Effectiveness and cost-effectiveness of opportunistic screening and stepped-care interventions for older alcohol users in primary care.

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Abstract

Objective: To compare the clinical effectiveness and cost-effectiveness of a stepped-care intervention versus a minimal intervention for the treatment of older hazardous alcohol users in primary care.
Design: A multi-centre, pragmatic RCT.
Setting: Primary care general practices in England and Scotland.
Participants: Patients aged >= 55 years scoring >=8 on the Alcohol Use Disorders Identification Test.
Interventions: Minimal intervention consisted of 5-minutes of brief advice. Stepped care consisted of an initial 20-minutes of behavioural change counselling. Step 2 was three sessions of Motivational Enhancement Therapy. Step 3 was a referral to local alcohol services. Progression between each step was determined by outcomes one month after each step.
Main outcome measures: Average drinks per day, AUDIT-C, alcohol-related problems using the Drinking Problems Index, health-related quality of life using the Short Form 12. Costs measured from a NHS/Personal Social Care perspective. Estimated health gains in quality adjusted life-years measured assessed EQ-5D.
Results: Both groups reduced alcohol consumption at 12 months but the difference between groups was small and not significant. No significant differences were observed between the groups on secondary outcomes. In economic terms stepped care was less costly and more effective than the minimal intervention.
Conclusions: Stepped care does not confer an advantage over a minimal intervention in terms of reduction in alcohol use for older hazardous alcohol users in primary care. However stepped care has a greater probability of being more cost-effective.
Trial Registration: Current controlled trials ISRCTN52557360

Introduction

There exists a wealth of evidence of the detrimental impact of excessive alcohol consumption on the physical and psychological health of the population. It is estimated to account for 150 000 hospital admissions and up to 22 000 deaths annually in the United Kingdom (Academy of Medical Sciences, 2004). In the older population, those aged 55 years or more, alcohol consumption is associated with an array of physical, psychological and social problems (Coulton, 2009). There is evidence of an association between increased alcohol consumption and coronary heart disease, hypertension, haemorrhagic and ischaemic stroke, alcoholic liver disease and a range of cancers (Department of Health, 1995). Consuming alcohol is considered one of the three main risk factors for falls (Wright and Whyley, 1995), a major cause of morbidity and mortality in this population. The Royal College of Physicians estimate that 60% of older people admitted to hospital because of repeated falls, chest infections and confusion have undiagnosed alcohol problems (Royal College of Physicians, 2001). Excessive alcohol consumption in older age also contributes to the early onset of dementia, age-related cognitive deficits, Parkinson's disease, depression and anxiety (Thomas and Rockwood, 2001). Alcohol is implicated in one-third of suicides among older people (Crome, 1991). It is estimated that 80% of those aged 60 years or more take prescribed medication and poly-pharmacy is common, with one-third taking four or more medications (Falaschetti et al., 2002). Alcohol is contraindicated for many of the medications prescribed and negative interactions common (Moore et al., 2007). Increased alcohol consumption in older age is also associated with a range of social problems including self-neglect, poor nutrition, social isolation and hypothermia (Woodhouse et al., 1987).

The prevalence of hazardous drinking, a pattern of drinking that puts the individual at-risk of adverse health events, in those older than 55 years is generally considered to be lower than the wider adult population and research using data derived from the General Practice Research Database suggests that only 5% of older people who are hazardous alcohol users are identified in primary care settings (Drummond et al., 2004). Older people are less likely to

seek treatment for alcohol-related problems (Callahan and Tierney, 1995) and alcohol-related presentations are often atypical or masked by comorbid physical or psychiatric illness making diagnosis more difficult (Reid and Anderson, 1997). At the turn of the century 16% of the population was aged 55 years or more and this is expected to increase to 21% by 2026, as the average age of the population increases the absolute number of older people consuming alcohol at hazardous levels will increase even if the prevalence remains stable.

Opportunistic screening is a pro-active screening approach that has been used with success in a variety of clinical areas including type II diabetes and chlamydia infection and is particularly useful in identifying health-related problems in populations who would not usually seek treatment for those problems. The Alcohol Use Disorders Identification Test (AUDIT; (Saunders et al., 1993)) is a short screening tool with high levels of sensitivity and specificity in primary care populations (Coulton et al., 2006) and has been found to be superior to other screening approaches in older populations (Philpot et al., 2003).

While there is a substantial evidence base for the efficacy of brief interventions to reduce alcohol consumption in primary care attendees (Ballesteros et al., 2004; Bertholet et al., 2004; Kaner et al., 2007; Whitlock et al., 2004) there is a paucity of evidence based reviews or sub-group analyses that focus on older populations. There is contradictory evidence from primary research on the efficacy of brief interventions to reduce alcohol use in older populations. Moore et al (Moore et al., 2011) compared minimal brief advice with a multi-faceted intervention including physician advice and behavioural counselling for older adults in primary care. While reductions were observed in both groups at 12 months no significant differences were observed between the groups. Yet in a trial of brief interventions for older alcohol users, Fleming et al (Fleming et al., 1999) reported a 34% reduction in alcohol use and a 64% reduction in those engaged in hazardous drinking at 12 months, significantly better than those who received no intervention. Similarly, Blow and Barry (Blow, 2001) report significantly greater reductions in alcohol use in older

people receiving brief interventions in primary care.

Screening for alcohol use disorders identifies a range of needs that are likely to require a range of type and intensity of intervention. One reason why many general practitioners are reluctant to conduct screening is because they perceive themselves as lacking appropriate skills to deal with the more severe cases identified (Menninger, 2002). Older problematic alcohol users are often typified as having early onset with a drinking profile which is a continuation of lifetime at-risk drinking, or late onset drinkers, who initiate at-risk drinking later in life, often as a reaction to significant life changes such as retirement or bereavement. Late onset drinkers are more likely to benefit from a brief intervention approach whereas early onset drinkers often have more entrenched drinking behaviours that require a more intensive intervention. One such intensive intervention is Motivational Enhancement Therapy (MET), which is of relatively short duration, usually three 40-minutes sessions delivered by a trained specialist. Research has shown MET to be as effective as other more intensive interventions such as Cognitive Behavioural Therapy, 12-step facilitation therapy and Social Behaviour and Network Therapy (Project Match Research Group, 1997; UKATT Research Team, 2005b).

Stepped care interventions offer a potentially resource efficient means of meeting the needs of the older people by delivering more intensive interventions only to those who fail to benefit from less intensive interventions. This is more in keeping with rational clinical decision making than the blanket use of one intervention strategy. Stepped care approaches have been advocated and implemented in a variety of clinical areas including depression, smoking, back pain and alcohol use (Drummond et al., 2009).

The aim of the AESOPS study was to evaluate the effectiveness and cost-effectiveness of a stepped-care intervention for older hazardous alcohol users in primary care.

Method

AESOPS was a prospective, multicentre, pragmatic, parallel arm randomised controlled trial with concurrent economic evaluation. Eligible and consenting participants were randomised by a secure independent randomisation service using variable length random permuted blocks stratified by GP practice. Follow-up was conducted at 6 and 12 months by a self-completed postal questionnaire. Neither interventionist nor participant was blind to allocation. The study was conducted in accordance with the declaration of Helsinki and received full NHS multi-centre ethical approval (ref:07/MRE08/24).

Hypotheses

The primary hypothesis, stated as a null hypothesis was:
Stepped care interventions are no more effective at reducing alcohol consumption, assessed using average drinks per day, than a minimal intervention 12 months after randomisation.

Secondary hypotheses were

1. Stepped care is no more cost-effective than minimal intervention.
2. Stepped care will not reduce alcohol-related problems in comparison with minimal intervention 12-months post randomisation.
3. Stepped care will not increase health-related quality of life compared with minimal intervention 12-months post-randomisation.

Sample size

As there was little prior research in this specific area, our sample size calculation was based on similar UK randomised controlled trials addressing alcohol use in primary care populations(Drummond et al., 2009; Wallace et al., 1988) these reported effect size differences between stepped care and minimal intervention of 0.36 and 0.27 respectively. Similar effects have been reported from studies in the United States (Fleming and Manwell, 1999; Gordon et al., 2003; Moyer et al., 2002) and an effect size of 0.3 is considered clinically important for alcohol brief intervention studies (Moyer et al., 2002). In order to detect this size of effect with power at 80%, alpha of 0.05 and a two-sided test requires 175 participants in each of the two groups. Our previous experience with alcohol-using populations and older adults (Drummond et al.,

2009; RESPECT Trial Team, 2010; UKATT Research Team, 2005b) indicated that, with assiduous follow-up regimens, loss to follow-up would be unlikely to exceed 20% at 12 months. Taking this into account we erred on the side of caution and estimated loss to follow-up to be 30%, inflating the sample at baseline to 500 participants, 250 in each group.

Participants

We recruited general practice patients across 53 practices located in eight geographical regions of England and Scotland: North Yorkshire, East Yorkshire, West Yorkshire, Fife, Norfolk, Kent, County Durham and Tyneside.

Participants were considered eligible if they were aged 55 years or more, screened positive for hazardous alcohol use, with a score of 8 or more on the AUDIT, resided within commutable distance of the general practice and were able and willing to provide consent to the study and follow-up.

Participants were not considered eligible if they had accessed treatment for substance use, including alcohol but excluding nicotine, in the previous 90 days, they were currently seeking help for alcohol use, or if they had a severe physical or psychological illness that precluded participation in the study as judged by the general practitioner.

Procedure

Two approaches were used to identify potential participants. In some practices the receptionist provided consecutive attendees with a sealed screening pack to be completed in situ or taken home and returned using a freepost envelope. In other practices, potential participants were identified from the practice list and sent a screening pack by post with a return freepost envelope. Each screening pack contained a trial information sheet and a copy of the AUDIT questionnaire. All participants were encouraged to return the screening pack and if interested in participating in the study to add contact details. Those who scored 8 or more on the AUDIT and provided contact details were invited to an appointment with the practice nurse or a research nurse within seven days. At this appointment, the study was discussed,

eligibility assessed and the participant provided with an opportunity to ask questions, informed consent was taken and the baseline assessment completed prior to allocation. The practice or research nurse delivered the intervention immediately after allocation.

Interventions

Control group minimal intervention

Participants received a 5-minute structured advice session by the practice or research nurse. The session included feedback and interpretation of the screening results, tailored information on the risks associated with their level of consumption and advice about reducing their alcohol consumption. In addition, each participant received a short self-help booklet outlining the consequences of excessive alcohol consumption and including details of where to seek help locally for alcohol issues.

Stepped care

The stepped care intervention consisted of three consecutive steps where progression between steps was dependent on the response to the previous step.

Step 1 consisted of a 20-minutes session of behavioural change counselling delivered by the practice or research nurse using a motivational interviewing approach (Rollnick et al., 1999) that explored the participants' motivation to change their drinking behaviour. The intervention was protocol guided and the practice or research nurse was trained and assessed as competent in the intervention delivery prior to the start of the trial. Four weeks later the participant was contacted by the practice nurse and alcohol consumption assessed using the consumption questions of AUDIT (AUDIT-C, (Bradley et al., 2007)). If the participant was still consuming alcohol at a hazardous level a referral to step 2 was made.

Step 2 was delivered by an experienced alcohol therapist in the primary care environment. The intervention, MET, was protocol guided and delivered over three, 40-minute sessions on a weekly basis. MET addresses the six basic

principles of increasing motivation to change; feedback on consumption, responsibility for change, the individual as the agent of change, maintenance of an emphatic therapeutic style and enhancing the individual's self-efficacy. All therapists attended a training course and were assessed as competent in delivery of MET prior to the start of the study. Four weeks later the participant was contacted by the practice nurse and alcohol consumption assessed, again using the AUDIT-C. If the participant was still consuming alcohol at a hazardous level a referral to step 3 was made.

Step 3 consisted of a referral to a specialist alcohol treatment services There was no limit on the intensity or duration of the step 3 intervention.

Training nurses to deliver the control condition and step 1 intervention
Training was delivered by the training centre and lasted 2 days. Training for the control intervention involved interpreting the AUDIT questionnaire, feeding back the results to the participant and making recommendations to reduce alcohol consumption. Training for the step 1 intervention encompassed motivational interviewing skills, feeding back of AUDIT scores in a manner that elicits concern and negotiating a behaviour change goal. All training was supported by a written protocol and took the form of a simulated consultation, followed by a seminar and further simulated consultations. Prior to staff seeing any study participants, an assessment of competence was made from a recording of a session rated by an independent expert. On-going support and supervision was provided throughout the study by an expert trainer.

Training alcohol therapists to deliver the step 2 intervention
Existing experienced alcohol therapists attended specialist MET training at the specialist training centre. Training and delivery of MET was governed by a specific protocol and therapists had the opportunity to observe practice delivery and engage in role-play. Supervision was given during a number of therapy sessions and two recorded sessions were reviewed with an expert trainer prior to therapists seeing study participants. The supervision provided the main opportunity for practising skills and delivering the structure and

content of treatment.

Study measures

Screening

AUDIT was used to establish eligibility for entry in the study. The instrument addresses frequency and quantity of alcohol consumed, alcohol-related problems and aspects of dependence. The 10-item questionnaire is self-completed and a score of 8 or more is indicative of hazardous alcohol use. The AUDIT exhibits high levels of sensitivity and specificity in UK adult primary care populations and older populations (Coulton et al., 2006; Philpot et al., 2003).

Primary outcome

Alcohol consumption interpreted as average drinks per day (ADD) was derived from the first three consumption items of AUDIT (AUDIT-C). This was assessed at baseline and then again at months 6 and 12 by postal questionnaire.

Secondary outcomes

In addition to ADD the AUDIT-C provides a dichotomous positive or negative outcome of hazardous consumption at a cut-point of 5 or more (Bradley et al., 1998). Alcohol-related problems were assessed using the 17-item Drinking Problems Index (DPI; (Finney et al., 1991)). The instrument is self-completed and specifically designed to assess drinking problems in older populations. Quality of life was assessed using the short form SF12 (Ware et al., 1996). SF12 is a self-completed instrument with established reliability and validity for the measurement of both physical and mental health-related quality of life. In this study we employed a version designed specifically for older populations (Isglesias et al., 2001). All outcomes were measured at baseline and then 6 and 12 months post-randomisation by postal questionnaire.

Economic outcomes

Quality of life was measured using the EQ5D (EuroQuol Group, 1990), this 5-item participant completed questionnaire has established psychometric

properties and is extensively used in health economic evaluation to calculate the quality adjusted life-year (QALY) (EuroQuol Group, 1990). The use of QALY's allows economic costs and benefits to be compared across a variety of different conditions and treatments and allows for decisions to be made regarding the allocation of health resources.

Participants use of health services, other alcohol services outside the study, public and criminal justice services was assessed using a self-completed service utilisation questionnaire developed over a number of alcohol intervention studies (Drummond et al., 2009; UKATT Research Team, 2005a). Service use was assessed for the 6 months prior to entry into the study and the 12 months after randomisation. All costs were estimated for the year 2009-10 in pounds sterling.

Process and fidelity outcomes

All intervention sessions, with the exception of step 3, were audio recorded with the consent of participants. A 30% random sample, stratified by site and intervention (control, step 1 or step 2) were independently rated and assessed for compliance with treatment protocols. A 20% proportion of sampled tapes were double rated for quality assurance purposes.

Analysis

Analysis of effectiveness

All analyses were performed on an intention-to-treat basis, whereby participants are analysed as members of their allocated group irrespective of whether treatment was received, as this provides a pragmatic interpretation of effectiveness. A two-sided 5% significance level was employed and all analyses were conducted using SAS version 9.2 (SAS institute, Cary USA).

The primary outcome ADD derived from the AUDIT-C at 12-months post-randomisation was analysed using a hierarchical linear model in order to adjust for any effect of GP practice and practitioners and this was adjusted for baseline ADD and baseline AUDIT score. Model checking was performed by assessing residual plots to ensure models derived fitted the data and where

necessary transformations were employed to make the model a better fit. A sensitivity analysis was conducted using PROC MI and MI analysis commands in SAS to assess the impact of missing data.

Secondary outcomes that were continuous in nature were analysed in a similar manner. As AUDIT-C status at months 6 and 12 was dichotomous analysis employed was a hierarchical logistic regression model.

Analysis of cost-effectiveness

The costs of screening were derived from the actual local cost of this activity and multiplied by the numbers screened. The time spent on delivering the control intervention and the first two tiers of the stepped intervention was derived from time sheets maintained by practice nurses and therapists. The costs associated with these activities were calculated using the local costs including costs associated with training, supervision, management and overheads using methods developed for the UKATT trial (UKATT Research Team, 2005a). Use of specialist services for step 3 of the intervention were recorded and costed using established sources (Raistrick et al., 2004). The incremental cost-effectiveness of stepped care compared with minimal intervention was assessed from both a health and personal social services and a wider public sector resource perspective following NICE guidelines (National Institute for Clinical Excellence, 2013). Quantities of resources used were derived from the service use questionnaire at baseline, 6 and 12 months and multiplied by national sources of unit costs (Curtis, 2010). Health utility values were derived from the EQ5D and combined with population values and the QALY change calculated using the area under the curve method (Richardson and Manca, 2004). Incremental cost-effectiveness analysis combined the total costs of the interventions with the QALY changes, using the costs in the intervention group over and above the control divided by the incremental QALY's in the intervention group over and above the control. A non-parametric bootstrapping resampling technique was employed to test the sensitivity of the calculated incremental cost effectiveness ratios and cost-acceptability curves were generated to explore the different probabilities that

stepped care was the most cost-effective option at different thresholds of the commissioner's willingness to pay.

Analysis of fidelity

Independent raters derived four summary scores for each type of intervention encompassing session management, specific task, therapist style and session content. These scores were analysed using a mixed model with interventionist fitted as a random effect to explore compliance with treatment protocols. Inter-rater reliability was assessed by deriving mixed model intra-class correlation coefficients for each rater.

Results

Sample characteristics

Overall 21 545 screening questionnaires were returned of which 21 529 could be scored. Of these 1625 (7.6%) scored 8 or more on AUDIT and 949 (58.4%) provided contact details, of these 928 met the eligibility criteria (97.8%) and 529 (57%) consented to participate in the study (Figure 1). The prevalence of hazardous alcohol use was similar in those sampled as attendees at primary care and those responding to mailed questionnaires. Overall 529 were randomised, 266 allocated to stepped care and 263 to the minimal intervention. The majority of participants were male (425; 80%) and the average age was 63 years (SD 5.8; range 55-85 years). Demographic and baseline outcome measures by allocated group are provided in Table 1. Follow-up rates were high at 6 and 12 months (89.6 and 87.5%) and the requirements of the sample size calculation were met. A full CONSORT statement is provided in Figure 1. An overview of outcomes at baseline, month 6 and month 12 is provided in Table 1.

Primary outcome

The distribution of ADD at month 12 was skewed and a natural logarithmic transformation was undertaken to improve the model fit. At 12-months alcohol consumption had significantly reduced in both groups, and while the stepped care group had a marginally higher ADD this was not significant (table 2). The GP random effect was not significant suggesting that ADD did not vary

between practices. Sensitivity analysis imputing missing values provided similar estimates and non-imputed results are presented.

Secondary outcomes

At month 6 the ADD was lower in the stepped care group than the minimal intervention group but this was not statistically significant. No statistical differences were observed in terms of AUDIT-C status at 6 and 12 months, DPI, and mental and physical components of health-related quality of life, measured using SF12, at 6 and12 months (Table 2). At month 12, 51% of participants reported that they consumed less alcohol than at the beginning of the study, this was similar across the stepped care and minimal intervention groups, 48% and 52% respectively.

Process outcomes

Of those allocated to minimal intervention 99.7% (262/263) received the intervention. Of the 266 allocated to stepped care 99.7% (265) received step 1. Of these 146 were assessed as being eligible for referral to step 2 but only 41 (28%) attended any session of step 2. Of those who attended step 2, 30 were found eligible for referral to step 3, although only 5 participants attended step 3.

Fidelity assessment identified distinct differences between the content and delivery of the minimal intervention and step 1 consistent with the intervention manuals. The delivery of MET was found to be consistent with the intervention manual.

Economic outcomes

Costs associated with interventions for both groups are presented in Table 3. The mean EQ-5D scores were lower for both groups at months 6 but higher than baseline values at months 12 (Table 4). The mean unadjusted QALY gain at month 12 was 0.8067 and 0.7717 for the stepped care and minimal intervention groups respectively. The mean service utilisation over this period was £906 and £1077 respectively. The cost-effectiveness plane (Figure 2) shows that the majority of plots lay in the south-east quadrant suggesting that

stepped care appears to be more effective and less costly than minimal intervention, and cost-effectiveness acceptability curve (Figure 2) indicates that the probability that stepped care is the most cost-effective intervention given the NICE willingness to pay threshold of £20 000 to £30 000 per QALY is between 93.50 and 93.84%. The potential impact of GP practice was explored using a multi-level modelling approach and this indicated that net monetary benefit did not significantly differ by GP practice.

Discussion

Relevance of findings

A total of 21 529 older people were screened using the AUDIT questionnaire as part of this study and 7.6% were found to be positive for hazardous drinking, lower than other estimates of circa 20% in this population (Holley-Moore and Beach, 2016; Wadd and Papadopoulus, 2014) but similar to prevalence estimates of this age group in recent studies (Kaner et al., 2013). As the prevalence was similar between those who actually attended primary care and those on the practice list this difference is unlikely to be due to the health status of participants and the size of the sample confirms the prevalence of at-risk alcohol use in this population is lower than younger adults (Drummond et al., 2009).

The study demonstrates that alcohol screening and brief interventions can be implemented in routine clinical practice with almost all of those participants willing to engage in a brief alcohol intervention with the practitioner. In the stepped care arm, only 28% of eligible participants attended MET and 17% eligible attended step 3, suggesting that increasing intensity of intervention is less acceptable to participants.

Alcohol consumption significantly reduced in both groups over the 12-month follow-up period and 51% of participants reported drinking less alcohol at 12 months. No significant differences were observed between the groups at 12 months in terms of alcohol consumed, alcohol-related problems or quality of life. This would suggest that more intensive interventions confer no advantage over and above screening, feeding back the meaning of screening results and

brief advice, an observation made in recent UK studies across a variety of populations (Drummond et al., 2014; Kaner et al., 2013; Newbury-Birch et al., 2014).

The cost-effectiveness analysis suggested that the cost of the stepped care intervention was estimated as 20 times that of the minimal intervention. Taking into account the participants' use of health and social care resources in the 12 months after randomisation, the stepped care intervention was more likely to be cost-effective at a willingness to pay (WTP) threshold range of £20 000-30 000 per QALY. This is due to the fact that while stepped care is costlier to implement overall, only a small number of participants engaged in all of the steps. In addition, higher costs were offset by lower use of health and social care resources in the 12 months after randomisation, due in the main to fewer hospital inpatient days. The probability that stepped care was more cost-effective than minimal intervention was over 93% at the 12-month follow-up.

Compared with the clinical results this counter-intuitive finding has been identified previously in primary care settings (Drummond et al., 2009; Kaner et al., 2013) and warrants further discussion. It is important to note that the primary outcome for economic analysis is the EQ5D, to allow comparability between different health conditions that are meaningful to decision makers. This outcome is different from the condition specific clinical outcome, average drinks per day, and this difference in outcome may have influenced the differences in observed clinical and economic results. We should also note that cost-effectiveness analysis is not reliant on traditional 95% significance level in the same way as the clinical outcomes. At a WTP of £20 000- 30 000 per QALY stepped care was only the better approach in 93% of scenarios, and this was closer to 80% when the WTP was zero.

It may the case that stepped care may have a greater impact on those with more severe alcohol use and by extension those with greater resource use, but the small numbers of these in our study makes post-hoc analysis unreliable. Alternatively the result may be indicative that the effect of stepped

care is greater than that of minimal intervention but the size of this effect is far smaller than would be considered clinically important in routine care. But the nature of economic data and the results from a single study suggests we should err on the side of caution in interpreting the economic results. More research is needed to gain a better understanding of the relationship between clinical and cost-effectiveness outcomes of brief interventions for alcohol users, probably through the use of meta-analytical approaches across multiple studies.

There are a number of potential limitations we need to consider in the study. The lower than expected prevalence rates may have been due to response bias, but we saw no evidence of this. Of those who responded to the survey and met the eligibility criteria the mean AUDIT score was similar for those who responded anonymously compared to those who left their contact details (11.1 versus 12.0). Further, those who consented are representative of participants who would be willing to engage in an intervention in primary care to address alcohol consumption. In common with other studies in the field we excluded those with severe psychological illness on the basis that brief interventions are not designed to meet their needs except in the context of a comprehensive mental health intervention. We did not include blood investigations to provide collateral confirmation of alcohol use and this was due to the limitations in populations consuming alcohol at hazardous levels and evidence that paper based assessments are more reliable and valid (Coulton et al., 2006). Some researchers in the field have argued that the potential harms associated with alcohol use in older populations require specific screening tools to address domains of harm not covered by AUDIT, but as yet there is no alcohol screening tool for older populations that demonstrates better diagnostic properties than the AUDIT.

Implementation

While our initial motivation to conduct this study was based on the premise that stepped-care approaches may offer a practical clinical approach to the treatment of alcohol problems in the older population we found no convincing evidence that the approach offered any additional benefit over and above

simple screening and feeding back of screening results, and this is a similar finding of other recent studies in primary care settings (Drummond et al., 2014; Kaner et al., 2013). More intensive interventions appeared less acceptable to the target population and we would recommend that screening and brief interventions for alcohol users in primary care for older populations follow a similar process to that recommended for adults in general; regular screening and brief advice on the outcomes of the screen an approach recently recommended based on a review of the research evidence (McCambridge and Saitz, 2017). More research is required to explore whether more intensive interventions, and stepped interventions have additional benefits for those at the higher end of the alcohol problem spectrum, such as those scoring 16 or more on the AUDIT and whether more intensive interventions are more cost-effective than minimal interventions.

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Declaration of interest

None of the authors have any conflict of interest to declare.

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Table 1: Demographic and outcome measures at baseline, month 6 and month 12 for those followed up by allocated group.

	Baseline		Month 6		Month 12	
	Stepped Care (n= 266)	Minimal (n=263)	Stepped Care (n=240)	Minimal (n=234)	Stepped Care (n=234)	Minimal (n=232)
Demographic characteristics						
Male n (%)	220 (82.7)	205 (77.9)	-	-	-	-
Mean age (SD)	62.9 (5.82)	62.7 (5.86)	-	-	-	-
Smoker n (%)	44 (17.2)	46 (18.3)	-	-	-	-
In employment n (%)	89 (34.5)	93 (36.0)	-	-	-	-
Married/ cohabiting n (%)	188 (71.5)	172 (66.9)	-	-	-	-
Owner-occupier n (%)	211 (80.2)	202 (78.6)	-	-	-	-
Outcome measures						
Average drinks per day (ADD) [a]						
Mean (SD)	3.38 (2.24)	3.42 (2.19)	2.45 (1.85)	2.81 (2.03)	2.56 (2.09)	2.49 (1.93)
AUDIT-C Score						
Mean (SD)	8.26 (2.19)	8.25 (2.26)	7.02 (2.48)	7.38 (2.55)	7.07 (2.48)	6.96 (2.66)
Positive n (%)	250 (95.1)	244 (94.2)	203 (85.3)	205 (88.7)	194 (84.7)	188 (82.1)
Drinking Problems Index (DPI) *(Higher scores equate to more problems)*						
Mean (SD)	2.64 (2.90)	3.08 (3.33)	1.79 (2.60)	2.41 (3.22)	1.90 (3.03)	2.25 (3.04)
Health Related Quality of Life (SF12) *(Higher scores equate to better QoL, population mean 50)*						
Mean physical components (SD)	47.7 (11.2)	47.3 (11.0)	47.4 (11.3)	47.7 (11.2)	47.2 (11.9)	47.5 (11.0)
Mean mental components (SD)	51.8 (9.51)	50.2 (10.7)	55.0 (9.80)	50.5 (10.6)	52.0 (9.72)	51.5 (9.85)

[a] standard drink = 1 unit = 8g ethanol

Table 2: Adjusted outcomes and mean difference versus minimal group at 6 and 12 months by allocated group.

	Stepped Care	Minimal	Mean difference (95% CI)	p-value
Mean natural logarithm transformed ADD (SD) [n]				
Month 6	1.119 (0.034) [234]	1.192 (0.034) [230]	-0.073 (-0.156 to 0.011)	0.088
Month 12	1.129 (0.037) [226]	1.104 (0.037) [223]	0.025 (-0.062 to 0.112)	0.575
Mean AUDIT-C Score (SD) [n]				
Month 6	7.085 (0.159) [236]	7.373 (0.160) [228]		0.156
Month 12	7.116 (0.166) [227]	6.957 (0.166) [226]	-0.288 (-0.687 to 0.111)	0.445
Proportion AUDIT-C Positive % [n]			0.160 (-0.250 to 0.569)	
Month 6	81.8 [236]	81.6 [228]		0.427
Month 12	89.0 [227]	89.4 [226]		0.289
			0.81 (0.48 to 1.37)[a]	
Mean natural logarithm transformed Drinking Problems Index (SD) [n]			1.37 (0.76 to 2.47)[a]	
	0.799 (0.040) [236]	0.864 (0.040) [229]		0.247
Month 6	0.793 (0.038) [227]	0.802 (0.038) [225]		0.735
Month 12			-0.064 (-0.173 to 0.045)	
Mean Physical Health-related quality of Life (SF12) (SD) [n]	51.21 (0.443) [234]	51.30 (0.448) [228]	-0.018 (-0.125 to 0.088)	0.889
Month 6	51.63 (0.462) [224]	52.11 (0.463) [223]		0.466
Month 12				
Mean Mental Health-related quality of life (SF12) (SD) [n]	47.15 (0.423) [234]	47.87 (0.429) [228]	-0.088 (-1.329 to 1.153)	0.232
Month 6	47.07 (0.489) [224]	47.71 (0.490) [223]		0.692
Month 12			-0.478 (-0.809 to 1.766)	
			-0.722 (-1.905 to 0.462)	

			-0.637 (-1.998 to 0.723)	

[a] Adjusted odds ratio reported for proportion.

Table 3: Costs associated with screening and interventions (2010 prices in £ sterling)

Source of cost	Stepped Care (£ sterling)	Minimal (£ sterling)
Opportunistic screening cost		
Information letter and copy of AUDIT	1.63 / participant	1.63 / participant
Practice nurse (5 minutes) – interpret and arrange appointment	3.89 / participant	3.89 / participant
Minimal intervention		
Practice nurse (5 minutes)	-	2.17 / participant
Self-help booklet [a]	-	0.17 / participant
Step one – Behavioural Change Counselling		
Nurse training cost	3.69 / session	-
Practice nurse (20 minutes)	8.72 / session	-
Self-help booklet [a]	0.17 / participant	-
Four-week telephone assessment [b]	2.42 / participant	-
Step two – Motivational Enhancement Therapy		
Therapist training cost	12.71 / session	-
Three sessions with therapist (40 minutes)	36.84 / participant	-
Four-week telephone assessment [b]	2.42 / participant	-
Step 3 – Specialist alcohol intervention	811 / patient	-

[a] "Safer drinking: A self-help guide".
[b] Includes practice nurse time, call costs at 5p per minute and line rental.

Table 4: Economic outcomes at baseline, 6 and 12 months and mean difference versus minimal by allocated group.

	Stepped Care	Minimal	Mean difference (95% CI)
Mean resource use in previous 6 months £ (SD)			
Baseline	522.53 (1233.05)	468.25 (727.41)	54.28 (-139.67 to 248.23)
Month 6	443.78 (832.70)	467.52 (903.42)	-23.74 (-189.96 to 142.49)
Month 12	410.65 (729.81)	602.38 (2263.20)	-191.74 (-512.90 to 129.43)
Screening Cost £	5.52	5.52	0
Mean Treatment Cost £ (SD)	46.63 (145.88)	2.34	44.29 (24.50 to 64.08)
Mean overall cost at month 6 £ (SD)			20.56 (-146.75 to 187.87)
Unadjusted	495.53 (843.78)	474.98 (903.42)	6.38 (-164.09 to 151.33)
Adjusted [a]	488.48 (826.32)	482.10 (826.32)	
Mean overall cost at month 12 £ (SD)			-171.18 (-574.06 to 231.70)
Unadjusted	906.18 (1369.31)	1077.36 (2635.77)	-193.57 (-585.06 to 197.93)
Adjusted [a]	895.04 (2049.45)	1088.61 (2049.47)	
Mean EQ5D Score (SD)			0.0299 (-0.0152 to 0.0751)
Baseline	0.8066 (0.2204)	0.7767 (0.2507)	0.0446 (-0.0003 to 0.0895)
Month 6	0.8052 (0.2238)	0.7606 (0.2451)	0.0207 (-0.0229 to 0.0644)
Month 12	0.8098 (0.2304)	0.7891 (0.2257)	
QALY at 6 months (SD)			0.0186 (-0.0024 to 0.0396)
Unadjusted	0.4030 (0.1026)	0.3843 (0.1164)	0.0058 (-0.0018 to 0.0133)
Adjusted [b]	0.3966 (0.0394)	0.3908 (0.0394)	
QALY at 12 months (SD)			0.0350 (-0.0055 to 0.0755)
Unadjusted	0.8067 (0.2012)	0.7717 (0.2214)	0.0117 (-0.0084 to 0.0318)
Adjusted [b]	0.7951(0.1054)	0.7834 (0.1054)	
ICER (£ / QALY)[c]			-1100 (-85991 to 95546)
Month 6	-	-	-7997 (-238341 to 172319)
Month 12	-	-	

[a] Adjusted for baseline resource use.
[b] Adjusted for baseline EQ5D.
[c] Incremental cost-effectiveness ratio (pound sterling/quality adjusted life-year).