

## Implementation strategies to enhance management of heavy alcohol consumption in primary health care: A meta-analysis

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## **Declarations of interest**

Myrna Keurhorst declares that she has no competing interests

Irene van de Glind declares that she has no competing interests

Michaela Bitarello do Amaral-Sabadini declares that she has no competing interests

Peter Anderson declares that he has no competing interests

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Dorothy Newbury-Birch declares that she has no competing interests

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## **Abstract**

**Aims** Screening and brief interventions (SBI) delivered in primary health care (PHC) are cost-effective in decreasing alcohol consumption; however, they are underused. This study aims to identify implementation strategies that focus on SBI uptake and measure impact on: 1) heavy drinking; and 2) delivery of SBI in PHC.

**Methods** Meta-analysis was conducted of controlled trials of SBI implementation strategies in PHC to reduce heavy drinking. Key outcomes included alcohol consumption, screening, brief interventions and costs in PHC. Predictor measures concerned single versus multiple strategies, type of strategy, duration and physician-only input versus that including mid-level professionals. Standardised mean differences (SMD) were calculated to indicate the impact of implementation strategies on key outcomes. Effect sizes were aggregated using meta-regression models.

**Results** The 29 included studies were of moderate methodological quality. Strategies had no overall impact on patients' reported alcohol consumption (SMD 0.07;95%-CI -0.02–0.16), despite improving screening (SMD 0.53;95%-CI 0.28–0.78) and brief intervention delivery (SMD 0.64;95%-CI 0.27–1.02). Multifaceted strategies, i.e. professional and/or organisational and/or patient oriented strategies, seemed to have strongest effects on patients' alcohol consumption ( $p<0.05$ , compared to professional oriented strategies alone). Regarding SBI delivery, combining professional with patient oriented implementation strategies had the highest impact ( $p<0.05$ ). Involving other staff besides physicians was beneficial for screening ( $p<0.05$ ).

**Conclusions** Strategies should include a combination of patient, professional and organisational oriented implementation approaches and involvement of mid-level professions as well as physicians. Evidence for a new and innovative combination of multiple implementation approaches to increase alcohol focused SBI uptake in PHC, is required.

## Introduction

Worldwide, heavy alcohol consumption is a leading cause of ill-health and premature death (1). World Health Organization (WHO) recommends that health professionals provide alcohol screening, brief interventions, counselling and, when necessary, pharmacotherapy for heavy drinkers (2). There is a wealth of evidence in primary health care (PHC) for the effectiveness of alcohol screening and brief interventions (SBI) in adults (3-6). Previous research demonstrates that SBI is effective in various groups, either for identification of risky drinking, alcohol use disorders, excluding addicted patients, and for those who are not seeking treatment for alcohol-related problems (6-9). Brief interventions to reduce heavy drinking are cost-effective and could be widely available in PHC (3). However, SBI is underused with less than 10% of those who might benefit from SBI, receiving a brief intervention (10). Large-scale studies that have attempted to increase the uptake of brief interventions have shown that implementing brief interventions in PHC remains difficult (11-13).

Studies that address the issue of integrating evidence into practice are referred to as 'implementation research' (14). Changing provider behaviour and implementing new programs or innovations into practice could be achieved by various implementation strategies, as shown in the broader implementation literature (15-17). Promisingly, an increasing number of implementation studies are being conducted in the field of PHC-based alcohol prevention. In the last decade, three reviews have summarised the evidence to enhance the implementation of SBI in PHC (18-20). These reviews found that the effectiveness of multi-component implementation programmes on SBI delivery showed the most promising results (20). Effectiveness of implementation strategies on SBI delivery generally increased with the intensity of the intervention effort (19). Furthermore, it is suggested that nurses and other mid-level professionals, besides physicians, can enhance the uptake of SBI in PHC (21-23).

However, current literature provides little practical guidance on how to improve implementation. The impact of SBI on patients' alcohol consumption has been studied in many trials (e.g. (11, 24, 25)), but earlier systematic reviews did not provide practical guidance in how to increase SBI uptake in practice (4, 6, 7, 26). More insight is needed on how the uptake of SBI in PHC practice can be increased to contribute to health benefits. Therefore, the current review aims to identify effective SBI implementation strategies that 1) reduce heavy drinking and 2) increase SBI delivered in PHC. The review will also ask if involving nurses and other professionals has a positive impact in improving SBI delivery and decreasing patient alcohol consumption.

## **Methods**

This review is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) standards (27). The review protocol is available from [http://www.odhinproject.eu/resources/documents/cat\\_view/3-odhin-project-documents/6-technical-reports-and-deliverables.html](http://www.odhinproject.eu/resources/documents/cat_view/3-odhin-project-documents/6-technical-reports-and-deliverables.html).

We followed the Cochrane Effective Practice and Organisation of Care (EPOC) criteria, which define implementation strategies as “interventions designed to improve professional practice and the delivery of effective health services”. EPOC offers guidance on conducting reviews of interventions that improve professional practice and delivery of effective health services. To connect this study to broader implementation research, we used the EPOC search strategy, the EPOC template for data extraction, and the EPOC taxonomy to categorise implementation strategies, and their checklist for quality appraisal (28).

### **Data sources and searches**

The following computerised databases were searched since onset until May 2013: MEDLINE, EMBASE, Cinahl and Cochrane Central Register of Controlled Trials (CENTRAL). The search strategy is listed in Appendix 1. In addition, reference lists of relevant review articles and books were screened, and global experts in the field were contacted in order to identify grey literature and recent published studies not yet indexed.

### **Study selection**

Two reviewers (MK and ML) independently screened relevant titles and abstracts. Full text copies of potentially relevant studies were then obtained and independently screened for inclusion by the same two reviewers. Disagreements between the reviewers were resolved through discussion, or a third reviewer was contacted to make the final decision (PA or IVDG).

In order to be included, a study had to meet the following PICO criteria (27): first, it had to be focused on a PHC setting; second, it had to include implementation strategies that were compared with a control group (usually defined as care as usual); third, it had to address decreasing heavy alcohol consumption, and/or cost outcomes, and/or increasing screening, and/or increasing brief interventions, but not alcohol dependence as defined by WHO (29)

and the ICD-10 Classification of Mental and Behavioural Disorders (30); and, fourth, it had to be a controlled trial with an English or Dutch language full text copy available.

Effectiveness studies, e.g. examining the effectiveness of a 5-minute brief intervention compared to a 15-minute brief intervention, were excluded as they did not evaluate implementation strategies as defined by EPOC.

### **Data extraction and quality assessment**

Data for each included study were extracted on: participants, setting, methods, SBI procedures, method of strategy, outcomes (alcohol consumption, screening, brief intervention, costs) and methodological quality. Implementation strategies were first classified into one of the following categories of the EPOC taxonomy: professional, financial, organisational, structural and regulatory interventions (<http://epoc.cochrane.org/epoc-taxonomy>); and, second, implementation strategies were classified into the EPOC elements, such as audit and feedback within professional oriented strategies (28). Two reviewers in different combinations (MK, MBAS, DNB, EK, PA, ML, JB, and IVDG) independently extracted the data. Any disagreement was resolved by discussion or by asking a third reviewer (from the review team) when consensus was not reached between the two reviewers.

Methodological quality of each paper was assessed by both reviewers using the EPOC checklist for quality criteria (28). Quality assessment was based on concealment of allocation, presence of professionals' behaviour or patient outcomes (alcohol consumption), follow-up, blinded assessment of primary outcome, baseline measurement of primary outcome, reliable (objective) primary outcome measures and protection against contamination. Any disagreement on fulfilling the criteria was resolved by discussion. Inclusion of studies was not influenced by methodological quality.

### **Data synthesis and analysis**

All study outcomes were categorised by alcohol consumption, screening and/or brief interventions or costs, and type of implementation strategy.

Methods described by the Cochrane Collaboration were followed (31).

First, to identify effects of implementation strategies on the key outcomes, included studies were pooled with MetaEasy version 1.0.4 (32). Standardised mean differences (SMD) were calculated, both for dichotomous and continuous outcomes. Due to heterogeneity of included studies, we estimated effect sizes using a random-effects model based on DerSimonian and Laird's (DL) approach (33).

Second, effect sizes of predictor measures, such as single versus multiple strategies, were calculated by meta-regression analyses. One advantage of such an approach is that, in case of no overall statistical effect being found from pooled studies, the regression allows distinction between effective and ineffective predictor measures. The predictor measures comprised 1) use of a single implementation strategy versus the use of multiple implementation strategies; 2) the type of implementation strategy as categorised by EPOC taxonomy (28), e.g. professional oriented strategies, such as audit and feedback, or organisational oriented strategies, such as task substitution; 3) whether or not the programme included multiple elements within their implementation strategy; 4) study duration  $\leq 12$  months versus study duration  $>12$  months; and, 5) whether the implementation strategies were focused on physician-only or those including nurses and other mid-level professionals. As instructed for fixed-effects meta-regression, we used weighted least squares regression, weighted by the inverse of the variance to identify relationships between predictors in explaining effect sizes (34). A random-effects meta-regression was attempted, but did not converge. The cause of non-convergence was that the random effects of the predictors involved could not be estimated (probably because the number of studies was not sufficient to distinguish predictor random effects different from 0). Meta-regression was applied with use of SPSS version 20 [IBM SPSS Statistics, USA].

## **Results**

### **Search results**

Our literature search identified 4,594 citations, of which 3,968 unique titles and abstracts were screened (figure 1). The full paper sift included 211 papers. Included in this were eight published papers that were identified by manual review of the reference lists of the studies and consultation of global experts. In the second sift, reasons for exclusion were design failures (n=83), setting failures (n=42), not being focused on implementation (n=24) and not including alcohol consumption or SBI outcomes (n=29). Thirty-five papers, reporting on 29 studies were included in the final analysis.

[INSERT FIGURE 1 ABOUT HERE]

### **Methodological quality**

All included studies were randomised controlled trials (RCT) (86%) or controlled clinical trials (CCT) (14%) (table 1). Concealment of allocation was not reported in eight studies (28%) and was not clear in seven studies (24%). In eight studies (28%), substantial differences across study groups were found, or no baseline measurements of primary outcomes were reported. Protection against contamination was not addressed in eleven studies (38%) and not clear in five studies (17%).

[INSERT TABLE 1 ABOUT HERE]

### **Study characteristics**

Most studies were carried out in the United States, followed by Australia/New Zealand, Europe, and Canada (table 2). Participating professionals were physicians (16 studies), or physicians in combination with other primary care staff such as nurses (5 studies), nurse practitioners (2 studies), physician assistants (1 study), practice assistants (1 study) or other health professionals (1 study). In the remaining studies the profession of participating professionals was not reported. In over a half of studies (55%), the age of the patient groups ranged between 30-69 years. Other patient characteristics were not reported.

The included studies varied in applied implementation strategies and elements (table 1). The majority of studies (n=11) applied solely professional oriented implementation strategies (25, 35-44). Most common elements were educational meetings (n=6), educational outreach visits (n=5) and audit and feedback (n=4). Three studies reported only organisational oriented strategies in which two applied a change in the scope and nature of benefits and services (45, 46), and one applied a change in the service delivery due to counselling by phone (47). One further study reported a patient oriented strategy, which consisted of printed educational materials for patients (48). In addition, six studies reported a combination of professional oriented and organisational oriented implementation strategies, in which in all educational meetings were applied, combined with either changes in medical record systems, formal integration of services or skill mix changes (49-54). Eight studies reported various combinations of professional oriented, organisational oriented, patient oriented and financial oriented strategies (11, 23, 24, 55-59).

Nineteen studies reported patient alcohol consumption outcomes (11, 23, 24, 35, 38, 43-45, 47, 48, 50-53, 55-59). Studies reported one or more professional-related outcomes, that is: screening rate (n=12) (11, 25, 35-37, 39-42, 46, 49, 54) and brief intervention (BI) rate



(n=13) (11, 23, 25, 37-43, 46, 49, 50). Only two studies reported outcomes related to costs or cost-effectiveness (table 3) (40, 41).

[INSERT TABLE 2 ABOUT HERE]

[INSERT TABLE 3 ABOUT HERE]

### **Elements of effective implementation strategies**

Twenty-six studies were pooled and 24 studies were included in the meta-regression.

#### *Effects on alcohol consumption*

Of the 19 studies reporting on alcohol consumption, 15 were pooled for an overall effect size (11, 23, 24, 44, 45, 47, 48, 50-53, 56-59). Due to substantial heterogeneity ( $I^2=86\%$ ), we applied a random effects model. The random effects model showed no statistically significant effect of the pooled estimate of implementation strategies on alcohol consumption (SMD DL model -0.02; 95%-CI -0.17 – 0.14) (figure 2). One study, Kypri et al 2004 (59) identified very strong opposite effects in a negative direction, meaning increased alcohol consumption, which was different to most other included studies. This could be due to the unique outcome measure used in the study (alcohol consumption in the last two weeks), whereas the rest of the studies reported on changes in drinking classification, AUDIT screening test scores, or mean weekly alcohol consumption, which are more representative measures. Using a post-hoc analysis without Kypri et al 2004 resulted in decreased heterogeneity ( $I^2=56\%$ ). Still, no significant difference in pooled effect was found, compared to control groups (SMD DL model 0.07; 95%-CI -0.02 – 0.16) (figure 2). However, the remaining heterogeneity can be primarily explained by the type of implementation strategy, as presented from the meta-regression results in table 4 (omitting Kypri et al 2004). Table 4 shows that combinations of professional, organisational and patient oriented strategies were significantly more effective at decreasing patients' alcohol consumption than solely professional oriented implementation strategies (table 4).

[INSERT FIGURE 2 ABOUT HERE]

[INSERT TABLE 4 ABOUT HERE]

### *Effects on SBI*

Of the twelve studies with outcomes on screening, ten provided sufficient data for pooling (11, 25, 35-37, 39, 42, 46, 49, 54). Due to high heterogeneity ( $I^2=94\%$ ), we applied a random effects model (figure 3). Pooling showed that the implementation strategies increased screening delivery (SMD DL model 0.53; 95%-CI 0.28–0.78). Wilson et al (1992) (46) showed the least positive effect and Adams et al (49) the strongest positive effect. Studies with significant effects included both physicians other health professionals (such as nurses) in screening for alcohol consumption more so than studies with little effect.

The meta-regression analysis (table 5) showed that multiple types of implementation strategies (e.g. professional combined with organisational oriented implementation strategies) were more effective in changing screening behaviour compared to a single implementation strategy (e.g. only a professional oriented implementation strategy). Furthermore, we found that combining professional and patient oriented strategies was more effective than only professional oriented strategies. Lastly, involving nurses and other mid-level professionals as well as physicians in implementation strategies, showed statistically significant higher effects than focusing on physicians only.

[INSERT FIGURE 3 ABOUT HERE]

[INSERT TABLE 5 ABOUT HERE]

With regard to the 13 studies that reported process outcomes on brief interventions, outcomes of nine studies were pooled (11, 25, 37, 41-43, 46, 49, 50). These studies showed high heterogeneity ( $I^2=97\%$ ). Ferrer et al (2009) (50) was the only study in which patients had the opportunity to choose which lifestyle topic to tackle (alcohol, smoking, physical activity or diet). The majority of patients preferred to discuss lifestyle factors other than alcohol. This approach was judged to be substantially different from the other studies. Therefore this study was not included in the analysis and forest plot (figure 4). The forest plot shows that the implementation strategies resulted in increased brief intervention delivery (SMD DL model 0.64; 95%-CI 0.27 – 1.02).

The meta-regression analyses showed that multiple inclusion of implementation strategies was more effective than single types (table 6). Furthermore, the combination of professional and patient oriented implementation strategies, multiple component strategies and study duration of twelve months or more were of added value.

[INSERT FIGURE 4 ABOUT HERE]

[INSERT TABLE 6 ABOUT HERE]

## **Discussion**

This study aimed to identify implementation strategies that focused on increasing SBI uptake with an impact on patient alcohol consumption and/or either SBI delivery in PHC. The predictor measures comprised: 1) use of a single implementation strategy versus the use of multiple implementation strategies; 2) the type of implementation strategy as categorised by EPOC taxonomy (28), e.g. professional oriented strategies such as audit and feedback, or organisational oriented strategies such as task substitution; 3) whether or not the programme included multiple elements within their implementation strategy; 4) study duration  $\leq$  12 months versus study duration  $>$ 12 months; and 5) whether the implementation strategies were focused on physicians or on nurses and other mid-level professionals as well.

From the meta-analysis, it can be concluded that with all implementation strategies pooled, there was a lack of statistically significant impact on patients' self-reported alcohol consumption, although professional SBI behaviour improved. However, those specific studies that combined two of the professional, patient and organisational implementation strategies were significantly more effective in reducing alcohol consumption than solely professional oriented implementation strategies. This shows that it does matter which implementation strategy is selected. Regarding screening, combining professional with patient oriented strategies and involving primary health care staff besides physicians (e.g. nurses as well as physicians), led to increased activity. In terms of brief intervention delivery, implementation strategies had more effect when multiple components of different implementation strategies were applied, for example combining educational outreach visits (professional oriented) with patient self-management education materials (patient oriented).

In line with the wider alcohol-related literature, our study confirms that multi-component programs seemed to be the most promising implementation strategies (20). Our study added to this finding by identifying specific predictor variables for successfully changing provider SBI activity or patients' alcohol consumption behaviour, such as effectiveness of combining professional and patient oriented strategies. Similar to Nilsen et al

(19) and Williams et al (18), this present study showed that the implementation strategy effectiveness generally increased with the intensity of the implementation effort, a finding different from general implementation research (60). We have added to this general finding by identifying elements that made the implementation strategies more effective, such as combining professional, patient and organisational implementation strategies.

Furthermore, the present study demonstrates that, in order to increase screening behaviour, involving nurses and other mid-level professionals is more effective than focusing only on physicians delivering the screening, which is in line with other studies in PHC (21, 22, 61).

. Whereas reviews (3-7) find significant reductions in alcohol consumption from implemented SBI, this positive effect was not found in our meta-analyses, which focused on strategies to increase SBI uptake and not on SBI effectiveness itself (62). We found that multiple implementation approaches have a significant impact in increasing SBI delivery, but not on reducing patient alcohol consumption. The marginal benefits of additional services provided through multiple implementation approaches are low. Therefore, new and innovative combinations of multiple implementation approaches are required to increase SBI uptake in primary health care. It is possible that the delivered brief interventions might have been suboptimal in the included studies, resulting in less reduction in patients' alcohol consumption as potentially could be achieved (63). Low fidelity in delivering lifestyle-changing interventions have been reported in several other studies (61, 64, 65). However, we were not able to correct for this assumption as included studies did not report on fidelity of the intervention. Finally, another reason for failing to find effects of implementation strategies on alcohol consumption is that studies may have lacked sufficient power to detect significant differences; we found that half of the included studies did not report on or achieve sufficient power.

A strength of our study includes the categorisation of interventions defined by the EPOC taxonomy (28). There are alternatives to the EPOC taxonomy including the Behaviour Change Wheel, Leeman Taxonomy and behaviour change techniques (66); however, they are all based on the EPOC taxonomy (67).

Another strength of our study is that it is the first systematic review that included a meta-regression analysis regarding implementation strategy outcomes on subsequent patient alcohol consumption. Nevertheless, the meta-analysis should be interpreted with caution as the standardised mean differences cannot give quantitative outcomes that could be easily

translated into daily practice. Moreover, the studies included in this review often did not report sufficient details (on cost outcomes, on implementation strategies, on fidelity, on power calculations). We were unable to draw firm conclusions regarding the cost-effectiveness of different strategies – thus, we propose the need for more health economic research. Similarly, implementation strategies were often poorly described in most of the included papers, a common finding in implementation trials (68), making it hard for reviewers to clearly identify and characterise effective elements of strategies. Finally, several sources of variation may have impacted on patient-level outcomes, such as different populations from different countries, variables that we were not able to include in the meta-regression. All studies with outcomes on patient alcohol consumption were pooled and showed no effect. It is important to bear in mind that this does not imply that implementation strategies cannot change alcohol consumption; rather, it suggests that it is important to purposefully select implementation strategies, as they may differ in effectiveness. For instance, combining patient and professional oriented strategies appears to be more effective compared to a professional oriented single strategy. Due to a lack of studies with common elements within the main categories of EPOC and a high heterogeneity of implementation strategies, we could only draw conclusions based on the main categories of EPOC's taxonomy of interventions (professional, organisational and patient oriented implementation strategies). Pooling of implementation strategy elements would have provided more precise information.

In conclusion, in order to increase SBI delivery and decrease patients' alcohol consumption, this study has shown that implementation should ideally include a combination of patient, professional and organisational oriented implementation strategies and involvement of other staff working with physicians. To explain the lack of effect on alcohol consumption when SBI delivery was increased, the fidelity of SBI delivery to detect effects in patient's alcohol consumption should be investigated. Furthermore, evidence for new and innovative combinations of multiple implementation approaches to increase alcohol focused SBI uptake in PHC, is required.

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## **Legends for Figures**

Figure 1: Flow chart of study selection

Figure 2: Random effects meta-analysis of studies with alcohol consumption outcomes\*

\* Excluding Kypri et al, 2004

Figure 3: Random effects meta-analysis of studies with screening outcomes

Figure 4: Random effects meta-analysis of studies with brief intervention outcomes\*

\* Excluding Ferrer et al, 2009

## Tables

**Table 1 Quality scores of included studies, based on Cochrane Effective Practice and Organisation of Care checklist**

Author year	Power calculation reported and sufficient	Unit of Allocation is unit of analysis or statistical correction for clustering	Concealment of allocation	Follow-up of professionals/ patients achieved	Blinded assessment of primary outcome(s)	Baseline measurement of primary outcome(s)	Reliable primary outcome measures	Protection against contamination
Adams 1998	Not done	Done	Not clear	Not clear	Done	Not clear	Not clear	Not clear
Beurden van 2012	Not clear	Done	Done	Not done	Done	Done	Not done	Done
Bonevski 1999	Done	Done	Done	Done	Not done	Done	Not done	Done
Borgiel 1999	Done	Not clear	Done	Done	Not done	Done	Not done	Not done
Bradley 2002	Not done	Not done	Not clear	Not done	Done	Not done	Not clear	Done
Brown 2007	Done	Not done	Done	Done	Done	Done	Not clear	Not done
Butler 2003	Not done	Not done	Not done	Not clear	Not done	Done	Not done	Done
Chossis 2007	Not clear	Done	Done	Done	Not done	Done	Not done	Not clear
Drevenhorn 2012	Done	Not done	Not done	Prof: not done ; patients: done	Not clear	Not done	Not clear	Not done
Ferrer 2009	Not done	Done	Done	Done	Not done	Not done	Done	Not done
Fink 2005	Not done	Done	Not clear	Done	Not done	Done	Done	Not clear
Friedmann 2006	Not done	Done	Not clear	Not clear	Not clear	Not clear	Not clear	Not done
Funk 2005	Done	Done	Done	Done	Not clear	Not done	Done	Done
Helzer 2008	Not done	Done	Not clear	Done	Not done	Done	Not clear	Not done

Kaner 2003	Done	Not done	Not done	Not done	Not done	Not done	Not clear	Done
Kypri 2004	Done	Done	Done	Done	Not done	Done	Done	Done
Kypri 2005	Done	Done	Done	Done	Done	Not clear	Done	Done
Kypri 2008	Not done (sample size not achieved)	Done	Done	Done	Not done	Not clear	Not done	Not clear
Lockyer 1996	Not done	Done	Done	Done	Not done	Done	Not done	Not done
Oslin 2003	Not done	Done	Done	Done	Not clear	Done	Not clear	Done
Oslin 2006	Not done	Done	Not clear	Done	Done	Done	Done	Not clear
Reiff- Hekking 2005	Done	Done	Not done	Done	Not done	Not clear	Not done	Done
Rodney 1985	Not done	Done	Not done	Not clear	Not done	Not done	Not clear	Not done
Rose 2008	Not done	Done	Not clear	Not clear	Not done	Done	Not done	Done
Saitz 2003	Done	Done	Done	Done	Not done	Done	Not clear	Done
Vinson 2000	Not done	Done	Not done	Done	Not done	Done	Not done	Done
Wang 2010	Not done (sample size not achieved)	Done	Done	Not done	done	Not done	Not done	Not done
Williams 201	Not done	Not done	Not done	Done	Not clear	Not done	Done	Not done
Wilson 1992	Not done	Not done	Not done	Not done	Done	Done	Done	Not done

**Table 2 Characteristics of included studies**

Study, year (ref)	Design, study duration	Setting (country; setting; type of health care professionals)	Participants	Implementation strategy (IS) vs Control	Outcome type*: Effect Size (95%-CI)#;
<i>Professional oriented implementation strategies</i>					
Bonevski 1999 (35)	RCT, study duration assumed to be 5 months	- Australia - Primary health care practice - GPs	General practitioners N=19 Patients N=575 (Group 1 N=154; Group 2 N=143; Group 3 N=138; Group 4 N=140)	<u>IS</u> : Computerised feedback about: guidelines and consensus standards of care, individual goals, calculated performance rates. Practitioner feedback about patients' smoking status, benzodiazepine use, blood pressure screening, cholesterol screening, and the delivery of programme elements (Audit and feedback) <sup>a</sup> <u>Control</u> : Usual care	Screening: z=2.3079 (p<0,02)
Borgiel et al 1999 (36)	RCT, study duration 2 years	- Canada - Primary health care practice - Physicians	Family physicians N=56 (Intervention group N=29; Control group N=27)	<u>IS</u> : Practice assessment report, continuing Medical Education with additional plan and follow-up visit by mentors (Audit and feedback; educational meeting; educational outreach visits) <sup>b</sup> <u>Control</u> : Usual care	Screening: NR (p>0.05)
Bradley et al 2002 (37)	CCT, study duration 6 months	- United States - Primary health care practice - Resident or fellow MD, Faculty/staff MD, family nurse practitioner	General internal medicine clinic N=17(6 resident or fellow MDs; 6 faculty/staff MDs; 5 family nurse practitioners); Patients N=47 (Intervention group N=17; Control group N=30)	<u>IS</u> : Educational meeting; feedback report (Audit and feedback; educational meeting) <sup>b</sup> <u>Control</u> : Professional oriented: Single educational meeting	Screening: NR (p<0.005) BI: NR (p=0.035)
Chossis et al 2007 (38)	RCT, study duration assumed to be 9 months	- Switzerland - Outpatient clinic (i.e. ambulatory care provided by specialists/hospitals) - GPs	Primary care residents N=26 (Intervention group N=13; Control group N=13)	<u>IS</u> : Two educational meetings on an interactive Brief Alcohol Intervention, with theory, role-play exercises, checklists, and a textbook. Educational materials for professionals handing out to the patient (Educational meetings; educational materials) <sup>b</sup> <u>Control</u> : Professional oriented: Lipid management workshop, including alcohol use	BI: NR (p>0.05) Alcohol consumption: NR (p>0.05)
Friedmann et	RCT, study	- United States	Physicians N=18	<u>IS</u> : Three educational meetings (initial training about the care	Screening: OR

Study, year (ref)	Design, study duration	Setting (country; setting; type of health care professionals)	Participants	Implementation strategy (IS) vs Control	Outcome type*: Effect Size (95%-CI) <sup>#</sup> ;
al 2006 (39)	duration 2 years	<ul style="list-style-type: none"> <li>- Primary health care practice</li> <li>- GPs (15 physicians and 3 mid-level clinicians)</li> </ul>	(Intervention group N= 12; Control group N=6)	model, a luncheon 6 weeks later, a booster training session 6 months later. Educational materials clipped to the charts of eligible patients (Educational meetings; reminders) <sup>b</sup> <u>Control</u> : Usual care	2.8 (1.3 – 5.8) BI: OR -0.15 (-0.26 – -0.06)
Funk et al 2005 (40) (including secondary studies (69-71)	RCT, study duration unknown, implementation period of 12 weeks	<ul style="list-style-type: none"> <li>- Australia, New Zealand, England, Belgium, Catalonia, Denmark;</li> <li>- Primary health care practice;</li> <li>- GPs</li> </ul>	General practitioners N=727 (Intervention group 1 N=255; Intervention group 2 N=263; Control group N=209)	Two <u>IS</u> 's. <u>IS 1</u> : Outreach training session relating to a brief intervention programme (Educational outreach visits) <u>IS 2</u> : Outreach training session relating to a brief intervention programme and ongoing support and advice regarding programme implementation issues through biweekly telephone calls (England) and/or practice visits (Australia) (Educational outreach visits) <sup>a</sup> <u>Control</u> : Usual care	Screening: NR (p<0.005) BI: NR (p<0.001) cost-effectiveness <sup>¥</sup>
Kaner 2003 (41)	RCT, study duration 3 months	<ul style="list-style-type: none"> <li>- United Kingdom;</li> <li>- Primary health care practice;</li> <li>- Nurses</li> </ul>	Practices N=128. (Intervention group 1 N=50; Intervention group 2 N=48; Control group N=30). N participating nurses unclear.	Two <u>IS</u> 's. <u>IS 1</u> : Educational outreach visits about the programme, SBI procedures and practical problems (Educational outreach visits) <u>IS 2</u> : Same educational outreach visits as above + two-weekly telephone calls for support and advice (Educational outreach visits) <sup>a</sup> <u>Control</u> : Professional oriented: written implementation guidelines	Screening: NR (p=0.0025) BI: p=0.025 costs; cost-effectiveness <sup>¥</sup>
Lockyer et al 1996 (42)	RCT, study duration assumed to be 4 months	<ul style="list-style-type: none"> <li>- Canada;</li> <li>- Primary health care practice;</li> <li>- Family physicians and general practitioners</li> </ul>	Family physicians and general practitioners N=54 (Intervention group N=26; Control group N=28)	2 intervention groups. Group 1: family physicians; Group 2: general practitioners. <u>IS</u> : Educational program: one day education including visits to five local treatment facilities and their therapeutic programs; and three evening sessions (Educational meetings; educational outreach visits) <sup>b</sup> <u>Control</u> : Assumed to be usual care.	Screening: F [2,49]=4,82 (p<0.033) BI: F [2,49]=16,69 (p<0.001)



Study, year (ref)	Design, study duration	Setting (country; setting; type of health care professionals)	Participants	Implementation strategy (IS) vs Control	Outcome type*: Effect Size (95%-CI)#;
Rose et al 2008 (25)	RCT, study duration 2 years	- United States; - Primary health care practice; - Assumed to be GPs	22 practice units (Intervention group N=11; Control group N=11). N individual professionals not clear	<u>IS</u> : Written materials, on site academic detailing, performance feedback through practice reports, network meetings (Distribution of educational materials; educational outreach visits; audit and feedback; educational meetings) <sup>b</sup> <u>Control</u> : Professional oriented: written materials.	Screening: OR 8.1 (1.7-38.2) BI: OR 5.5 (1.3-23.3)
Saitz et al 2003 (43)	RCT, study duration 1,5 years	- United States; - Primary health care practice; - GPs	Faculty and resident primary care physicians N=41 (Intervention group N=20; Control group N=21) Patients N=312 (Intervention group N=168; Control group N=144)	<u>IS</u> : Feedback patients' alcohol screening results to physicians with recommendations (Patient mediated interventions) <sup>a</sup> <u>Control</u> : Usual care	BI: NR Alcohol consumption: NR
Williams et al 2010 (44)	RCT, study duration 3 years	- United States; - Outpatient clinic; - Physicians, residents, nurse practitioners physician assistants	Physicians, residents, nurse practitioners, and physician assistants (N= not clear) Patients N = 1,358 (Intervention group N=692; Control group N=666)	<u>IS</u> : Reminder for primary care provider after patients' positive alcohol screen; e-mail alerts to professionals (Reminders) <sup>a</sup> <u>Control</u> : Assumed to be usual care	Alcohol consumption: NR (p0.25)
<i>Organisational oriented implementation strategies</i>					
Brown et al 2007 (47)	RCT, study duration 12 months	- United States; - Primary health care practice; - Counsellors. Type of health care professionals not reported	Patients N= 897. Sub set of n=472 patients with alcohol abuse (Intervention group n=231; Control group: n=241)	<u>IS</u> : Delivery of counseling via telephone and mail (Changes to the setting/ service delivery) <sup>a</sup> <u>Control</u> : Usual care	Alcohol consumption: NR (p>0.05)

Study, year (ref)	Design, study duration	Setting (country; setting; type of health care professionals)	Participants	Implementation strategy (IS) vs Control	Outcome type*: Effect Size (95%-CI)#;
Vinson et al 2000 (45)	RCT, study duration 12 months	- United States; - Primary health care practice; - GPs	Patients N=80 (N participants per group not reported)	<u>IS</u> : Computer-Generated Written Behavioural Contracts. Physician reviewed the contract briefly with the patient, signed it, and encourage compliance with its terms (Changes in scope and nature of benefits and services) <sup>a</sup> <u>Control</u> : Usual care	Alcohol consumption: 0.34 (p>0.05)
Wilson et al 1992 (46)	CCT, study duration not clear	- United Kingdom; - Primary health care practice; - GPs	Physicians N=16. Allocation at the level of days/sessions (N sessions Intervention group N=1,411; Control group 1 N=1,478; Control group 2 N= 1,432)	<u>IS</u> : Expanding consultation time from on average 7.5 minutes to 10 minutes per patient. <u>Control group 1</u> : matched for time of day and day of the week, drawn from the period before the trial (Changes in scope and nature of benefits and services) <u>Control group 2</u> : matched for time of day and day of the week, during the trial phase, in the alternate weeks when an experimental session was not scheduled (Changes in scope and nature of benefits and services) <sup>a</sup>	Screening: 1-NR (p<0.05) 2-NR (p>0.05) BI: 1:NR (p<0.001) 2:NR (p<0.01)
<i>Patient oriented implementation strategies</i>					
Wang et al 2010 (48)	RCT, study duration 1 month	- United States; - Emergency department setting	Patients N=252 (Intervention group N=95; Control group N=93)	<u>IS</u> : Subjects in the intervention group were given a brochure titled, "Alcohol, How Much is Too Much?" (Printed educational materials for patients) <sup>a</sup> <u>Control</u> : Assumed to be usual care	Alcohol consumption: NR (p=0.95)
<i>Professional and organisational oriented implementation strategies</i>					
Adams et al 1998 (49)	RCT, study duration 32 months	- Assumed to be in United States; - Primary health care practice; - Physicians, nurses	Physicians N=21; Resident N=1 resident; Nurse practitioners N=7; Patients N=344 (Intervention group N=200; Control group N=144)	<u>IS</u> : Educational meetings: Training in motivational interviewing and topics about alcohol (2,5 hours). + intervention algorithm (Educational meetings; changes in medical record system) <sup>b</sup> <u>Control</u> : Usual care	Screening: NR (p<0.001) BI: NR (p<0.001)
Ferrer 2009 (50)	RCT, study duration median time = 360 days (range 159-565;	- United States; - Primary health care practice;	GPs (N unclear); Medical Assistants (N=100); Patients N=864 (Intervention group N=437)	<u>IS</u> : Professional role revision: assessments and referrals were performed by medical assistants; Educational meetings: three training sessions about how to assess, inform, encourage and refer patients (Educational meetings; Skill mix changes) <sup>b</sup>	BI: NA alcohol consumption: NR (p>0.05)

Study, year (ref)	Design, study duration	Setting (country; setting; type of health care professionals)	Participants	Implementation strategy (IS) vs Control	Outcome type*: Effect Size (95%-CI)#;
Oslin et al 2003 (52)	10th percentile 215; 90th percentile 441) RCT, study duration 24 weeks	- GPs and medical assistants - United States; - General practice/ primary health care clinic/ family practice - Clinicians	of which N=57 drinking; Control group N=427 of which N=67 drinking) Clinicians from different primary care settings N=37; patients N=97 (Intervention group; N=46 control group N=51)	<u>Control</u> : Usual care  <u>IS</u> : Patient Telephone disease management by a behavioural health specialist + educating professionals (Skill mix changes; educational meetings) <sup>b</sup> <u>Control</u> : Usual care	Alcohol consumption: OR=0.28 (p=0.142)
Oslin et al 2006 (51)	RCT, study duration 9 months	- United States; - Primary health care practice; and Community based care/ community health centres	Patients N=560 (Intervention group 1 N= 227; Intervention group 2 N= 239; no control group)	Two <u>IS</u> 's, no control group. <u>IS1</u> . Integrated care model: participants receive mental health or substance abuse services in the primary care clinic from a mental health or substance abuse provider + education (Educational meetings) <u>IS2</u> . Enhanced specialty referral model includes referral from primary care and provides mental health or substance abuse services in a specialty mental health or substance abuse clinic (Educational meetings; formal integration of services) <sup>b</sup>	Alcohol consumption: MD -0.1 (-2.5– 2.2; p=0.913)
Reiff-Hekking 2005 (53) (including secondary study (72))	RCT, study duration 3 years	- United States; - Ambulatory primary health care setting; - Physicians; nurses	Physicians N=38; Nurses N=8; Patients N=530 (Intervention group N=248; Control group N=233)	<u>IS</u> : Training; Individual tutorial (including education materials); role-play; office support system (lifestyle interview summary sheet; intervention algorithm) (Educational meetings; educational materials; changes in medical record system) <sup>b</sup> <u>Control</u> : Professional oriented: Encouraged to identify and intervene with patients with alcohol related issues; Encouraged to attend weekly conference series	Alcohol consumption: NR (p=0.03)
Rodney et al 1985 (54)	CCT, study duration 5 years	- United States; - Primary health care practice; - Physicians, Nurses,	Physicians N= assumed to be 22 residents (medicine) and 32 family physicians; Nurses N=2; Psychologist N=1; licensed clinical social worker N=1;	<u>IS</u> : Education, educational materials + reminders (face sheet on record) (Educational meetings; educational materials; reminders; changes in medical record systems) <sup>b</sup> <u>Control</u> : Professional and organisational oriented: year 1-3: similar intervention group. Year 4-5: chart review sessions in which residents reviewed three to five of their records during	Screening: NR (p>0.05)

Study, year (ref)	Design, study duration	Setting (country; setting; type of health care professionals)	Participants	Implementation strategy (IS) vs Control	Outcome type*: Effect Size (95%-CI)#;
		Psychologist, social worker, dietician	dietician N=1; Patients N=390 (Intervention group N=114; Control group N=110)	July, November and April	
<i>Professional and patient oriented Implementation strategies</i>					
Drevenhorn 2012 (23) (secondary study included (73))	RCT, study duration 2 years	- Sweden; - ? - Nurses	Nurses N=33 (intervention group N=19; Control group N=14). Patients N=213 (Intervention group N=153; Control group N=60)	<u>IS</u> : educational outreach visits, with education in stages of change, Motivational Interviewing and applying guidelines for cardiovascular prevention, lifestyle factors and pharmacological treatment. Distribution of educational materials for nurses. Educational materials for patient to support patients' self-management (Educational outreach visits; Distribution of educational materials; Patient self-management education materials) <sup>b</sup> <u>Control</u> : Usual care	BI: NR Alcohol consumption: NR
Fink et al 2005 (57)	RCT, study duration 2,5 years	- United States; - Primary health care practice; - Physicians	Physicians (N= not clear) and patients N=665 (Intervention group 1 N=245; Intervention group 2 N=198; Control group N=222)	Two <u>IS</u> 's. <u>IS1</u> : Combined report, in which physicians and patients received reports of patients' drinking classifications and patients also received education (Patient mediated interventions; patient feedback; patient education); <u>IS2</u> : Patient report, in which patients received reports and education, but their physicians did not receive reports (patient feedback; patient education) <sup>b</sup> <u>Control</u> : Usual care	Alcohol consumption: NR (1;p<0.05, 2;p>0.05)
<i>Organisational and patient oriented implementation strategies</i>					
Kypri et al 2004 (59)	RCT, study duration 6 months	- New Zealand; - Community based care/ community health centres	Patients N=104 (Intervention N=42; Control N=41)	<u>IS</u> : Web-based screening and brief intervention including patient feedback (changes to the setting/ site of service delivery; patient feedback) <sup>b</sup> <u>Control</u> : Organisational oriented: 'Alcohol Facts and Effects' leaflet was given by the research assistant	Alcohol consumption: Ratio of geometric means 0.80 (0.63-1.02;p0.08)
Kypri et al 2005 (58)	RCT, study duration 6 weeks	- New Zealand; - General practice/ primary health care clinic/ family	Patients N=218 (Intervention Group 1: N=72; Intervention Group 2 N=74; Control: N=72)	Two <u>IS</u> 's. <u>IS1</u> . Computerised assessment + feedback and advice on patients' fruit and vegetable consumption, physical activity, alcohol consumption, and smoking (changes to the setting/	Alcohol consumption: F = 0.208 (p=0.813)

Study, year (ref)	Design, study duration	Setting (country; setting; type of health care professionals)	Participants	Implementation strategy (IS) vs Control	Outcome type*: Effect Size (95%-CI)#;
Kypri et al 2008 (24)	RCT, study duration 12 months	- New Zealand; - General practice/ primary health care clinic/ family practice	Patients N=429 (Intervention Group 1: N=138; Intervention Group 2: N=145; Control: N=146)	practice site of service delivery; patient feedback) <sup>b</sup> <u>IS2</u> . Computerised assessment only <u>Control</u> : Untargeted activity: Minimal contact at baseline Two <u>IS</u> 's. <u>IS1</u> . Web-based motivational intervention (changes to the setting/ site of service delivery) <u>IS2</u> . Web-based motivational intervention with further interventions 1 and 6 months later (including personalised feedback) (changes to the setting/ site of service delivery; patient feedback) <sup>b</sup> <u>Control</u> : Patient oriented: Information pamphlet on health effects of alcohol consumption	Alcohol consumption: 1(6months):Rate ratio 0.79 (0.68 to 0.94), 2(6months):Rate ratio 0.85 (0.73 to 1.00), 1(12 months): Rate ratio 0.86 (0.74 to 1.01), 2(12months): Rate ratio 0.92 (0.79 to 1.07)
<i>Professional, organisational and patient oriented implementation strategies</i>					
Beurden van 2012 (11) (secondary study included (74))	RCT, study duration 2 years	- Netherlands; - Primary health care practice; - GPs	General practitioners N=119 (Intervention group N=47; Control group N=47);  Patients N=712 (Intervention group N=346; Control group N=366)	<u>IS</u> : Distribution of the guideline; a reminder-card to display on the GPs desk; educational training session tailored to professionals' attitudes; feedback report on patient alcohol consumption risk level; facilitation of the cooperation with local addiction services for support and referral; outreach visits by a trained facilitator tailored to needs of practice; patient information letters, leaflets and self-help booklets about alcohol offered to general practices to be distributed to patients; poster in the waiting room; personal feedback to the patient based on their alcohol consumption risk category (Distribution of educational materials; educational meetings; reminders; audit and feedback; formal integration of services; educational outreach visits; patient feedback) <sup>b</sup> <u>Control</u> : Guidelines were mailed to GPs; information letters about problematic alcohol consumption were sent to patients. Patients also received personal feedback on alcohol consumption after closure of the intervention period.	Screening:NR (p=0.60) BI: NR (p=0.57) Alcohol consumption: NR (p=0.01 in opposite direction)

Study, year (ref)	Design, study duration	Setting (country; setting; type of health care professionals)	Participants	Implementation strategy (IS) vs Control	Outcome type*: Effect Size (95%-CI)#;
Butler et al 2003 (56)	CCT, study duration not clear	<ul style="list-style-type: none"> <li>- United States;</li> <li>- Primary health care practice;</li> <li>- Physicians, nurse practitioners, nurses, practice assistants</li> </ul>	Physicians N=33; Nurse practitioners N=7; Nurses N=5; Practice assistants N=3 (Intervention group professionals N=62; Control group professionals N=66); Patients (N=2053)	<u>IS</u> : Computerised health assessment, and training how to use this, and tailored feedback to patients (Educational outreach visits; changes to the setting/ service delivery; patient feedback) <sup>b</sup> <u>Control</u> : Usual care	Alcohol consumption: NR (p>0.05)
<i>Organisational, patient and financial oriented implementation strategies</i>					
Helzer et al 2008 (55)	RCT, study duration 6 months	<ul style="list-style-type: none"> <li>- United States;</li> <li>- Primary health care practice;</li> <li>- Type of healthcare professionals not reported</li> </ul>	care professionals (profession not reported) N=112 (Intervention group 1 N=75; Intervention group 2 N=75; Intervention group 3 N=53; Control N=81); Patients N=338	Three <u>IS</u> 's. <u>IS1</u> : Daily phone calls for 6 months to an automated Interactive voice response system to report alcohol consumption (Changes to the setting/ service delivery) <u>IS2</u> : As group 1 + monthly patient feedback (Changes to the setting/ service delivery; patient feedback) <u>IS3</u> : As group 2 + financial compensation based on frequency of participants' daily calls (Changes to the setting/ service delivery; provider incentives; patient feedback) <sup>b</sup> <u>Control</u> : Usual care	Alcohol consumption: NR

**Table 3 Reported cost outcomes**

Author, year, ID	Elements	Unit of outcome reporting	Outcome intervention	Outcome control	Effect	P value or CI-95%
<i>Professional oriented interventions</i>						
Funk et al 2005 (40) (including secondary studies (69-71))	Educational outreach visits		Cost per GP giving at least one intervention			
		Provider level – materials and instructions only		£74.29		
		Provider level – one educational outreach visit		£92.80		
		Provider level – one educational outreach visit and six telephone support contacts		£128.92		
			Cost per patient advised			
		Patient level – materials and instructions only		Aus\$ 3.51		
		Patient level – one educational outreach visit		Aus\$ 2.16		
		Patient level – one educational outreach visit and six telephone support contacts		Aus\$ 4.33		
			Cost per patient advised			
		Patient level – materials and instructions only		£8.19		
Patient level – one educational outreach visit		£6.02				
Patient level – one educational outreach visit and six telephone support contacts		£5.43				

<b>Author, year, ID</b>	<b>Elements</b>	<b>Unit of outcome reporting</b>	<b>Outcome intervention</b>	<b>Outcome control</b>	<b>Effect</b>	<b>P value or CI-95%</b>
Kaner 2003 (41)	Educational outreach visits	Median number of patients screened	Full cost for trained practice: £157  Full cost for trained and supported practice £163	Full cost of promoting and implementing SBI £93 per practice	When full costs of GP-led SBI were considered, nurses were more cost-effective at delivering brief interventions. However, if just promotional costs were considered, GPs' were more cost-effective.	p<.001



**Table 4. Meta-regression analysis: predictor variable effects on alcohol consumption based on 21 outcomes from 14 studies**

Comparison	$\beta$	95%-CI	<i>p</i>
1. Single implementation strategy	-0.022		
Multiple implementation strategy	0.108	-0.068 – 0.284	0.206
2.* Organisational oriented	0.202	-0.014 – 0.417	0.063
Patient oriented	0.071	-0.193 – 0.336	0.543
Professional+organisational oriented	0.258	0.116 – 0.400	0.004
Professional+patient oriented	0.258	0.091 – 0.426	0.008
Organisational+patient oriented	0.154	0.037 – 0.271	0.017
Professional+organisational+patient oriented	-0.165	-0.332 – 0.002	0.053
3. Single component strategy	-0.022		
Multiple component strategy	0.108	-0.068 – 0.284	0.206
4. Study duration $\leq$ 12 months	0.056		
Study duration 12 months or longer	-0.046	-0.361 – 0.270	0.758
5. Physician participants only	0.019		
Physician participants combined	-0.011	-0.408 – 0.386	0.947

\* Professional oriented implementation strategy was the reference category

**Table 5. Meta-regression analysis: predictor variable effects on screening based on 11 outcomes from 10 studies**

Comparison	$\beta$	95%-CI	<i>p</i>
1. Single implementation strategy	0.158		
Multiple implementation strategy	0.675	0.021 – 1.330	0.044
2.* Organisational oriented	-0.129	-0.457 – 0.119	0.358
Professional+organisational oriented	0.034	-0.774 – 0.841	0.919
Professional+pat oriented oriented	1.231	0.562 – 1.900	0.005
Professional+organisational+patient oriented	-0.114	-1.383 – 1.156	0.827
3. Single component strategy	0.192		
Multiple component strategy	0.121	-0.380 – 0.623	0.591
4. Study duration $\leq$ 12 months	0.349		
Study duration 12 months or longer	-0.051	-0.725 – 0.622	0.862
5. Physician participants only	0.168		
Physician participants combined	0.767	0.24-1.295	0.010

\* Professional oriented implementation strategy was the reference category

**Table 6. Meta-regression analysis: predictor variable effects on brief interventions based on 10 outcomes from 8 studies**

Comparison	$\beta$	95%-CI	<i>p</i>
1. Single implementation strategy	0.169		
Multiple implementation strategy	1.018	0.165 – 1.871	0.027
2.* Organisational oriented	-0.077	-0.630 – 0.477	0.720
Professional+patient oriented	1.262	0.243 – 2.281	0.026
Professional+organisational+patient oriented	-0.091	-1.868 – 1.686	0.893
3. Single component strategy	0.147		
Multiple component strategy	0.985	0.310 – 1.660	0.012
4. Study duration $\leq$ 12 months	-0.121		
Study duration 12 months or longer	1.003	0.023 – 1.983	0.046

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5.	Physician participants only	0.189			
	Physician participants combined	-0.089	-0.882	-0.703	0.797

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\* Professional oriented implementation strategy was the reference category

Figures

Figure 1

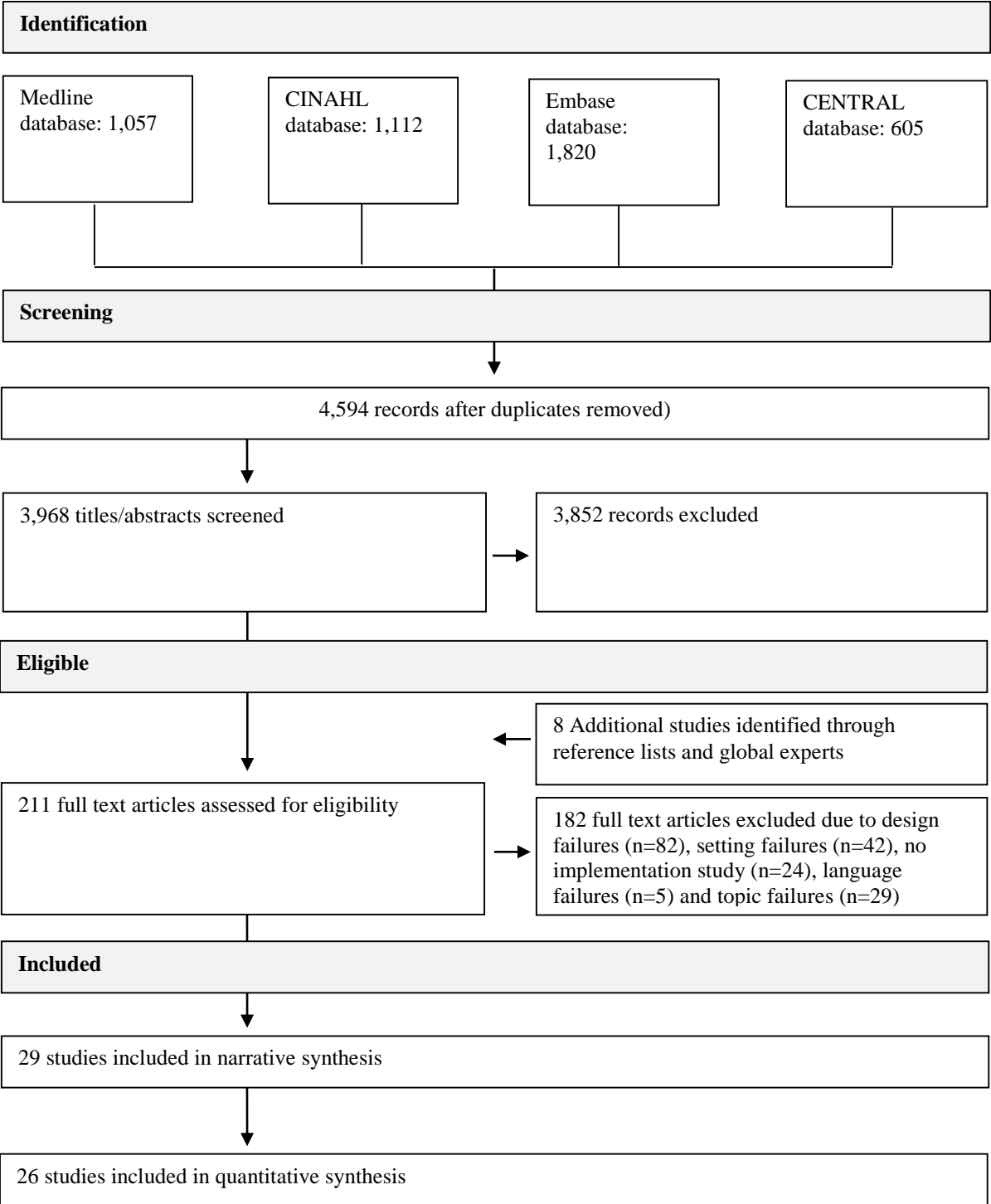
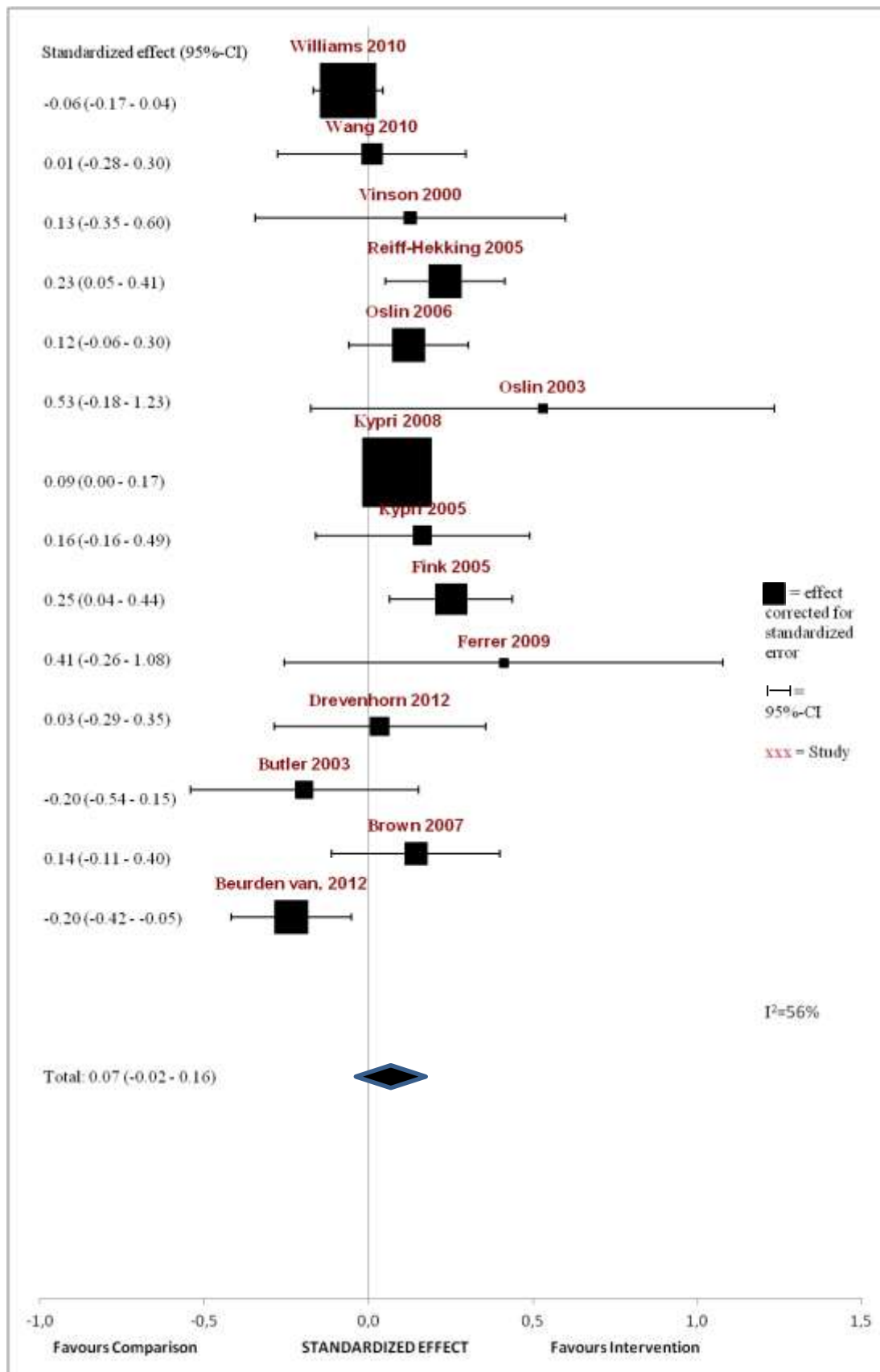
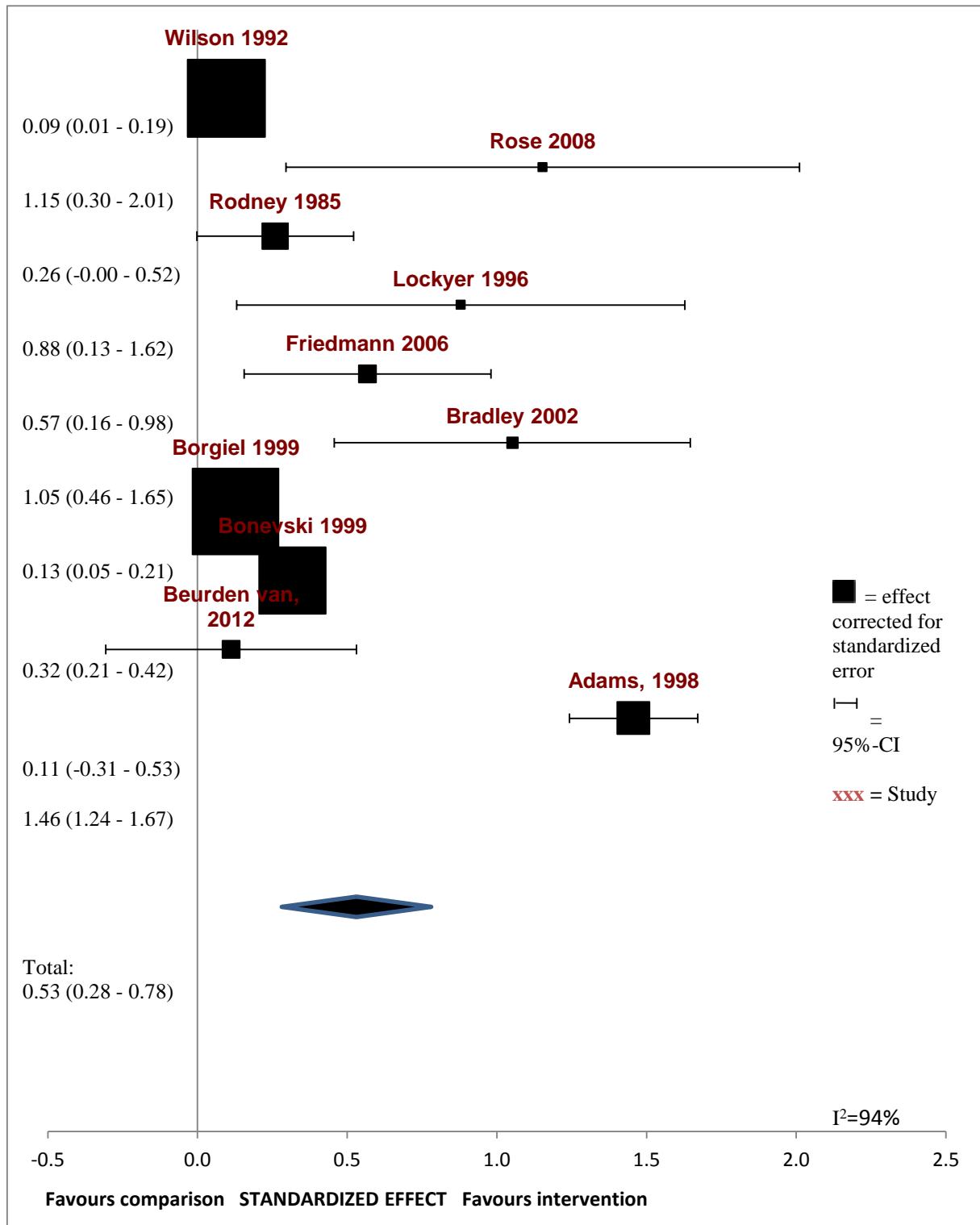


Figure 2



**Figure 3**



**Figure 4**

