Title

Efficacy of a theory-driven program to implement alcohol screening and brief interventions in primary health care: A cluster randomized controlled trial

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Abstract

Background and Aims. Screening and brief interventions (SBI) in primary health care practices (PHCPs) are effective in reducing reported alcohol consumption, but have not been routinely implemented. Most programs seeking to improve implementation rates have lacked a theoretical rationale. This study aimed to test whether a theory-based intervention for PHCPs could significantly increase alcohol SBI delivery.

Design. Two-arm, cluster-randomized controlled, parallel, 12-month follow-up, trial.

Setting. PHCPs in Portugal.

Participants. Staff from 12 PHCPs (N=222, 81.1% women): nurses (35.6%), general practitioners (28.8%), receptionists (26.1%) and family medicine residents (9.5%); patients screened for alcohol use: intervention N=8,062; controls N=58.

Intervention and Comparator. PHCPs were randomized to receive a training and support program (N=6; 110 participants) tailored to the barriers and facilitators for implementing alcohol SBI following the principles of the Behaviour Change Wheel/Theoretical Domains Framework approach, or to a waiting-list control (N=6; 112 participants). Training was delivered over the first 12 weeks of the trial.

Measurements. The primary outcome was the proportion of eligible patients screened (unit of analysis: patient list). Secondary outcomes included the brief intervention (BI) rate per screen-positive patient and the population-based BI rate (unit of analysis: patient list), and changes in health providers' perceptions of barriers to implementation and alcohol-related knowledge (unit of analysis: health provider).

Findings. The implementation program had a significant effect on the screening activity in the intervention practices compared with control practices at the 12-month follow-up (21.7% vs. 0.16%, intention-to-treat analysis, P=0.003). Although no significant difference was found on the BI rate per screen-positive patient (intervention 85.7% vs. control 63.6%, P=0.55, Bayes Factor = 0.28), the intervention was effective in increasing the population-based BI rate (intervention 0.69% vs. control 0.02%, P=0.006). Health providers in the intervention arm reported fewer barriers to SBI implementation and higher levels of alcohol-related knowledge at 12-month follow-up than those in control practices.

Conclusion. A theory-based implementation program, which included training and support activities, significantly increased alcohol screening and population-based brief intervention rates in primary care.

Key words. Alcohol-Induced Disorders, Screening, Counselling, Primary Health Care, Psychological theory, Randomized Controlled Trial [Publication Type].

Introduction

Worldwide, alcohol is one of the most important risk factors for mortality (1). Several randomized controlled trials and meta-analyses have found alcohol screening and brief interventions (SBI) in primary healthcare practices (PHCPs) to be effective and cost-effective or cost-saving (2-5). Notwithstanding recent debates concerning this effectiveness evidence (6), SBI continues to be advocated by many organizations, including the World Health Organization (7), for addressing individuals with hazardous/harmful alcohol use in PHCPs. Whilst alcohol SBI may work in controlled trials, researchers are still searching for the optimal approach to achieve effective implementation in routine practice (8). The majority of primary healthcare (PHC) professionals do not routinely deliver such interventions (9, 10) and few individuals engaged in risky alcohol use visiting PHC currently receive alcohol-related advice or intervention (9, 11, 12).

Several studies have identified barriers and facilitators to the implementation of alcohol SBI in PHCPs (12-15). Most implementation programs in practice and research have not been underpinned by a theoretical rationale for how they would address these barriers in order to change practitioner behaviour (16-18). We sought to address these limitations by developed a theory-driven intervention to increase SBI delivery in PHCPs. Individual components of the intervention tested in this trial were selected after a thorough analysis and mapping of previously-identified barriers and facilitators to their respective theoretical constructs (19). By identifying theoretical concepts underpinning identified barriers to and facilitators of implementation, researchers can select intervention techniques that are hypothesised to lead to behaviour change (16, 20-22).

The aim of this trial was to evaluate the effectiveness of a theory-based behaviour change intervention delivered to PHCPs. Therefore, to minimize contamination, the unit of randomisation was the PHCP. The primary objective was to: 1) compare the alcohol screening rate in PHCPs that received the intervention to those practices assigned to a waiting list (treatment as usual) condition at the 12-month follow-up. Secondary objectives were: 2) to compare the brief intervention (BI) rate for the screened patient population between intervention and control; 3) to compare the BI rate for the total patient population between intervention and control; 4) to compare differences between the groups concerning perceived barriers to implementation among practice staff; and 5) to compare levels of alcohol-specific knowledge in intervention and control PHC staff groups.

Methods

Trial Context and Design

We conducted a cluster-randomised, waiting-list controlled trial with two parallel groups and with stratified randomisation in the Dão-Lafões Grouping of PHC Centres, Portugal (with no trial deviations). The Dão-Lafões Grouping of PHC Centres comprises 26 PHCPs, funded by the National Health Service. Each practice is comprised of family physicians (FPs), nurses, and receptionists. Each FP works consistently with the same nurse and receptionist, providing care to a list of patients (1600 to 1900 patients on average). Since 2005, PHCPs in Portugal can be categorized into one of two models: the 'Personalized Health Care Practices' (traditional PHCPs), in which professionals receive a fixed salary; and the 'Family Health Practices', in

which professionals work together to provide a more personal and flexible approach to the care of patients. Professionals at level-A Family Health Practices still receive a fixed salary but if they achieve the quality indicators targets, they are upgraded to level-B. Monthly income for professionals working in a level-B practice depends on the base salary, patient list size, and pay for performance. The trial protocol is registered at clinicaltrials.gov/ct2/show/NCT02968186 and published elsewhere (23). The unit of randomization was the PHCP. PHCPs, stratified by model and level of organization, were randomised by ballot without replacement to receive either a new theory-driven program of training and support as outlined below (intervention group) or to a waitlist that received the intervention after the trial (control group). The study protocol received approval from the Ethics Committee of the Faculty of Medicine of Lisbon (Ref. 359/19) and by the Ethics Committee of the Centre Regional Health Authority (Ref. 77/2016). All participants provided informed consent. Data were collected between November 2016 and May 2018.

Participants

The study flowchart is outlined in Figure 1. Recruitment was conducted during the above-mentioned meeting with the coordinators of all the 26 PHCPs. To be included, each practice needed to have ≥5 FPs (one patient list per FP) and have no specific alcohol program implemented (e.g., alcohol addiction treatment program). Patient list is defined as the register of patients whose management is the responsibility of an FP and a nurse. Eighteen practices were eligible to participate, of which 12 were randomly selected. Next, individual meetings with each selected practice were scheduled to present the project to staff (FPs, nurses and receptionists). All those

willing to participate were enrolled. All patients aged 18+ with at least one appointment at the practices during the trial period were eligible for screening. Screened patients were not considered study participants.

<Insert Figure 1 about here>

Intervention/comparator

The intervention was a package of training and support for PHC staff. Prior to intervention design, we identified the barriers and facilitators to the implementation of alcohol SBI in PHC using a two-step approach. The methods are described in detail in the published protocol (23) and summarised here. Firstly, Portuguese qualitative data on barriers and facilitators identified in the BISTAIRS (Brief interventions in the treatment of alcohol use disorders in relevant settings) (24) and ODHIN (Optimizing delivery of health care interventions) (25) European Union co-funded projects were mapped. Secondly, a systematic review of the literature (19, 26) was conducted to identify barriers and facilitators to SBI delivery in PHC from prior research. All barriers and facilitators identified from both approaches were collated and analysed with the Behaviour Change Wheel (BCW)/Theoretical Domains Framework (TDF). The BCW/TDF (Table S1) is a comprehensive framework for designing interventions (21, 27) that enables identification of behaviour change techniques (BCT) with the potential to be effective in bringing about the desired change in the target behaviour. BCTs are the smallest components of an intervention with the potential to change behaviour (28). A BCT taxonomy has been developed to standardize the reporting of intervention content (20). This taxonomy was used to code and operationalize the

BCTs employed in the intervention for this trial. The content of the implementation program has been described in detail elsewhere (23). The implementation period lasted for one year. The program used 29 distinct BCTs (excluding repetitions) to address a total of 27 barriers to implementation. The barriers mapped to all 14 TDF domains and Capability-Opportunity-Motivation components (the BCW's behaviour change model at the centre of the wheel or COM-B model).

Health professionals in the intervention arm received four training sessions (a total of 30 hours) in the first 12 weeks of the trial (February to May 2017). Training was mainly delivered by FR, a certified trainer by the Portuguese Institute for Employment and Vocational Training, with experience in delivering training on alcohol SBI. The first training session included: evidence regarding alcohol-related harm; evidence on the efficacy of SBI in primary healthcare; examples of what constitutes a standard drink, risk continuum, daily drinking limits and binge drinking; how to screen with the Alcohol Use Disorders Identification Test (AUDIT); how to provide simple advice; and barriers and facilitators to implementation. Participants were encouraged to start implementing the programme right from the first training session and to share tasks across the PHC team e.g. receptionists handing the AUDIT screening tool to patients upon arrival for appointments; and doctors/nurses confirming the scoring with patients and delivering a BI to those who screen positive. The second training session was devoted to: sharing experiences of implementation efforts; BI core concepts focusing on the OARS skills (Open-ended questions, Affirmations, Reflections, Summaries) and the transtheoretical model for assessing patients' readiness to change. The third session was dedicated to tailoring BIs to patients' stage of readiness to change and working with patients with alcohol

dependence. Finally, in the fourth session, participants practised their skills in response to different hypothetical clinical scenarios.

During the training sessions, several BCTs were used, either isolated or combined, to address barriers to implementation. For example, the barrier 'lack of knowledge and skills' (COM-B component Capability, TDF domains Knowledge and Skills) was addressed with the BCTs 'behaviour practice/rehearsal', 'demonstration of the behaviour', 'habit formation', 'information about health consequences', 'information about social and environmental consequences', 'instruction on how to perform a behaviour'; the barriers 'alcohol is not a priority', 'alcohol SBI could damage doctor-patient relationship', 'counselling is difficult' and 'professionals' frustration and sense of low self-efficacy' (COM-B component Motivation, TDF domains Beliefs about capabilities, Beliefs about consequences, Goals, Emotions and Optimism) were addressed with the BCTs 'anticipated regret', 'framing/reframing', 'imaginary reward', 'information about emotional consequences', 'social comparisons' and 'verbal persuasion about capability'); and the barriers 'lack of time', 'lack of support' and 'lack of screening and counselling materials' (COM-B component Opportunity, TDF domain Environmental Context/Resources) were addressed with the BCTs 'adding objects to the environment', 'imaginary reward', 'pros and cons', 'restructuring the social environment', 'social support', 'verbal persuasion about capability'.

Additional support was continuously available to practices to help participants with difficulties in implementing the project. Meetings were held with the intervention practices every two months to address barriers such as 'lack of incentives', 'lack of opportunities for sharing experiences' and 'lack of support' (COM-B components

Motivation and Opportunity, TDF domains Environmental context/resources, Reinforcement, Social influences) with the BCTs 'feedback on behaviour', 'social comparison', 'social reward' and 'social support'. Participants in the control arm were provided with the Portuguese guidelines for conducting alcohol SBI without any SBI demonstration, discussion or support, along with materials for the collection of research data. They received the intervention after the trial.

No payment was offered to any participants for SBI activity conducted during the trial.

Outcome Measures

Screening and brief intervention activities were assessed using paper tally sheets which included the AUDIT, a tick box to indicate whether a BI was delivered to eligible patients, and a field to input patients' medical record number. Health providers were asked to screen each adult (ages 18+) who was not a repeat attender during the 12-month implementation period. Eligible patients were screened based on the Portuguese guidelines (29) which define individuals engaged in risky alcohol use as those scoring ≥8 on the AUDIT. Providers were asked to deliver a BI to individuals scoring 8 to 19 on the AUDIT (as defined by the Portuguese national guidelines: individuals scoring 8 to 19 should be offered a BI; individuals scoring 20+ should be referred to specialist services).

Primary outcome

Screening rate (objective 1)

The primary outcome was the proportion of eligible patients screened with the AUDIT per patient list, that is the number of presenting patients screened divided by the total number of presenting patients per patient list.

Secondary outcomes

Brief intervention rate (objective 2)

The BI rate was the proportion of individuals with hazardous/harmful alcohol use to whom a BI was delivered per patient list, i.e., the number of individuals scoring 8–19 in the AUDIT who received a brief intervention divided by the total number of individuals scoring 8–19 per patient list.

An additional off-protocol analysis was conducted to determine the efficacy of the intervention in increasing the population-based BI rate, i.e., the proportion of patients with visits at the PHCPs who received a BI (regardless of being screened or not) per patient list.

Differences in perceived barriers to implementing alcohol screening and brief intervention (objective 3) and related knowledge (objective 4).

Doctors and nurses completed a questionnaire prior to randomization, and 1-2 months after the end of the trial, to assess perceived barriers to implementation and alcohol-related knowledge. Barriers to implementation were assessed with an adapted prior questionnaire (30) which asked participants to express their level of agreement on a Likert scale, with 33 statements mapped to the TDF (Cronbach's alpha=0.86). Results are expressed as the average score across all participants for

each statement. Four multiple-choice questions assessed knowledge of key concepts related to alcohol SBI that were framed based on Portuguese guidelines (29), for which the average percentage of correct answers is reported.

Sample size

The sample size was calculated on the basis of the primary hypothesis. Assuming a screening rate of 50% in the intervention arm, and 10% in the control group, power of 80%, alpha of 5%, intraclass correlation coefficient (ICC) of 0.05, and a minimum of five patient lists per practice (i.e., minimum of five measurement units per practice), each arm needed to include five PHC practices. The intervention rate estimation was based on a previous systematic review on the effectiveness of different strategies used to increase alcohol screening rates (31). The control rate was estimated using the local three-year screening rate; clinicians can record alcohol consumption on electronic patient records based on questions regarding quantity and frequency of drinking. The intraclass correlation coefficient was based on a previous cluster RCT in the Netherlands as we had no local data on this matter (32). To avoid loss of power due to loss to follow-up, six practices were included in each arm of the trial.

Randomization and blinding

A joint meeting was held with the coordinators of all 26 PHC practices. All practices were willing to participate in the trial. Eligible practices were randomly selected by ballot without replacement by FR, stratified by model and level of organization. Next, individual meetings were held with each one of the 12 practices selected, to present

the project and invite all PHC professionals to participate. Participants who signed a consent form were randomized at the PHC level into the intervention arm or the waiting list control arm by ballot without replacement by FR, stratified by model and level of organization. Practices' randomization into the trial arms took place only after collection of the baseline data. Due to the nature of the study design, neither the research team nor the participants were blinded to the practices' allocation.

Analyses

Data were gathered, independently inputted into an Excel database and checked for inconsistencies and errors by the members of the local implementation team. Computations were conducted on an intention-to-treat basis. The effect of the implementation program on the screening and BI rates was analysed at the level of the patient list using linear mixed effects regression models with random intercepts (ICC for this trial = 0.81). Normal distribution of the outcome variables was assumed after performing arcsine transformation of the SBI rates. The effect of the implementation program on the barriers to implementation and alcohol-related knowledge was conducted at the provider level with Student's t-test for independent and related samples, as appropriate. Bayes factors (BF) were computed to assess strength of evidence. Analyses were performed using R 3.6.3.

Results

Figure 1 shows the trial flow diagram. Participants were recruited between October 2016 and January 2017. Of the 26 PHC practices, eight did not meet the inclusion criteria. Of the remaining 18 PHC practices, 12 were randomly selected, providing care to a mixed urban and rural population of 156,272 patients of all ages. The median number of patient lists per PHC practice was 7 (range 5 to 10); the number of adult patients per list averaged 1,441 (SD=104). A total of 286 PHC professionals working in the selected practices were asked to participate from which 222 (77.6%) gave written informed consent. Participation was higher among nurses (N=79, 85.9%) and receptionists (N=58, 84.1%) than among FPs (N=64, 71.9%) and family medicine residents (N=21, 58.3%). Mean participant age was 43.1 years (SD=11.5) and 81.1% were female. Table 1 describes the baseline characteristics of the participants.

<Insert Table 1 about here>

Primary outcome

A total of 74,087 adult patients had at least one appointment with his/her personal FP or family nurse during the trial period, of which 8,120 (11.0%) were screened Table 2).

<Insert Table 2 about here>

We found a significant effect of the implementation program on screening activity, which was 136 times higher in the intervention than in the control practices (Table 3).

<Insert Table 3 about here>

Only one PHC practice in the intervention group followed the protocol concerning using receptionists throughout the study period to systematically deliver the AUDIT to patients prior to the consultation with a healthcare professional. Some of the remaining PHC practices used receptionists for short periods, whilst others relied exclusively on doctors and/or nurses to screen patients during consultations. The screening rate of the one PHC practice that used receptionists as per protocol was 3.8 times higher than the average screening rate of the remaining PHC practices (60.2% vs. 15.7%; $F(1,4)=5.28$; $P=0.083$; $d=2.07$, 95%CI: 1.06–3.05; BF=3.62).

In total, 339 (4.2%) patients scored 8+ on the full AUDIT, of which 28 (8.3%) scored 20+ (probable dependence) and were excluded for calculating BI rates. Overall, 300 patients in the intervention arm and 11 in the control arm were eligible to be offered a BI (Table 2).

Secondary outcomes

Brief intervention rate

A total of 264 patients (84.9%) received a BI (Table 2). No difference was found between intervention and control on the efficacy of the implementation programme in increasing the likelihood of delivering a BI to screen positives (Table 3). Notwithstanding, we found a significant effect of the implementation program on the population-based BI rate, which was 34.5 times higher in the intervention than in the control practices.

Barriers to implementing alcohol SBI

Table S2 reports the mean baseline scores of the participants in each arm of the trial concerning their views on barriers to implementation. Differences at the 12-month follow-up are shown in Table 4. We found evidence of small to large effect sizes of the intervention in all 10 items assessing Capability and all 7 items assessing Opportunity (components of the BCW). Evidence of small to large effect sizes of the intervention were also found on most, but not all, the measured theoretical constructs assessing the Motivation component of the BCW. Within group analysis of the domains where between group differences at the 12-month follow-up were not significant showed significant decreases on barriers linked to four items mapped to the TDF domains Optimism, Reinforcement and Goals in the intervention group (Tables S3 and S4).

<Insert Table 4 about here>

Knowledge

At baseline, no differences were found between intervention and controls concerning doctors' and nurses' alcohol-related knowledge (24.4% vs. 19.8%, P=0.11). Table S5 details the proportion of correct responses for each knowledge item per trial arm. At the 12-month follow-up, a higher percentage of correct answers was found in the intervention arm (50.5%) than controls (27.4%) ($t(158)=5.43$; $P<0.001$; $d=0.86$, 95%CI: 0.52–1.20; BF>100).

Discussion

The results of this trial provide strong evidence of the efficacy of a theory-based implementation program in increasing alcohol screening delivery in primary health at 12-month follow-up as well as the overall rate of BI delivery, in increasing relevant knowledge, and in reducing perceived barriers to implementation.

The significantly higher levels of alcohol screening delivery associated with the intervention (effect size = 1.81) compare favourably with that found in a recent meta-analysis (non-significant effect size of 0.77) (31). In our study, the intervention group screened 21.7% of eligible patients while controls only screened 0.16%. These figures also compare favourably with other trial results. Screening rates of 6% and 9% (versus 1% in controls, all after 12 weeks) were found in a three-arm multicountry implementation trial from 2005 (33). Rates of 9.2% in the primary care physicians' arm (versus 50.9% and 3.5% in the non-physician+medical assistant and control arms, respectively) were found in a US trial from 2015 (34). No significant improvement was found at 12 months in a Dutch trial from 2012 (32). More recently, the ODHIN five country factorial trial (35) found that a combination of training+support+financial incentives yielded a 17.6% screening rate at 12 weeks

compared with the 3.5% from the care as usual control group. For training+support alone, the screening rate was 5.5%.

Other US-based studies report higher screening rates. In a Veterans Affairs before-after uncontrolled study, Bradley and colleagues reported a post-implementation screening rate of 93% using the AUDIT-C (compared to 85% at baseline using the CAGE questionnaire) (36). Besides not having a control group, screening was already a common feature on the studied practices with a baseline screening rate of 85% using the CAGE questionnaire. Bobb and colleagues at Kaiser Permanente Washington reported a 62% post-implementation screening rate (compared to 8.9% at baseline) using the AUDIT-C (37). This was a before-after uncontrolled, per protocol analysis, study in which practices "*were selected by health system leaders due to site leaders' receptivity to behavioral health integration, (...) leaders at all three pilot sites decided to implement only in some of their clinics; at each site, about half of the providers implemented. (...) By chance, leaders had also assigned Site 1 to participate in another quality improvement project testing the feasibility of the population-based management of patients with AUD or other substance use disorders by social workers*". In a Veterans Affairs cross-sectional study in which the primary outcome was receipt of specialty addictions treatment, Frost and colleagues report a BI rate of 73.7% following a positive AUDIT-C screen (38). In another Veterans Affairs study, Lapham and colleagues conducted a retrospective cohort study to evaluate the prevalence of documented BI in the medical records before and after implementation of a national performance measure (39). The authors report an increase in BI rates from 5.5% pre-implementation to 29% after 27 months. Finally, Sterling and colleagues at Kaiser Permanente in Northern California conducted a cluster three-arm randomized controlled trial to compare SBI implementation in paediatric care, targeting

adolescents aged 12 to 18 years (40). The study found that patients in the paediatrician arm, as well as those assigned to the paediatricians+embedded behavioral health care practitioners' arm had higher odds of receiving BIs compared with patients in the usual care arm. Any comparison of these studies with our trial should be interpreted with caution in light of the several differences between them: a) Setting and population – in our trial, the included primary health care practices were part of the publicly funded national health service, which aims to provide all kind of health services to all people living in the country. Veterans Affairs provides healthcare services to eligible military veterans; Kaiser Permanente is a private institution providing care to people with a health insurance plan or who are able to pay for the health services. Therefore, the population in our study is not directly comparable to the population studied in these two settings; b) Health Providers – primary care in Portugal is mainly delivered by general practitioners/family physicians and family nurses. Primary care delivery at Veterans Affairs and Kaiser Permanente includes, besides these providers, other professionals that were eligible for the above-mentioned studies, which included medical assistants, social workers, paediatricians, internal medicine and other specialties and clinical health educators. Therefore, the participants (and the tasks each is due to perform in daily practice) are also not directly comparable and could have an influence in the results reported; c) Outcome measures – in our trial we used the AUDIT-C as a first step screening tool which, if positive, demanded the need to perform the remaining seven AUDIT questions. The majority of the above-mentioned studies used shorter screening tools (e.g., the AUDIT-C). The use of simpler screening tools is a known facilitator to screening implementation (19) which could have contributed to the high screening rates reported in these studies; d) Study design – our study was a cluster randomized

controlled trial comparing a novel theory-based intervention to care as usual. The majority of the studies above-mentioned studies were either observational (38, 39) or before-after studies with no control group (36, 37). Notwithstanding the spectacular results achieved in these studies, the design used is prone to bias that makes results difficult to compare with the present study.

The amount of training and support tested in the present trial was substantially higher than that delivered in many programs tested so far (ranging from 2 to 9 hours) (32, 34, 35, 41, 42). Longer training sessions for busy primary care providers could be demotivating for some and could in some settings act as a barrier to implementation. Notwithstanding, like any other behaviour, changing an ingrained behaviour takes time and longer theory-based training sessions could contribute to a more effective change in the behaviour of interest (in this case, SBI delivery). Therefore, the time spent in training should be carefully considered to achieve the right balance between training length and efficacy in changing the behaviour of interest. Support from leadership and local policymakers can also be key in implementation efforts (42), including making more complex and time-consuming implementation programs available to all primary care providers. Given our results, the potential of similar behaviour change theory-based interventions should be further explored, as a potential way of increasing the implementation of alcohol screening in general practice in other countries and settings.

The provision of written guidelines to the control group had little effect, in line with evidence showing that passive dissemination of guidelines alone is unlikely to result in behavior change (43). Although no data are available in Portugal to assess compliance with the guidelines on alcohol screening and BIs, there is a general sense

that it is seldom applied, if at all. Notwithstanding, we were surprised to find such a low screening rate in the control group, as we expected a positive research participation effect (44) but this may have been diminished by the 'waitlist' design. Such low rates may reflect normal practice, or the 'waitlist' design may actually have suppressed rates to below normal.

Despite it being in our protocol, most practices did not routinely involve receptionists in the screening process as also found in other studies (45, 46). The screening rate in the PHC practice that used receptionists as per protocol was nearly four times higher than in other intervention practices; Kaner and colleagues (45) also found that practices which involved receptionists screened significantly more patients (by a factor of 4.2); Mertens and colleagues noted in their trial that the two practices with the highest screening rates were those in which the screening tool was provided to patients by the receptionist. This left to the health professional the task of recording screening results in the clinical record and delivering a BI when appropriate. Practices in which physicians had to do all alcohol SBI activities themselves achieved significantly lower screening rates, most likely because of their many competing priorities (34). Therefore, involving receptionists in the screening process seems to be a key enabler of screening in PHC. Further study of the factors affecting receptionist involvement, and its effectiveness and impact on screening accuracy are merited. The effect of other screening enablers (e.g., pay-for-performance screening indicators (47), electronic health record prompts for screening (37)) should also be considered in efforts to achieve increased screening.

We did not find any significant effect of the implementation program in changing the percentage of individuals engaged in risky alcohol use given advice, perhaps

surprising since the baseline rates were low by international comparison (48). A systematic review also failed to find a significant effect of interventions in increasing the rate of BIs to patients screening positive (31). Our trial was not powered to detect differences in BI rates, and the screening activity in the control group was much lower than expected, also reducing power relating to this outcome. Furthermore, we distributed paper tally sheets to both intervention and control PHC practices which could have had inflated the BI rates in the control group. Future trials aiming to detect such differences should take these issues into account. Importantly, since screening increased in the intervention group, and the delivery rate per screen positive patient was not different between the groups, it is likely that more BIs were being delivered by intervention PHC practices. The significant increase in the rate of BI delivery per patient consulted, which we report as an additional off-protocol analysis, supports the hypothesis that our intervention also increased the number of patients who had the opportunity to benefit from being counselled.

This study found a significant effect of the intervention on all the measured constructs of the TDF domains within the Capability and Opportunity components of the BCW, and in half of the TDF domains in the Motivation component. The intervention increased providers' capacity to deliver alcohol SBI (e.g., knowledge and skills, remembering to deliver alcohol SBI) and positively modified factors in the work environment (e.g., availability of screening tools, perceived time constraints) as well as motivating factors (i.e., Beliefs about Capabilities, Emotion, Intentions and Professional Role/Identity). Although we were unable to detect significant differences between intervention and control in certain TDF domains linked to the Motivation component of the BCW, within group analysis showed a significant effect of the implementation program in decreasing the barriers in the intervention group in the

TDF domains Optimism, Reinforcement and Goals (construct action planning). It is likely that our inability to show these differences is due to the "regression to the mean" effect and that the trial was underpowered to detect such differences. Better tailoring of the intervention program to the barriers and facilitators not addressed in this trial may further improve outcomes. Adding an alcohol-related performance indicator to the PHC contract (49), stronger engagement from management and policymakers (50), and more public and media awareness e.g. to generate public demand for SBI (6), are examples of actions that could result in greater priority being attached to addressing alcohol in PHC.

Doctors' and nurses' knowledge of key concepts related to alcohol SBI were significantly higher at 12 months follow up, but still low. We did not measure knowledge immediately after training. Knowledge may have been higher right after the training and decreased over time, especially for providers with low screening activity. Infrequent use of the knowledge acquired through training could have led providers to forget what was learned. Booster training sessions could be useful to increase providers' knowledge retention.

Strengths and limitations

Intervention programs underpinned by theory are more likely to be effective in changing behaviour than those that are not (27). The use of a theory-based intervention is a strength of this study and allowed the identification of areas on which to focus the implementation program. This methodology also enhances reproducibility and could inform the design of future interventions. Another strength of this study is that PHC practices were randomly selected and all agreed to

participate, in contrast with several previous trials. Trials relying on a subsample of volunteers (32, 35) are less likely to be generalisable to 'typical' PHC practices. A final strength of this study is its adequately powered cluster design. The cluster design was chosen to minimize 'contamination' within practices. In general, cluster randomized trials have lower statistical power than individually randomized trials because observations on participants in the same cluster tend to be correlated. Therefore, we conducted a power analysis prior to the start of trial and calculated we would need at least five practices per trial arm, each practice containing at least five patient lists (i.e., five observations per practice) to detect significant differences on the primary outcome. We ended up analysing six practices per trial arm, with a median of seven observations per practice.

At least six limitations ought to be considered in interpreting our findings. Firstly, although the results could be extrapolated to other practices in the Dão-Lafões region, they may not hold for other regions in Portugal or other countries. Differences in PHC and population demographics might require tailoring of the implementation program to local needs and barriers. Nonetheless, future implementation programs could build on the intervention used in this trial as many barriers and facilitators to SBI delivery are common across different jurisdictions including lack of time (10, 51-54) and lack of training (10, 12, 51, 54-64). Secondly, pen-and-paper screening tools are unusual in practice (65) and may have inhibited some providers from conducting screening, potentially contributing to lower screening rates in some practices. Thirdly, we included all the options for giving advice in the same tally sheet used to record screening, and so the tally sheet may have acted as an intervention in itself, across both trial arms, possibly contributing to our inability to detect significant differences in BI delivery rates to screen positive patients. Furthermore, when designing the trial,

we were not expecting such low levels of screening in the control arm, which could have reduced statistical power to detect significant differences on the BI rate delivered to screen positive patients. Fourthly, we did not verify whether or not BIs were actually delivered, nor fidelity in BI content, quality, or length, BI effectiveness or patient outcomes. BI trials have suffered criticism for being based on self-reported alcohol consumption, and evidence of impact on morbidity and mortality is limited (6). Further research would therefore need to examine whether the implementation programme improved patient outcomes. Fifthly, all relevant barriers to SBI delivery were not addressed, because of budget constraints. For example, including financial incentives in the implementation program could have had a significant positive impact on screening activity (35, 47, 66). Finally, we did not collect data on the costs of delivering the intervention, and therefore cannot ascertain its potential cost-effectiveness, although relatively expensive interventions have previously been estimated to be cost-effective in several European countries (2).

A theory-based implementation program, which included training and support activities, was effective in increasing alcohol screening rates in primary care. The results from this study could inform future theory-based programs aiming to implement alcohol screening and brief interventions in primary health care.

Consort statement

This paper was written in accordance to the CONSORT 2010 guidelines [59].

Contributions

FR was involved in the conceptualization of the trial protocol, and in implementing the trial, analysing the data and writing the drafts of the manuscript. MV, LP and NF contributed to the conceptualization of the trial protocol and revised the manuscript critically. CA and CR revised the manuscript critically. All authors read and approved the final manuscript.

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Table 1. Descriptive statistics of the participants at baseline in each arm of the trial.

Variable	**Intervention**	**Control**
Occupation – N (%)		
FPs	32 (29.1)	32 (28.6)
Residents	12 (10.9)	9 (8.0)
Nurses	38 (34.5)	41 (36.6)
Receptionists	28 (25.5)	30 (26.8)
Age – Mean±SD	42.6±11.5	43.6±11.5
Sex Female – N (%)	89 (80.9)	91 (81.3)

FPs – Family physicians

Table 2 – Screening and brief intervention activity (absolute numbers) in both arms of the trial at the 12-month follow-up

	Unique visits	Patients screened	Screened positive (scored 8+)	Screened positive eligible for BI (scored 8-19)	BIs delivered to eligible screen positives
PHCPs intervention arm					
1	7433	39	6	6	2
2	7703	1029	35	29	16
3	6296	1989	79	72	70
4	7086	959	25	23	21
5	4989	3005	120	114	95
6	3716	1041	61	56	53
Total	37223	8062	326	300	257
PHCPs control arm					
7	8962	3	2	1	1
8	7276	0	0	0	0
9	7046	18	6	5	3
10	6106	0	0	0	0
11	3427	30	3	3	2
12	4047	7	2	2	1
Total	36864	58	13	11	7
All PHCPs	74087	8120	339	311	264

PHCPs – Primary HealthCare Practices

Table 3 – Screening and brief intervention rates per trial arm at the 12-month follow-up

	Intervention % (95%CI)	Control % (95%CI)	F-test (df)	P	d (95%CI)	BF
Screening rate	21.7 (21.2–22.1)	0.16 (0.12–0.20)	15.2 (1,10)	0.003	1.81 (1.22–2.39)	24.5
BI rate	85.7 (81.3–89.3)	63.6 (33.3–86.5)	0.39 (1,8)	0.55	0.27 (-0.52–1.05)	0.28
Population-based BI rate	0.69 (0.61–0.78)	0.02 (0.008–0.04)	11.98 (1,10)	0.006	1.46 (0.92–1.99)	2.00

BF – Bayes Factor; BI – brief intervention; df – degrees of freedom

Table 4. Doctors' and nurses' views on barriers to implementing alcohol screening and brief interventions at the 12-month follow-up.

BCW Component	TDF Domain	Construct	Item	Intervention N=78	Control N=82	p	d	BF
Capability	D1 Knowledge	Knowledge	I know the content and objectives of the guideline on alcohol screening and brief intervention	5.3±0.9	4.1±1.4	<0.001	0.95	>100
		Procedural knowledge	I know how to screen for alcohol misuse and how to deliver a brief intervention	5.4±0.9	4.3±1.2	<0.001	1.00	>100
	D2 Skills	Skills	I have been trained on how to screen for alcohol misuse and how to deliver a brief intervention	5.1±1.6	3.3±1.7	<0.001	1.13	>100
			I have the skills to screen for alcohol misuse and to deliver a brief intervention	5.1±1.0	3.7±1.3	<0.001	1.20	>100

Motivation	D3 Social/ professional role and identity	Professional role	Screening and advising for alcohol misuse are part of my work as a doctor/nurse	5.8±0.9	5.1±0.9	<0.001	0.80	>100
			It is my responsibility as a doctor/nurse to screen and advise for alcohol misuse	5.8±0.9	5.2±1.0	<0.001	0.64	>100
	D4 Beliefs about capabilities	Self-efficacy	I am confident that I can screen and advise for alcohol misuse even when the patient is not motivated	4.9±1.3	4.5±1.0	0.028	0.35	1.64
			I am confident that I can screen and advise for alcohol misuse even when there is little time	4.7±1.1	4.1±1.2	<0.001	0.60	91.9
		Perceived behavioural control	For me, screening and advising for alcohol misuse is difficult	3.6±1.2	4.4±1.1	<0.001	0.64	>100

	D5 Optimism	Optimism	With regard to screening and advising for alcohol misuse I am always optimistic about the future	4.4±0.9	4.1±1.0	0.08	0.28	0.71
			With regard to screening and advising for alcohol misuse overall, I expect more good things to happen than bad	4.5±0.9	4.4±0.9	0.24	0.19	0.32
	D6 Beliefs about consequences	Outcome expectancies	If I screen and advise for alcohol misuse it will benefit public health	6.1±1.0	5.7±0.9	0.005	0.45	6.50
			If I screen and advise for alcohol misuse it will have disadvantages for my relationship with the patient	2.9±1.4	2.8±1.1	0.56	0.09	0.20
Motivation	D7 Reinforcement	Reinforcement	Whenever I screen and advise for alcohol misuse, I feel like I am making a difference	5.4±1.0	4.9±1.1	0.006	0.44	5.72

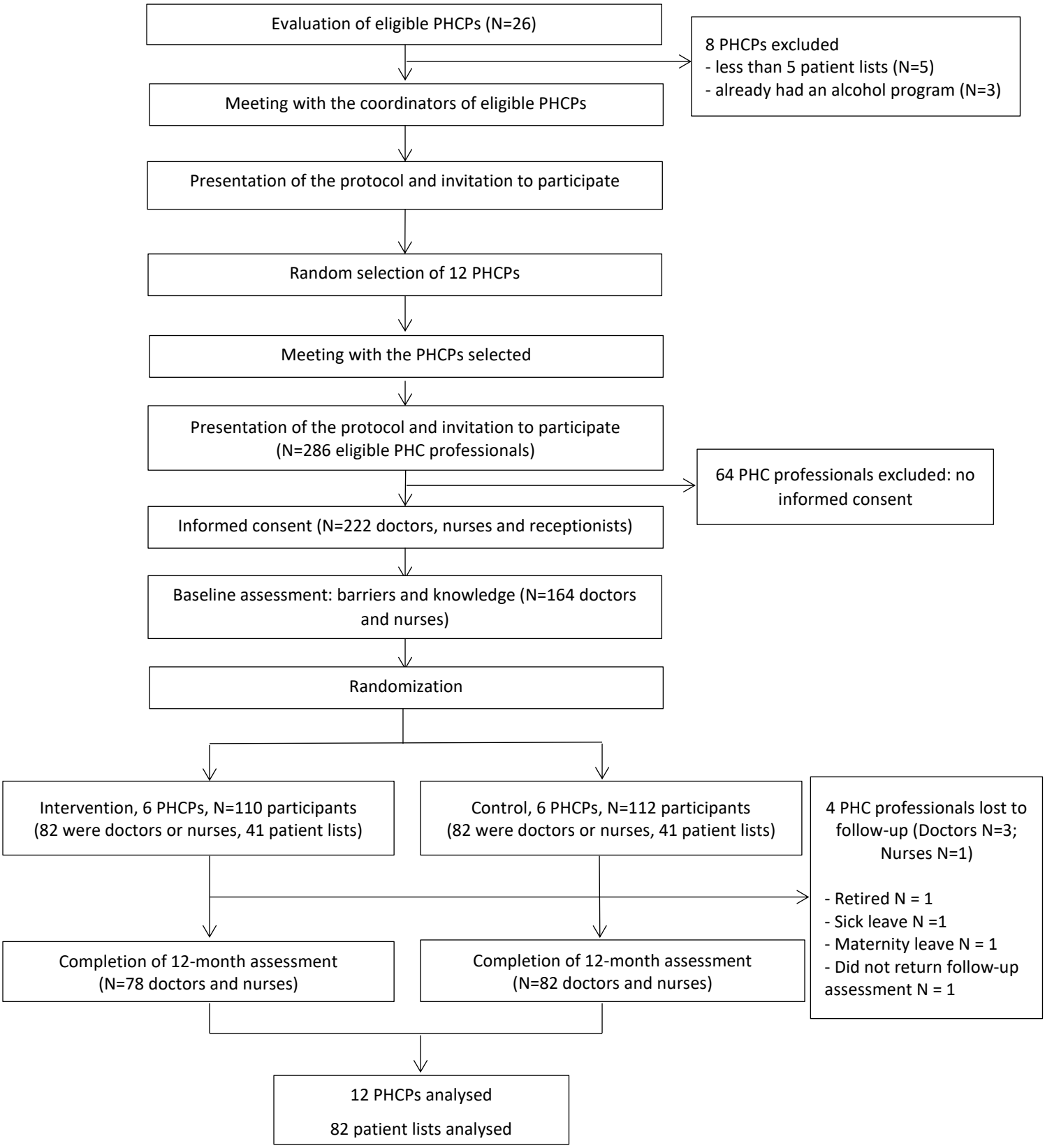
		Whenever I screen and advise for alcohol misuse, I get recognition from professionals who are important to me	4.4±1.0	4.2±1.0	0.34	0.15	0.26
D8 Intention	Intention	I intend to screen and advise for alcohol misuse in the next appointment	5.2±0.9	4.7±1.0	0.002	0.51	19.0
		I will definitely screen and advise for alcohol misuse in the next appointment	4.9±1.1	4.4±1.0	0.002	0.50	14.2
D9 Goals	Action planning	I have a clear plan of how often I will screen and advise for alcohol misuse	4.2±1.0	3.9±1.0	0.047	0.32	1.07
	Priority	Generally, I am more pressured to cover something else than to screen and advise for alcohol misuse	5.1±1.3	5.0±1.3	0.53	0.1	0.21

Capability	D10 Memory, attention and decision processes	Memory	Screening and advising for alcohol misuse are difficult to remember	3.4±1.1	3.8±1.2	0.018	0.38	2.31
			I often need to check the guideline on alcohol screening and brief intervention before screening and advising for alcohol misuse	3.6±1.1	4.2±1.2	<0.001	0.57	50.4
Opportunity	D11 Environmental context and resources	Resources/ material resources	Screening and advising for alcohol misuse have a good fit with routine practice	4.4±1.1	3.9±0.9	0.002	0.51	16.7
			In the organization I work screening and advising for alcohol misuse is routine	4.3±1.2	3.8±1.1	0.019	0.38	2.30
			In the organization I work there is enough time to screen and advise for alcohol misuse	3.4±1.3	3.0±1.2	0.015	0.39	2.69

			In the organization I work I have the tools to screen and advise for alcohol misuse	5.1±1.0	3.7±1.1	<0.001	1.27	>100
			In the organization I work I have a working network for referring patients with alcohol dependence	4.8±1.1	4.0±1.2	<0.001	0.68	>100
Opportunity	D12 Social influences	Social support	I can rely on a dedicated team of professionals when things get tough when screening and advising for alcohol misuse	4.7±1.3	4.0±1.2	<0.001	0.55	36.1
			I can rely on my colleagues when things get tough when screening and advising for alcohol misuse	4.8±1.1	4.4±1.1	0.028	0.35	1.60

Motivation	D13 Emotion	Affect	I feel nervous when screening and advising for alcohol misuse	2.7±1.1	3.4±1.2	<0.001	0.61	>100
Capability	D14 Behavioral regulation	Automaticity	Screening and advising for alcohol misuse is something I do automatically	4.2±1.2	3.8±1.1	0.026	0.36	1.70
		Self-monitoring	I tend to notice my successes while working towards screening and advising for alcohol misuse	5.0±1.0	4.5±1.0	<0.001	0.57	51.3
		Action planning	I have a clear plan when I will screen and advise for alcohol misuse	4.2±1.0	3.5±0.9	<0.001	0.72	>100
			I have a clear plan of how I will screen and advise for alcohol misuse	4.5±1.0	3.5±1.1	<0.001	0.97	>100

BF: Bayes Factor; D: Domain



PHC – Primary Health Care; PHCPs – Primary health care practices

Figure 1 – Flowchart of the trial.