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Screening for at-risk alcohol consumption in primary care: a randomised evaluation of screening approaches.

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Running Head: Screening for at-risk alcohol consumption in primary care

**Keywords:** Alcohol screening, brief intervention, primary care, randomised, targeted screening, universal screening.

Trial registration: Current Controlled Trials ISRCTN06145674.

#### Abstract

**Aims:** The aim of the study was to explore the relative efficiency and effectiveness of targeted versus universal screening for at-risk alcohol use in a primary care population in the United Kingdom.

**Methods:** The study was a randomised evaluation of screening approach (targeted versus universal) for consecutive attendees at primary care aged 18 years or more. Targeted screening involved screening any patient attending with one of the targeted presentations, conditions associated with excessive alcohol consumption: mental health, gastro-intestinal, hypertension, minor injuries or a new patient registration. In the universal arm of the study all presentations in the recruitment period were included. Universal sceening included all patients presenting to allocated practices.

**Results:** A total of 3562 potential participants were approached. The odds ratio of being screen positive was higher for the targeted group versus the universal group. Yet the vast majority of those screening positive in the universal group of the study would have been missed by a targeted approach. A combination of age and gender was a more efficient approach than targeting by clinical condition or context.

**Conclusions:** While screening targeted by age and gender is more efficient than universal screening, targeting by clinical condition or presentation is not. Further universal screening is more effective in identifying the full range of patients who could benefit from brief alcohol interventions, and would therefore have greater public health impact.

# Background

Reducing alcohol-related morbidity and mortality is a key priority for health services worldwide. Internationally alcohol consumption accounts for 3.8% of all avoidable deaths and 4.6% of disability adjusted life years (DALY). This figure is higher in developed countries such as the UK, where alcohol is the third largest risk factor, accounting for 9.2% of DALY's (Global Burden of Disease Study, 2015). In the UK, it is estimated that 24% of of the adult population, aged 16 or more, are at-risk drinkers (33% of men and 16% of women)(HSCIC, 2009). Yet 98% of these are not identified at the time of presentation in primary care (Anderson et al., 2016) (Brown et al., 2016) (Cheeta et al., 2008) (Kaner et al., 1999). This is despite the fact that 90% of patient contact with the health service occurs in the primary care setting.

There is considerable evidence of the benefits of screening and brief intervention for at-risk alcohol users in primary care, aimed at reducing consumption and subsequent alcohol-related harm (Moyer et al., 2002) (Bertholet et al., 2005; Kaner et al., 2007a; Whitlock et al., 2002). There is also evidence that paper based screening tests, such as the Alcohol Use Disorders Identification Test (AUDIT; (Saunders et al., 1993)), are more effective than biochemical markers of excessive alcohol use (Coulton et al., 2006). In addition, shorter screening tools such as the Fast Alcohol Screening Test (FAST; (Hodgson et al., 2002)) and Single Alcohol Screening Question (SASQ; (Canagasaby and Vinson, 2005)) also demonstrate excellent diagnostic properties when compared with AUDIT. Despite this, screening is rarely conducted in practice (Brown et al., 2016) (Kaner, 2010), and the efficiency and acceptability of screening for alcohol use in primary care has been questioned (Beich et al., 2002; Beich et al., 2003).

Where screening does take place concern has been expressed regarding the relative value of screening all attendees in primary care, universal screening, as opposed to those attending with a higher likelihood of alcohol-related problems, targeted screening (Prime Minister's Strategy Unit, 2004). Yet targeted as opposed to universal screening approaches have not been formally evaluated in terms of their efficiency or effectiveness. Moreover, while a number of key health conditions are known to be associated with excessive alcohol consumption based on attributable risk fractions (Anderson and Baumberg, 2006; Rehm et al., 2009), these conditions are far less prevalent in primary care settings than inpatient settings. In addition, while the prevalence of excessive alcohol use is known to vary by age and gender, the potential of these demographic indicators as targets for screening activity has not been formally evaluated.

In order to address these gaps in the evidence, we evaluated targeted versus universal screening approaches as part of a large multi-centre cluster randomised controlled trial of screening and brief interventions in primary care in the United Kingdom, the SIPS Primary Healthcare trial (SIPS-PHC) (Kaner et al., 2013a; Kaner et al., 2009).

# Methods/Design

The reported study was planned as one element of a cluster randomized trial of opportunistic screening and brief interventions for alcohol use in primary care settings in the United Kingdom (Kaner et al., 2009). The results of the brief intervention aspect of the trial are reported elsewhere (Kaner et al., 2013b).

Initially, a questionnaire survey was undertaken to ascertain suitable targets for

screening in primary care. Doctors and nurses in participating practices were invited to take part in the survey. The survey aimed to ascertain practitioner preferences regarding appropriate clinical targets for alcohol screening. Based on a review of the literature participants were asked whether they considered key clinical conditions or key contexts as the appropriate target for screening. Additionally, practitioners were asked on a scale from 1 to 5, where 1 indicated 'extremely important' and 5 'not at all important', the relative importance of a number of key conditions and key contexts. Respondents were provided with an opportunity to add any key conditions or contexts they felt had not been identified by the literature review.

The evaluation of screening approach incorporated cluster randomisation of practices, to avoid the risk of bias through contamination. Practices were allocated at random to either targeted or universal screening, and screening using one of two screening tools, FAST (Hodgson et al., 2002) or the SASQ (Canagasaby and Vinson, 2005). Random allocation was stratified by geographical area, North versus South, ensuring a similar number of practices in each geographical area. Each screening approach, targeted or universal, employed both of the screening tools. The outcome was scoring positive for at-risk alcohol consumption on the allocated screening tool.

#### Settings

Twenty-nine general practices across London, South East and North East England participated in the study between May 2008 and July 2009. All participating practices delivered a full range of medical services across a range of urban and rural, socially deprived and affluent communities. At the time of the study none of the participating practices routinely screened patients for alcohol use.

#### Randomisation

Randomisation was conducted independent of the research team, after practices had been recruited and consented to participate. An additional five stand-by practices were later randomly allocated due to insufficient recruitment in the initial practices.

# Inclusion and exclusion criteria

We included patients who were: alert and orientated, aged 18 or over, resident within 20 miles of the practice, and able to understand English sufficiently to complete study questionnaires. In the targeted group only those who presented with one of the targeted conditions were included. We excluded patients already involved in an alcohol research study or who were specifically seeking help for alcohol problems. Patients who were severely injured or unwell, grossly intoxicated or who had no fixed abode were also excluded.

### Consent

Primary care staff initially established verbal consent to check eligibility for the study. At this stage, they collected basic demographic information and screened the patient, recording the presenting condition. Full ethical approval was provided by the NHS MREC (06/MREC02/90) and governance approval was granted by all participating Primary Care Trusts.

### Outcome tools

FAST (Hodgson et al., 2002) is a four item alcohol screening test derived from the AUDIT (Saunders et al., 1993). It is designed for use in a busy clinical settings, as the majority of respondents are identified as positive on the first question. This asks about the frequency of heavy episodic alcohol use in a similar manner to item 3 of AUDIT. If a respondent answers monthly or less the remaining three questions are assessed, corresponding to items 8, 9 and 10 of the AUDIT. A score of 3 or more is considered positive for at-risk alcohol consumption.

SASQ (Canagasaby and Vinson, 2005) was validated in the United States and is similar to question 1 of FAST and item 3 of AUDIT. A response of 'daily or almost daily', 'weekly' or 'monthly' is a positive screen. We modified the original SASQ to reflect UK definitions of heavy episodic alcohol use; 8 or more standard drinks for men and 6 for women in a single drinking episode. A standard drink contains 8g of ethanol. We use the acronym M-SASQ to reflect this modification.

### Analysis

We compiled and analysed the results of the study using STATA v14.

Initially we calculated the mean ranking of key conditions and contexts in the practice staff survey. The five highest ranked conditions or contexts were selected as the main targets in the targeted group of the study.

We used logistic regression to estimate the odds ratio of positive screens in the universal and targeted groups of the study. We incorporated screening instrument into the analysis to explore for any potential interaction between screening tool and screening approach. As the study was clustered, with patients nested within practices, we adjusted our analysis using the Huber-White Sandwich Estimator to provide robust standard errors associated with our odds ratio and 95% confidence intervals.

In order to explore the efficiency of targeted screening, we established whether participants in the universal group had presented with one of the conditions or contexts associated with the targeted group. Two independent clinical experts assessed and categorised the reason for presentation, independently resolving any divergence through consensus.

To assess the potential role of age and gender as targets for screening we conducted an exploratory analysis using patients in the universal arm of the study.

#### Results

Responses were received from 90 (83%) of those clinical staff surveyed. At least one response was received from each of the participating practices. The majority of respondents expressed a preference for targeted rather than universal screening (67.8% vs 14.4%), and targeting using key conditions rather than contexts (54.4% vs 24.4%). In terms of key conditions, the highest mean rating was for gastrointestinal and mental health conditions, with hypertension and minor injuries considered moderately important. In terms of key contexts new patient registrations were rated higher than any other. Ratings for key conditions and contexts are presented in Table 1. When asked if any other conditions or contexts were considered important,

respondents replied with a varied selection including blood tests, obesity, medical certificates and exercise referrals.

The targeted group of the study approached all participants who attended with any one of the five most important conditions or contexts: mental health problems, gastrointestinal problems, hypertension, minor injuries and new patient registrations.

Overall 3562 potential participants were approached and 3021 (85%) were deemed to be eligible and consented to be screened. Of whom, 908 (30%) scored positive for at-risk alcohol consumption using one of the screening tools. Those in the targeted group were slightly younger (48.8 vs 51.8 years), more likely to be male (56.3% vs 41.5%) and more likely to smoke (26.7% vs 22.7%) compared with the universal group (Table 2).

The prevalence of at-risk alcohol consumption was significantly higher in the targeted group (36.2%) than the universal group (25.6%). The odds ratio of at-risk consumption was significantly higher for the targeted group versus the universal group (1.65; 95% CI 1.41 to 1.93) (table 3). This was not influenced by the tool used for screening.

In the targeted group, the most commonly used targets for screening were hypertension (633; 49.5%) and new patient registrations (275; 21.5%) (Table 3). Out of the five targets, four had significantly higher odds ratio of a positive screen than universal screening; mental health conditions, gastrointestinal problems, hypertension and minor injuries. When we selected out of the universal group those presentations which would have fallen into one of the targeted conditions, no targeted condition is significantly associated with screening positive for at-risk drinking. In the universal group of the study the most common presentations were hypertension (142; 8.2%) and mental health conditions (95; 5.4%). Overall, 1388 (79.7%) of participants did not fall into any of the targeted screening conditions or contexts. This accounted for 81% of those who screened positive for at-risk alcohol consumption in the universal group.

The impact of age and gender as predictors of excessive alcohol consumption were explored using the universal arm of the study alone. The youngest age-group, 18 – 24 years had the highest prevalence of at-risk alcohol consumption and the oldest, 65 years or more, the lowest (41.1% vs 12.8%). Yet at the same time, they represented the smallest proportion of attendees (8.8%). The 18-24 year age group had a significantly higher odds ratio compared with the rest of the population of screening positive (2.18; 95% CI 1.55 to 3.08). More marked differences were apparent when gender was taken into consideration with males significantly more likely to screen positive than females (2.54; 95% CI 2.04 to 3.16), and this was particularly apparent in the 18-24 (3.95; 95% CI 2.38 to 6.56), 45-54 (1.83; 95% CI 1.19 to 2.81) and 55-64 (2.38; 95% CI 1.29 to 4.41) age groups. Screening all attendees aged 18 to 34 years, and all older age males would involve screening 57% of attendees. This would yield 78% of all positive screens, a more efficient approach than targeting by clinical condition or context, but this approach still missed 22% of screen positives.

# Discussion

The study aimed to address two important questions regarding screening (or case identification) for at-risk alcohol consumption in primary care settings. The first concerned the efficiency and effectiveness of targeted as opposed to universal screening. The design of the study was pragmatic and targets for screening were selected by experts from the existing literature. Then those involved in the actual screening used their own clinical judgement and experience to derive the five most important conditions, or contexts for screening. The results indicate that in terms of efficiency, targeted screening overall yields a higher prevalence of at-risk alcohol users than universal screening, and the probability of consuming alcohol at at-risk levels in the targeted group was significantly higher than the universal group.

Yet in terms of effectiveness, targeted screening is less effective at identifying those who may benefit from intervention, as 81% of those who screened positive in the universal group would have been missed by applying the targeted criteria. When we consider that the effectiveness of screening and brief interventions for alcohol use in primary care, in terms of the numbers needed to treat (NNT), is of the order of 7 - 9 (Fleming et al., 2002; Kaner et al., 2007b; Ockene et al., 1999) and that this compares favourably with the NNT for other medical conditions managed in primary care such as, the use of statins to prevent cardiovascular mortality (NNT 30 – 90) (SIGN, 2000), and interventions for smoking cessation (NNT 20) (Stead et al., 2008). Universal screening is likely to be the more effective screening approach in primary care and should mirror the universal screening for smoking every 27 months in the Quality and Outcomes Framework for General Practice (NHS, 2012).

The second question addresses whether other demographic factors, age and gender, may be more appropriate targets for screening activity than clinical presentations. The results tend to suggest that those attendees aged 18-35 years and males aged over 35 are significantly more likely to be at-risk alcohol users. Targeting by age and gender is more efficient than targeting by clinical condition or context, but this still misses almost a quarter of those who may benefit from intervention.

The strengths of the study are that it was a large-scale cluster randomised evaluation that embedded screening into ordinary clinical practice. The study used established, valid and reliable screening tools. Rates of eligibility and consent to be screened were higher than in most similar studies and the sample is similar to the population routinely attending primary care in the UK.

Limitations in the study can be considered from two perspectives. We used a small number of targeted conditions and contexts, to maximise the acceptability of targeted screening. This may have excluded some appropriate targets. Yet we based this on existing evidence and the clinical experience of those working in primary care settings. Further, our analysis of the universal arm of the study did not identify any additional potential targets that had an odds ratio significantly better than universal screening alone. Increasing the number of targets may increase the coverage of the primary care population, but as the number of targets increase the approach becomes more complex to implement and starts to emulate universal screening. In terms of the relevance of the findings, we need to consider the results of this study alongside those of the larger trial exploring the effectiveness of brief interventions (Kaner et al., 2013b). The results of this study do not provide compelling evidence of any increased benefit of more intensive interventions compared with screening and feedback alone. In addition, there is some evidence of the potential benefit of opportunistic screening alone in reducing alcohol consumption (Jenkins et al., 2008; McCambridge and Day, 2007). It may be the case, particularly for those who consume alcohol at the lower end of the alcohol use spectrum, that screening with an appropriate tool and feedback of the screening results may have beneficial effects. In addition, this would be more acceptable to primary care practitioners, who have expressed concern over the additional burden of implementing alcohol screening and brief intervention (Aalto et al., 2003; Hutchings et al., 2006).

In order to maximise the impact of alcohol screening and brief intervention in public health the results of this study point to universal screening being significantly more effective than targeted screening in primary care, akin to recommendations in dental care (Roked et al., 2014). This has important implications for policy and practice. The evidence presented here provides further scientific foundation for the National Institute for Health and Clinical Evidence guidance for alcohol screening (National Institute for Health and Clinical Excellence (NICE), 2009). This guidance recommends that where feasible and practical NHS professionals should routinely carry out alcohol screening as an integral part of clinical practice.

### **Competing Interests**

All authors have completed the Unified Competing Interest form at <u>www.icmje.org/coi\_disclosure.pdf</u> (available on request from the corresponding author) and declare: all authors had financial support from the Department of Health in England (Alcohol Policy Unit) for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous 3 years; no other relationships or activities that could appear to have influenced the submitted work.

# Authors' contributions

This paper is published on behalf of the SIPS programme research group. A full list of the research group members is available at <a href="http://sips.iop.kcl.ac.uk/contactus.php">http://sips.iop.kcl.ac.uk/contactus.php</a>. The study was funded by the Department of Health. The views expressed herein do not necessarily reflect those of the Department of Health or the National Health Service in England and Wales. All of the authors contributed to the design and development of this trial protocol. CD was chief investigator and EK deputy chief investigator. Expertise on clinical aspects of the research was provided by TP, CD and EG. SC, VD, SP, CG took responsibility for the screening aspects of the study and provided statistical and methodological input for the study. Trial conduct and delivery expertise was provided by PD, DNB, RP and KP. Brief intervention expertise was provided by CD, EK, and JS. SC wrote the first draft of the paper and all authors contributed to successive drafts. All authors read and approved the final manuscript.

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	n	Mean rating (SD)
<b>Conditions</b> Mental Health Gastrointestinal Hypertension Minor injuries	86 84 82 85	1.60 (1.08) 1.94 (1.08) 2.17 (0.95) 2.38 (1.01)
Contexts New patients Chronic disease review Sexual health Smoking cessation	85 83 81 83	1.69 (1.07) 2.22 (1.01) 2.35 (1.17) 2.41 (1.06)

 Table 1: Mean (SD) clinician ratings for key conditions and contexts for targeted screening.

	Targeted (n = 1280)	Universal (n = 1741)	Overall (n=3021)
Mean age in years (SD)	48.9 (17.7)	51.8 (18.4)	50.1 (18.0)
<b>Age group n (%)</b> 18 – 24 25 – 34 35 – 44 45 – 54 55 – 64 65+	100 (7.8) 193 (15.1) 166 (13.0) 206 (16.1) 244 (19.2) 368 (28.8)	141 (8.8) 289 (16.8) 287 (16.7) 317 (18.3) 311 (18.1) 367 (21.3)	251 (8.4) 482 (16.1) 453 (15.1) 523 (17.4) 555 (18.5) 735 (24.5)
Males n (%)	720 (56.3)	722 (41.6)	1442 (47.8)
White n (%)	1058 (82.7)	1401 (80.8)	2459 (81.6)
Smoker n (%)	342 (26.7)	392 (22.6)	734 (24.3)
Single n (%)	301 (23.6)	478 (27.7)	779 (26.0)
Presentation n (%)			
Mental Health Gastrointestinal Hypertension Minor injuries New patients Other Not specified	167 (13.0) 124 (9.7) 623 (48.7) 75 (5.9) 273 (21.3) 0 18 (1.4)	95 (5.5) 73 (4.2) 142 (8.2) 23 (1.3) 20 (1.1) 1388 (79.7) 0	262 (8.7) 197 (6.5) 765 (25.3) 98 (3.2) 293 (9.7) 1388 (45.9) 18 (0.7)
Screen positive n (%)	463 (36.2)	445 (25.6)	908 (30.1)
Weekly episodic use n (%)	382 (30.1)	352 (20.6)	734 (24.7)

Table 2: Demographics and reasons for attendance overall and by allocated group for those consenting to screen.

Table 3: Odds ratio and 95% confidence intervals for screen positive in
targeted group, overall and by presentation, compared to universal group.

	Screened n (%)	Positive n (%)	OR versus universal (95% CI)	p-value
Targeted Overall	1280	463 (36.2)	1.650 (1.411; 1.931)	<0.001
Targeted Presentation Mental Health Gastrointestinal Hypertension Minor Injuries New Patient Universal Overall Universal Presentation Mental Health Gastrointestinal Hypertension Minor injuries New patient No target	169 (13.2) 126 (9.8) 633 (49.5) 77 (6.0) 275 (21.5) 1741 95 (5.4) 73 (4.3) 142 (8.2) 23 (1.3) 20 (1.1) 1388 (79.7)	86 (50.9) 44 (34.9) 208 (32.8) 30 (40.0) 85 (30.9) 445 (25.6) 23 (24.2) 20 (27.4) 32 (22.5) 4 (17.4) 7 (35.0) 359 (24.1)	3.092 (2.241; 4.267) 1.602 (1.092; 2.350) 1.460 (1.197; 1.780) 1.942 (1.208; 3.120) 1.317 (0.997; 1.739) - 0.927 (0.572; 1.501) 1.104 (0.652; 1.868) 0.835 (0.555; 1.258) 0.610 (0.206; 1.802) 1.577 (0.625;	<0.001 0.02 <0.001 0.05 - 0.76 0.71 0.39 0.37 0.33 -
			3.979)	

	Screened n (%)	Positive n (%)	OR (95% CI)	p-value
Age group 18-24 25-34 35-44 45-54	151 (8.8) 289 (16.8) 287 (16.7) 317 (18 4)	62 (41.1) 99 (34.3) 77 (26.8) 86 (27 1)	2.183 (1.548; 3.080)ª 1.656 (1.262; 2 172)ª	<0.001 <0.001 0.622 0.510
55-64 65 or more	311 (18.1) 367 (21.3)	71 (22.8) 47 (12.8)	1.075 (0.807; 1.432) <sup>a</sup> 1.097 (0.833; 1.445) <sup>a</sup>	0.206 <0.001
Male	722 (41.6)	260 (36.0)	0.829 (0.620; 1.108) <sup>a</sup> 0.357 (0.257; 0.495) <sup>a</sup> 2.539 (2.036; 3.165) <sup>b</sup>	<0.001

Table 4: Odds ratio and 95% confidence intervals for screen positive by age and gender in the universal screen group.

<sup>a</sup> Compared to all other age groups <sup>b</sup> Compared to females