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STUDY PROTOCOL.

Effectiveness of Primary Care nurse-supervised educational group interventions for giving up smoking: A Randomised Controlled Trial

Abstract:

Background: To analyse the effectiveness of two group interventions for smoking cessation (with support from the app) conducted by primary care nurses. **Methods:** A multicenter randomised controlled clinical trial occurred across eight Health Centres in the Murcia Region from 2018 to 2019. It involved daily smokers aged 18 and older who wanted to quit, had internet access, and spoke Spanish. Pregnant women, polydrug users, and individuals with psychiatric disorders were excluded from participation. Participants were randomly divided into two groups: one attending a single 4-hour Workshop, and the other attending a Course consisting of four 2-hour sessions. The analysis of smoking abstinence was performed using SPSS V22, with intragroup differences assessed through the chi-square test.

Keywords: Nurses, Nursing Evaluation Research, Primary Health Care, Smoking Cessation, Mobile Applications.

1. Introduction

Smoking represents the largest preventable health hazard, leading to the highest loss of disability-adjusted life years [1]. It is a key risk factor for cardiovascular diseases and is linked to 14 types of cancer as well as major Chronic Non-Communicable Diseases (NCDs). This creates significant demand on Primary Health Care (PHC) services [2,3]. Smoking is associated with eight of the ten leading causes of death [4], contributing to approximately eight million fatalities globally each year [5], including around 56,000 in Spain [6]. The ICD-11 classifies it as an addictive behavioural disorder.

In 2017, 27% of the European Union population were smokers (32% of men and 23% of women), with a prevalence of 26% in Spain and the Region of Murcia (men: 25.6%–28.5%; women: 18%) [7,8].

The United Nations, as part of the 2030 Agenda for Sustainable Development, set a key priority in target 3, "Good Health and Well-being," which focuses on enhancing the Framework Convention on Tobacco Control [9] and, as a result, lowering tobacco use rates. Similarly, the WHO MPOWER Strategy for Tobacco Control identifies the provision of assistance to quit smoking as one of its key actions towards reaching the smoking "Endgame" [10].

In Spain and the Region of Murcia, smoking cessation support is offered through the PHC service, primarily involving individual interventions, with referrals to specialised units based on specific criteria [11,12]. Successful smoking cessation strategies incorporate both behavioural and pharmacological methods [13,14]. Behavioural strategies include minimum systematised (healthcare advice), intensive (individual or group), specialised (individual or group), community-based (social support, mass media, and health promotion), and technology-based (mobile messages, software, and online applications) [15,16]. Smoking cessation approaches should be tailored to the user's profile, life stage, social situation, presence of other addictions, motivation level, health condition, and any chronic diseases [17].

Research shows that individual and group health education are similarly effective for quitting smoking [18,19]. Nevertheless, group education presents extra advantages in terms of efficiency and effectiveness [20]. Adults tend to learn primarily from their own

significant experiences and their peers' experiences (vicarious learning). Group therapy combines these two learning styles, enabling participants to share their personal experiences and compare them with those of others [21]. These interventions should apply techniques focused on promoting behavioural change [22]. There is no agreement on the optimal number of sessions for smoking cessation programs, which can range from four to ten sessions [20].

Due to its accessibility and ongoing, focused attention to the population, PHC is the ideal environment for delivering impactful group health education interventions against NCDs [23], including smoking. Nursing professionals have the expertise to implement these interventions with a gender and equity perspective [17,24,25,26,27]. However, there is limited evidence regarding the effectiveness of nursing interventions for smoking cessation [28].

This study aims to compare the effectiveness of a four-session, group-based stop-smoking program ("Course") with that of a single-session program ("Workshop"), both conducted by PHC nurses and supported by the S'ACABÓ app [29].

2. Materials and Methods

2.1. Study Design and Setting

A multicenter randomised controlled clinical trial occurred in the Health Centres (HC) of the Health Areas (HA) in the Murcia Region from May 2018 to December 2019, including a one-year follow-up. The study adhered to the CONSORT guidelines to ensure quality and to report the findings accurately.

2.2. Participants

The participants were daily smokers over 18 years old, with at least a year of smoking experience, who wanted to quit within a month, communicated in Spanish, and possessed a mobile device with internet access. Individuals were excluded if they used other drugs (excluding cannabis), had participated in smoking cessation programs in the last year, were diagnosed with an acute psychotic disorder, or were adolescents or pregnant women.

Published evidence [20, 30] indicates that the anticipated success rates for different interventions varied between 11% and 35%. To achieve a confidence level of 95% and a power of 85%, a sample size of 74 participants was necessary, dividing 37 individuals into each intervention group.

2.3. Intervention

Two group educational interventions were implemented: the "Workshop," which included a single 4-hour session, and the "Course," consisting of four weekly sessions totalling 8 hours (2 hours each). A researcher independent from the HCs randomly and proportionately assigned 10–15 participants to each group, stratified by sex.

The project guide and educational material used were the document "New Proposals for Group Educational Intervention" [21]. Additionally, all participants were instructed to utilise the "S'Acabó" App (Spanish term indicating that something is no longer available or has been phased out) to assist with smoking cessation [29].

Both interventions focused on group health education, employing cognitive-behavioural techniques alongside a motivating approach that capitalised on the group's collective experiences. The first two sessions aimed to prepare participants for quitting, while the third and fourth sessions emphasised maintaining the new lifestyle and preventing relapses. A PowerPoint presentation and a procedural guide were developed to standardise the interventions and reduce interprofessional variability.

Nurses in primary healthcare who wanted to participate in the project were recruited through the Murcian Society of Family and Community Nursing (SEAPREMUR). They

received specialised training consisting of 12 hours of online theoretical instruction on smoking and group health education, alongside 8 hours of hands-on practice focused on educational methods for smoking cessation, motivational interviewing, and group management.

2.4. Instruments and Data Collection

A personalized record was created detailing tobacco use, including the quantity and type of tobacco, nicotine dependence level (Fagerström test), motivation level (Richmond test), intervention type (Workshop or Course), gender, employment status, personal circumstances, average income, educational background, country of origin, social standing, chronic disease presence, weight, blood pressure, heart rate, anxiety level (Hamilton Test), and cannabis (CAST) and alcohol consumption (AUDIT) [12].

Follow-up calls occurred at 3 and 9 months, while in-person visits occurred at 6 and 12 months. These interactions gathered data on tobacco use, length of abstinence, relapse reasons, app usage, additional support measures, and co-oximetry readings.

2.5. Ethical considerations

Each health centre chose 20 to 30 eligible participants, providing them with a study information sheet and an informed consent form. All participants were anonymised to protect their privacy. The study adhered to Spanish laws to ensure the confidentiality, anonymity, and autonomy of the subjects involved. It received approval from the Clinical Research Ethics Committee of the Health Areas of the Region of Murcia (Code 2018-3-2-HCUVA).

2.6. Statistical Analysis

An anonymised database was developed in Excel. Data processing utilised the SPSS V22 statistical software. A descriptive analysis was conducted, summarising quantitative variables with central measures (mean, median) and standard deviation (SD). The chi-squared test was applied to qualitative variables, while Student's t-test and Fisher's exact test were employed for quantitative variables. Non-parametric analysis using the Mann-Whitney test was performed for variables that failed to meet normality assumptions. A p-value of <0.05 was regarded as statistically significant.

to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted by the Declaration of Helsinki and approved by the Clinical Research Ethics Committee of the Health Areas of the Region of Murcia (Code 2018-3-2-HCUVA).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

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