EFAR Spain: randomised controlled non-inferiority trial of primary care-based facilitated access to an alcohol reduction website in Catalonia (Spain)

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Introduction

Alcohol consumption is the third leading cause of disease and disability worldwide. 20% of patients attending in primary health care (PHC) are risky drinkers. To reduce their alcohol consumption, screening and brief intervention (SBI) in PHC has been demonstrated to be cost-effective. However, implementation of SBI has proved challenging and as a result less than 10% of risky drinkers attending PHC benefit. A number of studies have indicated the effectiveness of internet applications for SBI (e-SBI), and this technology could have an important place in health care settings. A number of studies have indicated the feasibility and acceptability of GPs providing facilitated access to internet interventions, but there is currently no evidence about the effectiveness of this approach relative to face to face intervention for alcohol. The EFAR-FVG study has been designed to provide this information in Italy, and similar evidence is needed for Spain.

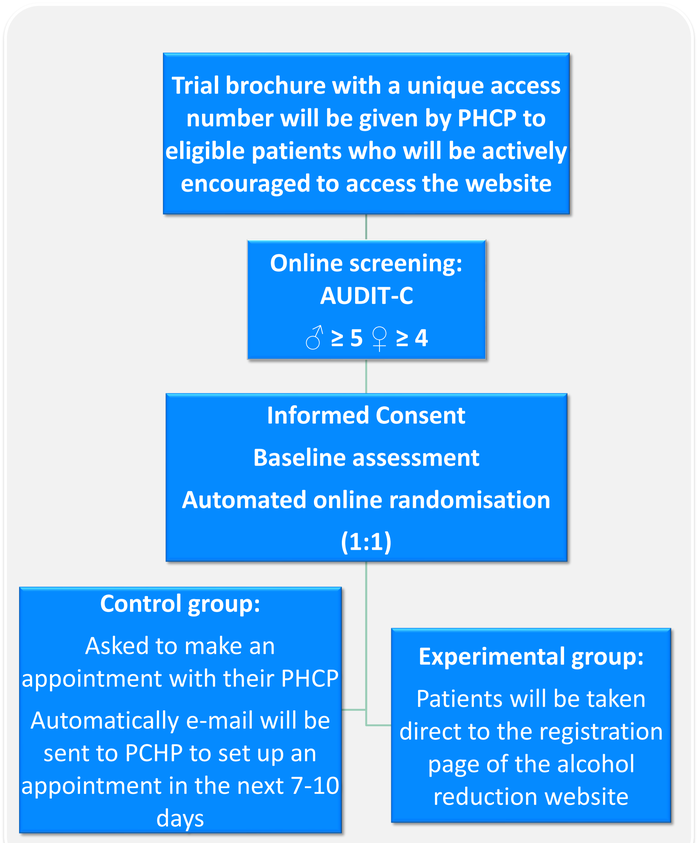
Objectives

In Catalonia, we would like to evaluate the non-inferiority of facilitated access to a web-based SBI for risky drinkers against face-to-face BI delivered by primary health care professionals (PHCP). We present below the overall protocol, the recruitment and implementation strategy and the customization process to ensure adaptation of the web-based SBI for use in Spain.

Methods

A randomised controlled non-inferiority trial comparing both interventions in primary care health centres will be carried out in Catalonia embedded in the usual implementation activities of the "Drink-less" project. Up to 60 primary healthcare professionals (PHCPs) will be recruited from the database of alcohol referents in Catalonia. Adults attending in PHC and willing to participate will be invited by their PHCP to use a personalised log-in to access the web for on-line assessment. Those screening positive (AUDIT-C: women ≥ 4, men ≥ 5) will be asked to consent to the trial and will undergo baseline assessment before being randomized(1:1) to the offer of brief intervention online or face-to-face. Follow-up assessment will be conducted online at months 3 and 12 and the main outcome will be the proportion of risky drinkers.

Customization of the website will be done in two stages; first alcohol experts will revise the translated contents in order to make sure that they fit with country alcohol standards and requirements and second recruited professionals and PHC users will be invited to check its usability.



Expected Results

We expect to be able to recruit all professionals, conduct the training and to finalize the customization of the web-based SBI by the end of this year. Implementation will start by 1st of December of 2014 and will last until June 2016. In summary, we expect that at month three the reduction in the proportion of risky drinkers in the experimental group will be not >10% lower than in the control group. We also expect that these results will be maintained at month twelve. We hypothesise that the implementation of SBI will be significantly higher for the experimental group.

Expected Conclusions

We expect to determine whether facilitated access to web-based SBI tools can be an effective complement to improve implementation of SBI on alcohol in primary health care and whether it will be more cost effective. Framing the study in the context of the wider SBI implementation will facilitate recruitment in both PHC professionals and patients. The way to embed this kind of tools in the framework of the so-called citizen health file being implemented in Catalonia to ensure their sustainability after the study will have to be analysed.

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