# **BMJ Open** Associations between alcohol brief intervention in primary care and drinking and health outcomes in adults with hypertension and type 2 diabetes: a population-based observational study

Felicia W Chi <sup>(D)</sup>, <sup>1</sup> Sujaya Parthasarathy, <sup>1</sup> Vanessa A Palzes, <sup>1</sup> Andrea H Kline-Simon, <sup>1</sup> Constance M Weisner, <sup>1</sup> Derek D Satre, <sup>1,2</sup> Richard W Grant, <sup>1</sup> Joseph Elson, <sup>3</sup> Thekla B Ross, <sup>1</sup> Sameer Awsare, <sup>4</sup> Yun Lu, <sup>1</sup> Verena E Metz, <sup>1</sup> Stacy A Sterling<sup>1</sup>

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For numbered affiliations see end of article.

Correspondence to Ms Felicia W Chi; felicia.w.chi@kp.org

# ABSTRACT

**Objectives** To evaluate associations between alcohol brief intervention (BI) in primary care and 12-month drinking outcomes and 18-month health outcomes among adults with hypertension and type 2 diabetes (T2D). **Design** A population-based observational study using electronic health records data.

**Setting** An integrated healthcare system that implemented system-wide alcohol screening, BI and referral to treatment in adult primary care.

**Participants** Adult primary care patients with hypertension (N=72 979) or T2D (N=19 642) who screened positive for unhealthy alcohol use between 2014 and 2017.

Main outcome measures We examined four drinking outcomes: changes in heavy drinking days/past 3 months, drinking days/week, drinks/drinking day and drinks/week from baseline to 12-month follow-up, based on results of alcohol screens conducted in routine care. Health outcome measures were changes in measured systolic and diastolic blood pressure (BP) and BP reduction ≥3 mm Hg at 18-month follow-up. For patients with T2D, we also examined change in glycohaemoglobin (HbA1c) level and 'controlled HbA1c' (HbA1c<8%) at 18-month follow-up. **Results** For patients with hypertension, those who received BI had a modest but significant additional -0.06 reduction in drinks/drinking day (95% CI -0.11 to -0.01) and additional -0.30 reduction in drinks/week (95% Cl -0.59 to -0.01) at 12 months, compared with those who did not. Patients with hypertension who received BI also had higher odds for having clinically meaningful reduction of diastolic BP at 18 months (OR 1.05, 95% Cl 1.00 to 1.09). Among patients with T2D, no significant associations were found between BI and drinking or health outcomes examined.

**Conclusions** Alcohol BI holds promise for reducing drinking and helping to improve health outcomes among patients with hypertension who screened positive for unhealthy drinking. However, similar associations were not observed among patients with T2D. More research is needed to understand the heterogeneity across diverse

#### STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Our study is among the first large-scale populationbased studies of associations between alcohol brief intervention and both drinking and health outcomes among adult primary care patients with hypertension and type 2 diabetes.
- ⇒ Potential confounding and selection bias were limited by inclusion of a comprehensive set of covariates in the electronic health record and by application of causal inference statistical methods.
- ⇒ Limitations include potential residual confounding from unmeasured confounders and limited generalisability of findings to other healthcare systems or uninsured populations.

subpopulations and to study BI's long-term public health impact.

#### INTRODUCTION

Hypertension and type 2 diabetes (T2D), two of the most prevalent and costly health conditions in the USA<sup>1</sup> are chronic diseases exacerbated by alcohol consumption. According to the Centers for Disease Control and Prevention, more than 34 million (about 1 in 10) Americans have diabetes (among them 90%-95% have T2D) and 108 million (or 45%) have hypertension.<sup>23</sup> Hypertension and T2D prevalences continue to rise worldwide, with hypertension cases predicted to increase from 1.3 billion in  $2016^4$  to 1.56 billion by 2025,<sup>5</sup> and T2D cases from 415 million to 642 million by 2040.<sup>6</sup> The major cause of morbidity and mortality in both conditions is cardiovascular disease (CVD), a leading cause of death in the US and globally.<sup>6</sup> Given the impact of CVD on population health, improved management of hypertension and T2D is key to reducing CVD risk and mortality.

Unhealthy alcohol use (encompassing subclinical at-risk drinking and alcohol use disorder<sup>7</sup>) complicates clinical management of hypertension and T2D and increases CVD risk.<sup>8</sup> The relationship between alcohol consumption and CVD risk has been described as a J-shaped curve with many studies finding moderate drinking (generally <3 standard drinks/day) associated with reduced CVD risk compared with abstinence or heavier drinking.9-12 However, a recent genetic epidemiology study found that the previously observed associations between moderate drinking and reduced CVD risk may not be causal.<sup>13</sup> Another study found even moderate drinking was associated with hypertension and elevated CVD risk in patients with T2D.<sup>14</sup> Alcohol consumption is an important modifiable risk factor that providers can address; reduction in alcohol intake can lead to lower CVD vulnerability among T2D<sup>15 16</sup> and hypertension patients.<sup>17</sup> Given that most hypertension and patients with T2D are managed in primary care, this setting provides a key opportunity to address unhealthy alcohol use for these patients.

For over 20 years, public health leaders have recommended routine screening, brief intervention and referral to treatment (SBIRT) in adult primary care as an evidencebased, population health strategy to address unhealthy drinking.<sup>18</sup> In addition to systematic screening using validated measures, core components include brief intervention ('BI') and referral to specialty treatment ('RT') as needed. BI is the essential feature providing a first-line opportunity to engage patients in discussion about the risks of unhealthy alcohol use, and to encourage them to cut back or abstain. However, clinical trials designed to determine the efficacy of BIs in reducing unhealthy use have had mixed results,<sup>19–26</sup> and effectiveness research in the context of real-world implementation is rare.

Evidence for the real-world effects of alcohol BI on health outcomes, such as blood pressure (BP) and glycohaemoglobin (HbA1c)-related outcomes among hypertension and patients with T2D, is even more limited. A systematic review<sup>27</sup> identified six studies on alcohol BI among patients with hypertension. While findings suggest positive effects of alcohol BI on BP outcomes, only three examined BP outcomes, of which two had small sample sizes. The same review identified two studies of alcohol BI among patients with diabetes in primary care, with positive findings regarding BI's effect on drinking outcomes. However, samples in both studies were small and diabetesrelated outcomes, including cardiovascular risk factors, the leading cause of death among patients with T2D,<sup>28</sup> were not included. In a large pragmatic trial comparing SBIRT modalities at Kaiser Permanente Northern California (KPNC), alcohol BI delivered by primary care providers was positively associated with better BP control at 18 months, and for those with lower heavy drinking frequency and poor BP control at index screening.<sup>2</sup> However, no other large-scale SBIRT implementation studies have examined the impact of alcohol BI on

health outcomes. Expanding the scientific knowledge base on the relationship between alcohol BI and health outcomes for primary care patients with chronic conditions addresses a critical knowledge gap, and findings could provide a strong incentive for physicians to help patients reduce unhealthy drinking.

To address these substantial gaps in the literature, the current study examined associations between receiving alcohol BI and 12-month drinking outcomes and 18-month health outcomes among adult patients with hypertension and T2D who screened positive for unhealthy alcohol use in adult primary care. The study was conducted in the context of a systematic, populationbased SBIRT programme in an integrated healthcare delivery system; findings could contribute substantially to understanding the effectiveness of alcohol BI in these clinical populations.

# Methods

# Study setting

KPNC is a non-profit integrated healthcare system of over four million members, representing about a third of all Northern Californians, with a socioeconomically diverse membership similar to the local and state-wide insured population, excluding those with very low income. KPNC provides care to a population insured through employer-based plans, Medicare, Medicaid and health insurance exchanges and its members are highly representative of the US population with access to care.<sup>30 31</sup> KPNC has 21 medical centres, 233 medical offices and 2147 adult primary care physicians and providers, and provides specialty psychiatry and addiction treatment as a covered benefit. Sociodemographics, diagnoses, clinic visits, procedures, medications and laboratory measurements were maintained in KPNC electronic health record (EHR), which the study principal investigator and the lead analyst had full access to.

#### Systematic alcohol screening and BI

The Alcohol as a Vital Sign (AVS) initiative is an SBIRT workflow in adult primary care (Internal Medicine or Family Practice) at KPNC. Using National Institute on Alcohol Abuse and Alcoholism (NIAAA) evidence-based screening instruments embedded in the EHR, medical assistants ask a single-item question about heavy drinking ('How many times in the past 3 months have you had five or more drinks in a day' (for men aged 18–65 years), or 'four or more drinks' for men aged ≥66 years and women of all ages), followed by two questions on typical drinking days per week and typical number of drinks per drinking day.<sup>32</sup> Medical assistants ask these questions as they collect other vital sign information, and record patient answers in the EHR.

Drinking that exceeds recommended daily and/or weekly limits (>7 drinks/week for women and men aged 66 and older, or >14 drinks/week for men aged 18–65), is considered positive for unhealthy drinking. Per protocol, physicians offer patients who screen positive a BI based on motivational interviewing principles,<sup>33</sup> including a referral to outpatient addiction medicine treatment if indicated. The EHR alerts medical assistants with a reminder to screen patients annually, except for those who had a prior positive alcohol screening, in which case the reminder is issued every 6 months until the patient has a negative screening. See online supplemental document 1 for detailed descriptions of the AVS protocol.

## Sample

We identified 440 882 patients who screened positive for unhealthy drinking in KPNC adult primary care between 1 January 2014 and 31 December 2017; the index date was defined as the date of the first positive screen for unhealthy drinking during this period (the index screening).

Among them, a sample of patients with hypertension (N=95 022) was identified based on the International Statistical Classification of Diseases, 9th/10th revision (ICD-9/ICD-10) codes (online supplemental table 1) received in the prior year. We excluded patients who: (1) did not have continuous membership in the year prior to index date (N=13 735), (2) were older than 85 on the index date (N=1795) or (3) did not have complete alcohol index screening data (N=6513); resulting in a final analytical sample of 72 979 patients with hypertension ('hypertension sample'). We also identified a sample of patients with T2D using KPNC's diabetes registry<sup>34 35</sup> (N=24 996). We excluded patients who: (1) did not have continuous membership in the prior year (N=3516), (2) were older than 85 on the index date (N=319) or (3) did not have complete alcohol index screening data (N=1519); resulting in a final analytical sample of 19 642 patients with T2D ('T2D sample'). The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) diagrams<sup>36</sup> are available for both samples (online supplemental figure 1 and online supplemental figure 2).

#### Patient and public involvement

No patient involved.

#### **Measures**

### BI at index screening

BI on the index date was determined by using ICD-9 (V65.42 and V65.49) or ICD-10 codes (Z71.41 and Z71.89), Current Procedural Terminology codes (96160, 99420, 99408 and 99409) and Healthcare Common Procedure Coding System codes (G0396, G0397, G0443 and H0050).

#### Alcohol consumption at index screening

Based on self-reported drinking levels at index screening, we further classified patients in both samples into mutually exclusive groups as 'exceeding only daily limit', 'exceeding only weekly limit' or 'exceeding both daily and weekly limits', per NIAAA guidelines.

#### Other index screening measures

We defined index year of screening, as well as the index facility and department, based on the index positive screening.

## Drinking outcomes at 12-month follow-up

We examined four drinking outcomes: change in heavy drinking days/past 3 months (ie, days drinking exceeding daily limits, 'heavy drinking'), change in drinking days/ week ('drinking frequency'), change in drinks/drinking day ('drinking intensity') and change in drinks/week ('total consumption') from baseline to 12-month follow-up, using follow-up AVS alcohol screenings derived from EHR data. Because patients may not have had a follow-up alcohol screening exactly 12 months postindex, we identified follow-up screenings between 6 and 12 months postindex date; if a patient had more than one screening during this period, the one closest to 12-month follow-up was chosen.

#### Health outcomes at 18-month follow-up

For patients with hypertension, the health outcome measures were changes from baseline in systolic and diastolic BP (SBP and DBP) at 18-month follow-up per EHR records. We also created a binary measure of  $\geq$ 3 mm Hg reduction from baseline at 18 months, an indicator of clinically meaningful change.<sup>37-40</sup> For patients with T2D, we examined the above BP measures given the prevalence of hypertension and importance of BP control in CVD risk reduction among them,<sup>14 41 42</sup> as well as change in HbA1c level and 'controlled A1c' (HbA1c<8%),<sup>43</sup> at 18-month follow-up per EHR lab records. We identified follow-up health outcome measures between 12 months and 18 months postindex date; for multiple EHR measures, the one closest to 18-month follow-up was chosen.

#### Patient characteristics

From the EHR, we extracted patients' sex, age, race/ ethnicity and insurance type at the index date. Smoking status was determined based on the most recent tobacco screening in the year before the index date. We used the most recent record of self-reported physical activity in the prior year and classified individuals into three groups: inactive (0 min/week), insufficient activity (>0 but <149 min/week) and sufficient activity ( $\geq 150 \text{ min/week}$ ).<sup>44</sup> Similarly, we used the most recent record of body mass index in the prior year and created four groups: underweight (<18.5), normal weight (18.5-24.9), overweight (25.0-29.9) and obese  $(\geq 30.0)$ .<sup>45</sup> To adjust for medical comorbidity burden, we used the Charlson Comorbidity Score<sup>46</sup> and categorised results into 0, 1, 2,  $\geq$ 3. We also identified whether individuals had an alcohol use disorder, drug use disorder or mental health condition<sup>47 48</sup> (depression, bipolar disorder, schizophrenia, schizoaffective disorder, anxiety disorder, obsessive-compulsive disorder, pervasive developmental disorder, anorexia nervosa and bulimia nervosa) in the year prior to index date, based on ICD-9 and ICD-10 codes (online supplemental table 1). We used neighbourhood deprivation index<sup>49</sup> as a proxy for individual socioeconomic status. In addition, we extracted patients' service utilisation (emergency department, inpatient and primary care) in the year prior to the index screening and summarised each of them into categories of 0, 1, 2,  $\geq$ 3.

For the hypertension sample, we extracted the following clinical characteristics associated with receipt of BI, drinking or health outcomes in prior studies<sup>50</sup>: adherence to antihypertensive medication in the year prior to index screening, measured as proportions of days covered and categorised into 'no prescriptions', '<50%', '50%-79%', '80%-89%' and '90%-100%'; BP level at the index visit categorised into 'hypertension' (systolic BP  $\geq$ 140 or diastolic BP  $\geq$ 90), 'elevated/prehypertension' (systolic BP=120-139 or diastolic BP=80-89), 'normal' (systolic BP <120 or diastolic BP <80) per KPNC guideline.<sup>51</sup> Similarly, we extracted EHR data on the following clinical characteristics for those in the T2D sample: whether they were already on insulin in the prior year; adherence to oral glycaemic-lowering medication, antihypertensive medication and lipid-lowering medication in the prior year (same categories as above); HbA1c level at the index visit  $(<7\%', `7\% \text{ to } <8\%', `8\% \text{ to } <9\%', `\geq9\%');$  BP level (same categories as above); estimated glomerular filtration rate (eGFR) at index t based on serum creatinine and categorised into 'normal or high', 'mildly decreased', 'mildlymoderately decreased', 'moderately-severely decreased', 'severely decreased' or 'kidney failure'.<sup>52</sup>

#### **Provider characteristics**

For primary care providers of the index screening, we extracted providers' age, sex, race/ethnicity, specialty (internal medicine, family practice) and years of service from KPNC administrative databases.

#### **Statistical analysis**

We used marginal structural models with inverse probability weighting (MSM-IPW) to examine differences in: (1) drinking outcomes at 12 months and (2) health outcomes at 18 months between those who did and did not receive BI for unhealthy alcohol use, among patients with hypertension and T2D separately. Marginal structural models are a class of statistical methods that aim to fully adjust for measured confounders to enhance treatment group comparability in observational studies, thus allowing estimating causal associations in a way approximating randomised controlled trials. Analyses for (1) involved four steps. First, for each patient, we generated inverse probability of treatment weight (IPTW) for receiving BI for the index positive screening by fitting logistic regression models on a set of patient and provider characteristics that were hypothesised to be associated with receiving BI and/or the drinking outcomes within that sample, based on preliminary analyses and the literature. Second, for each patient, we generated inverse probability weights for being censored (IPCW) at 12 months for each patient by fitting logistic regression models on

the same set of covariates as above, plus receipt of BI for the index screening. Third, for each patient, a stabilised weight was generated as the product of IPTW and IPCW. Fourth, for each drinking outcome at 12 months, we estimated the associations between BI and each of the drinking outcomes by fitting weighted regression models using the stabilised weights, with estimates and robust standard errors acquired using SAS SURVEYREG procedure. Analyses for (2) involved similar four steps, with step 2 estimating IPCW at 18 months and step 4 estimating the associations between BI and each of the health outcomes at 18 months using SURVEYREG and SURVEYLOGISTIC for continuous and binary outcome measures, respectively.

We also examined whether associations between BI and outcomes differ by the following baseline patient characteristics: index alcohol consumption level, BP level, sex and age group  $(18-29/30-44/45-64/\geq 65)$ .<sup>53</sup> For each of these variables, we re-estimated the weights within each level of the variable, then estimated associations between BI and each of the drinking and health outcomes using a single weighted model including the interaction terms between BI and the variable. Significance was defined at p<0.05 and all tests were two tailed. Analyses were performed using SAS V.9.4 (SAS Institute).

#### RESULTS

#### Sample description

Most patients with hypertension (n=72 979) and T2D (n=19 642) who screened positive for unhealthy drinking were male (68% and 79%, respectively) and white (71% and 53%, respectively), with mean age around 60 (mean (SD) =61.7 (12.7) and 59.8 (12.6), respectively) (table 1). About 17% and 15% reported drinking at levels exceeding daily and weekly limits, respectively. In both samples, about 5% had an alcohol use disorder diagnosis and about 15% had comorbid mental health conditions in the prior year; over three-fourths were overweight or obese and about one-seventh reported current smoking. At the index visit, 83% and 78% of patients with hypertension and T2D had BP at elevated/prehypertension or hypertension levels, respectively.

Proportions receiving BI at the index positive screening were 45% (32 835 out of 72,979) and 43% (9406 out of 19 642) in the hypertension sample and T2D sample, respectively. We calculated the standardised differences of means (for continuous variables) and proportions (for categorical variables) with and without applying the inverse probability weighting; results indicated that weighting improved the balance in patient characteristics between BI and no-BI groups (online supplemental tables 2–12).

#### Associations between BI and 12-month drinking outcomes

About half of both samples had a follow-up alcohol screening at 12 months. Among each, all four drinking outcomes decreased from baseline, with an average

Table 1         Characteristics of patier	nts with hypertension and T2D who screened positive for	or unhealthy drinking	
		Hypertension sample (N=72 979)	T2D sample (N=19 642)
Alcohol consumption level (%)	Exceeding only daily limits	39.7	52.4
	Exceeding only weekly limits	43.5	32.6
	Exceeding both daily and weekly limits	16.8	15.1
Receiving BI (%)		45.0	42.8
Age, mean (SD)		61.6 (12.7)	59.8 (12.6)
Male (%)		67.5	79.0
Race/ethnicity (%)	Asian/Pacific Islander	6.9	11.8
	Black	7.7	8.5
	Hispanic	12.9	24.5
	Other	2.0	2.5
	White	70.5	52.8
Insurance type (%)	Commercial	50.7	56.0
	Medicaid	1.6	2.2
	Medicare	47.4	41.4
	Other/unknown	0.4	0.4
Comorbidities 1 year prior (%)	Any alcohol use disorders	4.8	4.6
	Any drug use disorders	1.2	1.1
	Any mental health disorders	17.0	14.8
Charlson Index (%)	0	53.1	7.8
	1	22.2	41.6
	2	11.9	22.3
	≥3	12.8	28.4
Body mass index category	Normal	16.7	9.0
	Obese	42.8	56.4
	Overweight	35.5	30.2
	Underweight	0.5	0.1
	Unknown	4.5	4.3
Smoking status	Non-smoker	84.4	82.9
	Smoker	14.0	15.2
	Unknown	1.6	1.8
Physical activity level (%)	Inactive	35.8	41.5
	Insufficient activity	24.7	24.9
	Sufficient activity	37.9	30.4
	Unknown	1.5	3.3
Blood Pressure at Index Visit (%)	Normal (SBP <120 and DBP <80)	12.4	16.7
	Elevated or prehypertension (SBP 120–139 or DBP 80–89)	63.0	63.4
	Hypertension (SBP ≥140 or DBP ≥90)	20.2	14.3
	Unknown	4.4	5.6
HbA1c Level (%)	<7%	_	42.2
	7% to <8%	_	21.8
	8% to <9%	_	9.3
	≥9%	_	15.0
	Unknown		11.6

Continued

Table 1   Continued			
		Hypertension sample (N=72 979)	T2D sample (N=19 642)
On insulin 1 year prior (%)	No	-	84.8
	Yes	_	15.2
eGFR stages (%)	G1 (normal or high)	_	35.2
	G2 (mildly decreased)	_	39.1
	G3a (mildly-moderately decreased)	-	8.1
	G3b (moderately-severely decreased)	-	2.8
	G4 (severely decreased)	-	0.5
	G5 kidney failure	-	0.1
	Unknown	-	14.3
Medication adherence 1 year price	or (%)		
Oral glycaemic lowering	No Rx	-	40.2
Medication	<50%	-	7.2
	50%–79%	_	13.6
	80%-89%	-	9.5
	90%–100%	_	29.5
Antihypertensive medications	No Rx	17.1	26.2
	<50%	5.8	5.7
	50%–79%	11.8	10.7
	80%–89%	11.4	9.9
	90%–100%	53.9	47.6
Lipid-lowering medications	No Rx	_	32.2
	<50%	-	8.7
	50%–79%	-	16.0
	80%–89%	-	13.0
	90%–100%	-	30.1
Utilisation 1 year prior (%)			
Emergency department visits	None	81.4	80.8
	1	13.7	13.7
	2	3.1	3.5
	>=3	1.8	2.0
Inpatient encounters	None	95.0	95.3
	1	4.0	3.7
	2	0.8	0.7
	≥3	0.3	0.4
Primary care visits	None	55.9	55.2
	1	27.7	27.9
	2	9.7	9.8
	≥3	6.7	7.1

BI, brief intervention; DBP, diastolic blood pressure; eGFR, estimated glomerular filtration rate; HbA1c, glycohaemoglobin; SBP, systolic blood pressure; T2D, type 2 diabetes.

decline of 2.4 heavy drinking days/past 3 months, 1.1 drinking day/week, 0.9 drinks/day and 4.0 drinks/week in patients with hypertension and an average decline of

3.0 heavy drinking days/past 3 months, 1.0 drinking day/ week, 1.1 drinks/day and 3.9 drinks/week in patients with T2D. We did not find significant associations between BI and change in heavy drinking days or change in drinking days/week at 12 months in either sample. For the hypertension sample, those who received BI had additional reductions of -0.06 drinks/day (95% CI -0.11 to -0.01) and -0.30 drinks/week reduction (95% CI -0.59 to -0.01) at 12 months compared with those who did not receive BI (table 2).

However, associations between BI and drinking outcomes varied by patient characteristics among patients with hypertension. For them, receiving BI resulted in greater reduction on all four drinking outcomes at 12 months for those exceeding only daily drinking limits at baseline, but not for those exceeding only weekly limits or for those exceeding both daily and weekly limits; the heterogeneity was significant for change in heavy drinking days/past 3 months and drinks/drinking day at 12 months (p value for the interaction between BI and alcohol consumption <0.05 for both). We also found heterogeneity by age: receiving BI resulted in significant reductions in drinking days/week, drinks/drinking day and drinks/week in 45–64 years old, but not in other age groups. Hypertension patients with hypertensive baseline BP who received BI had a significant reduction in drinks/ drinking day (mean difference (95% CI) -0.19 (-0.32 to -0.06), p=0.003).

For patients with T2D, receiving BI resulted in significantly greater reduction in drinks/drinking day in 30–44 years old (-0.64 (-1.16 to -0.12), p=0.016) but not in other age groups. Those with hypertensive baseline BP who received BI had a significant reduction in the number of heavy drinking days (mean difference (95% CI) = -2.59(-4.89 to -0.28), p=0.028) compared with those who did not receive BI, but the p value for the interaction between BI and baseline BP level was not significant (p=0.058).

#### Associations between BI and BP outcomes at 18 months

Over 60% of patients with hypertension and T2D had BP measures at 18-month follow-up. On average, there was a 1.3 mm Hg decrease in diastolic BP and 0.9 mm Hg decrease in systolic BP at 18 months, with 45% had a reduction  $\geq$ 3 mm Hg for each among hypertension patients, and a 0.9 mm Hg decrease in diastolic BP and 0.01 mm Hg increase for systolic BP at 18 months, with 43% had a reduction  $\geq$ 3 mm Hg for each among patients with T2D, respectively.

Among patients with hypertension, those who received a BI had an additional -0.26 mm Hg decline in DBP at 18 months (95% CI=-0.54 to 0.01, p=0.062) compared with those who did not, and had 5% higher odds of having a  $\geq 3$  mm Hg DBP reduction at 18 months (OR=1.05, (95% CI)= (1.00 to 1.09), p=0.043), but there was no difference in change in SBP (table 3). We found no heterogeneity by patient characteristics. However, results suggested that for patients with hypertension who drank at levels exceeding only weekly limits, receiving BI resulted in 7% higher odds of having DBP reduced  $\geq 3$  mm Hg at 18 months (95% CI=1.01 to 1.14, p=0.032). We did not find significant associations between BI and BP outcomes at 18 months among patients with T2D. However, women with T2D who received a BI had significantly higher SBP and lower odds of having SBP reduced  $\geq$ 3 mm Hg at 18 months than women who did not receive a BI (mean difference (95% CI)=2.86 (1.07 to 4.65) and OR (95% CI)=0.74 (0.61 to 0.89), respectively), while no significant associations between BI and change in SBP were found for men with T2D.

# Associations between BI and HbA1c outcomes at 18 months among patients with T2D $\,$

About 59% of patients with T2D had HbA1c measures at 18-month follow-up. Among them, 71% had HbA1c <8% at 18-month follow-up. We found no significant associations between BI and HbA1c outcomes at 18 months among patients with T2D, overall or by patient characteristics (table 4).

# DISCUSSION

We examined relationships between receiving an alcohol BI from a primary care physician and four drinking outcomes at 12 months and health outcomes at 18 months, among adults with hypertension and T2D who screened positive for unhealthy alcohol use during routine population-based screening within an integrated healthcare system. On average, we found that self-reported drinking decreased at 12- month follow-up, whether or not a BI was received. Results from MSM-IPW analyses found that for patients with hypertension, those who received BI had a modest but significant additional reduction in drinking intensity (an additional -0.06 reduction in drinks/drinking day) and total consumption (an additional -0.30 reduction in drinks/week) at 12 months, compared with those not receiving a BI. However, receiving BI was not significantly associated with change in heavy drinking or drinking frequency among patients with hypertension, nor with any of the four drinking outcomes among patients with T2D. While results suggested a minimal overall BI effectiveness on reducing drinking at 12 months in both samples, we found potential heterogeneity by patient characteristics, indicating that BIs may be more effective for specific subgroups. BI was beneficial in reducing drinking for patients with hypertension who were exceeding only daily limits at the index date, for men and for adults aged 45-64; and possibly for patients who had DBP >90/SBP >140 at the index date.

Effects of alcohol on cardiovascular health are heterogeneous and vary according to consumption dose and pattern.<sup>17</sup> Some studies suggest that average quantity of alcohol consumption plays a more important role in the risk of hypertension than frequency of drinking,<sup>54</sup> whereas others suggest consistent long-term heavy drinking is a cause for elevated hypertension risk.<sup>55</sup> More research is needed to determine whether, why and for whom BI is more effective on some drinking outcomes than others. 
 Table 2
 Associations between BI and 12-month drinking outcomes among patients with hypertension and T2D who screened positive for unhealthy drinking

	Effect size of receiving BI, yes vs no					
	Hypertension sample         T2D sample					
	Est. (95% CI)	P value	Int. P value	Est. (95% Cl)	P value	Int. P value
Outcome=change in heavy drinking days/past 3 months						
Overall	-0.10 (-0.64 to 0.44)	0.709	_	-0.07 (-1.04 to 0.89)	0.883	-
Baseline alcohol consumption level			0.005			0.551
Exceeding only daily limits	-0.46 (-0.85 to -0.07)	0.022		-0.49 (-1.13 to 0.15)	0.132	
Exceeding only weekly limits	0.38 (0.01 to 0.75)	0.046		0.06 (-0.77 to 0.90)	0.881	
Exceeding both daily and weekly limits	-1.30 (-3.46 to 0.86)	0.238		0.66 (-4.62 to 5.95)	0.806	
Baseline BP category			0.224			0.058
Normal	-0.11 (-1.34 to 1.11)	0.855		-0.86 (-2.42 to 0.69)	0.275	
Elevated/prehypertension	0.06 (-0.57 to 0.69)	0.853		0.47 (-0.77 to 1.71)	0.457	
Hypertension	-1.14 (-2.35 to 0.07)	0.064		-2.59 (-4.89 to -0.28)	0.028	
Sex			0.244			0.244
Female	0.34 (-0.31 to 0.98)	0.305		0.70 (-0.62 to 2.02)	0.298	
Male	-0.23 (-0.93 to 0.47)	0.522		-0.33 (-1.46 to 0.80)	0.565	
Age group			0.916			0.773
18–29	-0.99 (-3.92 to 1.93)	0.505		-0.48 (-6.13 to 5.17)	0.869	
30–44	-0.43 (-2.18 to 1.31)	0.627		-1.29 (-3.96 to 1.38)	0.344	
45–64	-0.03 (-0.93 to 0.88)	0.955		0.19 (-1.17 to 1.56)	0.782	
65+	-0.25 (-0.80 to 0.30)	0.381		-0.47 (-1.62 to 0.67)	0.419	
Outcome=change in drinking days/week						
Overall	-0.05 (-0.12 to 0.03)	0.214	-	-0.05 (-0.16 to 0.06)	0.370	-
Baseline alcohol consumption level			0.315			0.125
Exceeding only daily limits	-0.08 (-0.16 to -0.01)	0.028		0.08 (-0.04 to 0.20)	0.176	
Exceeding only weekly limits	0.01 (-0.09 to 0.10)	0.851		-0.17 (-0.38 to 0.04)	0.120	
Exceeding both daily and weekly limits	-0.03 (-0.25 to 0.19)	0.801		-0.04 (-0.42 to 0.33)	0.821	
Baseline BP category			0.736			0.682
Normal	-0.04 (-0.21 to 0.12)	0.627		-0.07 (-0.33 to 0.20)	0.622	
Elevated/prehypertension	<0.01 (-0.07 to 0.07)	0.994		-0.05 (-0.18 to 0.09)	0.520	
Hypertension	-0.08 (-0.30 to 0.14)	0.467		0.10 (-0.21 to 0.41)	0.539	
Sex			0.432			0.249
Female	-0.09 (-0.19 to 0.02)	0.102		-0.18 (-0.44 to 0.07)	0.159	
Male	-0.03 (-0.12 to 0.06)	0.534		-0.02 (-0.14 to 0.11)	0.785	
Age group			0.274			0.730
18–29	0.25 (-0.22 to 0.73)	0.298		0.11 (-0.59 to 0.81)	0.754	
30–44	-0.16 (-0.56 to 0.24)	0.437		0.08 (-0.28 to 0.44)	0.664	
45–64	-0.09 (-0.19 to <-0.01)	0.047		-0.12 (-0.29 to 0.05)	0.183	
65+	<-0.01 (-0.09 to 0.09)	1.000		-0.04 (-0.21 to 0.14)	0.699	
Outcome=change in drinks/drinking day						
Overall	-0.06 (-0.11 to -0.01)	0.020	-	-0.11 (-0.24 to 0.02)	0.087	-
Baseline alcohol consumption level			0.021			0.589
Exceeding only daily limits	-0.12 (-0.20 to -0.04)	0.004		-0.13 (-0.28 to 0.03)	0.106	
Exceeding only weekly limits	0.01 (-0.05 to 0.07)	0.690		-0.07 (-0.23 to 0.10)	0.437	
Exceeding both daily and weekly limits	-0.11 (-0.28 to 0.05)	0.165		-0.29 (-0.69 to 0.12)	0.161	

Continued

#### Table 2 Continued

	Effect size of receiving BI, yes vs no					
	Hypertension sample			T2D sample		
	Est. (95% Cl)	P value	Int. P value	Est. (95% CI)	P value	Int. P value
Baseline BP category			0.033			0.934
Normal	-0.08 (-0.21 to 0.06)	0.259		-0.07 (-0.31 to 0.18)	0.582	
Elevated/prehypertension	-0.01 (-0.07 to 0.05)	0.798		-0.13 (-0.29 to 0.04)	0.140	
Hypertension	-0.19 (-0.32 to -0.06)	0.003		-0.12 (-0.44 to 0.20)	0.459	
Sex			0.142			0.495
Female	-0.01 (-0.07 to 0.05)	0.791		-0.05 (-0.24 to 0.15)	0.646	
Male	-0.08 (-0.15 to -0.01)	0.027		-0.13 (-0.28 to 0.02)	0.085	
Age group			0.009			0.029
18–29	-1.20 (-2.86 to 0.46)	0.156		1.27 (0.01 to 2.53)	0.048	
30–44	-0.23 (-0.47 to <0.01)	0.053		-0.64 (-1.16 to -0.12)	0.016	
45–64	-0.10 (-0.19 to -0.01)	0.024		-0.05 (-0.25 to 0.14)	0.593	
65+	0.03 (-0.02 to 0.07)	0.297		-0.05 (-0.17 to 0.07)	0.417	
Outcome=change in drinks/week						
Overall	-0.30 (-0.59 to -0.01)	0.043	_	-0.13 (-0.79 to 0.53)	0.706	-
Baseline alcohol consumption level			0.788			0.710
Exceeding only daily limits	-0.33 (-0.55 to -0.10)	0.005		0.03 (-0.29 to 0.36)	0.833	
Exceeding only weekly limits	-0.19 (-0.53 to 0.14)	0.258		-0.30 (-1.13 to 0.52)	0.469	
Exceeding both daily and weekly limits	-0.40 (-1.37 to 0.58)	0.424		-0.45 (-2.92 to 2.02)	0.721	
Baseline BP category			0.256			0.943
Normal	-0.31 (-0.87 to 0.25)	0.276		-0.27 (-1.25 to 0.70)	0.583	
Elevated/prehypertension	-0.11 (-0.41 to 0.20)	0.492		-0.08 (-0.92 to 0.75)	0.849	
Hypertension	-0.80 (-1.58 to -0.02)	0.045		-0.30 (-1.70 to 1.09)	0.672	
Sex			0.558			0.370
Female	-0.18 (-0.49 to 0.13)	0.267		-0.57 (-1.43 to 0.29)	0.190	
Male	-0.32 (-0.71 to 0.06)	0.099		-0.05 (-0.80 to 0.70)	0.890	
Age group			0.439			0.575
18–29	-1.22 (-5.69 to 3.25)	0.593		1.77 (-0.99 to 4.53)	0.209	
30–44	-0.18 (-1.66 to 1.31)	0.817		-0.42 (-2.22 to 1.39)	0.652	
45–64	-0.56 (-1.03 to -0.09)	0.019		0.01 (-0.96 to 0.99)	0.981	
65+	-0.12 (-0.40 to 0.16)	0.405		-0.18 (-0.83 to 0.46)	0.580	

Bold values denote statistical significance at the p < 0.05 level.

BI, brief intervention; BP, blood pressure; NS, non-significant at p<0.05 level; T2D, type 2 diabetes.

Nevertheless, the current results are encouraging, as our prior research found that among KPNC adult primary care patients who drank, those with hypertension and T2D were more likely to exceed the drinking limits,<sup>56</sup> and our findings suggest that alcohol screening and BI in adult primary care may be an important cost-effective service for chronic disease prevention and intervention, given its brevity, low cost and potential reach.<sup>57</sup> Further, population-level impacts of primary care SBIRT implementation in health systems may be substantial.

When examining associations between BI and BP outcomes, we found that among patients with

hypertension, those who received BI had higher odds of clinically meaningful reduction of DBP at 18 months. In addition, BI may have been beneficial for those exceeding only weekly drinking limits at the index date. Epidemiological studies suggested that a 2–3 mm Hg decrease in BP is associated with lower CVD risk, for example, a 2 mm Hg increase in BP increases mortality from stroke by 10% and from coronary artery disease by 7%,<sup>37</sup> while a 2–3 mm Hg decrease in BP is associated with a 4% lower risk of coronary death and a 6% lower risk of stroke death in middle age.<sup>40</sup> Thus, to put into a population health perspective, our findings of significant BI effectiveness on

 Table 3
 Associations between BI and 18-month blood pressure outcomes among patients with hypertension and T2D who screened positive for unhealthy drinking

	Effect size of receiving BI, yes vs no					
	Hypertension sample     T2D sample					
	Est. (95% Cl)	P value	Interaction p value	Est. (95% CI)	P value	Interaction p value
Outcome=change in diastolic BP						
Overall	-0.26 (-0.54 to 0.01)	0.062	-	0.21 (-0.27 to 0.69)	0.393	-
Baseline alcohol consumption level			0.658			0.440
Exceeding only daily limits	-0.32 (-0.79 to 0.15)	0.186		0.18 (-0.51 to 0.87)	0.600	
Exceeding only weekly limits	-0.36 (-0.73 to <0.01)	0.051		-0.08 (-0.87 to 0.72)	0.849	
Exceeding both daily and weekly limits	0.01 (-0.70 to 0.72)	0.985		1.04 (-0.47 to 2.56)	0.178	
Baseline BP category			0.740			0.744
Normal	-0.05 (-0.67 to 0.57)	0.874		0.52 (-0.48 to 1.51)	0.310	
Elevated/prehypertension	-0.19 (-0.46 to 0.09)	0.180		0.10 (-0.45 to 0.65)	0.716	
Hypertension	-0.44 (-1.20 to 0.33)	0.260		-0.07 (-1.84 to 1.70)	0.938	
Sex			0.537			0.979
Female	-0.40 (-0.83 to 0.04)	0.072		0.18 (-1.02 to 1.38)	0.767	
Male	-0.22 (-0.57 to 0.12)	0.205		0.20 (-0.34 to 0.74)	0.466	
Age group			0.919			0.188
18–29	1.19 (-3.02 to 5.39)	0.581		0.73 (-3.82 to 5.29)	0.752	
30–44	-0.35 (-1.42 to 0.73)	0.530		0.90 (-1.04 to 2.83)	0.364	
45–64	-0.23 (-0.68 to 0.22)	0.321		0.51 (-0.19 to 1.21)	0.151	
65+	-0.27 (-0.60 to 0.06)	0.103		-0.49 (-1.18 to 0.21)	0.169	
Outcome=change in systolic BP						
Overall	-0.18 (-0.61 to 0.25)	0.410	-	0.33 (-0.43 to 1.09)	0.392	-
Baseline alcohol consumption level			0.604			0.188
Exceeding only daily limits	-0.21 (-0.91 to 0.49)	0.555		0.16 (-0.88 to 1.20)	0.763	
Exceeding only weekly limits	-0.34 (-0.91 to 0.24)	0.255		-0.01 (-1.29 to 1.27)	0.990	
Exceeding both daily and weekly limits	0.32 (-0.82 to 1.45)	0.585		2.62 (0.02 to 5.22)	0.049	
Baseline BP category			0.649			0.055
Normal	0.21 (-0.69 to 1.11)	0.652		-0.10 (-1.67 to 1.48)	0.903	
Elevated/prehypertension	-0.21 (-0.63 to 0.21)	0.326		-0.22 (-1.04 to 0.60)	0.603	
Hypertension	0.11 (-0.94 to 1.15)	0.843		3.26 (0.54 to 5.97)	0.019	
Sex			0.781			0.002
Female	-0.12 (-0.80 to 0.55)	0.723		2.86 (1.07 to 4.65)	0.002	
Male	-0.24 (-0.78 to 0.29)	0.366		-0.27 (-1.12 to 0.57)	0.526	
Age group			0.845			0.181
18–29	-0.57 (-5.25 to 4.11)	0.811		1.60 (-3.46 to 6.65)	0.535	
30–44	0.46 (-1.05 to 1.97)	0.548		2.46 (-0.32 to 5.24)	0.083	
45–64	-0.14 (-0.84 to 0.56)	0.695		0.48 (-0.61 to 1.58)	0.388	
65+	-0.26 (-0.80 to 0.28)	0.342		-0.61 (-1.79 to 0.58)	0.315	

Continued

# Table 3 Continued

	Effect size of receiving	BI, yes vs	no			
	Hypertension sample T2D sample		T2D sample			
	Est. (95% CI)	P value	Interaction p value	Est. (95% Cl)	P value	Interaction p value
Outcome=decrease in diastolic BP ≥3 mm Hg						
Overall	1.05 (1.00 to 1.09)	0.043	-	1.00 (0.92 to 1.08)	0.933	-
Baseline alcohol consumption level			0.714			0.883
Exceeding only daily limits	1.04 (0.96 to 1.12)	0.336		0.98 (0.87 to 1.11)	0.784	
Exceeding only weekly limits	1.07 (1.01 to 1.14)	0.032		1.02 (0.89 to 1.18)	0.759	
Exceeding both daily and weekly limits	1.02 (0.92 to 1.14)	0.678		0.97 (0.77 to 1.21)	0.759	
Baseline BP category			0.830			0.503
Normal	1.02 (0.88 to 1.18)	0.804		0.88 (0.69 to 1.12)	0.302	
Elevated/prehypertension	1.05 (1.00 to 1.11)	0.058		1.03 (0.93 to 1.14)	0.626	
Hypertension	1.02 (0.92 to 1.13)	0.737		1.04 (0.82 to 1.32)	0.754	
Sex			0.562			0.382
Female	1.07 (0.99 to 1.14)	0.083		1.08 (0.89 to 1.30)	0.457	
Male	1.04 (0.98 to 1.09)	0.176		0.98 (0.89 to 1.07)	0.638	
Age group			0.622			0.864
18–29	0.72 (0.42 to 1.25)	0.244		0.81 (0.36 to 1.81)	0.609	
30–44	1.05 (0.90 to 1.22)	0.532		1.06 (0.79 to 1.43)	0.688	
45–64	1.05 (0.98 to 1.12)	0.192		0.97 (0.85 to 1.10)	0.632	
65+	1.04 (0.98 to 1.10)	0.181		1.02 (0.90 to 1.15)	0.763	
Outcome=decrease in Systolic BP ≥3 mm Hg						
Overall	1.04 (0.99 to 1.08)	0.097	-	0.98 (0.90 to 1.06)	0.576	
Baseline alcohol consumption level			0.327			0.147
Exceeding only daily limits	1.05 (0.98 to 1.13)	0.168		0.95 (0.84 to 1.08)	0.453	
Exceeding only weekly limits	1.05 (0.99 to 1.12)	0.111		1.08 (0.94 to 1.24)	0.306	
Exceeding both daily and weekly limits	0.96 (0.87 to 1.07)	0.479		0.84 (0.67 to 1.05)	0.117	
Baseline BP category			0.958			0.221
Normal	1.02 (0.86 to 1.20)	0.854		1.01 (0.76 to 1.33)	0.957	
Elevated/prehypertension	1.04 (0.99 to 1.09)	0.138		1.02 (0.92 to 1.13)	0.713	
Hypertension	1.03 (0.91 to 1.16)	0.653		0.78 (0.59 to 1.04)	0.087	
Sex			0.614			0.001
Female	1.05 (0.98 to 1.13)	0.146		0.74 (0.61 to 0.89)	0.001	
Male	1.03 (0.98 to 1.09)	0.268		1.04 (0.95 to 1.15)	0.371	
Age group			0.839			0.263
18–29	1.18 (0.69 to 2.04)	0.547		0.64 (0.29 to 1.41)	0.266	
30–44	1.01 (0.87 to 1.17)	0.927		0.84 (0.63 to 1.13)	0.257	
45–64	1.05 (0.98 to 1.13)	0.141		0.97 (0.85 to 1.10)	0.589	
65+	1.02 (0.96 to 1.08)	0.491		1.07 (0.95 to 1.21)	0.278	

Bold values denote statistical significance at the p < 0.05 level.

BI, brief intervention; BP, blood pressure; HbA1c, glycohaemoglobin; NS, non-significant at p<0.05 level; T2D, type 2 diabetes.

 
 Table 4
 Associations between BI and 18-month HbA1c outcomes among patients with T2D who screened positive for unhealthy drinking

	Effect size of receiving BI, yes vs no			
	Est. (95% Cl)	P value	Interaction p value	
Outcome=change in HbA1c level				
Overall	-0.03 (-0.09 to 0.03)	0.400	-	
Baseline alcohol consumption level			0.411	
Exceeding only daily limits	0.01 (-0.08 to 0.11)	0.812		
Exceeding only weekly limits	-0.07 (-0.16 to 0.01)	0.082		
Exceeding both daily and weekly limits	-0.05 (-0.22 to 0.12)	0.557		
Baseline BP category			0.158	
Normal	0.08 (-0.05 to 0.21)	0.242		
Elevated/prehypertension	-0.04 (-0.12 to 0.03)	0.257		
Hypertension	-0.14 (-0.35 to 0.07)	0.196		
Sex			0.588	
Female	0.01 (-0.12 to 0.13)	0.909		
Male	-0.03 (-0.10 to 0.04)	0.356		
Age group			0.825	
18–29	0.10 (-0.76 to 0.97)	0.813		
30–44	-0.11 (-0.41 to 0.20)	0.493		
45–64	0.02 (-0.09 to 0.12)	0.748		
65+	-0.03 (-0.09 to 0.04)	0.418		
Outcome=HbA1 c level<8%				
Overall	1.08 (0.99 to 1.18)	0.100	_	
Baseline alcohol consumption level			0.521	
Exceeding only daily limits	1.04 (0.92 to 1.17)	0.584		
Exceeding only weekly limits	1.09 (0.91 to 1.30)	0.357		
Exceeding both daily and weekly limits	1.22 (0.94 to 1.59)	0.135		
Baseline BP category			0.341	
Normal	0.96 (0.76 to 1.20)	0.705		
Elevated/prehypertension	1.09 (0.97 to 1.22)	0.170		
Hypertension	1.25 (0.95 to 1.64)	0.112		
Sex			0.909	
Female	1.07 (0.85 to 1.35)	0.569		
Male	1.09 (0.98 to 1.20)	0.107		
Age group			0.652	
18–29	1.48 (0.66 to 3.32)	0.346		
30–44	1.18 (0.91 to 1.53)	0.218		
45–64	1.02 (0.90 to 1.17)	0.735		
65+	1.09 (0.92 to 1.28)	0.320		

BI, brief intervention; BP, blood pressure; HbA1c, glycohaemoglobin; NS, non-significant at p<0.05 level; T2D, type 2 diabetes.

BP outcomes among patients with hypertension provide further support for the potential for BI to have a substantial public health impact.

Among patients with T2D, we found no significant associations between BI and BP outcomes. Rather, women who received a BI had worse 18-month SBP outcomes compared with those who did not, while no significant difference was found between men who did or did not receive BI. BI was not significantly associated with 18-month HbA1c outcomes either, overall or among patient subgroups. There are several possible explanations for this lack of impact, as glycaemic control involves a wide array of factors, including disease severity, medication intensity and patient adherence to medications and lifestyle changes.<sup>58</sup> It is also challenging to address the many competing demands of patients with T2D within the time constraints of a typical primary care visit.<sup>59 60</sup> While we were unable to explore the underlying mechanisms of these (significant or null) results, the findings underscore that different approaches, including tailoring to population subgroups or health conditions, may be needed to address unhealthy drinking and related health outcomes, especially for women. For example, the literature suggests that BP check-ups and hypertension awareness were higher among women than men but did not translate into better antihypertensive medication practice,<sup>61</sup> and women with T2D exhibit worse control of HbA1c, BP and lipids than men.<sup>62–65</sup> Research by our group<sup>66 67</sup> and other researchers<sup>68 69</sup> also found that women were less likely to receive BI when screened positive for unhealthy alcohol use, but a growing literature has described potential BI adaptations for women<sup>70</sup> that might improve outcomes. Future studies, including non-randomised longitudinal studies with appropriate analytical approaches such as MSM-IPW, are also needed to estimate causal effects of BI over time while addressing time-varying confounders, including disease severity, provider attitudes and biases, psychological confounders and corresponding medication adherence. Findings may help inform better treatment strategies tailored to patient subgroups, with the ultimate goal of reducing cardiovascular mortality in the population.

The study has several limitations. Measures of drinking outcomes were based on results of brief alcohol screens conducted in routine care, which could limit their precision. Despite adjustment for rich, key covariates from a well-established EHR, there may be residual confounding from unmeasured confounders. Similar to other EHR-based studies, data on BI were limited to what was documented in the EHR, and BI quality could not be assessed. Data on other covariates such as alcohol consumption and exercise were based on selfreport and subject to social desirability bias, however, questions were designed to support patient candour.<sup>67</sup> KPNC has a well-established EHR and has a membership that is racially diverse and reflects the US population with access to care, which allows us to study a large population-based sample of patients and providers, yet it is unknown how well the study's findings generalise to other healthcare systems and populations. Our analyses examining interactions between BI and patient characteristics may have limited power, especially for analyses of the T2D sample. Other limitations of subgroup analyses examining potential treatment heterogeneity should be taken into consideration when interpreting results.<sup>71</sup> Further, examination of long-term and cumulative BI effects is beyond the scope of current work but warrants future research.

#### **CONCLUSION**

In a large healthcare system that implemented systematic primary care-based SBIRT, we found that alcohol BI may hold promise for reducing drinking and helping to improve health outcomes among patients with hypertension who screened positive for unhealthy drinking, but similar effects are undetermined among patients with T2D. BIs offered as part of a programme of systematic screening and BI for unhealthy alcohol use may be an important addition to the primary care chronic disease prevention and intervention armamentarium. More research is needed to understand heterogeneity across diverse subpopulations and to study BI's long-term public health impact.

#### Author affiliations

<sup>1</sup>Division of Research, Kaiser Permanente Northern California, Oakland, California, USA

<sup>2</sup>Department of Psychiatry, University of California San Francisco, San Francisco, California, USA

<sup>3</sup>Permanente Medical Group, San Francisco, California, USA <sup>4</sup>Permanente Medical Group, Campbell, California, USA

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**Contributors** Study concept and design: SAS, FWC and SP. Acquisition of data: FWC, VAP and YL. Statistical analysis: FWC. Interpretation of data: FWC, SAS, SP, VAP, AK-S, CMW, DDS and VEM. Drafting of the manuscript: FWC and SAS. Critical review and editing of the manuscript: FWC, SAS, SP, VAP, AK-S, CMW, DDS, RWG, JE, TBR, SA, YL and VEM. Study supervision: SS. Author responsible for the overall content as the guarantor: SAS.

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#### **ORCID iD**

Felicia W Chi http://orcid.org/0000-0001-8191-9622

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