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

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Kaner E., Bland M., Cassidy P. et al. BMJ: 2013, 346, e8501.

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The primary care arm of the largest alcohol screening and brief intervention study yet conducted in Britain found that the proportion of risky drinkers fell just as much after the most minimal of screening and intervention methods as after more sophisticated and longer (but still brief) alternatives.

**Summary** The SIPS project embraces three trials of brief interventions in different settings in England. This account focuses on the primary care trial; see these Findings analyses for the studies in emergency departments and probation offices.

First this account describes the common features of the three SIPS trials, based primarily on formal accounts of their methodology (1 2 3). Then results from primary care are described drawing almost entirely on the featured report and the relevant methodology report, but also occasionally on preliminary findings released by the SIPS project on its web site in the form of factsheets and conference presentations rather than peerreviewed articles in academic journals. At the time of writing, the same sorts of documents are the primary sources for findings from the other two settings referred to in the **FINDINGS** commentary to set the primary care findings in context. Later more scientifically formal accounts of these findings will be incorporated as they emerge, so the detailed findings and perhaps too the conclusions are subject to change.

#### **Common features of the SIPS trials**

The project was funded by the UK Department of Health in 2006 to evaluate the

effectiveness and cost effectiveness of different ways of identifying risky drinkers through routine screening, and different forms of brief advice to help them cut back. Another aim was to assess the feasibility of implementing such procedures in typical practice settings. The rationale for the study rests on the observation that in Britain, hazardous and harmful drinkers outnumber dependent drinkers 7:1, and the implication that the greatest population-wide impact on alcohol-related problems can be made by identifying and intervening with these drinkers, even before they are aware of any problems or seek help.

Conducted in three English regions (London; South East; North East), the project took the form of three trials in nine emergency departments, 29 general practices, and 20 probation offices. All three involved random allocation of practices, departments or offender managers to different variants of screening and intervention. Staff seeing adult patients or offenders for usual purposes in these settings asked them to consent to screening and basic data collection. Those who screened positive were then asked to join the study of the interventions, usually delivered by the same staff after training by the study. To assess changes in their drinking and related issues, patients and offenders who were eligible for and agreed to participate in the intervention study were followed up six and 12 months later.

#### Screening methods

Three quick ways to identify hazardous or harmful drinkers were tested for feasibility and accuracy, the latter defined by how well they duplicated corresponding results from the **AUDIT screening questionnaire**, widely used to determine whether someone is probably drinking at hazardous, harmful or possibly dependent levels. This assesses both alcohol intake and indicators of alcohol-related problems.

Single question The simplest and quickest method was to ask, "How often do you have eight (or for women, six) or more standard drinks on one occasion?" Monthly or more was considered a positive screen, meaning the respondent would be offered a brief intervention to help them cut back.

FAST Alcohol Screening Test As used in the study, this begins with the question above and registers a positive screen if the response is weekly or more often. Otherwise three further questions are asked. Scores in response to the four questions are summed to determine whether to proceed with intervention.

Paddington Alcohol Test (PAT) Used only in the emergency department study.

#### Interventions and assessing their impacts

Patients identified as risky drinkers by these methods were all offered advice of some kind, so the study could not assess whether advice was better than doing nothing, only how the impacts of one sort differed from those of another. The main yardsticks were the proportions of patients who six and 12 months later did not score as hazardous (or worse) drinkers on the AUDIT questionnaire. Other assessments included drink-related problems, quality of life, and use of services. Crime and health service costs before the study and over the 12-month follow-up were used to assess cost effectiveness in terms of gains in quality-adjusted years of life per £ change in total costs to society.

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All patients and offenders in the intervention trial were given a standard alcohol information and advice booklet, supplemented by a sticker with contact information for local treatment services. At issue was whether also offering different types and degrees of advice would make a difference to later drinking.

Brief feedback At its most basic, the booklet was accompanied only by very brief feedback from the practitioner who did the screening that this had indicated the patient or offender was drinking "above safe levels, which may be harmful to you". Brief advice The next level supplemented booklet and feedback with five minutes of advice closely related to the booklet. This was based on a leaflet which the worker left with the drinker after working through it with them according to a pre-set protocol, including comparing their drinking with typical drinking levels across the population. Though not always the case, ideally this would be seamlessly delivered by the person who did the screening and handed over the booklet.

Brief lifestyle counselling The longest of the interventions added what was intended to be about 20 minutes of lifestyle counselling to the brief advice described above. This too was based on a leaflet, but practitioners could adapt the intervention to the needs of the drinkers and their willingness to think about further controlling their drinking. Staff were trained to use techniques from motivational interviewing and health behaviour change counselling to lead the drinker to consider the pros and cons of their drinking and their readiness to cut down, before (if appropriate) formulating a plan for doing so and overcoming possible obstacles. This counselling was done at an appointment made after the brief advice phase of the intervention.

#### The primary care study

Generally the first point of contact with health services, primary care seems an ideal screening/brief intervention venue. One in five primary care patients drink at hazardous or harmful levels, and studies have found brief interventions there reduce drinking by 4–5 standard drinks per week.

Additional to the common objectives of the SIPS trials, the primary care study tested its two screening methods in a 'universal' form, which involved asking all eligible adult patients about their drinking, and also in a 'targeted' form, which posed these screening questions only to those newly registering with the practice or whose complaints suggested excessive drinking – a strategy which might make screening more acceptable to both staff and patients, and therefore more widely implemented. Also, after screening the most extended intervention was to be delivered by specially trained practice staff rather than (as in the other settings) by specialist alcohol workers recruited for the trial.

As per the study's design, 24 GP practices joined the study evenly divided between the North East and combined London/South East regions. They were randomly allocated so that within each region, one practice was allocated to each of the possible 12 combinations of the two screening strategies, two screening methods, and three brief interventions. But patient recruitment was slow and nine of the 24 practices did not reach the target of 31 patients, so five standby practice were activated. Also, five practices which had already completed their targeted recruitment agreed to be randomly reallocated to a more intensive intervention. This meant that 34 unique combinations of practices were

financially compensated for the time spent on research procedures and for each patient screened and advised or counselled about their drinking, with a greater payment for the more extended counselling. Remuneration levels were in line with those expected if alcohol screening and brief intervention were among national quality criteria for general practice.

## Main findings

Over 15 months, 3562 patients were approached for the study of whom 2991 were eligible to be screened. Of these, 900 (3 in 10) screened positive and 756 agreed to join the intervention study. Typically married white men, they averaged 45 years of age and an AUDIT score of 12.7, a medium severity of drinking problems, though around a quarter scored in the more severe range and nearly a fifth did not score as hazardous or harmful drinkers at all. Around 80% were followed up six and 12 months later.

Positive screen patients were then allocated to different forms of intervention. Virtually all allocated to brief feedback or advice received this plus the alcohol advice booklet, the full intended interventions. This was not the case for those allocated to lifestyle counselling; though nearly all received the five-minute brief advice and booklet delivered immediately after screening, only 57% attended a later appointment for more extended counselling.

Six and 12 months later the proportions of patients scoring as at least hazardous drinkers on the AUDIT questionnaire (initially around 80%) had fallen overall by 13% and 18% respectively, but neither on this measure nor on all the other major yardsticks of patient drinking and welfare (average AUDIT scores, health-related quality of life, and alcoholrelated problems) had there been significantly greater changes after one type of intervention than another. At 12 months the reductions in the proportions of AUDITpositive patients were 19% and 15% after the two briefest options and only slightly more – 21% – among patients allocated to counselling. At both follow-up points the 'no difference' finding remained when only those patients who actually received their allocated intervention were included. Neither could it be shown that one intervention was better than another for particularly heavy drinkers. Nor as measured by the AUDIT was a particular combination of screening method or approach and intervention significantly more effective than any other.

On one measure there was however a statistically significant extra improvement among patients allocated to counselling – the proportions who said they were at least trying to cut their drinking. Among patients just given the booklet and a very brief warning this barely changed over the course of the study, hovering around 30%, but among counselling patients it increased from 28% at baseline to 45% and then 48% six and 12 months later. Looking back 12 months later, counselling patients too were on average slightly but significantly more appreciative than leaflet/warning patients of the quality of the communication and the general manner of the interventions they had experienced.

#### The authors' conclusions

The featured study strongly suggests that screening followed by simple feedback and written information may be the most appropriate strategy to reduce hazardous and harmful drinking in primary care. No significant differences between the brief interventions were found for alcohol-related problems or health-related quality of life.

This study therefore does not support the additional delivery of five minutes of brief advice or 20 minutes of brief lifestyle counselling over and above feedback on screening plus a patient information booklet.

Strengths of the study include a high follow-up rate and the fact that practices offering the less intensive interventions had no training in the more intensive alternatives, preventing them using this training to elaborate on the more basic interventions. However, consultations between patient and doctor were not monitored to check whether the interventions were delivered as intended.

Though this seems unlikely, one possibility which (without a no-intervention control group) cannot be eliminated is that reduced drinking after all three interventions was not due to those interventions at all, but simply reflected the fact that relatively atypical behaviour tends to shift over time to more typical behaviour. Instead it is likely that the cumulative impact of screening, assessment, simple feedback, and the delivery of written information overwhelmed the additional elements in the more extended interventions.

High levels of consent to this trial and the high rates of screening and immediate delivery of brief intervention indicate that routinely-presenting patients in primary care are willing to receive feedback, written information, and advice about their drinking. In addition, the high levels of patient satisfaction after brief intervention support the acceptability of this type of input. However, many patients did not come back for brief lifestyle counselling, suggesting that brief intervention should if possible be delivered directly after screening.

Nevertheless, in patients who did return there were significant positive changes in motivation to reduce drinking and in patient satisfaction. While most hazardous and harmful drinkers in primary care require minimal input after screening, some may value and benefit from additional support. Hence a 'stepped care' approach might be helpful; the least intensive (and less costly) intervention used with most risky drinking patients, while further intervention is reserved for patients who do not respond or ask for more support.

**FINDINGS** The following commentary first summarises key features of the **featured** study, before setting these in context by exploring common themes across all three settings. Finally, policy implications are explored. These comments are expanded on in the background notes, which also offer further citations and information.

#### The featured study – primary care

Taking in all information available to date including preliminary reports, it seems that given financial incentives, training and specialist support, most primary health care practices can implement alcohol screening and brief intervention, but in the circumstances at least of a research trial, they screen and intervene with few of their patients. Least well implemented was the lifestyle counselling intervention, which required appointments to be made and kept, rather than seamless delivery of briefer interventions during the patient's initial attendance.

In terms of screening, FAST proved best at identifying risky drinkers. When it came to how to respond to these risky drinkers, anticipated extra benefits from the longer and more sophisticated, theory-based interventions did not materialise, even for heavier

drinkers.

It might be thought this was due to fewer patients actually going through the lifestyle counselling intervention, but findings were unchanged when the analysis was limited to patients who *had* undergone their allocated intervention – remarkable, because in this analysis not only did counselling have the intended advantage of time and its supposed active psychological ingredients, it also had the presumed advantage of being tested only on patients concerned and diligent enough to return for counselling. This seems to dash hopes that if only the counselling could have been delivered straight after screening to nearly all the patients, it would have proved the most effective intervention.

Instead the featured report argues that the study "strongly suggests" that the least intensive intervention is the best way to reduce hazardous and harmful drinking in primary care. But as the authors acknowledged, this was a suggestion the study was not set up to test because it did not feature a no-intervention or usual-care control group. Given (> below) how much control groups improve in brief intervention studies, it seems possible that doing nothing other than screening and usual care would have equalled the most effective of the interventions in the featured report, undermining the argument that at least the study showed the interventions were better than no intervention.

#### Primary care in the context of trials in emergency and probation departments

Across the three settings, the general picture from preliminary reports is that implementation often required specialist support, there were no great differences between how well the screening methods identified patients, and no significant differences between how well the interventions helped them reduce the severity of their drinking. Brief feedback, consisting of an unadorned warning plus information booklet, intended as a 'control' condition against which scientifically developed and longer interventions could shine, turned out instead to be the better option, reaping what clinical benefits there were at the lowest direct cost in money and time.

#### Implementation often needs specialist support; throughput low

To maximise real-world applicability, in each setting usual staff were meant to undertake screening and intervention, except for lifestyle counselling, which in probation and emergency departments was delegated to a specialist alcohol worker, how such programmes would probably be implemented in routine practice. However, usual staff also undertook the research tasks involved in recruiting patients to the trial and collecting baseline information, an extra burden which may have suppressed the numbers screened and offered intervention.

Broadly, each study found that while implementing the programmes was possible, at many sites researchers and specialist alcohol workers who had trained the staff had to help with screening and intervention. Workload pressures, lack of knowledge, and feeling there were insufficient back-up alcohol services, were common themes. In emergency departments and in probation, inability to implement was the norm. Incentivised with per patient payments, most primary care practices managed to implement fully. However, even there numbers screened seem to have been small, equivalent to less than two per GP practice per week. Emergency departments screened about 12 per department a week; each probation office averaged one or two a fortnight.

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These findings cast doubt over the potential for screening and intervention in these settings to make a significant contribution to public health; numbers reached may simply be too low. Reinforcing this doubt was uncertainty over resultant impacts on those who were screened and advised (> below).

Of the settings commonly associated with brief interventions, primary care has the greatest potential to reach the greatest numbers, partly because of its coverage, and partly because there is a national requirement and framework for paying practices to undertake this work. Decisively influenced by financial incentives, Scotland's national brief intervention programme was overwhelmingly implemented in primary care rather than other settings. In England the national requirement to offer surgeries screening and intervention contracts has generated more activity, but implementation has been patchy, and the quality and even the reality of the services has been questioned.

## FAST screening edges it

Screening results from the trials have been amalgamated in conference presentations (1).

Of the three methods, **FAST** had the broadest applicability, in all three settings virtually equalling or bettering the alternatives in terms of its ability to identify risky drinkers. Generally only the first (about frequency of excessive drinking) of the four questions had to be asked, and the test picked up 8 in 10 of the risky drinkers who would have been picked up by the longer AUDIT questionnaire.

Whether screening is best implemented universally or targeted at certain patients or appointments was answered in favour of universal screening, if the yardstick was identifying the greatest number of risky drinkers while not missing out people (around 4 in 10 were missed) who would have screened positive. On the assumption that a universal strategy truly would be universally implemented, not missing risky drinkers may be the decisive consideration. But if targeted screening – favoured by primary care staff – encourages more complete implementation, the balance could shift in its favour.

## Minimal or extended advice - it doesn't matter because each is equally (in?) effective

The final link examined by the studies was how best to advise risky drinkers identified through screening.

There was a remarkable uniformity in trends in drinking among risky drinkers who agreed to join the intervention studies. Six months later the proportions still scoring as risky drinkers had fallen by 11–13%, 12 months later, by 16–18%. With one minor and possibly chance exception, on this primary yardstick an alcohol advice booklet plus a few sentences of feedback alerting someone to their risky drinking was not improved on by adding more extended and individualised interventions.

As the researchers acknowledged, this does not mean the interventions were equally effective; they may have been equally *in*effective. Without a no-intervention comparator, there is no way of knowing whether the interventions played any hand in the outcomes. Even before the interventions, 15–20% of emergency patients and a quarter in primary care said they were trying to reduce their drinking. Reinforcing doubts over the impact of the interventions is the general finding (1 2) that many control groups in alcohol brief

intervention studies who received no or minimal intervention on average reduced their drinking by amounts equal to or greater than AUDIT score reductions in the SIPS trials.

Set against this is the overall **positive record** of brief interventions in previous primary care trials. However, this record left considerable doubt over whether such reductions (internationally and in Britain in particular) would survive once intervention was 'scaled up' to practices in general, and applied by the general run of doctors to the general run of patients.

Neither can it be said that screening plus booklet and a few sentences of feedback is all it takes to get whatever benefits are available. These came after patients and offenders had been quizzed about their drinking and related problems and their readiness to do something about these – possibly thought-provoking interventions in themselves – and whether brief feedback really was as terse as intended is unknown.

#### Cost may be decisive

The clearest difference between the interventions was in cost, likely to be persuasive given equivocal or no evidence that spending more gained more. Not only did the briefest intervention directly cost least, but on the health service's primary yardstick – quality-adjusted life years – in both probation and primary care, it gained most years for each £ of social costs incurred by the drinkers. Only in emergency departments did the longest intervention have the edge, but this was minimal, and may have been partly due to these patients starting the study with the lowest quality of life of the three intervention groups and catching up somewhat in a natural levelling up.

### **Policy implications**

The 2012 English alcohol strategy said government was awaiting the results of the SIPS project before deciding whether to incorporate alcohol screening and brief intervention in to the national quality framework for primary care, a major national driver of practice. The strategy also encouraged accident and emergency departments and hospitals in general to check for and offer brief advice about hazardous drinking.

In general, all areas covered by the strategy are expected to implement national guidance and standards (1 2 3 4) which insist that health service staff must be given time and resources to carry out screening and brief intervention. This seems a tall order given the consistent appeal in the SIPS studies to workload pressures as a reason for incomplete implementation, and the need for specialist support.

The guidelines' preferences for targeted screening may also need to be re-evaluated, though SIPS' findings on this issue are probably not definitive enough to override the greater feasibility of targeting due both to workload pressures and staff preferences. It seems questionable too whether the precision of the 10-item AUDIT screening questionnaire is sufficient to warrant the guidelines' preference for this as a first-line option or triaging tool.

Where guidance is clearly at odds with the findings is in its backing for the equivalent of the mid-level intervention, brief advice, and, subject to local conditions, the most extended option – motivationally based counselling – for heavier but probably still non-dependent drinkers. For reasons outlined above, the message taken from the studies that

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only the very briefest contact is needed may be misleading because even in this option, much more was (and yet more may have been) done with the patients. But with no convincing reason to spend more money and time, it is easy to imagine that hard-pressed staff and austerity-hit commissioners will do the least seemingly justified by studies on which the government itself said it would rely for its policy decisions.

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