

Relapse Prevention Programme Effectiveness Based on Mindfulness, in Order to Decrease Alcoholic Patients Craving

Ester Casas Gavilán¹ and Teresa Peña Lorente^{2*}

¹Nurse Mental Health Specialist, Center of Orientation and Treatment of Addictions COTA-Vitoria-Alava, Spain

²Mental Health Specialist Nurse, Basque Health Service, Spain

*Corresponding Author: Teresa Peña Lorente, Mental Health Specialist Nurse, Basque Health Service, Spain.

Received: March 05, 2020; Published: November 30, 2020

Abstract

Introduction: The most consumed drug in Spain is alcohol. The excessive consumption of alcohol has important physical, psychological and social consequences and it is recognised as a mental disorder nowadays. The treatment for the disorder of alcohol abuse is complex, dynamic and multidisciplinary. One of the main psychological factors that appears to influence at the time of a relapse is craving, understood as compulsion or an intense desire to consume. There are diverse pharmacological and psychological treatments in order to help the patient to avoid relapses. During the last years, interest on mindfulness for the treatment of mental disorders has grown exponentially. This is how the relapse prevention programme based on Mindfulness has been developed.

Objective: Test the MBRPs effectiveness over an alcoholic detoxification patient group so that they learn to manage and reduce the craving, and thus, stay abstinent.

Methodology: Clinical trial with control group.

Population to Study: n = 162 patients that fulfil the criteria of inclusion.

Inclusion criteria: Patients diagnosed with an alcoholic consumption disorder by the criteria of the DSM V, commitment to assist to the sessions, commitment to practice at home and normal auditory capacity.

Keywords: Alcoholism; Craving; Mindfulness; Secondary Prevention; Alcohol Abstinence; Professional Category and Workplace

The alcohol

Of all the substances considered drugs (substances with psychoactive effects, capable of producing changes in perception, mood, awareness and behavior; capable of being self-administered) [1], the most consumed in Europe is alcohol, with an average of 12.5 liters per person per year [2]. In our country these figures are slightly lower, placing consumption at an average of 9 - 10 liters per inhabitant and year. According to the data of the Household Survey on Alcohol and Drugs conducted by the Ministry of Health [3] alcohol is the drug most consumed by the Spanish in the last year (77.6% of the population, followed by tobacco with 40.7%). Between 7 and 10% of our population are risk drinkers and 50% of risk drinkers meet dependency criteria.

Excessive alcohol consumption has important physical, psychological and social repercussions. In fact, in Spain alcohol is responsible for 3.3 million annual deaths, which represents 5.9% of total mortality [4] and is attributed a cost close to 2,700 million euros annual [5].

Despite studies and dissemination campaigns on its harmful effects, as well as its direct relationship with traffic accidents and domestic violence, there is still a low social awareness of the problem, since alcohol is perceived as the least dangerous addictive substance [6], while data from the different public health services show that 34,000 people with alcohol dependence problems are served annually in our country [7].

Today, alcohol use disorder is recognized as a mental pathology by the DSM-V [8], where alcoholism is described as “a problematic model of alcohol consumption that causes clinically significant deterioration or discomfort” which is manifested within 12 months by the presence of at least 2 of the following criteria:

- Alcohol is consumed frequently in higher quantities or for a longer time than expected.
- There is a persistent desire or unsuccessful efforts to abandon or control alcohol consumption.
- A lot of time is invested in the activities necessary to get alcohol, consume it or recover from its effects.
- Craving or a powerful desire or need to consume alcohol.
- Recurrent alcohol consumption that leads to non-fulfillment of fundamental duties at work, school or home.
- Continued alcohol consumption despite suffering persistent or recurring social or interpersonal problems, caused or exacerbated by the effects of alcohol.
- Alcohol consumption causes the abandonment or reduction of important social, professional or leisure activities.
- Recurrent alcohol consumption in situations where it causes a physical risk.
- Alcohol consumption continues despite knowing that there is a persistent or recurrent physical or psychological problem likely caused or exacerbated by alcohol.
- Tolerance, defined by any of the following acts:
 - A need to consume increasing amounts of alcohol to achieve poisoning or the desired effect.
 - A noticeably reduced effect after continued consumption of the same amount of alcohol.
- Abstinence, manifested by one of the following facts:
 - Presence of the characteristic alcohol withdrawal syndrome.
 - Alcohol (or some very similar substance, such as a benzodiazepine) is consumed to relieve or prevent withdrawal symptoms.

The treatment of alcohol dependence is complex, dynamic and long, and should be understood as a process [9]. The goal of treatment is to help the patient avoid compulsive alcohol consumption; For this, it is proposed not only to maintain abstinence but also to change patterns that prevent relapse [10].

The basic therapeutic scheme in alcoholism is: 1) Detoxification: Which can be done in a hospital or outpatient way 2) Disabling and maintaining withdrawal: The goal of this phase is for the patient to adopt healthy lifestyles. Datable and stay motivated to change. During this phase it is important to pay special attention to craving, since it is demonstrated that this uncontrollable desire to consume is the main psychological factor that precipitates relapses [11]. For this purpose, various psychological interventions, support groups and/or administration of aversive or anticraving drugs are used and 3) Recovery and social reintegration [9].

As the United States National Institute of Drug Abuse collects it [12], psychological interventions are fundamental in long-term treatment.

Numerous studies have been carried out to evaluate the efficacy of all these treatments and although it seems that the most effective interventions for the treatment of alcoholism are those of cognitive and cognitive-behavioral type, today no treatment It has proved to be completely effective [13].

That is why over the past three decades there has been a growing interest in mindfulness-based psychotherapies for the treatment of addictions. This derives from various research studies that confirm the usefulness of meditation in reducing stress derived from some chronic organic pathologies. Mindfulness is also being used to address multiple psychopathologies (anxiety disorders, mood disorders, borderline personality disorder, etc.) [14,15].

Thus, at the beginning of the 21st century, Allan Marlatt, Neha Chawla and Sara Bowen designed the Mindfulness Based Relapse Prevention Program (MBRP onwards) for all those people who, once the detoxification phase is completed, have a motivation for maintenance of abstinence and need skills to face future relapses [16].

Mindfulness is understood as the conscience that appears when deliberately paying attention, in the present moment and without judging, observing how the experience unfolds moment by moment, derived from Buddhism.

Unlike in other abstinence maintenance therapies, in which it is advisable to use a technique of distraction and avoidance of unpleasant experiences before an episode of craving, Buddhist psychology places special emphasis on recognizing, feeling and accept the discomfort when it arises and understand the experience in all the depth instead of trying to get rid of it continuously. In this way it provides effective means to face the impulses and desires without being carried away by them. With the continued practice of mindfulness, it is intended to promote a state of introspection that provides the opportunity to respond effectively to the desire to consume alcohol and not simply to react automatically [17]. Mindfulness seems to influence cognitive and behavioral responses to the sensation of craving, explaining the reduction in substance abuse in the post-intervention among the groups receiving such intervention [18].

According to the study by Skanavi., *et al.* [19] mindfulness can help addicts to accept unusual physical sensations that can be confused with withdrawal symptoms, decentralizing the patient from an intense urgency to consume and preventing him from acting impulsively.

Likewise, in a randomized pilot study [20], the evolution of 18 patients with substance abuse who for 8 weeks received mindfulness therapy plus usual treatment was compared with that of 13 other patients who only received usual treatment, observing a more global evolution favourable in the group that received mindfulness training.

Bowen., *et al.* [21] carried out a randomized controlled trial to verify the viability and effectiveness of the MBRP program by comparing it with the standard care of the service in which they worked. Participants in MBRP demonstrated more significant drops in desire over the 4 month period compared to patients in the standard treatment group. Participants in both groups demonstrated a global reduction in the days of alcohol and drug use; however, the days of substance use decreased significantly higher in the MBRP group.

The interest in the application of mindfulness in the psychotherapeutic field is recent, so there is very little evidence about its efficacy for the treatment of mental disorders, and more specifically of addictions. However, the study by Skanavi., *et al.* [19] concludes that mindfulness-based interventions to treat alcohol addiction disorders show very promising results.

In view of the aforementioned results it follows that the intervention of mindfulness can help reduce the severity of craving and, therefore, maintain abstinence.

Hypothesis

The use of MBRP as a therapy in the prevention of relapses in the alcoholic patient will improve the severity of craving by keeping the patient abstinence during the intervention and 3 months after it.

Objectives of the Study

- Compare the intensity of craving of the patients of the intervention group before, at the end of the intervention and 3 months later, using the Penn Alcohol Craving Scale (PACS onwards) [22].
- Carry out a comparative analysis of the intensity of the craving of the patients of the intervention group and the control group, using the PACS scale, during the same time that the intervention lasts with the group that will receive mindfulness.

Methodology

Study design

Randomized clinical trial in parallel groups with control group.

Field of study

The study will be carried out at the center for Counselling and Addiction Treatment (COTA) in Vitoria (Álava-Spain).

Target population

Alcoholic patients who have performed a detoxification cure.

Population under study

Alcoholic users of COTA after having performed a detoxification cure (either hospital or outpatient), who are motivated to maintain abstinence and who meet eligibility criteria (inclusion and exclusion criteria).

Inclusion criteria

- Patients diagnosed with alcohol use disorder according to the DSM-V criteria.
- Commitment to attend sessions.
- Commitment to practice at home.

Exclusion criteria

- Severe mental disorder in decompensation phase.
- Patients diagnosed with antisocial personality disorder.
- Evidence in the Clinical History of illiteracy or IC less than 85 and/or cognitive impairment.

- Be receiving treatment with anti-ticketing drugs.
- Non-normalized hearing ability.

Methodology

The study will be carried out at the Center for Orienting and Addiction Treatment (COTA) in Vitoria-Gasteiz at 11 am on Thursday morning for 8 weeks. Patients will be evaluated by psychiatrists who work in the External Consultation Unit of COTA when they meet the diagnostic criteria for alcohol use disorder according to the DSM-V and will be recruited by the sick mental health specialists who direct the intervention. These will be responsible for explaining to the patient what the intervention consists of and obtaining informed consent from him/her.

Prior to signing the informed consent, the motivation will be measured with the Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES) [23], a self-administered scale of 19 items, designed to assess the motivation of the client for change and alcohol withdrawal. It is composed of 3 subscales: Cognitive problems, ambivalence and steps to take, which are scored separately. A score equal to or greater than 67 points will be taken as the cut-off point. Once the Socrates scale is passed, if the patient reaches the cut-off score, the poisoning cure will be included in the study immediately.

Patients who meet the eligibility criteria, are interested in participating in the study and sign the informed consent, will be randomized to one of the study groups (intervention group or control group) by computer generated sequence that is will keep hides researchers until the time of assignment. The ratio of patient assignment to both groups will be 1: 1. Each MBRP group will consist of a minimum of 6 patients and a maximum of 10. Patients who will receive the intervention should remain abstinent until the group is completed.

Mindfulness group (GM)

The members of the experimental group will receive in addition to the usual treatment (regular visits with their referring therapists + anxiolytic drugs and/or antidepressants) a 90-minute MBRP group session at the rate of 1 session/week for 8 weeks. In addition, at the end of each session they will be given a series of guidelines to practice full awareness exercises at home.

The day before the start of the study, the principal investigators will summon the participants to their consultation to establish a first contact with them, as well as deliver the PACS scale.

The sessions will be held in a group, with a number of 6 - 10 patients per group.

Session content:

- Session 1: Autopilot and relapses.
- Session 2: Awareness of triggers and desires.
- Session 3: Mindfulness in everyday life.
- Session 4: Mindfulness in high risk situations.
- Session 5: Acceptance and effective action.

- Session 6: See thoughts as thoughts.
- Session 7: Self-care and balanced lifestyle.
- Session 8: Social support and continuation of practice.

The sessions consist of a group theoretical class, with the patients and the nurse who directs the session sitting comfortably in a circle, in which the content reflected in the session title is developed; The research nurse directs the session, which is interactive, since patients must Borar with their contributions to the group. No more material is needed than the living room, chairs and an audio device. Then each patient takes home a CD with the most important contents of each session so that he listens at home, at least twice, until the next session. At the end of the eighth session, the PACS scale will be passed back to all participants.

Parallel to the beginning of the group, as well as in the following three months, the patients will go to perform urinocontroles once a week.

Losses will be considered if the patient does not perform the 8 sessions and/or does not attend the scheduled appointments with his therapist and/or does not perform the established urinocontrol.

Control group (GC)

Same number of patients as GM. They will receive the usual treatment, which consists of performing regular urinals and regular visits with their referring therapists, in addition to the anxiolytic and/or antidepressant medication prescribed by their physician. It will be your referring therapists responsible for delivering the PACS Scale at the same times established as for the GM. Likewise, they will perform weekly urinocontroles during the duration of the study.

Patients belonging to this group will be recruited with the same inclusion criteria as GM patients and will be considered losses if, during the 8 weeks of the study, the patient did not attend scheduled appointments with his therapist and/or will not perform the established urinocontroles.

Sample size calculation

Taking as a reference the study by Witkiewitz., *et al.* [18] in which the standard deviation of the control group was 1.42 and the intervention group of 1.05 when craving was compared after the treatment of mindfulness with the PACS scale and considering clinically relevant for this study a difference of 0.58 points in said scale; applying a power of 80% and a significance level of 5%, 73 people per group would be needed. Considering losses of 10%, the number of patients to be recruited will be 161 people in total (sum of the two groups).

Main outcome variables

Craving: Intense desire or experience of a compulsion to consume a psychotropic substance or to experience its toxic effects. The craving measurement will be carried out with the PACS Scale.

The Penn Alcohol Anxiety Scale (PACS) is a multi-choice scale with a single response that is easily and quickly self-administered. The PACS scale consists of 5 items and measures the frequency, intensity and duration of craving, as well as a general/global rating of craving during the previous week. Each item has 6 possible answers, being able to obtain a minimum score of 0 and a maximum score of 30. The higher the score obtained, the greater the desire for consumption.

The PACS shows excellent internal consistency and predictive validity for alcohol relapses. The internal consistency of the PACS is 0.87.

Abstinence: Action to abstain from something, in this case of consuming alcohol.

The assessment of withdrawal will be carried out through the performance of urinocontroles, according to the COTA protocol.

These urinocontroles will be carried out on a weekly basis. The substance to be analyzed is ETG (ethylglucuronic acid), a secondary metabolite of ethyl alcohol or ethanol, which is eliminated in urine for up to 5 days after consumption of alcoholic beverages. This test has a high sensitivity, a concentration in urine > 500 mg/dL being considered positive.

Adjustment variables:

- Age: > 18 years old
- Gender: Male/Female
- Level of studies: Without studies/Basic level/Medium level/University
- Marital status: Single/Married/Divorced/Widowed
- Employment situation: Active/not active
- Alcohol consumption start date
- Associated consumption of other toxins: Describe which.
- Previous disabling treatments: Describe how many and how.

Statistical analysis

The statistical analysis will be quantitative. A descriptive analysis of the sample under study will be carried out. Quantitative variables will be described by the mean and standard deviation in the case of following a normal distribution, or by the median and interquartile range in the case of non-normal distributions. Categorical variables will be described by frequencies, percentages and 95% confidence intervals.

The initial comparability of the groups under study will be carried out by comparing the main characteristics of the sample using the Student's T test or Mann-Whitney's U test for continuous variables and the Chi-square test for categorical ones.

To compare the means in the intensity of craving according to the PACS scale, intragroup pre-test and post-test (at the end of the intervention and 3 months later), the Student's T test will be used for paired data or Wilcoxon test, according to corresponding. To compare the intensity of craving between the intervention group and the control, the Student's T test will be used for unpaired or Mann-Whitney U data, as appropriate.

To study the relationship of the confounding factors (age, sex, marital status, employment status, consumption of other toxins) with the result of the PACS scale, a linear regression model will be applied with those variables that reach a significance. < 0.2 in univariate comparisons.

The analysis of the results will be performed with a level of statistical significance of 95% ($p < 0.05$) and the statistical program SPSS version 23 for Windows will be used.

Results and Discussion

Scientific and partnership relevance of the study

Involuntary attempts by people dependent on alcohol to suppress cognitive-emotional reactions to craving for alcohol can hide these responses from consciousness only to perpetuate and intensify them within the cognitive unconscious. In the domain of unconscious mental life, automatic processes function smoothly and efficiently without being inhibited by volitional control [24]. Therefore, trying to avoid the reactions of appetite in the unconscious, the alcohol-dependent individual can just increase the response he is trying to suppress and exacerbate the psychophysiological reactivity to alcohol signals.

Mindfulness training can serve to undo this process, making unconscious responses conscious.

Therefore, the practice of mindfulness can promote the recovery of people dependent on alcohol through the unauthorization of the alcohol consumption behavior scheme, resulting in diminished attention to the signals subliminals of desire to consume alcohol and reduction of craving. Consequently, mindfulness training can be a manageable means of promoting lasting behavior change.

Although motivational interventions can be highly effective in driving the desire for sobriety, participants in such motivational improvement therapies remain prone to relapse; In fact, relapse is often a part of the recovery process.

As such, interventions that consolidate the positive effects of short-term treatment on a broader lifestyle change are of great importance to the field of addiction treatment. During the gradual practice of mindfulness, the person learns to work with negative emotions in a metacognitive context, resulting in non-reactivity to difficult thoughts and better self-regulation against stressful factors.

The process of developing and incorporating the principles of mindfulness in all aspects of life can consolidate the gains obtained in the previous treatment and provide an effective long-term approach to cope with relapses. The practice of mindfulness can attenuate the reactivity to stress and the suppression of addictive thoughts giving rise to a greater awareness of desire and a greater ability to cope with and recover from alcoholic desires in the various contexts of life. Therefore, training in mindfulness could be considered as a very interesting cost-effective alternative for the treatment of the alcoholic patient.

Limitations

- “Hawthorne Effect” bias: By knowing that they are being studied, they can act in a different way.
- Social desirability bias: Refers to the need of the individual who undergoes an experiment to look good with the experimenter, do what they are supposed to do, or favor in some way the result experimental desired.

Ethical aspects

All participants will receive oral study information and a copy of the informed consent form and will have the opportunity to ask questions. Informed consent will be obtained from all participants. They will also receive a copy of the revocation document of the informed consent. The data collection instruments do not contain any personal data.

This study will be approved by the Clinical Research Ethics Committee CEIC and the corresponding Board of Directors of the Center where the study will be carried out.

The researchers ensure the confidentiality of the information in all phases of the study. The study takes into account the basic ethical principles and those set forth in the Declaration of Helsinki (Review of Strength) and in the Convention for the Protection of Human Rights

and the Dignity of the Human Being with respect to applications of Biology and Medicine (Oviedo 1997) The legislation on data protection is also contemplated (Organic Law 15/1999 of December 13 on the Protection of Personal Data and its RD 1720/2007 Development Regulation) and the Law 41/2002 of November 14, Basic Regulatory of Patient Autonomy and Rights and Obligations in Information and Clinical Documentation.

Resources and budget

Personal:

- Psychiatrists who evaluate patients.
- Mental Health specialist nurses, who perform the intervention.
- Person who performs the statistical analysis.

Material:

- Place: the sessions will be conducted in the COTA Library, of sufficient size so that all participants can be comfortably seated and/or lying down during the sessions, with a temperature of between 20 - 25°C, with adequate luminosity to exercise at Perform in each session.
- Mat for lying down.
- Blackboard.
- Folios, pens.
- CDs with recordings of the exercises that should be done at home.

Statistic 3000 €

Mats € 200

Folios, pens € 50

CDs € 40

Total: € 3290

Schedule.

Recruitment of patients

August 2018. People who perform it: nurses specialists in Mental Health of COTA.

Once 10 patients are achieved, the intervention begins. In parallel, patients will continue to be recruited for the following groups.

Intervention

- September 2018 - December 2019. The MBRP will be carried out. In total there will be 8 groups (each group has a duration of 2 months). People who do it: principal investigators.
- August 2019 - March 2020: Collection of urinal controls (each subject 5 months in total). People who do it: principal investigators.

Data collect

April 2020. People who do it: principal investigators.

Data analysis

May 2020. Person who performs it: Computer-statistical.

Publication and dissemination of the study

June 2020. People who do it: main researchers

Conclusion

The process of developing and incorporating the principles of mindfulness in all aspects of life can consolidate the gains obtained in the previous treatment and provide an effective long-term approach to cope with relapses. The practice of mindfulness can attenuate the reactivity to stress and the suppression of addictive thoughts giving rise to a greater awareness of desire and a greater ability to cope with and recover from alcoholic desires in the various contexts of life. Therefore, training in mindfulness could be considered as a very interesting cost-effective alternative for the treatment of the alcoholic patients.

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Volume 2 Issue 12 December 2020

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