Patient-centered care interventions for the management of alcohol use disorders: a systematic review of randomized controlled trials

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Issues: Patient-centered care (PCC) is increasingly accepted as an integral component of good health care, including addiction medicine. However, its implementation has been controversial in people with alcohol use disorders.

Approach: A systematic search strategy was devised to find completed randomized controlled trials enrolling adults (>18 years) with alcohol use disorders. Studies had to use a PCC approach such that they should have been individualized, respectful to the patients’ own goals, and empowering. Studies until September 2015 were searched using PubMed, Scopus, the Cochrane Library, PsychINFO, and Web of Knowledge.

Key findings: In total, 40 studies enrolling 16,020 patients met the inclusion criteria. Assessment revealed two main categories of study: psychosocial (n=35 based on motivational interviewing) and pharmacological (n=5 based on an as needed dosing regimen). Psychosocial interventions were further classified according to the presence or absence of an active comparator. When no active comparator was present, studies were classified according to the number of sessions ($1). Results from single sessions of motivational interviewing showed no clear benefit on alcohol consumption outcomes, with few studies indicating benefit of PCC versus control. Although the results for studies of multiple sessions of counseling were also mixed, many did show a significant benefit of the PCC intervention. By contrast, studies consistently demonstrated a benefit of pharmacologically supported PCC interventions, with most of the differences reaching statistical significance.

Implications: PCC-based interventions may be beneficial for reducing alcohol consumption in people with alcohol use disorders.

Keywords: psychosocial intervention, pharmacological intervention, motivational interviewing, as-needed

Introduction

The Institute of Medicine has included patient-centered care (PCC) as one of the major aims in care quality and defines it as “providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions”. Although not a new phenomenon, it has recently attracted renewed attention. PCC advocates for a shift from disease-oriented to patient-oriented medicine. Doctors should no longer be authoritative figures who make all the relevant decisions. Instead, they must engage in a shared decision-making model where patients are acknowledged to be experts with regard to their own symptoms and values and where they are recognized as unique and diverse. In such a model, the responsibility is shared between a patient and a physician, and the physician’s key role is to strengthen the patient’s capabilities to handle his or her part of responsibility.
Application of PCC in the field of mental disorders remains a controversial issue. It has long been argued that patients with psychiatric disorders are vulnerable to impediments in decision making, and a paternalistic approach has been the preferred norm in the field. Conversely, a number of studies indicate that patients engaged in the decision-making process show greater satisfaction and collaboration, with greater efficacy of treatment.

While considering the field of alcohol use disorders, it is also likely that ideological bias and stigma have exacerbated the paternalistic approach. The harmful use of alcohol is one of the world’s leading health risks and is the leading risk factor for death of people aged 15–49 years. However, patients with alcohol use disorders often receive a lower quality of health care than those with other chronic conditions; many dependent patients go without treatment, and even when they are treated, pharmacotherapy is underutilized. Abstinence has been the prevailing goal, usually irrespective of patients’ own aims or desire. Crucially, patients do not always view abstinence as an acceptable, desirable, or realistic treatment goal, and there is an increasing debate about the possibility and the convenience of broadening treatment goals in accordance with a PCC model. For example, this could mean establishing reduction in heavy drinking as a possible objective for some patients. Reduction of alcohol consumption has been shown to reduce the annual and lifetime risk of alcohol-related death, and it could attract patients who are currently not inclined to seek treatment or do not accept abstinence as a treatment goal. Indeed studies show that patients with alcohol use disorders are more likely to achieve self-set goals (eg, reduction or abstinence), rather than goals that are imposed on them.

Several treatment options (psychosocial and pharmacological) are available for people with alcohol use disorders, but no single therapy has been proven to be more effective than another. PCC and shared decision making are considered especially appropriate when outcomes of the different treatments are similar and when an active role of the patient is needed. Thus, some experts consider alcohol use disorders as potentially a suitable situation to use a PCC approach. Although some of the components of PCC might have been previously tested for the treatment of alcohol use disorders, for example, in the form of individually tailored feedback and treatment, these have not been systematically assessed in a cohesive manner. The aim of this review was to systematically assess the efficacy of interventions based on a PCC health care approach, both pharmacological and psychosocial, for the management of alcohol use disorders.

Methods
This systematic review was conducted in accordance with the principles recommended by the Cochrane Handbook for Systematic Reviews of Interventions. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidance was followed for the reporting of procedures; its checklist can be seen in Supplementary materials.

Definition of PCC
Although patient centeredness is not an easy concept to define in a concise manner, a previous systematic review operationalized it under four defining attributes: holistic, individualized, respectful, and empowering. Many studies might be considered as PCC, but they might not use this exact expression, or any of the attributes of PCC previously reported. Thus, in order to conduct an appropriately sensitive electronic search, we predefined several adjectives and expressions to cover the four attributes. For example, alternative terms for “empowering” included “patient involvement”, “patient perspective”, “shared decision-making”, and “patient decision”, and alternative terms for “individualized” included “tailored”, “personalized”, and “customized”.

Data sources and searches
The following databases were searched: PubMed, Scopus (which contains EMBASE), the Cochrane Library, PsychINFO, and the Web of Knowledge. The search strategies for PubMed, Scopus, and the Cochrane Library are listed in Supplementary materials. The searches were run until September 2015. Additional hand searches of the reference lists of included randomized controlled trial and relevant systematic reviews were conducted. Finally, the following clinical trial registries were also searched for relevant studies: ClinicalTrials.gov, ISRCTN Register, UK Clinical Trials Gateway, and metaRegister of Controlled Trials.

Study selection
Individual (not cluster) randomized controlled trials enrolling adults (≥18 years) with alcohol use disorders (including hazardous or harmful drinking, alcohol dependence, or any other alcohol use disorder) were included. All the studies had to use a PCC approach such that they should have been individualized, respectful to the patients’ own goals, and empowering. Computerized interventions were not included in this review.

As described earlier, although interventions might not have been described with these same adjectives, they were fully reviewed to check whether they met the criteria (ie, the description of the intervention was individually assessed...
to determine whether it could be considered PCC). Studies could use any standardized outcome regarding alcohol consumption (eg, heavy drinking days, grams of alcohol, days of abstinence, percentage of patients drinking below recommended limits on validated screening tools). Only publications in English were considered.

To homogenize the review, studies of patient populations with psychiatric comorbidities were excluded from this review as were studies including populations with relevant and differential psychological variables (eg, mandated or incarcerated patients and pregnant women). Studies conducted in the inpatient setting and short-term studies with <3 months of follow-up were also excluded. Studies using cover stories where patients did not know the real intention of the intervention were also excluded, as this is clearly contrary to the concept of PCC. Finally, any comparator was eligible as long as it was not PCC based.

**Data extraction**

PB and AG independently screened all the studies for inclusion. Disagreements were resolved by discussion when possible. If not, a third person was consulted. Data were extracted by PB and independently checked by AG. The extracted data consisted of participant characteristics, setting, study methods, intervention characteristics, comparators, outcomes, and results.

**Quality assessment**

PB and AG independently evaluated the quality of the studies. Following the Cochrane guidelines and the methods used in a recent systematic review undertaken by Mdege et al.,\(^\text{20}\) a domain-based approach was used. The following criteria were applied: power calculation, adequacy of randomization, allocation concealment, adjustment for covariates in the analysis, blinding of participants when possible, blinding of outcome assessors, explanation of dropouts, and use of intention-to-treat analysis.

**Data synthesis**

Considerable heterogeneity existed between the studies, mainly in terms of reported outcomes, how the outcomes were defined and reported, and the duration of the studies. Given the different methodologies that were employed, the studies were grouped according to whether they primarily assessed a pharmacological or a psychosocial intervention. In the psychosocial group, a further grouping was made according to the number of sessions received, categorizing studies between 1 or >1 sessions.

A meta-analysis was conducted on the basis of our findings, by trying to build an outcome construct based on construct validity. However, given the significant methodological issues involved, the analysis was deemed inappropriate and a narrative synthesis was instead conducted.

**Results**

**Literature search**

A total of 7,048 records were screened through the search strategy, and 115 full-text articles were assessed for eligibility. An additional reference was identified by hand searching, and eventually, after exclusion criteria were applied (reasons for exclusion of full-text papers are available in the Supplementary materials), a total of 40 studies were included in the systematic review.\(^\text{29–68}\) Figure 1A depicts the flow diagram of the study.

**Study characteristics**

The 40 studies included in this review involved a total of 16,020 enrolled patients. Sample size in each study ranged from 54 to 987 patients. An initial assessment of the studies revealed two groups according to the main treatment evaluated: psychosocial or pharmacological, with 35 evaluating psychosocial interventions and five evaluating primarily pharmacological interventions.

All psychosocial interventions that met the inclusion criteria in this review were based on motivational interviewing (MI) principles, which might be considered as the cornerstone of patient-centered psychosocial interventions nowadays. MI is defined as “a directive, client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence”.\(^\text{64}\) Compared to nondirective counseling, it is more focused and goal directed. The examination and resolution of ambivalence is its central purpose, and the counselor is intentionally directive in pursuing this goal.

Regarding pharmacological interventions, all those fulfilling the inclusion criteria were based on the “as needed” concept. The “as needed” [or pro re nata] treatment paradigm is a well-understood medical concept, where the patient takes the medication in response to individual circumstances and not on a scheduled basis. Although it has been a standard practice for many years in asthma, diabetic, and allergy care, it represents a paradigm shift in the way that pharmacotherapy is used in the management of alcohol use disorders.\(^\text{70}\)

For further grouping studies, psychosocial interventions based on MI and with no active comparator (defined as receiving no further intervention or receiving only information, either orally or written materials) were divided
according to the number of sessions they contained (1 or >1), while the studies containing an active comparator (like cognitive behavioral therapy [CBT], for example) were included in a separate category. Thus, four categories were created to report the results of the systematic review: single-session PCC with no active comparator, more than one session PCC with no active comparator, PCC with active comparator, and patient-centered pharmacological interventions.

**Quality assessment**
The results of quality assessment of the included studies are shown in Supplementary materials. Overall, less than half (42.5%) of the studies were deemed as adequately powered, 57.5% had an adequate randomization, and 45% adequate allocation concealment. Around two-thirds (65%) used adjusted analysis and 67.5% reported blinding of the outcome assessors, and all but one study reported adequate information on the patients who dropped-out. Most (65%) of the studies stated clearly an intention-to-treat analysis (Figure 1B). In psychosocial intervention studies, it was not considered possible to blind participants to the delivered intervention; therefore, participant blinding was only assessed in pharmacological intervention studies, which were all deemed as adequate on this item.

**Efficacy of PCC**

**Single-session PCC with no active comparator**
Seventeen studies were included in this subgroup (Table 1). Globally, they failed to show a clear benefit of the PCC intervention over the control groups.

**Amount and frequency of alcohol consumption**
Seven studies reported on the number of drinks per week at study end, with only Daeppen et al reporting a statistically significant difference from baseline to follow-up (−1.5 vs −0.8; P = 0.004) favoring the PCC group.

Bischof et al reported a nonsignificant difference in grams of alcohol per day between groups, Emmen et al reported a nonsignificant difference in drinks per day, and Soderstrom et al reported on the number of drinks in the last 90 days, with no differences between groups.

Five studies reported the number of drinks per drinking day. Four could not find significant differences, while Carey et al only reported a small effect size, with no significance value.

Four studies reported on drinking days per week, none of them reaching statistical significance between groups. Similarly, Lee et al reported on drinking days/month, with no differences between groups. Chang et al reported no differences in the percentage of drinking days between groups, and Senft et al reported no differences in the percentages of abstinent patients.

**Hazardous and heavy drinking**
Seven studies reported on the number of binge episodes per month, with only Daeppen et al (2011) reported a statistically significant difference favoring the PCC group (baseline to follow-up difference −1.5 vs −0.8, P = 0.04).

Murphy et al reported the number of binges per week and Soderstrom et al reported the number of binges in the last 90 days, both of them showing no significant differences.
Table 1 Single-session patient-centered counseling – no active comparator

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention</th>
<th>Patients</th>
<th>Follow-up duration</th>
<th>Outcomes reported</th>
<th>Key findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bazargan-Hejazi et al.</td>
<td>1. BI</td>
<td>N=295</td>
<td>3 months</td>
<td>Changes in AUDIT category from baseline to follow-up ◦ Low risk: 0–6 ◦ At-risk/moderate risk: 7–18 ◦ High risk: 19–40</td>
<td>48% reduced their AUDIT risk category in the intervention group vs 38% in the control group. Differences were not statistically significant</td>
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<td>2. Usual treatment in the ED</td>
<td>ED attendants with CAGE score ≥1</td>
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<td>• All drinking outcomes in all groups (significance not reported)</td>
<td>In the subgroup of moderate risk, 34% of the intervention group had a risk reduction vs 13% in the control group (P=0.0099)</td>
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<tr>
<td>Bischof et al.</td>
<td>1. Full care: personalized feedback at baseline + MI + BCC on the phone at baseline, 1, 3, and 6 months in 30-minute sessions</td>
<td>N=408</td>
<td>12 months</td>
<td>• Average daily alcohol consumption ◦ HED</td>
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<td>2. Stepped care: if no improvement reported, then patients received personalized feedback at baseline + MI + BCC (as above)</td>
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<td>• Greater reduction of MCv for intervention group at 3 months in all drinking outcomes in all groups (significance not reported)</td>
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<td>3. Control: booklet on health behavior</td>
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<td></td>
<td>• Between groups effect sizes at 1 month were medium for intervention vs control group in drinks per drinking day, peak BAC and RAPI (0.41; 0.44 and 0.52)</td>
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<td>Brown et al.</td>
<td>1. One 30-minute brief MI session, adapted for DWI offenders</td>
<td>N=92</td>
<td>12 months</td>
<td>Percent of risky drinking days in the last 180 days (defined as ≥42 g of alcohol for males and ≥2 standard drinks (≥28 g of alcohol) for females</td>
<td>Group x time interaction not statistically significant</td>
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<td>2. Control</td>
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<td>• No differences between groups at either time</td>
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<td>• Significant reduction from 6 to 12 months in risky drinking days for intervention group (mean reduction (SD) = 6.1 (20.2) to 12.2 (25.0) for intervention group; 8.5 (22.4) to 7.5 (22.7); P&lt;0.02)</td>
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<td>• Greater reduction of MCV for intervention group at 3 months in MCV (mean (SD) = 9.6 (34.3) to 1.75 (23.9); P&lt;0.005)</td>
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<td>Carey et al.</td>
<td>1. TLFB + BMI enhanced with decisional balance</td>
<td>N=615</td>
<td>12 months</td>
<td>Drinks/week ◦ Drinks/drinking day ◦ Heavy drinking frequency</td>
<td>Reduction in all drinking outcomes in all groups (significance not reported)</td>
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<td>2. BMI enhanced with decisional balance</td>
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<td>• Between groups effect sizes at 1 month were medium for intervention vs control group in drinks per drinking day, peak BAC and RAPI (0.41; 0.44 and 0.52)</td>
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<td></td>
<td>3. TLFB + basic BMI</td>
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<td>• At 12 months also medium for intervention vs control group in peak BAC and RAPI (0.57 and 0.50)</td>
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<td>4. Basic BMI</td>
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<td>• All other outcomes resulted in small effect sizes</td>
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<td>5. TLFB</td>
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<td>6. Control: initial assessment only</td>
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<td>7. Control: brochure</td>
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<tr>
<th>Study</th>
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<th>Patients</th>
<th>Follow-up times</th>
<th>Outcomes reported</th>
<th>Key findings</th>
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<tr>
<td>Chang et al [23]</td>
<td>1. BI</td>
<td>• Outpatient women with hypertension, diabetes, osteoporosis, or infertility &lt;br&gt;• T-ACE alcohol screen-positive; and/or typically consuming ≥7 drinks a week or ≥2 drinks at a time</td>
<td>12 months</td>
<td>• Drinks per drinking day &lt;br&gt;• Percent drinking days &lt;br&gt;• Number of binge episodes, with binges defined as ≥4 drinks per occasion</td>
<td>Drinks per drinking day: &lt;br&gt;• Intervention group reduced from 2.1 (1.4) to 2.0 (2.0); control group reduced from 2.2 (1.5) to 1.9 (1.6). Differences not significant (P=0.60)</td>
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<td>2. Control</td>
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<td>Percent drinking days: &lt;br&gt;• Intervention group reduced from 2.6% to 22%; control group reduced from 21% to 20%. Differences not significant (P=0.52)</td>
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<td>Binge episodes:</td>
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<td>• Intervention group reduced from 7.4 (24) to 6.0 (21); control group reduced from 5.7 (17) to 3.8 (13). Differences not significant (P=0.17)</td>
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<td>At risk drinking:</td>
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<td>• Intervention group reduced from 87.5% to 63.8%; control groups reduced from 87.4% and 88.7% to 54.0% and 64.9%, respectively. No significant differences between groups. Within group differences significant for all groups (P&lt;0.01)</td>
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<td>Drinking days per week:</td>
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<td>• Intervention group reduced from 2.5 (0.2) to 1.8 (0.2); control groups reduced from 2.3 (0.2) and 2.3 (0.2) to 2.0 (0.2) and 2.1 (0.2), respectively. Differences between groups not significant. Within group differences only statistically significant for intervention group (P&lt;0.01)</td>
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<td>Drinks per drinking day:</td>
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<td>• Intervention group reduced from 5.6 (0.4) to 4.1 (0.4); control groups reduced from 5.0 (0.4) and 5.3 (0.4) to 3.5 (0.3) and 4.2 (0.4), respectively. Within group differences significant for all groups (P&lt;0.01). No differences between groups</td>
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<td>Maximum drinks per occasion last month:</td>
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<td>• Intervention group reduced from 9.3 (0.8) to 7.4 (0.6); control groups reduced from 6.7 (0.5) and 7.8 (0.5) to 6.1 (0.6) and 7.7 (0.6), respectively. No differences between groups. Within group differences only significant for intervention group (P&lt;0.05)</td>
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<td>Drinks per week among binge drinkers:</td>
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<td>• Intervention group baseline to follow-up difference −1.5 (13.2), control group 0.8 (10.8). Differences statistically significant (P=0.004)</td>
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<td>Binge drinking occasions per month among binge drinkers:</td>
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<td></td>
<td>• Intervention group baseline to follow-up difference −1.5 (3.4), control group −0.8 (3.2). Differences statistically significant (P=0.04)</td>
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</tbody>
</table>

Cherpitel et al [34] 2010, Poland 1. 20 minutes of BNI 2. Assessment only 3. Screening only  

• N=446  
• Patients attending the ED  
• Positive on any one of the four RAPS4 items during the last year, or reported ≥11 standard drinks per week for men (≥6 for women), or reported ≥4 drinks on a typical drinking day for men (≥3 for women) in the last year  

12 months  

• Percent at risk drinking  
• Drinking days per week  
• Drinker per drinking day  
• Maximum drinks per occasion last month  

Drinks per drinking day:  

• Intervention group reduced from 87.5% to 63.8%; control groups reduced from 87.4% and 88.7% to 54.0% and 64.9%, respectively. No significant differences between groups. Within group differences significant for all groups (P<0.01)  

Drinking days per week:  

• Intervention group reduced from 2.5 (0.2) to 1.8 (0.2); control groups reduced from 2.3 (0.2) and 2.3 (0.2) to 2.0 (0.2) and 2.1 (0.2), respectively. Differences between groups not significant. Within group differences only statistically significant for intervention group (P<0.01)  

Drinks per drinking day:  

• Intervention group reduced from 5.6 (0.4) to 4.1 (0.4); control groups reduced from 5.0 (0.4) and 5.3 (0.4) to 3.5 (0.3) and 4.2 (0.4), respectively. Within group differences significant for all groups (P<0.01). No differences between groups  

Maximum drinks per occasion last month:  

• Intervention group reduced from 9.3 (0.8) to 7.4 (0.6); control groups reduced from 6.7 (0.5) and 7.8 (0.5) to 6.1 (0.6) and 7.7 (0.6), respectively. No differences between groups. Within group differences only significant for intervention group (P<0.05)  

Drinks per week among binge drinkers:  

• Intervention group baseline to follow-up difference −1.5 (13.2), control group 0.8 (10.8). Differences statistically significant (P=0.004)  

Binge drinking occasions per month among binge drinkers:  

• Intervention group baseline to follow-up difference −1.5 (3.4), control group −0.8 (3.2). Differences statistically significant (P=0.04)
1. BMi (15–45 minutes)
2. Control
6 months

- Typical number of drinks per week (standard drink containing ~10 g of pure alcohol)
- Typical number of binge drinking episodes per month
- AUDIT score
- Number of drinks per occasion
- Number of drinking days per week

Hazardous drinkers:
- Intervention group reduced from 100% to 64.4%, control groups reduced from 100% to 66.0% and 63.0%, respectively. Differences not significant ($P = 0.71$)

Binge drinking episodes last month:
- Intervention group reduced from 4.2 (6.1) to 3.7 (5.8); control groups reduced from 4.0 (6.2) and 3.7 (6.1) to 3.6 (6.1) and 3.6 (4.4), respectively. Differences not significant ($P = 0.46$)

Number of drinks per occasion:
- Intervention group reduced from 4.0 (2.6) to 3.7 (2.9), control groups reduced from 3.8 (2.4) and 3.7 (2.8) to 3.5 (2.6) and 3.4 (2.6). Differences not significant ($P = 0.28$)

Number of drinking days per week:
- Intervention group reduced from 3.5 (2.3) to 3.0 (2.2), control groups reduced from 3.5 (2.4) to 3.2 (2.4) and 3.1 (2.4). Differences not significant ($P = 0.52$)

D'Onofrio et al. $^a$$^b$
1. BNI
2. BNI + booster
3. Standard care
2008, USA

- N=494
- Patients presenting to an ED

12 months

- Number of standard drinks per week
- Number of binge episodes (>4 drinks for women and >5 drinks for men) in the past 30 days
- Percent of participants in each treatment condition who exceeded NIAAA low-risk drinking limits in the past month

Drs per week:
- Intervention group reduced from 13.6 (11.6) to 9.8 (14.3); control group reduced from 12.4 (8.7) to 9.8 (10.9). Differences not significant

Binge episodes last month:
- Intervention group reduced from 6.0 (6.8) to 4.0 (6.7); control group reduced from 5.4 (5.4) to 3.9 (6.2). Differences not significant

Proportion of patients over NIAAA guidelines (with previous outcomes combined):
- Intervention group reduced from 99.2% to 62.0%; control group reduced from 98.0% to 65.4%. Differences not significant

Emmen et al.$^a$$^b$
1. Dutch Motivational Drinker's Check-Up
2. Control
2005, the Netherlands

- N=123
- Patients from a general internal medicine outpatient department
- Positive answer to one of the following questions: 1. Have you ever felt the need to cut down or stop drinking? 2. Do you ever drink to forget your worries? 3. Do close relatives ever worry about your drinking?

6 months

- Change in self-reported alcohol consumption in units/day
- Change in CDT

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<tr>
<th>Study</th>
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<th>Patients</th>
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</thead>
<tbody>
<tr>
<td>Gaume et al</td>
<td>1. BMI</td>
<td>N=446</td>
<td>6 months</td>
<td>Number of standard drinks (~10 g of pure alcohol) per week and number of heavy drinking episodes (~6 drinks on a single occasion) per month</td>
<td>Among heavy episodic users: Drinks per week: • Baseline to 6-month difference 0.4 (13.1) for the intervention group; 0.7 (19.1) for the control group. Differences not statistically significant (P=0.90)</td>
</tr>
<tr>
<td>2011, Switzerland</td>
<td>2. Control</td>
<td>Swiss army conscripts, who were heavy episodic users, defined as having ≥1 episode per month of ≥6 drinks on a single occasion</td>
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<tr>
<td>Hansen et al</td>
<td>1. BMI (10 minutes) and a brief telephone booster session</td>
<td>N=772</td>
<td>12 months</td>
<td>Number of drinks per week</td>
<td>The difference in the number of drinks per week between intervention and control group in change over time was 1.0 favoring intervention. Difference not significant (95% CI: -2.15 to 0.23; P=0.114)</td>
</tr>
<tr>
<td>2012, Denmark</td>
<td>2. Control</td>
<td>Patients attending a health examination, after completing an online survey Weekly alcohol consumption above the Danish National Board of Health limits (14 drinks =168 g of alcohol for women, 21 drinks =252 g for men) Dependent drinkers included</td>
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<tr>
<td>Lee et al</td>
<td>1. CAMI</td>
<td>N=54</td>
<td>6 months</td>
<td>Heavy drinking days/month DrInC</td>
<td>Significant within groups decline for both groups on drinking days/month; heavy drinking days/month, and DrInC (numbers not reported), with no between groups differences at 6 months</td>
</tr>
<tr>
<td>2011, USA</td>
<td>2. MI (1.5 hours)</td>
<td>Hazardous drinking (~5/4 drinks/ occasion for men/women or ~14/7 drinks/week for men/women) Hispanic nationality</td>
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<td>At 2 months, CAMI had a greater reduction than MI in drinking days/month</td>
</tr>
<tr>
<td>Murphy et al</td>
<td>1. Basics: MI (50 minutes)</td>
<td>N=54</td>
<td>9 months</td>
<td>Drinks per week Binge drinking days per week, drinking days per week, RAPI score, ADS score</td>
<td>Trend favoring CAMI (PCC) in reduction of heavy drinking days (P=0.08)</td>
</tr>
<tr>
<td>2001, USA</td>
<td>2. Education: 30-minutes of video watching and individual discussion</td>
<td>University undergraduate students on the upper third of the screening sample in terms of drinks per week, as measured by the DDQ Endorsed ≥2 alcohol-related problems on the RAPI</td>
<td></td>
<td></td>
<td>Significant time by treatment interaction on the DrInC Impulse scale at 6 months favoring CAMI</td>
</tr>
</tbody>
</table>
| 3. Control: assessment only |                                                                        |                                  |                 |                                                                                   | Drinks per week: • The intervention group reduced from 22.38 (12.04) to 16.63 (9.29); the control groups reduced from 21.29 (10.06) and 20.76 (10.75) to 15.72 (7.75) and 18.46 (14.17), respectively

**Heavy drinking episodes per month:**
- Baseline to 6-month difference -0.7 (3.2) for the intervention group; -0.8 (3.8) for the control group. Differences not statistically significant (P=0.61)
- The difference in the number of drinks per week between intervention and control group in change over time was 1.0 favoring intervention.
- Difference not significant (95% CI: -2.15 to 0.23; P=0.114)
### Binge drinking days per week

- The intervention group reduced from 2.57 (1.38) to 1.87 (1.11); the control groups reduced from 2.67 (1.05) and 2.44 (1.23) to 1.90 (1.33) and 1.93 (1.54), respectively
- Not significant multivariate effect of group ($P=0.22$)
- In general, both the groups showed moderate drinking reductions
- Within-group effect size across the three drinking measures was 0.48 for intervention group (PDF + MI) and 0.42 for control group (PDF alone)
- No significant differences between groups

### At 12 months:

- Intervention patients reported fewer drinking days per week (2.7 vs 3.1; $P=0.04$) than controls, but similar numbers of standard drinks (157 vs 179; $P=0.13$) and drinks per drinking day (3.6 vs 3.3; $P=0.20$)
- Intervention patients were more likely than controls to report drinking within daily recommended limits ($\leq 3$ for men, $\leq 2$ for women) (80% vs 73%; $P=0.07$)
- No significant differences in other drinking outcomes (percent abstinent, frequency of drinking $\geq 6$ drinks per drinking occasion, estimated peak blood alcohol concentration), or use of medical care in the year following intervention
- Within group significant declines in number of binge episodes during the last 90 days and number of drinks during the last 90 days
- No statistical significance between groups (final numbers not reported)

### Abbreviations:
- AA, alcohol abuse; AD, alcohol dependence; ADS, Alcohol Dependence Scale; AR, at-risk drinking; AUDIT, alcohol use disorders identification test; BAC, blood alcohol content; BAL, brief alcohol intervention; BCC, behavioral change counseling; Bi, brief intervention; BIA, brief intervention and advice; BMI, brief motivational interviewing; BNI, brief negotiated interview; CAMI, culturally adapted motivational intervention; CDT, carbohydrase deficient transferrin; DrInC, Drinker Inventory of Consequences; DWI, driving while intoxicated; ED, emergency department; HED, heavy episodic drinking; LAST, Luebeck alcohol dependence and abuse screening test; M-CIDI, Munich composite international diagnostic interview; MCV, mean cell volume; MI, motivational interviewing; NIAAA, National Institute on Alcohol Abuse and Alcoholism; PCC, patient-centered care; PDF, personalized drinking feedback; RAPi, Rutgers alcohol problem index; SD, standard deviation; TLFB, time line follow back.
between groups. Brown et al (2007) reported a significant difference only for men in the reduction in number of risky drinking days (30% vs 12.9%, significance not reported), and Senft et al found no differences in the frequency of risky drinking. Three studies reported the percentage of heavy drinkers at study end. Two could not find any significant difference, while the remaining study by Bischof et al reported a statistically significant difference only in the subgroup of patients with alcohol abuse (25% vs 41.3%; P=0.039), with no difference in the alcohol-dependent or heavy episodic drinking-only subgroups. Cherkit et al reported a nonsignificant difference in the percentage of at risk drinkers between groups or in the maximum number of drinks per occasion. Carey et al reported a medium effect size in peak blood alcohol favoring the PCC group (significance not reported), while Senft et al reported no significant difference in this outcome.

Scores
Bazargan-Hejazi et al reported a nonsignificant difference in the percentage of patients changing their drinking risk status according to the Alcohol Use Disorders Identification Test (AUDIT) score. In the subgroup of moderate risk (scores 7–18), the PCC group had a larger reduction (34% vs 13%; P=0.0099). Daéppen et al reported a nonsignificant difference between groups regarding the change in the AUDIT score.

More than one session PCC with no active comparator
Fifteen studies were included in this subgroup (Table 2). Taken together, data showed mixed results, with some studies reporting significant differences between groups, whereas others do not.

Amount and frequency of alcohol consumption
Nine studies reported data regarding the amount of alcohol consumption. Five studies reported it in the form of units of alcohol per week. Two failed to show statistically significant differences between groups, while the other three reported significant differences for the intervention groups. The amount of alcohol consumption in the two intervention groups in D’Onofrio et al decreased from 20.4 and 19.8 to 13.0 and 14.3, respectively, while that in the control group ranged from 20.9 to 17.6 (P=0.045). The reductions in Monti et al for the intervention and control groups were 13.07–6.10 and 10.77–8.83, respectively (P<0.01 in the treatment × time interaction).

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Hazardous and heavy drinking
Ten studies reported outcomes related to heavy or hazardous drinking. Curry et al reported a 19% difference between groups in the proportion of patients reporting any at risk drinking pattern, favoring the PCC group (42% vs 61%; P=0.003). Allen et al failed to show any significant difference on the same outcome. Sellman et al reported a significant decrease in the percentage of heavy drinking days in the past 6 months favoring the PCC group (42.9% vs 65%). Sommers et al and Beich et al reported on the relative risk of heavy drinking between groups. Although differences favored the PCC group, they were not statistically significant at study end.

Three studies reported on the number of risky drinking days in the last month. Brown et al did not find any significant difference, whereas the other two reported statistically significant differences favoring the PCC groups. D’Onofrio et al reported a decrease from 7.5 and 7.2 to 4.7 and 5.1 versus a decrease from 7.2 to 5.8 (P=0.03). Monti et al reported a statistically significant difference in the treatment × time interaction (4.52 versus 6.54; P<0.001). Longbaugh et al found no significant difference in the number of heavy drinking days between groups.

Noknoy et al reported on the number of binge episodes in the last week, with no significant differences between groups, and Sommers et al reported on the maximum units of alcohol in a 6-hour period, with no significant differences between groups at study end.
**Table 2** More than one session patient-centered counseling – no active comparator

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention Description</th>
<th>Patients Details</th>
<th>Follow-up Times</th>
<th>Outcomes Reported</th>
<th>Key Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aalto et al 2000, Finland</td>
<td>1. BI sessions at 0, 2, 6, 12, 18, 24, and 30 months (10–20 minutes based on FRAMES)</td>
<td>• N=118                                                                   • Female patients consecutively attending four primary care health clinics and one occupational health care clinic</td>
<td>36 months</td>
<td>• Drinking amount per week                                                          • Drinking frequency per week                        • Drinking amount per occasion</td>
<td>• No differences between or within groups at 3 years in alcohol consumption variables&lt;br&gt;• Significant reductions within all groups in MCV&lt;br&gt;• GGT decreased in intervention groups, while not in the control group (difference not statistically significant)</td>
</tr>
<tr>
<td></td>
<td>2. BI sessions at 0, 12, and 24 months</td>
<td>• Heavy drinker with self-reported alcohol consumption ≥190 g of absolute ethanol per week&lt;br&gt;• And/or ≥2 affirmative answers on CAGE</td>
<td></td>
<td>• CDT                                                                                • GGT</td>
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<tr>
<td></td>
<td>3. Control: patients were advised to reduce drinking and contact GP in the event of health problems</td>
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<tr>
<td>Aalto et al 2001, Finland</td>
<td>1. BI sessions at 0, 2, 6, 12, 18, 24, and 30 months (10–20 minutes based on FRAMES)</td>
<td>• N=296                                                                   • Male patients</td>
<td>36 months</td>
<td>• Drinking amount per week                                                          • Drinking frequency per week                        • Drinking amount per occasion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. BI sessions at 0, 12, and 24 months</td>
<td>• Heavy drinker with self-reported alcohol consumption ≥280 g of absolute ethanol per week&lt;br&gt;• And/or ≥3 affirmative answers on CAGE</td>
<td></td>
<td>• CDT                                                                                • GGT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Control: patients were advised to reduce drinking and contact GP in the event of health problems</td>
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</tr>
<tr>
<td>Allen et al 2011, Russia</td>
<td>1. MI up to four sessions</td>
<td>• N=441                                                                   • Male patients aged 25–54 years recruited from a longitudinal observational study (the Izhevsk Family Study II)&lt;br&gt;• Criteria for hazardous and harmful drinking were:&lt;br&gt;• Zapoi in the last year (behavior resulting in ≥2 days of continuous drunkenness)</td>
<td>3 months</td>
<td>• Self-report of hazardous and harmful drinking</td>
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<tr>
<td></td>
<td>2. Control</td>
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</tbody>
</table>
Table 2 (Continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention</th>
<th>Patients</th>
<th>Follow-up times</th>
<th>Outcomes reported</th>
<th>Key findings</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>• Drinking surrogates (nonbeverage alcohols) in the last year</td>
<td></td>
<td>• Drinking frequency</td>
<td>Units of alcohol per week:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Hangover and/or excessive drunkenness and/or going to sleep clothed due to being drunk twice or more per week on average over the past year</td>
<td></td>
<td>• Drinking diary</td>
<td>• Intervention group increased from 12.8 (8.7) to 13.5 (11.1); control group increased from 12.9 (9.0) to 13.6 (11.7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Weekly consumption of 250 mL or more of ethanol (from beverages) over the past year</td>
<td></td>
<td>• Binge drinking</td>
<td>• Differences not significant</td>
</tr>
<tr>
<td>Beich et al²⁰</td>
<td>1. Bi (10-minute session and follow-up session with GP)</td>
<td>• N=906</td>
<td>12–14 months</td>
<td>• AUDIT score</td>
<td>Men in the intervention group:</td>
</tr>
<tr>
<td>2007, Denmark</td>
<td>2. Control – no intervention</td>
<td>• Listed patients aged 18–64 years, scheduled to see their GP</td>
<td></td>
<td>• Compliance</td>
<td>• 17.3% decrease in 28-day alcohol consumption in standard drinks (from 69.4 to 57.4; P&lt;0.001)</td>
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<tr>
<td></td>
<td></td>
<td>• AUDIT score ≥8</td>
<td></td>
<td>• Number of drinks per month</td>
<td>• 30% decrease in number of risky drinking days (from 6.2 to 4.3; P&lt;0.001)</td>
</tr>
<tr>
<td>Brown et al²⁰</td>
<td>1. Male intervention MI (six sessions)</td>
<td>• N=897</td>
<td>3 months</td>
<td>• Risky drinking days per month</td>
<td>Men in the control group:</td>
</tr>
<tr>
<td>2007, USA</td>
<td>2. Male control</td>
<td>• Patients (21–59 years) who exceeded recommendations on low-risk drinking</td>
<td></td>
<td></td>
<td>• 12.9% decrease in 28-day alcohol consumption in standard drinks (from 82.1 to 71.5; P=0.002)</td>
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<tr>
<td></td>
<td>3. Female intervention MI (six sessions)</td>
<td>• DSM-IV criteria for alcohol abuse or dependence</td>
<td></td>
<td></td>
<td>• 8.3% decrease in number of risky drinking days (from 7.2 to 6.6; P=0.009)</td>
</tr>
<tr>
<td></td>
<td>4. Female control</td>
<td>• No alcohol treatment in the past 3 months</td>
<td></td>
<td></td>
<td>• Decreases in the intervention group significantly larger</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Men who exceeded 56 standard drinks in 28 days and men who had &gt;4 standard drinks in any 1 day</td>
<td></td>
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<td>Women in the intervention group:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Women who exceeded 44 drinks in 28 days and women who had &gt;3 drinks in any 1 day</td>
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<td>• 15.7% decrease in 28-day alcohol consumption in standard drinks (from 50.4 to 42.5; P&lt;0.001)</td>
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<td>• 20.7% decrease in number of risky drinking days (from 5.8 to 4.6; P&lt;0.001)</td>
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<td>Women in the control group:</td>
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<td>• 13.5% decrease in 28-day alcohol consumption in standard drinks (P&lt;0.001)</td>
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<td>• 15.4% decrease in number of risky drinking days (P&lt;0.001)</td>
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<td></td>
<td>• No differences between groups</td>
</tr>
<tr>
<td>Study</td>
<td>Intervention</td>
<td>Control</td>
<td>N</td>
<td>Setting</td>
<td>Outcomes</td>
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<tr>
<td>Curry et al. 2003, USA</td>
<td>1. BI</td>
<td>2. Control</td>
<td>N=307</td>
<td>Outpatients visiting their primary care provider</td>
<td>12 months</td>
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<tr>
<td></td>
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<td>Consuming an average of ≥2 alcoholic drinks per day in the past month (chronic drinking)</td>
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<td>≥2 episodes of binge drinking (defined as consuming ≥5 drinks on a single occasion) in the past month</td>
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<td>≥1 episode of driving after consuming ≥3 drinks</td>
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<td>Prevalence of at-risk drinking practices and weekly alcohol consumption</td>
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</tr>
<tr>
<td>D’Onofrio et al. 2012, USA</td>
<td>1. BNI</td>
<td>2. BNI + booster phone call at 1 month</td>
<td>N=889</td>
<td>Outpatients visiting their primary care provider</td>
<td>12 months</td>
</tr>
<tr>
<td></td>
<td>3. Standard care (screening with health questionnaire)</td>
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<td>Mean number of drinks in the past 7 days:</td>
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<td>Intervention groups reduced from 20.4 (18.8–22.0) and 19.8 (18.3–21.4) to 13.0 (10.5–15.5) and 14.3 (11.9–16.8); control group reduced from 20.9 (18.7–23.2) to 17.6 (14.1–21.2). Differences statistically significant (P=0.045)</td>
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<td>Mean number of binge days in past 28 days:</td>
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<td>Intervention groups reduced from 7.5 (6.8–7.9) to 4.7 (3.9–5.6) and 5.1 (4.2–5.9); control group reduced from 7.2 (6.2–8.2) to 5.8 (4.6–7.0). Differences statistically significant (P=0.03)</td>
<td></td>
</tr>
<tr>
<td>Hermansson et al. 2010, Sweden</td>
<td>1. Comprehensive intervention: patients were offered ≥3 sessions (BI + TLFB + drinking diary over 4 weeks)</td>
<td>2. BI (one 15-minute session)</td>
<td>N=194</td>
<td>Outpatients visiting their primary care provider</td>
<td>12 months</td>
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<td>3. Control: no feedback on screening or verbal counseling</td>
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<td>Change in AUDIT status:</td>
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<td>Overall, 51.3% of patients tested positive at baseline, and 22.8% at follow-up (~56% reduction, P&lt;0.0001)</td>
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<td>No significant differences between groups intervention groups reduced 1.55 (2.47) and 1.11 (1.95) points, respectively; controls reduced 1.11 (2.12) points (P=0.57)</td>
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</tr>
<tr>
<td>Longabaugh et al. 2001, USA</td>
<td>1. BI (40 minutes in ED) + booster MI session</td>
<td>2. BI (single 40-minute session)</td>
<td>N=539</td>
<td>Outpatients visiting their primary care provider</td>
<td>12 months</td>
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<td>3. Standard care</td>
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<td>Number of heavy drinking days:</td>
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<td>BI with booster session had a mean of 1.68 (1.15), BI of 1.72 (1.23) and standard care 1.70 (1.09)</td>
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<td></td>
<td>Differences between groups not significant</td>
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<td>DrInC inventory:</td>
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<td>BI with booster had the lowest score, with 2.24 (0.082). BI was 2.40 (0.078) and standard care was 2.52 (0.076)</td>
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<td>Differences between groups statistically significant (P=0.005)</td>
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<tr>
<td>Study</td>
<td>Intervention</td>
<td>Patients</td>
<td>Follow-up times</td>
<td>Outcomes reported</td>
<td>Key findings</td>
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</tr>
</tbody>
</table>
| Maisto et al\textsuperscript{55} 2001, USA | 1. MET (30–45 minutes session + two booster sessions)  
2. BI (1×10–15 minutes session)  
3. Standard care | • N=301  
• Adults attending a primary care clinic  
• AUDIT score ≥8  
• Or ≥16 standard (0.6 oz ethanol) drinks per week for men and ≥12 drinks for women | 12 months       | • Number of drinks in past 30 days  
• Drinks per drinking days, past 30 days  
• Number of days in the past month in which patients had between 1–6 drinks | Days abstinent:  
• Motivational enhancement therapy group showed the greatest reduction in the difference between baseline to 12-month follow-up: −3.58 (−5.57, −1.58).  
BI reduced −2.54 (−4.56, −0.53), and standard care −1.16 (−2.67, −0.34)  
• Regression models showed no significant differences between either MET or BI vs SC  

Number of drinks:  
• Motivational enhancement therapy group showed a reduction in the difference between baseline to 12-month follow-up of 22 drinks (11.65, 32.32).  
BI reduced 33.20 (18.21, 48.19), and standard care reduced 14.24 (4.21, 24.26)  
• Regression models showed no significant differences between MET vs SC. BI showed a regression coefficient of −1.27 (P<0.05)  

Drinks per drinking day:  
• Motivational enhancement therapy group showed a reduction in the difference between baseline to 12-month follow-up of 1.30 (0.64, 1.96).  
BI reduced 1.55 (0.79, 2.32), and standard care 1.48 (0.85, 2.11)  
• Regression models showed no significant differences between either MET or BI vs SC  

AUDIT-C score  
AUDIT-1:  
• The intervention group decreased from 2.76 (0.89) to 2.33 (0.94); the control group decreased from 2.74 (0.83) to 2.31 (1.07). Differences at 12 months not statistically significant (P=0.87)  

AUDIT-2:  
• The intervention group decreased from 1.53 (1.14) to 1.15 (1.03); the control group decreased from 1.59 (1.12) to 1.16 (1.14). Differences at 12 months not statistically significant (P=0.97)  

AUDIT-3:  
• The intervention group decreased from 1.84 (1.16) to 1.41 (1.13); the control group decreased from 1.88 (1.01) to 1.51 (1.16). Differences at 12 months not statistically significant (P=0.52)  

| Mello et al\textsuperscript{6} 2013, USA | 1. BMI  
2. Standard care | • N=285  
• Patients attending the ED  
• ≥14 drinks/week for male subjects,  
≥7 drinks/week for female subjects  
• Or ≥5 drinks/occasion for males,  
≥4 drinks/occasion for females | 12 months | • Changes in AUDIT-C  
• Alcohol-related injuries  
• DrInC score | AUDIT-C score  
AUDIT-1:  
• The intervention group decreased from 2.76 (0.89) to 2.33 (0.94); the control group decreased from 2.74 (0.83) to 2.31 (1.07). Differences at 12 months not statistically significant (P=0.87)  

AUDIT-2:  
• The intervention group decreased from 1.53 (1.14) to 1.15 (1.03); the control group decreased from 1.59 (1.12) to 1.16 (1.14). Differences at 12 months not statistically significant (P=0.97)  

AUDIT-3:  
• The intervention group decreased from 1.84 (1.16) to 1.41 (1.13); the control group decreased from 1.88 (1.01) to 1.51 (1.16). Differences at 12 months not statistically significant (P=0.52)  

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*Note: The table continues with additional data not shown in this excerpt.*
Alcohol-related injuries:
- Significant decrease favoring the intervention group (difference between baseline and 12-month: −0.33 (0.74) vs −0.16 (0.60); \( P=0.04 \))

DrInC score:
- Intervention group reduced from 3.54 (1.77) to 2.54 (1.72); the control group reduced from 3.38 (1.85) to 2.65 (1.86). Differences between baseline and 12-month score were −1.00 (1.50) for the intervention group and −0.74 (1.70) for the control group.
- Differences not statistically significant (\( P=0.09 \))

Number of days drinking in the last month:
- The intervention group reduced from 8.27 (6.35) to 4.52 (5.70); the control group reduced from 7.31 (6.27) to 6.54 (6.24). Differences statistically significant in the treatment \( \times \) time interaction (\( P=0.001 \))

Number of heavy drinking days in the last month:
- The intervention group reduced from 5.49 (5.94) to 2.26 (2.70); the control group reduced from 4.31 (4.48) to 3.53 (4.28). Differences statistically significant in the treatment \( \times \) time interaction (\( P=0.01 \))

Number of drinks per week in the last month:
- The intervention group reduced from 13.07 (11.59) to 6.10 (8.33); the control group reduced from 10.77 (15.40) to 4.72 (8.34). Differences statistically significant in the treatment \( \times \) time interaction (\( P=0.001 \))
- No differences in RAPi scores at 12 months

Drinks per drinking day in the last week:
- The intervention group reduced from 5.19 (4.30) to 2.26 (2.70); the control group reduced from 4.31 (4.23) to 4.02 (4.00). Difference at 6 months statistically significant between groups (\( P=0.018 \))

Drinks per week in the last week:
- The intervention group reduced from 13.27 (15.40) to 4.72 (8.34); the control group reduced from 10.55 (16.96) to 11.24 (17.74). Difference at 6 months statistically significant between groups (\( P=0.04 \))

Episodes of binge drinking in the last week:
- The intervention group reduced from 1.00 (1.49) to 0.45 (1.38); the control group reduced from 0.88 (1.54) to 0.32 (0.72). Difference at 6 months not statistically significant between groups (\( P=0.139 \))
Intervention

Heavy drinking: Met 42.9%, NDRL 62.5%, control 65%; N 53,56

Significance lost at 12-month follow-up

Key findings

Abstinence: no differences between groups

Patient-centered counseling strategies, mainly through MI, where compared against CBT and 12 steps facilitation in one study, against CBT in another,53 and against social behavioral network therapy in the other.62 Taken together, data from these studies suggest that all these counseling strategies are effective in the treatment of alcohol use disorders, with no significant differences between any of them.

Amount and frequency of alcohol consumption

The three studies failed to report a significant difference between groups while measuring outcomes related to alcohol consumption. Two reported on number of drinks per drinking day, with no significant differences between groups, although globally the whole study sample improved significantly (in the UK Alcohol Treatment Trial study, eg, the reduction was from 26.8 to 19.2).61,62 The same two studies reported also on percentage of days abstinent, with the same general improvement, with no group significant differences (again, in the UK Alcohol Treatment Trial study, it changed from 29.5% to 46.0% for the whole sample). The study by Shakeshaft et al reported a significant within PCC group decrease in the number of drinks per week (from 32.7 to 24.9; P<0.01), with no statistically significant differences when compared to CBT.63

Hazardous and heavy drinking

Two studies reported on measures related to heavy drinking.61,63 Project MATCH (Matching Alcoholism Treatments to Client Heterogeneity) reported a statistical superiority of 12 steps facilitation against CBT and motivational enhancement therapy in the survival analysis in relapse to heavy drinking (defined as three consecutive days of ≥5 drinks per day for men and ≥3 drinks per day for women), where 53% of 12 steps facilitation patients did not relapse, and 49% and 48% in the motivational enhancement therapy and CBT groups did not relapse.61 Shakeshaft et al reported a significant within PCC group decrease in heavy drinking episodes in the last 30 days (from 20.9 to 15.4; P<0.01). Again, no statistically significant differences were noted between groups.63

Patient-centered pharmacological interventions

Five studies were classified in this group (Table 4).64-68 They all shared the same strategy: targeted or as-needed.
<table>
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<tr>
<th>Study</th>
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<tbody>
<tr>
<td>Project MATCH&lt;sup&gt;41&lt;/sup&gt; 1997, USA</td>
<td>1. MET 2. CBT 3. 12-step facilitation</td>
<td>N=648</td>
<td>15 months</td>
<td>% days abstinent in last month; Drinks per drinking day in last month</td>
<td>No consistent and clinically meaningful differences in efficacy between treatments; In the outpatient arm, there was a tendency for CBT patients to have a slightly higher rate of drinking days over time than the other two groups</td>
</tr>
<tr>
<td>Shakeshaft et al&lt;sup&gt;63&lt;/sup&gt; 2002, Australia</td>
<td>1. One or multiple BI sessions (&lt;90 minutes) based on FRAMES 2. Face-to-face counseling for six consecutive weekly sessions, organized around specific themes</td>
<td>N=295</td>
<td>6 months</td>
<td>Weekly alcohol consumption; Binge alcohol consumption; Alcohol-related problems (APQ); AUDIT score; Cost-effectiveness</td>
<td>Intervention group reduced weekly consumption from 32.7 to 24.9 drinks (P&lt;0.01); and binge occasions last 30 days 20.9 to 15.4 (P&lt;0.01); No statistical significance when compared to control group on both outcomes (P=0.78 and P=0.98)</td>
</tr>
<tr>
<td>UKATT Research Team&lt;sup&gt;2&lt;/sup&gt; 2005, UK</td>
<td>1. MET 3×50 minutes sessions over 8–12 weeks 2. SBNT: 8×50-minute sessions over 8–12 weeks</td>
<td>N=742</td>
<td>12 months</td>
<td>Number of drinks per drinking day; Percent of days abstinent; Alcohol dependence, measured by the Leeds dependence questionnaire; Alcohol-related problems over the past 3 months, measured by the alcohol problems questionnaire and GGT levels</td>
<td>Improvement for the whole sample in all drinking outcomes at 3 and 12 months (significance not reported); No significant difference in percentage of days abstinent (MET 45.4% vs SBNT 46.6%; difference 1.19; 95% CI [-4.50 to 6.88]); No significant difference in number of drinks per drinking day (MET 18.7 vs SBNT 19.8; difference 1.14; 95% CI [-0.95 to 3.22])</td>
</tr>
</tbody>
</table>

Abbreviations: BI, brief intervention; BNI, brief negotiated interview; CBT, cognitive behavioral therapy; CI, confidence interval; DSM-III, Diagnostic and statistical manual of mental disorders, third edition; FRAMES, Feedback, Responsibility, Advice, Menu, Empathy, Self-efficacy; GGT, gamma glutamil transpeptidase; MET, motivational enhancement therapy; SBNT, social behavioral network therapy; UKATT, UK Alcohol Treatment Trial.
medication. Three used nalmefene as the study medication, and two used naltrexone. Overall, data clearly suggest a benefit of the PCC intervention, when compared with the control groups, in terms of reduction in alcohol consumption and heavy drinking, with most of the differences reaching statistical significance.

Amount and frequency of alcohol consumption
Four of the five studies in this group reported statistically significant reductions in the intervention group when compared with the control. Mann et al found a significant reduction in grams per day for the nalmefene group (−50.7 vs −39.7). Heinala et al reported a significant difference in grams/week when comparing the coping-naltrexone group with the rest combined (231 vs 354, 357, and 326; P=0.05). Karhuvaara et al reported statistically significant differences in both drinks per week and drinks per drinking day favoring the targeted nalmefene group (drinks per week in the last month: 23.2 vs 28.5, P=0.0018; drinks per drinking day in the last month: 6.3 vs 7.3, P=0.0134). Kranzler et al reported the targeted naltrexone group drinking 16.5% less than the other groups, although differences were not statistically significant. However, among men at week 12, the differences did reach significance (P=0.027). The remaining study by Gual et al reported a baseline to 6-month difference of −5.0 g/day favoring the PCC group, but it did not reach statistical significance (95% CI −10.6 to 0.7; P=0.08).

Hazardous and heavy drinking
The four studies assessing this outcome (Heinala et al, 2001, Karhuvaara et al, 2007, Mann et al, 2013, and Gual et al, 2013) reported statistically significant differences in heavy drinking favoring the PCC groups. The 6-month differences in heavy drinking days per month reported by Gual et al and Mann et al were −1.7 days/month (95% CI −3.1 to 0.4; P=0.012) and −2.3 days/month (P=0.0021), respectively, both favoring the nalmefene group. In the study by Heinala et al, the targeted naltrexone group combined with nonabstinence-oriented group therapy did better than the others in survival analysis for preventing relapse to heavy drinking, reaching statistical significance (exact numbers not reported). In the study by Karhuvaara et al, a statistically significant decrease in heavy drinking days per month favoring the targeted nalmefene group (from 15.5 to 8.8 vs 16.2 to 10.6; P=0.0065).

Discussion
In this paper, we systematically reviewed the efficacy of interventions based on a PCC health care approach for the management of alcohol use disorders. When reviewing the studies identified by our search, it was realized that all PCC trials selected for the review could easily be categorized into two groups: psychosocial interventions and pharmacological supported interventions, and hence, this grouping was adopted. Psychosocial interventions could then be classified further into single sessions of PCC and multiple sessions of PCC.

Regarding psychosocial interventions, our results are in line with previous systematic reviews conducted specifically for MI, which, as mentioned earlier, was the cornerstone of PCC psychosocial interventions found in this review.

Findings within the categories of trials on PCC interventions based on MI appeared mixed. If differences in alcohol consumption emerged between intervention and control groups, they were usually not significant if participants attended one counseling session only. The proportion of studies suggesting that PCC is more effective than control interventions increased if participants took part in several counseling sessions; that is, the number of counseling sessions seems to moderate the effectiveness of PCC. This is in line with the finding of a previous systematic review which concluded that PCC interventions of more than one session work by first increasing the patients’ readiness to change during the first session, and then effecting reduction in alcohol consumption in the follow-up sessions.

Regarding pharmacologically supported PCC interventions, based on the as needed approach, an effect seemed to emerge from our review. However, the effect cannot be attributed fully to pharmacological elements, since studies in this group also had a psychosocial component, and therefore interactions between the two should be taken into account when interpreting the findings. Considering the fact that only a very small percentage of patients with alcohol use disorders (<10%) receive treatment, this finding has significant implications for current health care. All the studies of pharmacological interventions were included in this review on the basis of their “as needed” use. This paradigm has been controversial in addiction medicine for many years, with many believing that medications for alcohol use disorders need to be taken on a supervised, strict basis. In this respect, a recent analysis of clinical trial data for nalmefene concluded that people with alcohol dependence are able to adhere to an as needed regimen. The data indicate that medication intake varies according to drinking patterns with some patients taking the medication daily and others taking medication at tailored intervals. In their recent editorial, Bradley and Kivlahan suggested that pharmacological...
Table 4 Patient-centered pharmacological interventions

<table>
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</table>
| Gual et al<sup>25</sup> | 1. Nalmefene: as-needed dosing of nalmefene 18 mg, 1–2 h before anticipated drinking. Patients also received BRENDA  
2. Control: placebo and BRENDA | • N=718  
• Adults with a primary diagnosis of alcohol dependence                     | 24 weeks         | • Heavy drinking days  
• Total alcohol consumption (g/day)  
• Mean number of heavy drinking days per month:  
  • The nalmefene group decreased from 19.8 (6.8) to 6.6 (8.9), the placebo group decreased from 18.3 (7.0) to 7.5 (9.2).  
  • The group difference at month 6 was –1.7 days/month favoring nalmefene (95% CI –3.1 to –0.4; P=0.012)  
|                        |                                                                             |                                                                           |                 |                                                                                                         | Total alcohol consumption in grams per day:  
  • The nalmefene group decreased from 93 (46) to 30 (36), the placebo group decreased from 89 (48) to 33 (38)  
  • The group difference at month 6 was –5.0 g/day favoring nalmefene (95% CI –10.6 to 0.7; P=0.08)  
|                        |                                                                             |                                                                           |                 |                                                                                                         | Grams per week (with SD) in the last 8 weeks of the study:  
  • Coping + naltrexone 23.1 (40); coping + placebo 35.4 (62); supportive + naltrexone 35.7 (81); supportive-placebo 32.6 (80); cop  
    ing + naltrexone significantly better than the rest of the groups, P=0.05)  
  • Differences not significant prior to this point, with coping + naltrexone tending to do better  
  • Overall comparison in survival analysis significant, with coping + naltrexone doing better in preventing relapses to heavy drinking. In the cop  
    ing group, naltrexone was better than placebo (P=0.008). Naltrexone did better in the coping group compared to the supportive group (P=0.041).  
|                        |                                                                             |                                                                           |                 |                                                                                                         | Heavy drinking days per month:  
  • The nalmefene group decreased from 15.5 (6.9) in the first month to 8.8 (7.3) in the last month; the control group reduced from 16.2 (6.9) to 10.6  
    (8.3). Differences between groups statistically significant (P=0.0065)  
|                        |                                                                             |                                                                           |                 |                                                                                                         | Heavy drinking days during the study period of 28 weeks:  
  • The nalmefene group had 58.2, the control group had 86.1 (risk of heavy drinking 32.4% smaller in the nalmefene group [95% CI 14.2%–46.8%; P=0.0013])  
| Heinala et al<sup>27</sup> | 1. Coping + naltrexone: coping group therapy at weeks 1, 2, 5, and 12 +50 mg of daily naltrexone for 12 weeks, then targeted naltrexone for 20 weeks  
2. Coping + placebo  
3. Supportive + naltrexone: supportive therapy at weeks 1, 2, 5, and 12 (emphasis on abstinence) +50 mg of daily naltrexone for 12 weeks, then targeted naltrexone for 20 weeks  
4. Supportive + placebo | • N=121  
• DSM IV diagnosis of alcohol dependence  
• Average consumption in the last 30 days of ≥5 drinks per day | 32 weeks | • Relapse to heavy drinking (defined as ≥5 drinks on one occasion, having ≥5 drinking occasions in 1 week, or arriving at a visit intoxicated)  
• Differences not significant prior to this point, with coping + naltrexone tending to do better  
|                        |                                                                             |                                                                           |                 |                                                                                                         |  
| Karhuvaara et al<sup>28</sup> | 1. Nalmefene: as-needed dosing patients also received limited elements of BRENDA  
2. Control: placebo and limited elements of BRENDA | • N=403  
• ≥18 heavy drinking days and no more than 14 consecutive abstinence days during the last 12 weeks  
• Sober at inclusion visit and with no withdrawal symptoms | 28 weeks | • Decrease in heavy drinking days per month (≥5 drinks/day in man, ≥4 in women)  
|                        |                                                                             |                                                                           |                 |                                                                                                         | (Continued)  

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</table>
| Kranzler et al²⁰ | 1. Targeted naltrexone  
2. Targeted placebo  
3. Daily naltrexone  
4. Daily placebo | 1. N=163  
2. Average weekly alcohol consumption ≥24 standard drinks for men and ≥18 for women | 12 weeks        | • Number of standard drinks per day | Drinks per week:  
• The nalmefene group reduced from 43.2 (22.4) in the first month to 23.2 (20.8) in the last month; the control group reduced from 45.0 (23.3) to 28.5 (23.7). Differences between groups statistically significant (P=0.0018)  
Drinks per drinking day:  
• The nalmefene group reduced from 9.6 (4.8) in the first month to 6.3 (3.9) in the last month; the control group reduced from 9.5 (4.0) to 7.3 (3.7). Differences between groups statistically significant (P=0.0134)  
Mean number of drinks consumed per day:  
• Targeted naltrexone group drank 16.5% less than other groups. Differences not statistically significant. Exact numbers not reported  
• Among men, at week 12 the targeted naltrexone group drank less than the other groups (P=0.027; exact numbers not reported)  
Mean number of heavy drinking days per month:  
• Nalmefene group decreased from 19 to 8, placebo group decreased from 20 to 11. Adjusted change from baseline to month 6 was −11.2 (0.6) for nalmefene, −8.9 (0.6) for placebo. Group difference of −2.3 days (95% CI −3.8 to −0.8) statistically significant (P=0.0021)  
Total alcohol consumption in grams per day:  
• The nalmefene group decreased from 84 to 33, the placebo group decreased from 85 to 45  
• Adjusted change from baseline to month 6 was −50.7 (2.4) for nalmefene, −39.7 (2.2) for placebo. Group difference of −11.0 g/day (95% CI −16.8 to −5.1) statistically significant (P=0.0003) |
| Mann et al²⁴ | 1. Nalmefene: as-needed dosing of nalmefene 18 mg, 1–2 hours before anticipated drinking  
2. Control: placebo and BRENDA | 1. N=598  
2. Adults with a primary diagnosis of alcohol dependence | 24 weeks        | • Heavy drinking days  
• Total alcohol consumption (g/day) | |

Abbreviations: BRENDA, Biopsychosocial evaluation, Report to the patient on assessment, Empathic understanding of the patient’s situation, Needs collaboratively identified by the patient and treatment provider, Direct advice to the patient on how to meet those needs. Assess reaction of the patient to advice and adjust as necessary for best care; DSM-IV, Diagnostic and statistical manual of mental disorders, fourth edition; SD, standard deviation.
interventions might help bring the concepts of PCC into the alcohol field. By understanding that effective treatments are available, health care professionals are better able to offer people with alcohol use disorders various evidence-based options, including medications and psychosocial support, to achieve recovery.

A key difficulty in conducting this review was the definition and operationalization of PCC as a concept that translates into alcohol use disorders. PCC is not a binary concept (present or absent), and the potential alcohol interventions had to be judged along a continuum of PCC interventions. Despite this fact, we had to simplify and finally dichotomize interventions as PCC or not PCC. For example, the efficacy of pharmacologically supported interventions was considered a key component of this research. Although medications are not PCC (they are just chemical compounds), as needed use allows them to be prescribed in accordance with the principles of PCC. Conversely, computerized interventions were not included in this review. Although one might argue that they can also be considered PCC depending on how they are structured and conducted, they are ultimately based on a predefined number of algorithms and options, thus making it difficult to truly individualize the intervention according to the needs of each patient.

The considerable heterogeneity of the studies included made it impractical to perform any meta-analyses of the data, and so we were limited to narrative descriptions. As discussed by the authors of other systematic reviews of alcohol interventions, this will remain a barrier until consensus is reached in the preferred methods for measuring alcohol consumption.28,71,74 It is therefore important to note that the European Medicines Agency now recommends total alcohol consumption and the number of heavy drinking days as suitable outcomes for studies of alcohol reduction as well as the continued abstinence rate for studies where abstinence is the stated goal. It further suggests that total alcohol consumption and heavy drinking days can also be used to assess the impact of an abstinence-based intervention when patients have a relapse (or lapse or slip).72 It is hoped that such guidance will aid the future standardization of studies.

Other potential limitations of our review include the broad definition of alcohol use disorders (hazardous or harmful drinking, alcohol dependence, or any other alcohol use disorder) and the consequent inclusion of patients with and without a diagnosis of alcohol dependence. It may be that patients with dependence require longer periods of interventions than those without dependence, and this factor might have contributed to some of the findings, especially for PCC psychosocial interventions. To try and homogenize the review, we did not include studies of patients with psychiatric comorbidities or with relevant and differential characteristics (eg, mandated or incarcerated patients and pregnant women). Although necessary for the purposes of this review, application of these exclusion criteria resulted in the exclusion of a number of potentially interesting studies. For example, one large long-term study with nalmefene73 was excluded because it included patients taking antipsychotics or antidepressants for current psychiatric comorbidities. Also, it is important to remark that an important share of alcohol patients do suffer from negative emotional and affective states that might indeed be produced by alcohol itself. Therefore, this exclusion might have oversimplified a complex reality such as the one of alcohol use disorders. Finally, the external validity of our findings is handicapped by the fact that male patients were more than twice as frequent as females in all the categories.

Conclusion

The limitations of the review, as well as the mixed results found in some of the categories investigated, prevent firm conclusions to be drawn. Single-session studies did not appear to show a clear benefit, multiple-session studies showed mixed results, and active comparator studies did not report significant differences while measuring outcomes related to alcohol consumption. Although pharmacological studies were found the most robustly effective, the shorter follow-up periods and the concomitant presence of psychosocial components in the studies prevent a full and clear attribution to be done. However, since we believe that PCC is increasingly accepted as a central tenet of high-quality health care, and some of the results of this review suggest PCC could indeed be an appropriate strategy for alcohol use disorders, there is an urgent need for additional research evidence on the effectiveness of PCC-based alcohol interventions.

Acknowledgments

H Lundbeck A/S funded this systematic review. The authors were solely responsible for the collection, analysis, and interpretation of data and in the writing of the report. There was no payment for the writing of the report, and the decision to submit the report for publication also rested with the authors. The authors thank Anita Chadha-Patel (ACP Clinical Communications Ltd. funded by H Lundbeck A/S) for editorial assistance (English language editing and referencing).
Disclosure
The authors report no conflicts of interest in this work.

References


