, 10.69 (0.24)	n=205, 10.49 (0.17)	n=203, 10.49 (0.40)	–0.20 (–0.83 to 0.43), 0.53	–0.25 (–1.19 to 0.68), 0.59

*Estimates from linear regression models adjusting for screening approach, screening tool, age, sex, and baseline AUDIT score.

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Table 5| **Results for readiness to change by condition and over time. Values are numbers (percentages) unless stated otherwise**

Interventions	Never think about drinking less	Sometimes think about drinking less	Have decided to drink less	Already trying to cut down	Ordered odds* (95% CI) compared with patient information leaflet	P value
6 months:						
Patient information leaflet (n=206)	61 (30)	56 (27)	24 (12)	65 (32)	—	—
Brief advice (n=206)	51 (25)	57 (28)	29 (14)	69 (34)	1.37 (0.95 to 1.98)	0.09
Brief lifestyle advice (n=208)	46 (22)	41 (20)	28 (14)	93 (45)	1.74 (1.27 to 2.39)	0.00
12 months:						
Patient information leaflet (n=188)	61 (32)	43 (23)	23 (12)	61 (32)	—	—
Brief advice (n=198)	51 (26)	49 (25)	24 (12)	74 (37)	1.24 (0.83 to 1.87)	0.29
Brief lifestyle advice (n=200)	36 (18)	43 (22)	26 (13)	95 (48)	1.86 (1.31 to 2.65)	0.00

*Ordered odds from regression models adjusting for screening approach, screening tool, age, sex, and baseline readiness to change questionnaire.

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Table 6| **Patient satisfaction at 12 months**

Items	Mean (SE) score			Mean difference (95% CI), P value	
	Patient information leaflet (n=173)	Brief advice (n=190)	Brief lifestyle counseling (n=193)	Brief advice/patient information leaflet	Brief lifestyle counselling/patient information leaflet
General satisfaction	3.93 (0.05)	3.90 (0.06)	4.03 (0.06)	–0.03 (–0.19 to 0.13), 0.72	0.10 (–0.07 to 0.26), 0.24
General communication	4.05 (0.04)	4.04 (0.06)	4.18 (0.05)	–0.004 (–0.14 to 0.13), 0.95	0.13 (0.01 to 0.26), 0.03
Interpersonal manner	4.06 (0.03)	4.02 (0.06)	4.16 (0.04)	–0.04 (–0.17 to 0.08), 0.51	0.10 (0.002 to 0.19), 0.05

*Estimates from linear regression models adjusting for screening approach, screening tool, age, sex, and baseline AUDIT (alcohol use disorders identification test) score.

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Figures

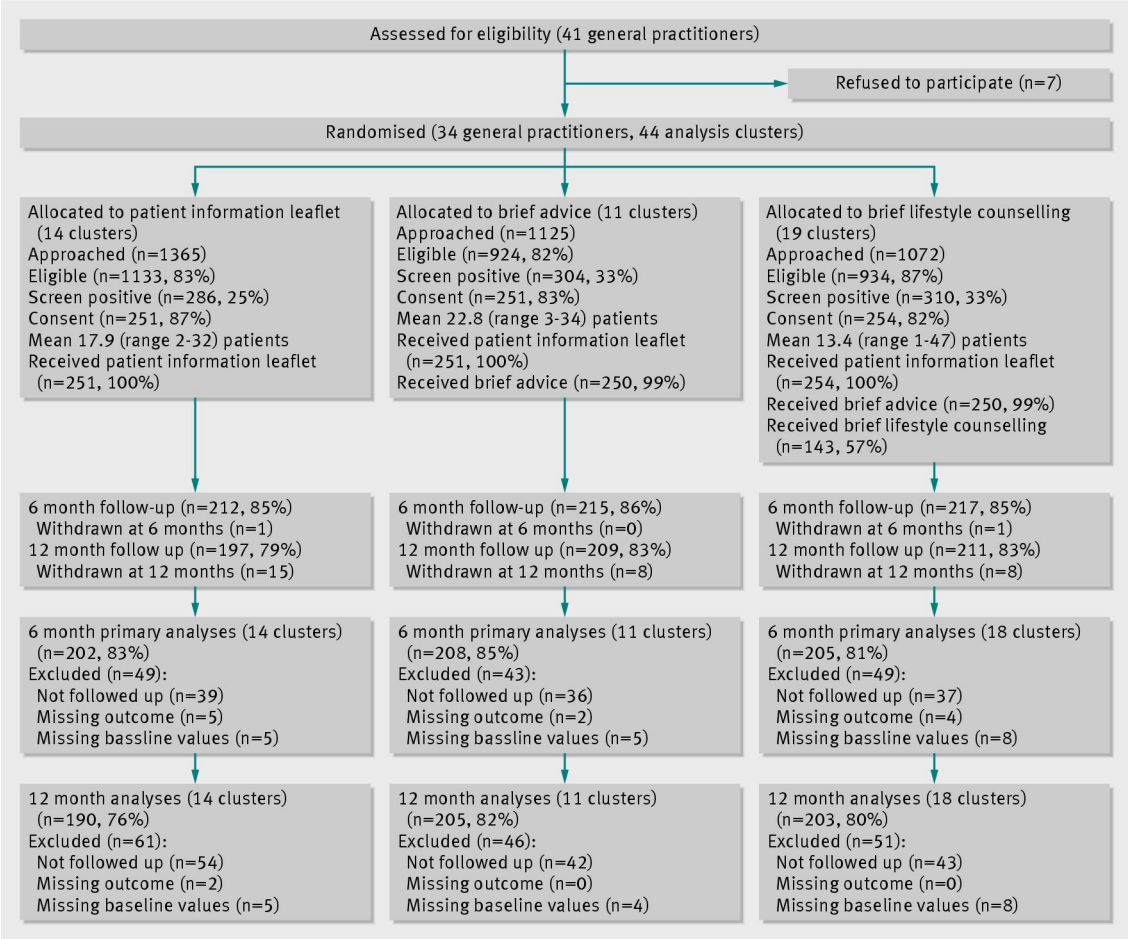


Fig 1 Flow of participants through trial

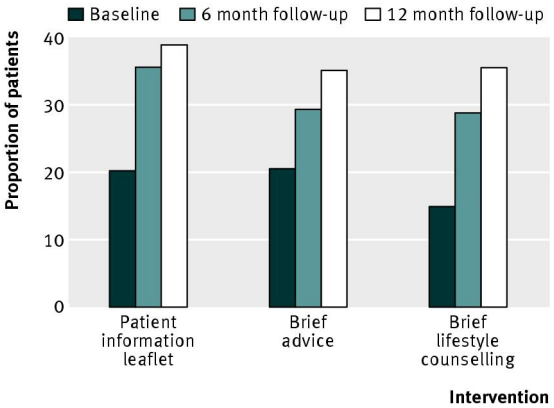


Fig 2 Proportion of patients scoring <8 (negative status) on alcohol use disorders identification test, representing non-hazardous or non-harmful drinking

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