Title The effectiveness of brief alcohol interventions delivered by community pharmacists: randomised controlled trial

List of authors: Ranjita Dhital[1], Ian Norman[1], Cate Whittlesea[2], Trevor Murrells[1], Jim McCambridge[3]

Author affiliations and addresses:

King's College London, Florence Nightingale Faculty of Nursing & Midwifery, James Clerk Maxwell Building, 57 Waterloo Road, London, SE1 8WA, UK,[1] School of Medicine, Pharmacy and Health, Durham University, Queen's Campus, University Boulevard, Stockton-on-Tees, TS17 6BH, UK,[2] Mental Health & Addictions Research Group, Department of Health Sciences, Faculty of Science, University of York, Heslington, YO10 5DD, UK[3]

Running head: Effectiveness of pharmacy alcohol BI

Word count (excluding abstract, tables, references): 3500

Declarations of interest: None

Current Controlled Trials: ISRCTN95216873

Key words/phrases:

Alcohol, Brief intervention, Community pharmacist, Community pharmacy, Hazardous and harmful drinking

Corresponding author: Ranjita Dhital

Abstract

Background & Aims

To undertake the first randomised controlled trial to evaluate the effectiveness of a brief intervention delivered by community pharmacists to reduce hazardous or harmful drinking.

Design

This parallel group individually randomised trial, allocated participants to brief alcohol intervention (n=205) or a leaflet-only control condition (n=202), with follow-up study after 3 months.

Setting

16 community pharmacies in one London borough, UK.

Participants

407 pharmacy customers (aged 18 or over) with AUDIT scores 8-19 inclusive.

Intervention

A brief motivational discussion of approximately 10 minutes duration for which 17 pharmacists received a half-day of training.

Measurements

Hazardous or harmful drinking was assessed using the Alcohol Use Disorders Identification Test (AUDIT) administered by telephone by a researcher blind to allocation status. The two primary outcomes were: 1) change in AUDIT total scores and 2) the proportions no longer hazardous or harmful drinkers (scoring <8) at three months. The four secondary outcomes were: the three sub-scale scores of the AUDIT (for consumption, problems and dependence), and health status according to the EQ-5D (a standardised instrument for use as a measure of health outcome).

Findings

At 3 months 326 (80% overall; 82% intervention, 78% control) participants were followed up. The difference in reduction in total AUDIT score (intervention minus control) was -0.57 95% CI -1.59 to 0.45, p = 0.28. The odds ratio for AUDIT <8 (control as reference) was 0.87 95%

CI 0.50 to 1.51, p = 0.61). For two of the four secondary outcomes (dependence score: -0.46 95% CI -0.82 to -0.09, p = 0.014; health status score: -0.09 95% CI -0.16 to -0.02, p = 0.013) the control group did better, and in the other two there were no differences (consumption score: -0.05 95% CI -0.54 to 0.44, p = 0.85; non-dependence problems score: -0.13 95% CI -0.66 to 0.41). Sensitivity analyses did not change these findings.

Conclusions

A brief intervention delivered by community pharmacists appears to have had no effect in reducing hazardous or harmful alcohol consumption.

Introduction

Alcohol use has been identified as the cause of approximately 3.3 million deaths worldwide every year, approximately 5.9% of all deaths (1). In the UK alcohol costs society £25.1 billion per annum, with National Health Service costs £2.7 billion and is the third leading cause of ill health (2). Reducing alcohol problems requires public policies to increase price, limit the accessibility of alcohol and challenge the social acceptability of heavy drinking (3). These policies can be supported by individual-level interventions to help people who drink heavily to reduce their alcohol intake. Brief alcohol interventions typically involve discussion with a health professional to help people reflect on their drinking and encourage self-directed behaviour change. There is strong support for the efficacy of brief interventions (BI) in reducing alcohol consumption in primary care settings (4). The World Health Organisation (5) has recommended widespread implementation of BI for hazardous and harmful drinkers across healthcare settings. The UK Department of Health has recommended that pharmacy based BI should be piloted and evaluated as part of the developing public health function of community pharmacies (6).

Pharmacists and pharmacy staff are the third largest professional health workforce in the world after nurses and doctors (7, 8). In recent years UK community pharmacy practice has developed to include extended roles for pharmacy staff (9). Pharmacies now offer a range of services designed to promote and protect public health, including medication use reviews, sexual health screening and smoking cessation. Most pharmacies now have consultation rooms to allow private discussions. There has also been the recent introduction of Healthy Living Pharmacies (10), where pharmacy teams actively engage with local communities and other health professionals. Development of services within pharmacies is thus a UK national priority for public health (6). This study was informed by a series of pre-trial studies (11-13), and tests the primary hypothesis that brief alcohol intervention delivered by community pharmacists is effective at reducing hazardous or harmful drinking among pharmacy

customers at three-month follow-up compared to a non-intervention leaflet-only control condition.

Method

The study is a parallel group randomised controlled trial conducted in 16 community pharmacies within the London borough of Hammersmith and Fulham, UK from May 2012 to May 2013. This borough has a population of 177100, which comprises a high proportion of young adults and is ethnically diverse (14). Local needs assessment suggests that Hammersmith and Fulham residents have the highest rates of high risk drinking in London (14). This study was ethically approved by the NRES Committee London and The West London Primary Care Consortium (for Research and Innovation) and a detailed account of the methods is available in the published protocol(15).

Sample size

Sample size consideration was originally based on a meta analytic effect size of 0.30 found on composite outcome measures in non-treatment seeking samples across settings at three-month follow-up in a previous review(16). In a one sided test a sample of 139 participants would be needed in each group to detect an effect of this magnitude on the AUDIT (17), assuming 80% power and a significance level of 5%. Generously allowing for 30% attrition at three months, 199 participants per group were required by the power calculation.

Findings from previous studies (11, 12, 18, 19) provided information on potential numbers of people who could be approached, the proportion of people who were risky drinkers based on a single question, and numbers screened positive who might agree to participate. We estimated that for every 15 customers approached initially, one customer would meet the criteria for entry into the study and agree to participate.

Participants and recruitment

All 40 community pharmacies with an NHS contract within the London Borough of Hammersmith and Fulham were invited to participate, with a requirement that the pharmacy

had a consultation room. Eligible trial participants were those aged 18 years or over who accessed services within the 16 participating community pharmacies who: a) had AUDIT scores 8-19 inclusive; b) were contactable by phone during the study; c) had a home address in the UK; and d) were able to speak, read and write in English; and d) were able to give informed consent. Exclusion criteria were: a) currently in treatment for alcohol problems; b) currently involved in other alcohol research; c) an employee of a pharmacy involved in the trial.

Pharmacy customers exhibiting one or more of the following behaviours were identified as potential participants by pharmacy staff: a) viewing study posters and flyers displayed within the pharmacy area; b) making a general health query or seeking advice linked to alcohol use; c) purchasing pharmacy over the counter products for smoking cessation aids, gastrointestinal remedies, sleep aids and central nervous system depressants (listed in the Medicine Chest directory) (20); d) receiving any of the following pharmacy services: smoking cessation, medication use review, health check or emergency hormonal contraception; e) presenting prescriptions for medications for any of the following conditions: cardiovascular disease, depression or anxiety, diabetes or gastric problems.

These customers were offered a copy of the participant information sheet by pharmacy support staff and invited to be screened for eligibility for the study. The number of customers informed about the study but who declined to be screened for eligibility was recorded as was anonymous information on customers' gender, activity in the pharmacy, reason given for not participating and the date. Customers who were willing to be screened were asked *"How often do you have three or more drinks on a single occasion?"* Those drinking this amount monthly or more frequently were invited to the second stage of the screening process, with the AUDIT administered by the pharmacist in the consultation room. Those who agreed provided formal consent to participate. Customers who scored ≥ 20 on the AUDIT were potentially dependent drinkers who were given a letter with their AUDIT result, advised to

take it to their GP, with an offer also to book an appointment with, and fax a letter to their GP. Customers identified as low risk drinkers (AUDIT ≤ 7) were also excluded from the study. Both excluded groups were given, “Units and You” booklet (21), a “Unit/Calorie Calculator Wheel”(22) and a leaflet listing alcohol services.

Consenting participants scoring 8-19 inclusive on the AUDIT were recruited and had data (i.e. age, gender, ethnicity, education, place of residence, being diagnosed with, or prescribed medications for, cardiovascular disease, depression/anxiety, diabetes or gastric problems) recorded at baseline by the community pharmacist who entered these details directly into a secure online recording system (23).

Randomisation and blinding

We estimated that each pharmacist would recruit 24 participants on average over a period of 6 months, with 1:1 randomisation stratified within each of the 17 participating pharmacists. The random sequence was generated by the first author in Excel in blocks of 12, with further blocks of the same size generated for those who recruited more participants. Allocation status was revealed only after pharmacists opened a sealed numbered envelope. Thereafter pharmacists were not involved in research data collection. Pharmacists received training on the importance of following trial procedures including allocation concealment. Possible subversion of randomisation was monitored by regular checking of sealed envelopes for evidence of tampering during visits and numerical ordering on the online data entry system. For the purposes of both follow-up study and data management, relevant personnel were blinded to randomisation status throughout the trial.

Interventions

Participants allocated to BI were offered a discussion with the pharmacist of up to 10 minutes duration (24). The purpose of the BI was to encourage participants to think further about their drinking and whether they should reduce it, and discuss how if they were ready to

do so. The intervention contained a number of structured components in the form of an intervention protocol (see online appendix). The conversation began by the pharmacist building rapport through asking questions about their experience of answering the AUDIT questions. Participants were then encouraged to talk about how drinking fitted in with their lives, explore any ambivalence and elicit their evaluation of their drinking including any associated problems. The conversation was closed by either the participant or the pharmacist providing a summary of the conversation. Participants were also given the “Units and You” booklet(21), a “Unit/Calorie Calculator Wheel” (22) and an alcohol services leaflet.

All trial pharmacists had been trained over 3.5 hours to deliver the intervention protocol including flexible use of these discussion topics in ways influenced by the counselling approach of motivational interviewing (25). In such a brief training workshop it was not feasible to aim to train the pharmacists in motivational interviewing as this approach requires ongoing supervision to learn it. A two hour evening follow-up training session was arranged seven weeks after the start of the trial to address challenges and share learning across the group, and was attended by 10 pharmacists.

Participants allocated to the control condition were not informed they were control participants, and immediately after the envelope was opened were given a leaflet by the pharmacist. This was, entitled “Alcohol: The Basics” and included information about alcohol not expected to be effective at promoting behaviour change (26).

Outcome evaluation

Outcomes were assessed using the AUDIT administered by telephone by a researcher blind to allocation status The primary outcomes were change in total AUDIT scores from recruitment to follow-up 3 months later, and the proportions remaining hazardous or harmful drinkers (scoring 8 or higher on AUDIT) at follow-up. Secondary outcomes were change in

AUDIT subscales scores (for alcohol consumption, problems, and dependence), and general health status assessed using the EQ-5D(27) at follow-up.

Statistical methods

Loss to follow-up was assessed using Pearson χ^2 (intervention or control, gender, ethnicity and education) and independent groups t-test (Age, AUDIT baseline and sub-scale scores). We followed the intent-to-treat (ITT) principle in accordance with an *a priori* statistical analysis plan. The primary analysis was specified as complete cases only. A sensitivity analysis was performed on the two primary outcomes whereby the baseline value was carried forward to investigate the impact of attrition. To ascertain whether non-response at 3 months was related to randomised group a Pearson χ^2 test was performed. Between group differences in AUDIT scores at follow-up were tested using a GLMM with fixed effects for baseline score and group, and random intercepts for pharmacist (n=17 in 16 pharmacies, closely matched). Fixed effects for gender, age, ethnicity (grouped into Black Minority Ethnic, White British, and any other white background) and education (degree or equivalent, continuing education but not to degree level, and no continuing education) were then added to this model. The moderating effect of each of these prognostic variables was tested by adding the interaction between each moderating and group variable to the model (total AUDIT score only). Histograms of the residual and Q-Q plots were inspected to make sure that the model assumptions were being met. A wild Bootstrap analysis was performed on the total AUDIT and sub-scale score models to assess the effect of potential violations to the model assumptions (28). For the binary primary outcome a generalised logistic mixed regression model was used to test the effect of randomised group using the same approach, except that baseline value was not included in the model because everyone was ≥ 8 at study entry. Within group changes in AUDIT scores from baseline to follow-up were tested using a generalised linear mixed model (GLMM) with fixed effects for group and time (nested within group) and random effects for pharmacist and participant (nested within pharmacist). All the statistical analyses were performed using IBM SPSS Version 22 (29).

Results

Recruitment and follow-up

Of the 2361 pharmacy customers who were approached, 561 (24%) were interested in participating, of whom 549 passed the first stage single question screen (see CONSORT flowchart in Figure 1). From this group 541 consented to participate and were administered the AUDIT. A further 134 were excluded; 94 (17%) were identified as a low risk drinkers (AUDIT ≤ 7); 38 (7%) as possible dependent drinkers (AUDIT ≥ 20); and 2 (0.4%) had incomplete data recorded by the pharmacist. The remaining 407 were randomised; 205 to intervention, 202 to control. At 3 months outcomes were collected from 80% of those randomised (n=326, see Figure 1). Loss to follow-up was similar in control or intervention groups (22% vs. 18% p=0.39). It varied only by age (responder 42.1 (SD 17.1) vs. non-responder 32.0 (SD 12.2 p<0.001) and AUDIT consumption score (responder 8.25 (SD 1.52) vs. non-responder 7.77 (SD 1.60) p=0.011).

Baseline characteristics

The socio-demographic characteristics are presented in Table 1 (see Table 1a online information for the characteristics of only those who completed follow-up). The ethnic diversity of trial participants reflected the ethnic backgrounds of residents from the inner London Borough of Hammersmith and Fulham (30). Information on the pharmacists and the pharmacies is presented in Tables 1b-1c (online information).

Primary outcomes

The AUDIT total score did not differ significantly between the two groups and did not change significantly between baseline and follow-up in either the intervention or control group (Table 2). The sensitivity analysis, carrying baseline values forward for people with missing follow-up scores produced similar outcomes (Unadjusted: 0.49 95% CI -1.33 to 0.36; Adjusted: -0.37, -1.18 to 0.45).The Bootstrap estimate for mean difference from the adjusted model was

very similar (-0.57 95% CI -1.62 to 0.46 p=0.32). None of the prognostic variables used in the adjusted model had any moderating effect on total AUDIT score at follow-up (p=0.22 to 0.46).

The odds ratio (OR) for the effect of the intervention upon the binary primary outcome was not statistically significant either in the unadjusted or adjusted models and this result was confirmed by the sensitivity analysis (Unadjusted OR 0.87, 0.53 to 1.42; Adjusted OR 0.95, 0.55 to 1.63).

Secondary outcomes

For secondary outcomes, AUDIT consumption sub-scale score did not differ significantly between groups but reduced significantly in both the intervention and control groups (see Table 2). The dependence sub-scale score differed significantly between groups at follow-up in both GLMMs (Table 2) but only decreased significantly, from baseline to follow-up, in the control group. The AUDIT problems sub-scale score did not differ significantly between groups and but did increase significantly from baseline to follow-up in the intervention group (Table 2). The bootstrap estimates for difference between groups and 95% confidence intervals for the three AUDIT sub-scale scores were very similar to those produced from the GLMMs. General health (EQ-5D) at follow-up was significantly better in the control compared to the intervention group in both the unadjusted and adjusted models. There were no adverse events reported by participants that were considered to be related to participation in the trial.

When participants were asked if they recalled having a discussion with the pharmacist about their drinking following the AUDIT questions, only 39% (n = 62) of control participants correctly responded, i.e. the majority reported that they had such a discussion. By comparison, 77% (n= 130) of intervention participants correctly reported they had a discussion about their drinking with the pharmacist.

Discussion

This randomised controlled trial was designed to determine if brief alcohol interventions delivered by community pharmacists were effective in reducing hazardous and harmful drinking amongst customers after three months in comparison with a leaflet only control condition. It found no evidence of effectiveness, with the two statistically significant between-group differences favouring the control group, meaning that it is safe to rule out entirely the possibility of any benefit of this particular BI with the brief training given to deliver it in routine practice. We interpret these two differences in secondary outcomes within the larger context of no difference between the groups. This study has direct implications for decision-making on NHS policy and practice, against the background of the developing public health role and remit of community pharmacies. Thus detailed consideration of the specific features of study design and internal and external validity of these findings is warranted.

This trial was implemented in accordance with a published study protocol (15) and we are confident that recruitment, randomisation, blinding, data collection and analysis were rigorously conducted. Allocation sequence generation was unbiased, and there was no evidence of problems with allocation concealment, serving high internal validity. Blinding of participants to group allocation was not possible in this study, and participants gave fully informed consent. This raises the possibility of some heightened potential for performance bias and for unintended differences between the groups resulting from participant reactivity to study conditions including allocation (31). Moreover all participants received AUDIT score feedback indicating that they were hazardous or harmful drinkers for eligibility purposes, so raising the possibility of behaviour change in response to feedback and/or having attention drawn to alcohol consumption through study participation (32-34). Data collection and analysis were undertaken by researchers who were fully blinded to group allocation. The parsimonious approach taken to outcome evaluation avoided selective outcome reporting, and attrition bias would have to be implausibly extreme to impact on the study's findings. A

two sided power calculation assuming 20% attrition (as observed) would require 220 participants per group (440 in total) to provide 80% power to detect an effect of 0.3 SD and increasing the sample size to this level would not alter the conclusions drawn. The findings were highly consistent across outcomes and methods used, whether they originated from the unadjusted, adjusted or bootstrap models, or from the sensitivity analyses. For these reasons, we judge our findings not to be vulnerable to conventionally understood forms of bias.

This study was undertaken in the context of routine service provision. This highly naturalistic study context is a substantial strength of the study, but also entails some weaknesses. Almost half of all pharmacists (n=17) in one London borough volunteered to participate, which compares very favourably with participation rates in BI trials in primary care. The pharmacists received a total of 3.5 hours training on intervention delivery, involving communication skills training influenced by the perspective of motivational interviewing (35). Whilst the BI intervention followed a structured protocol, some variability between pharmacists in their skills in engaging with participants should be expected, though no differences in outcomes were observed (data not reported).

There have been few process studies of alcohol BI and consequently there is limited understanding of the active ingredients of BI (36, 37). It is therefore difficult to appreciate how specific this null finding is to the particular intervention evaluated here. The BI evaluated here was certainly not motivational interviewing, but rather followed a structured protocol influenced by this approach delivered in a 10 minute discussion. It is highly likely that the pharmacists were under-trained in BI, and it is a study limitation that the naturalistic context precluded audio-recording. We do not interpret reductions over time as providing evidence that both groups have benefitted, as change scores are inappropriate for effectiveness inferences for many reasons (38).

Limited training of healthcare practitioners in routine practice has also affected the results of other NHS effectiveness trials. One hour training was provided to deliver brief structured alcohol advice within the SIPS primary care trial, which failed to demonstrate superiority over leaflet and very brief feedback; similar to the control condition in the present study (39). In PRE-EMPT GPs and Practice Nurses accessed largely online training for Behaviour Change Counselling for alcohol and other lifestyle issues, with limited skills acquisition, and little evidence of effectiveness (40). Recent NHS effectiveness trials across settings have largely failed to find benefit, in contrast to earlier primary care efficacy trials (41). It is also possible or likely that earlier studies were undertaken by highly motivated clinicians and researchers, potentially with allegiance effects (42), and as such may be more likely to be biased; this possibility is supported by the large effects of interventions studied in these early trials with challenging populations that have not since been replicated (43, 44).

Our study demonstrates that the community pharmacy setting is conducive to the delivery of BI. Pre-existing relationships between the pharmacist and customers within a healthcare environment are characteristics shared with general practice, where this evidence-base for BI has been assiduously developed over a period of approximately 30 years (4). Although accrual of evidence of benefit has been problematic in very busy clinical settings such as Accident and Emergency departments(45), setting-specific barriers to the delivery of BI are not obvious in community pharmacies. Community pharmacies have been identified by policy makers as promising for the delivery of preventive healthcare (46), being located where people live, work and shop (47). There are around 12,000 pharmacies in England and it is estimated 1.8 million people visit pharmacies every day (9). The UK government supports expanding the range of services provided by community pharmacists (48). On the basis of these findings, however, extending services with little or no additional training or other preparation for the wider public health role is inadvisable for activities targeting drinking, and most likely for behaviour change more broadly.

Redesign of intervention content and more intensive efforts to help prepare community pharmacists to become more ready and able to fulfil the wider professional role they are willing to embrace are now required. Strategic consideration of workforce development issues is also needed, which entails systemic changes that extend well beyond the provision of training. Although decision-making about resource use should be based on effectiveness and cost-effectiveness data, there may also be a role for efficacy trials in establishing that effectiveness is possible in this setting.

Acknowledgements: The research costs for this study is funded through the Hugh Linstead Fellowship Award by the Pharmacy Practice Research Trust, Royal Pharmaceutical Society of Great Britain and the Harold and Marjorie Moss Charitable Trust PhD award, both made to Ranjita Dhital. Jim McCambridge was supported by a Wellcome Trust Research Career Development fellowship in Basic Biomedical Science (WT086516MA). This study was awarded Service Support Payment by North West London CLRN (UKCRN number 11920). We thank all trial participants, trial pharmacists and pharmacy support staff for their involvement with this study. The funders had no role in the conduct of the study or in the decision to publish.

All authors were involved in the conduct of this trial, drafting initial text for the report and revising drafts to publication and approved the decision to submit to Addiction. RD, JM, IN and CW designed the study. RD and JM designed the intervention and delivered training to study pharmacists. RD delivered training to pharmacy support staff. RD managed the trial including all liaison work with pharmacy staff at all sites. RD conducted all telephone follow-up interviews with study participants. RD, TM and JM undertook the analysis for this trial. JM is the guarantor for this paper.

Figure 1 Trial recruitment and retention

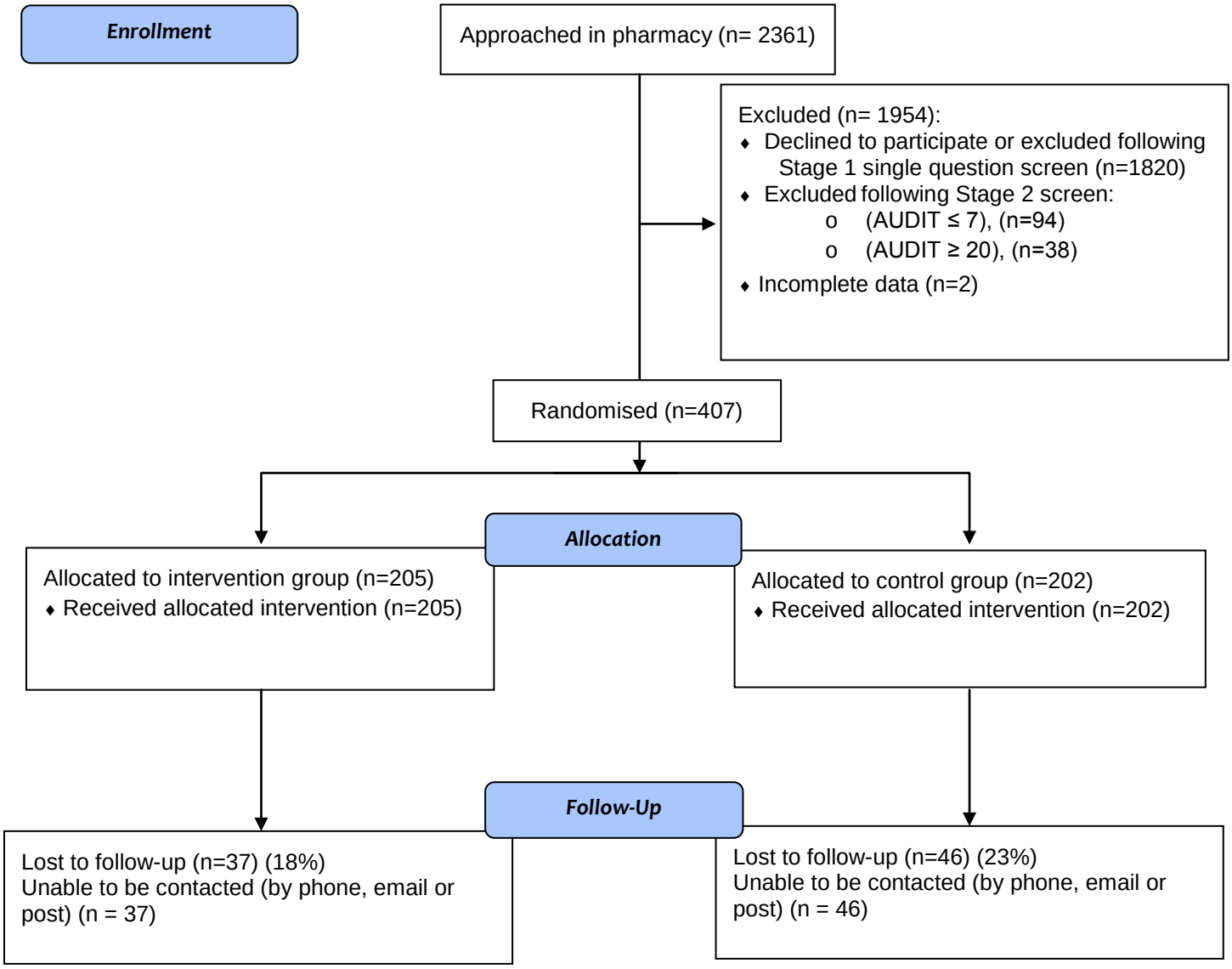

Table 1 Baseline characteristics at randomisation. Values are numbers (%) unless stated otherwise

Characteristics	Intervention group (*n* = 205)	Control group (*n* = 202)	Total (*n* = 407)
Place of residence:			
Hammersmith and Fulham	162 (79.0)	154 (76.2)	316 (77.6)
Other London Borough	34 (16.6)	37 (18.3)	71 (17.4)
Outside London	8 (3.9)	10 (5.0)	18 (4.4)
Missing values	1 (0.5)	1 (0.5)	2 (0.5)
Total	205 (50.4)	202 (49.6)	407 (100)
Age (years) mean (*SD*), range	39.6 (15.90), 18-74, (*n* = 192)	40.5 (17.48), 18-92, (*n* = 194)	40.0 (16.70), 18-92, (*n* = 386)
Missing values	13 (6.3)	8 (4)	21 (10.3)
Total	205 (50.4)	202 (49.6)	407 (100)
Gender:			
Female	98 (47.8)	88 (43.6)	186 (45.7)
Male	107 (52.2)	114 (56.4)	221 (54.3)
Total	205 (50.4)	202 (49.6)	407 (100)
Ethnicity:			
Asian british: any other asian background	3 (1.5)	2 (1.0)	5 (1.2)
Asian british: Indian	5 (2.4)	10 (5.0)	15 (3.7)
Asian british: Pakistani	0 (0.0)	2 (1.0)	2 (0.5)
Black british: any other black background	2 (1.0)	1 (0.5)	3 (0.7)
Black british: African	6 (2.9)	8 (4.0)	14 (3.4)
Black british: Caribbean	11 (5.4)	12 (5.9)	23 (5.7)
Mixed: any other mixed background	2 (1.0)	2 (1.0)	4 (1.0)
Mixed: white and asian	1 (0.5)	2 (1.0)	3 (0.7)
Mixed: white and black African	1 (0.5)	2 (1.0)	3 (0.7)
Mixed: white and black Caribbean	1 (0.5)	2 (1.0)	3 (0.7)
Not stated	0 (0.0)	2 (1.0)	2 (0.5)
Other ethnic groups:any other ethnic groups	3 (1.5)	0 (0.0)	3 (0.7)
Other ethnic groups: Chinese	4 (2.0)	0 (0.0)	4 (1.0)
White: any other white background	30 (14.6)	35 (17.3)	65 (16.0)
White: British	117 (57.1)	102 (50.5)	219 (53.8)
White: Irish	6 (2.9)	12 (5.9)	18 (4.4)
Missing values	13 (6.3)	8 (4.0)	21 (5.2)
Total	205 (50.4)	202 (49.6)	407 (100)
Continuing education after age 16:			
Yes	159 (77.6)	154 (76.2)	313 (76.9)
No	33 (16.1)	40 (19.8)	73 (17.9)
Missing values	13 (6.3)	8 (4.0)	21 (5.2)
Total	205 (50.4)	202 (49.6)	407 (100)

Table 2: All trial outcomes

Values are means/differences to baseline/between group differences/odds ratio with 95% confidence intervals and P value

	Intervention group (n:BL=205, FU=168)		Control group (n:BL=202,FU=158)		Between group differences, P value	
Primary outcomes						
Overall Score	**Mean (SD)**	**Difference to baseline†**	**Mean (SD)**	**Difference to baseline†**	**Unadjusted‡**	**Adjusted&**
Baseline	11.93 (3.24)	n/a	11.53 (3.19)	n/a	n/a	n/a
Follow-up	11.80 (5.88)	-0.11 (-0.82 to 0.61), 0.76	10.77 (5.54)	-0.74 (-1.47 to 0.00), 0.049	-0.63 (-1.69 to 0.43), 0.24	-0.57 (-1.59 to 0.45), 0.28
Overall Score < 8 at follow-up	**% < 8. (No < 8)**		**% < 8. (No < 8)**		**Unadjusted Odds Ratio**	**Adjusted Odds Ratio**
	22.6 (38)		26.6 (42)		0.80[b] (0.48 to 1.34), 0.40	0.87[c] (0.50 to 1.51), 0.61
Secondary outcomes						
Consumption sub-scale:						
Baseline	8.29 (1.55)	n/a	8.02 (1.53)	n/a	n/a	n/a
Follow-up	7.58 (2.31)	-0.75 (-1.08 to -0.41), <0.001	7.37 (2.52)	-0.69 (-1.03 to -0.35), <0.001	-0.05 (-0.53 to 0.43), 0.84	-0.05 (-0.54 to 0.44), 0.85
Dependence sub-scale:						
Baseline	1.04 (1.35)	n/a	1.05 (1.34)	n/a	n/a	n/a
Follow-up	1.23 (2.13)	0.22 (-0.05 to 0.50), 0.11	0.75 (1.54)	-0.29 (-0.57 to -0.01), 0.041	-0.51 (-0.89 to -0.13),0.008	-0.46 (-0.82 to -0.09),0.014
Problem use sub-scale:						
Baseline	2.60 (2.14)	n/a	2.46 (2.19)	n/a	n/a	n/a
Follow-up	2.99 (2.82)	0.42 (0.03 to 0.80), 0.033	2.65 (2.97)	0.26 (-0.13 to 0.65), 0.20	-0.18 (-0.72 to 0.36), 0.52	-0.13 (-0.66 to 0.41), 0.64
General Health (EQ-5D)[a] at follow-up:	1.28 (0.35)	n/a	1.20 (0.32)	n/a	-0.09 (-0.16 to -0.01), 0.019	-0.09 (-0.16 to -0.02),0.013

† pharmacist and person (nested with pharmacist) random effects; effect of time (difference to baseline) nested within intervention/control

‡ pharmacist random effect; adjusted for baseline score

& pharmacist random effect; adjusted for baseline score, gender, age, ethnicity and education

a EQ-5D General Health: mean of mobility, self-care, usual activities, pain-discomfort, anxiety-depression: general health; scoring (1 = no problem, 2 = some problems, 3 = severe problems/unable)

b pharmacist random effect

c pharmacist random effect adjusted for gender, age, ethnicity and education

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-5
	2b	Specific objectives or hypotheses	4-5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6 & 8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	None
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7 & 9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a, None
Sample size	7a	How sample size was determined	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a, None
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	8-9

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	9
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	19
	13b	For each group, losses and exclusions after randomisation, together with reasons	11 & 18
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	19
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	19
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	20
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	20
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	11-12
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	12
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14-16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	15-16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13-16
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

References

1. World Health Organisation. Global status report on alcohol and health 2014. URL:http://apps.who.int/iris/bitstream/10665/112736/1/9789240692763_eng.pdf?ua=1. Accessed: 2015-02-17. (Archived by WebCite® at http://www.webcitation.org/6WPbPtEFo), Geneva, Switzerland: World Health Organization.
2. Department of Health. Reducing Alcohol Harm: health services in England for alcohol misuse. National Audit Office, London The Stationery Office; 2008, 1-53.
3. Room R., Babor T., Rehm J. Alcohol and public health, *Lancet* 2005: 365: 519-530.
4. Kaner E. F., Beyer F., Dickonson H. O., Pienaar E., Campbell F., Schlesinger C. et al. Effectiveness of brief alcohol interventions in primary care populations, Cochrane Database of Systematic Reviews 2007: Art. No.: CD004148. DOI: 004110.001002/14651858.CD14004148.pub14651853.
5. World Health Organisation. European action plan to reduce the harmful use of alcohol 2012-2020. URL:www.euro.who.int/__data/assets/pdf_file/0008/178163/E96726.pdf?ua=1. Accessed: 2015-02-17. (Archived by WebCite® at http://www.webcitation.org/6WPalPEyG).
6. Department of Health. Choosing Health Through Pharmacy: A programme for pharmaceutical public health 2005-2015. London: Stationary Office 2005, 42-43.
7. Chan X. H., Wuliji T. Global Pharmacy Workforce and Migration Report: A Call for Action. URL:http://www.fip.org/files/fip/publications/PharmacyWorkforceMigration.pdf). Accessed: 2015-02-17. (Archived by WebCite® at http://www.webcitation.org/6WPcqtiEu); 2006.
8. International Pharmaceutical Federation. 2012 FIP Global Pharmacy Workforce Report: International Pharmaceutical Federation. URL:http://www.fip.org/static/fipeducation/2012/FIP-Workforce-Report-2012/?page=hr2012#/0. Accessed: 2015-02-17. (Archived by WebCite® at http://www.webcitation.org/6WPdVPsIH); 2012.
9. Pharmaceutical Services Negotiating Committee. URL:http://psnc.org.uk/services-commissioning). Accessed: 2015-02-17. (Archived by WebCite® at http://www.webcitation.org/6WPdee4xC).
10. Duggan C., Evans D., Holden M., Kennington E., Leach R., Root G. et al. Evaluation of the Healthy Living Pharmacy: Pathfinder Work Programme 2011-2012. URL:http://psnc.org.uk/wp-content/uploads/2013/08/HLP-evaluation.pdf). Accessed: 2015-02-17. (Archived by WebCite® at http://www.webcitation.org/6WPdrD00b); 2013.
11. Dhital R., Whittlesea C. M., Norman I. J., Milligan P. Community pharmacy service users' views and perceptions of alcohol screening and brief intervention, *Drug Alcohol Rev* 2010: 29: 596-602.
12. Dhital R., Whittlesea C. M., Milligan P., Khan N. S., Norman I. J. The impact of training and delivering alcohol brief intervention on the knowledge and attitudes of community pharmacists: a before and after study, *Drug Alcohol Rev* 2013a: 32: 147-156.
13. Khan N., Norman I., Dhital R., Mccrone P., Milligan P., Whittlesea C. Alcohol brief intervention in community pharmacies: a feasibility study of outcomes and customer experiences, *Int J Clin Pharm* 2013: 1178-1187.
14. National Health Service. NHS Hammersmith and Fulham Public Health Report 2008-09. Uptake of preventive services: who misses out. Public Health, London; 2008 2008, 1-88.
15. Dhital R., Norman I., Whittlesea C., Mccambridge J. Effectiveness of alcohol brief intervention delivered by community pharmacists: study protocol of a two-arm randomised controlled trial, *BMC Public Health* 2013b: 13: 152.
16. Moyer A., Finney J. W., Swearingen C. E., Vergun P. Brief interventions for alcohol problems: a meta-analytic review of controlled investigations in treatment-seeking and non-treatment-seeking populations., *Addiction* 2002: 97: 279-292.

17. Babor T. F., Higgins-Biddle J. C., Saunders J. B., Monteiro M. G. AUDIT - Alcohol Use Disorders Identification Test: Guidelines for Use in Primary Care Geneva: World Health Organization; 2001.
18. Watson M. C., Inch J., Jaffray M., Stewart D. Screening and brief interventions for alcohol misuse delivered in the community pharmacy setting: a pilot study: Abstract 50, *IJPP* 2011: 19 Supplement: 5.
19. Watson M. C., Blenkinsopp A. The feasibility of providing community pharmacy-based services for alcohol misuse: a literature review, *IJPP* 2009: 17: 199-205.
20. Proprietary Association of Great Britain. Medicine Chest Online. URL:http://www.medicinechestonline.com. Accessed: 2015-02-17. (Archived by WebCite® at http://www.webcitation.org/6WPeUmgcr).
21. Department of Health. Units and you; Department of Health, London: Crown copyright (currently out of print); 2009.
22. Drinkaware. URL:https://resources.drinkaware.co.uk/unit-calorie-calculator. Accessed: 2015-02-17. (Archived by WebCite® at http://www.webcitation.org/6WPefZUPE).
23. Sonarinformatics. Sonar informatics, London, UK. URL:http://www.sonarinformatics.com. Accessed: 2015-02-17. (Archived by WebCite® at http://www.webcitation.org/6WPerW92u).
24. Babor T., Higgins-Biddle J. Brief Intervention for Hazardous and Harmful Drinking: A Manual for Use in Primary Care: World Health Organisation, Department of Mental Health and Substance Dependence, Geneva; 2001.
25. Mccambridge J., Strang J. Development of a structured generic drug intervention model for public health purposes: a brief application of motivational interviewing with young people, *Drug Alcohol Rev* 2003: 22: 391-399.
26. Kypri K., Mccambridge J., Wilson A., Attia J., Sheeran P., Bowe S. et al. Effects of Study Design and Allocation on participant behaviour - ESDA: study protocol for a randomized controlled trial, *Trials* 2011: 12: 42.
27. Euroqol. The EuroQol Group, EuroQol-a new facility for the measurement of health-related quality of life. Health Policy. 1990: 16(3):199-208.
28. Liu R. Y. Bootstrap Procedures under some Non-I.I.D. Models, 1988: 1696-1708.
29. IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.
30. Hammersmith and Fulham Council. 2011 Census Statistics: Hammersmith and Fulham Briefing. URL:http://www.lbhf.gov.uk/Images/2011%20Census%20report_LBHF%20briefing_tcm21-177945.pdf. Accessed: 2015-02-17. (Archived by WebCite® at http://www.webcitation.org/6WPfamMkG).
31. Mccambridge J., Sorhaindo A., Quirk A., Nanchahal K. Patient preferences and performance bias in a weight loss trial with a usual care arm, *Patient Edu Couns* 2014: 95: 243-247.
32. Mccambridge J., Kypri K., Elbourne D. In randomisation we trust? There are overlooked problems in experimenting with people in behavioural intervention trials, *J Clin Epidemiol* 2014: 67: 247-253.
33. Mccambridge J., Kypri K. Can simply answering research questions change behaviour? Systematic review and meta analyses of brief alcohol intervention trials, *PLoS One* 2011: 6: e23748.
34. Mccambridge J., Kypri K., Elbourne D. Research participation effects: a skeleton in the methodological cupboard, *J Clin Epidemiol* 2014: 67: 845-849.
35. Miller W. R., Rollnick S. Motivational Interviewing, Third Edition: Helping People Change London: The Guilford Press; 2012.
36. Mccambridge J. Brief intervention content matters, *Drug Alcohol Rev* 2013: 32: 339-341.
37. Gaume J., Mccambridge J., Bertholet N., Daeppen J.-B. Mechanisms of action of brief alcohol interventions remain largely unknown – A narrative review, Frontiers in Psychiatry 2014: 5.

38. Mccambridge J., Kypri K., Mcelduff P. Regression to the mean and alcohol consumption: A cohort study exploring implications for the interpretation of change in control groups in brief intervention trials, *Drug and Alcohol Dependence* 2014: 135: 156-159.
39. Kaner E., Bland M., Cassidy P., Coulton S., Dale V., Deluca P. et al. Effectiveness of screening and brief alcohol intervention in primary care (SIPS trial): pragmatic cluster randomised controlled trial, *BMJ* 2013: 346: e8501.
40. Butler C. C., Simpson S. A., Hood K., Cohen D., Pickles T., Spanou C. et al. Training practitioners to deliver opportunistic multiple behaviour change counselling in primary care: a cluster randomised trial, *BMJ* 2013: 346: f1191.
41. Saitz R. SIPS trial findings most consistent with a lack of effectiveness of brief intervention in real clinical practice, *BMJ* 2013: URL:http://www.bmj.com/content/346/bmj.e8501/rapid-responses. Accessed: 2015-02-17. (Archived by WebCite® at http://www.webcitation.org/6WPh5O7D0).
42. Rosenthal R. Covert communication in classrooms, clinics, courtrooms, and cubicles, *Am Psychol* 2002: 57: 839-849.
43. Mccambridge J., Cunningham J. A. The early history of ideas on brief interventions for alcohol, *Addiction* 2014: 109: 538-546.
44. Mccambridge J., Rollnick S. Should brief interventions in primary care address alcohol problems more strongly?, *Addiction* 2014: 109: 1054-1058.
45. Havard A., Shakeshaft A., Sanson-Fisher R. Systematic review and meta-analyses of strategies targeting alcohol problems in emergency departments: interventions reduce alcohol-related injuries, *Addiction* 2008: 103: 368-376; discussion 377-368.
46. Public Health England. Developing Pharmacy's contribution to Public Health: A progress report from the Pharmacy and Public Health Forum London 2014. URL:https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/323365/PPHF_progress_report.pdf. Accessed: 2015-02-17. (Archived by WebCite® at http://www.webcitation.org/6WPhYJyV3).
47. National Pharmaceutical Association. Community Pharmacy Delivering Public Health on the Frontline: Report of the Pharmacy and Public Health Round Table, National Pharmaceutical Association 1-16 2010.
48. Department of Health. Pharmacy in England: Building on strengths - delivering the future; Department of Health, Norwich: The Stationary Office; 2008.

APPENDIX

Brief Intervention Protocol

RECORD START TIME:…….

GETTING STARTED

1. **Start by building rapport and encourage informal chat. Your goal is to try help the person feel comfortable before talking to you about their drinking.**
2. **Identify customers' experience of answering the AUDIT questions.**
   Questions you **may** ask:
   - 'What was it like to answer these questions?'
   - 'Was there anything that made you think?'
   - 'Was there anything that struck you?'
   - 'What did you like or not like about answering these questions?'

   Focus on questions with high scores:
   - 'For instance, your response to this question here?'

CORE CONVERSATION

3. **Encourage customer to talk about themselves:**
   - 'Why don't we start by telling me a little bit about yourself?'
   - 'Where does your drinking fit in with this?'
   - 'Is it okay to talk a bit more about your drinking?'
   - 'Tell me a bit about what's important in your life right now?'

4. **Explore ambivalence:**
   - 'What do you find positive about your drinking?'
   - 'What, do you find good about this?'
   - 'Tell me what's negative about your drinking?'
   - 'What do you find not so good about that?'

5. **Evaluate their drinking:**
   - 'On balance what do you think about your drinking?'
   - 'How do you see your drinking now?'
   - 'What do you feel is important for you?'
   - 'What would be most helpful for you to talk about next?'

CLOSING and SUMMARY

6. **Ending the conversation:**
   - 'Where do you feel you are right now with this?'
   - 'Where does this leave you?'
   - 'How did you find this?'
   - 'How would you summarise this conversation?'

Note: If necessary, provide a summary to the customer of your understanding of their situation:

- 'To make sure I've got it right…?'
- 'I remember what you told me…'

NOW COMPLETE THE BRIEF FORM ABOUT THIS CONVERSATION

RECORD END TIME: …… (try not to exceed 10 minutes)

<u>Giving information and discussing printed literature</u>:
Restrict giving information and avoid going through the leaflets with the customer.

Provide information only in response to specific requests by the customer or if you judge it is likely to be helpful to them.
Draw from the following resources:

a. NHS Units and You Booklet
b. Unit/Calorie Calculator Wheel
c. Alcohol Services leaflet

Remember to seek permission first (e.g. 'Is it okay to talk about X?')
Questions you **may** ask:

- 'Is there any information about alcohol you'd like to clarify?
- **'**How might this information be useful to you?' (before providing it)
- 'What do you think about that?' (after providing it)
- 'Does that change how you think about your drinking at all?'

<u>Aims of the conversation</u>:
Aim to leave the customer thinking about their drinking and whether they would like to change their drinking in any way. If this has already been established, the more explicit their planning the better e.g. 'I'm not going to drink anything this Friday night.'

Table 1a Baseline characteristics of groups who were followed up.
(Values are numbers (%) unless stated otherwise)

Characteristics	Intervention group (*n* = 168)	Control group (*n* = 158)	Total (*n* = 326)
Place of residence:			
Hammersmith and Fulham	135 (80.4)	121 (76.6)	256 (78.5)
Other London Borough	27 (16.1)	27 (17.1)	54 (16.6)
Outside London	6 (3.6)	9 (5.7)	16 (4.9)
Missing values	0 (0)	1 (0.6)	0 (0)
Total	168 (51.5)	158 (48.5)	326 (100)
Age (years), mean (SD), range	41.1 (16.08), 18-74, (*n* = 157)	43.2 (18.09), 18-92, (*n* = 150)	42.1 (17.09), 18-92, (*n* = 307)
Missing values	11 (6.5)	8 (5.1)	19 (5.8)
Total	168 (51.5)	158 (48.5)	326 (100)
Gender:			
Female	81 (48.2)	63 (39.9)	144 (44.2)
Male	87 (51.8)	95 (60.1)	182 (55.8)
Total	168 (51.5)	158 (48.5)	326 (100)
Ethnicity:			
Asian british: any other asian background	3 (1.8)	2 (1.3)	5 (1.5)
Asian british: Indian	4 (2.4)	7 (4.4)	11 (3.4)
Asian british: Pakistani	0 (0.0)	2 (1.3)	2 (0.6)
Black british: any other black background	2 (1.2)	1 (0.6)	3 (0.9)
Black british: African	5 (3.0)	6 (3.8)	11 (3.4)
Black british: Caribbean	8 (4.8)	10 (6.3)	18 (5.5)
Mixed: any other mixed background	2 (1.2)	1 (0.6)	3 (0.9)
Mixed: white and asian	1 (0.6)	2 (1.3)	3 (0.9)
Mixed: white and black African	1 (0.6)	1 (0.6)	2 (0.6)
Mixed: white and black Caribbean	1 (0.6)	1 (0.6)	2 (0.6)
Not stated	0 (0.0)	1 (0.6)	1 (0.3)
Other ethnic groups:any other ethnic groups	2 (1.2)	0 (0.0)	2 (0.6)
Other ethnic groups: Chinese	4 (2.4)	0 (0.0)	4 (1.2)
White: any other white background	23 (13.7)	28 (17.7)	51 (15.6)
White: British	97 (57.7)	80 (50.6)	177 (54.3)
White: Irish	4 (2.4)	8 (5.1)	12 (3.7)
Missing data	11 (6.5)	8 (5.1)	19 (5.8)
Total	168 (51.5)	158 (48.5)	326 (100)
Continuing education after age 16:			
Yes	129 (76.7)	119 (75.3)	248 (76.1)
No	28 (16.7)	31 (19.6)	59 (18.1)
Missing data	11 (6.5)	8 (5.1)	19 (5.8)
Total	168 (51.5)	158 (48.5)	326 (100)

Table 1b Demographic /professional backgrounds of pharmacists (*n* = 17)

Characteristics	No (%)
Gender	
Female	4 (24%)
Male	13 (77%)
Mean years (± SD)	
Age [a]	42 (± 11.7)
Registered as a pharmacist [b]	18 (± 11.0)
Practised as a community pharmacist [b]	17 (± 11.2)
Worked as a pharmacist in current pharmacy [b]	8 (± 6.6)
Current post [a]	
Employee pharmacist	6 (38%)
Locum pharmacist	1 (16%)
Pharmacy manager	2 (13%)
Pharmacy owner	7 (44%)
Mean hours of training undertaken since (± SD) registering as a pharmacist	
Hours of alcohol misuse training [a]	3 (± 3.1)
Hours of drug misuse training [a]	21 (± 16.2)
Hours of smoking cessation training [a]	25 (± 15.8)
Had heard of BI prior to the study? [a]	
Yes	4 (25%)
No	12 (75%)
Provided BI to service users prior to the study? [a]	
Yes	0 (0%)
No	16 (100%)
Attended evening additional follow-up training session	
Attended training	10 (59%)
Not attended training	7 (41%)

[a] Missing data for 1 pharmacist.
[b] Missing data for 2 pharmacists.

Table 1c Characteristics of pharmacies (*n* = 16)

Characteristics	Number of study sites (%)
Site type [a]	
Independent Chemist	10 (63)
Multiple Chemist	6 (38)
Site Location	
High street	11 (69)
Housing Estate	1 (6)
Shopping centre	3 (19)
Doctor's surgery	1 (6)
Average number of NHS prescription items dispensed per site per day [b]	
51 – 100	3 (19)
101 – 150	2 (13)
151 – 200	3 (19)
201 – 250	3 (19)
251 – 300	1 (6)
301 – 350	2 (13)

[a] Site type: 'Independent Chemist', operates retail pharmacy businesses from 9 or less premises. 'Multiple Chemist', operates retail pharmacy businesses from more than 9 premises.[1]

[b] Pharmacists at two sites declined to respond.

1 Pharmaceutical Services Negotiating Committee. Pharmaceutical Services Negotiating Committee Constitution.2011