Study protocol “Feasibility and Effectiveness of a Specialized Brief Intervention for Hazardous Drinkers in an Emergency Department.”

NCT03273283

This study protocol was aprooved by Ethics Comitee of Hospital Clínic de Barcelona the 8th of September of 2016. However, this document was translated and prepared for uploading in clinicaltrials.gov the 4th of May 2020.

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Study design :

We will perform a randomized controlled trial to assess the effectiveness of a sbirt program for at-risk drinkers in reducing alcohol use.

Selection of Participants:

All patients aged 18 or older presenting to the ED will be assessed. Those with cognitive impairment or who were medically unstable will be excluded. Patients explicitly demanding alcohol treatment during their attendance will also be excluded. All patients in the ED will be screened using the three-item version of the Alcohol Use Disorder Identification Test (AUDIT-C) by three psychiatrists from the addictions unit of the same hospital. Patients scoring more than 6 points for men and more than 5 for woman will be asked to participate and sign the informed consent.

Randomization Procedures:

Simple randomization was chosen. Prior to the study initiation a list of 250 participant numbers was randomized into two groups (intervention group or control group). To guard against bias, the enrollment packs for each group will be the same size and thickness and without external indicators of the group.

Procedures:

The control group will receive two leaflets: one about alcohol use with a list of treatment resources including contact details and the other providing information about the study protocol. The intervention group patients will receive the same leaflets, and will be included on an SBIRT program consisting of a BI and referral to treatment if needed.

Intervention:

The intervention is based on motivational techniques and lasts from 5 to 15 minutes, depending on patient response and characteristics. The aims of the intervention are to inform targeted patients about alcohol-related harms, to raise patients’ awareness about their alcohol intake and possible consequences, to enhance motivation and induce a state of change about alcohol use, and finally to give patients strategies to reduce alcohol use and further treatment options, offering an specialized appointment within the next week.

Measures:

Age, sex, and previous diagnosis of alcohol use disorder and/or other substances will be recorded at baseline, based on clinical records. The primary outcomes of the study are the proportion of at-risk drinkers (measured with AUDIT-C scale; patients scoring more than 6

points for men and more than 5 for woman) in each group and the proportion of patients who attend to specialized treatment following ED attendance.

Follow-up will be performed by phonecall.

Sample Size and Data Analysis:

The required sample size was calculated with 95% confidence and 80% power to detect a difference between groups of a 15% reduction of risky drinkers. With an estimated attrition rate of 30%, 223 patients in total are required.

Statistical analyses will be conducted using SPSS v23. At baseline, participants' demographic and enrollment-related characteristics will be compared across treatment conditions using t- and chi-square tests according to the nature of each variable. The main outcome of the study will be assessed using logistic regression models with all available variables as independent parameters (age, sex, alcohol- related presenting condition, alcohol use disorder or other substance use disorder previously diagnosed, AUDIT-C total score at baseline). We will also perform linear regression analysis to test global reductions in the AUDIT scores according to treatment condition.