

Online Data Supplement

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Staff Training

Prior to the initiation of the program, the occupational healthcare advisors of the three study centres received specific training in smoking cessation counselling skills. For this, a standardized manual of smoking cessation training for healthcare professionals was used [1]. In addition, techniques of brief motivational counselling advice were practiced. While employees from the University Hospital Basel and F. Hoffman-La Roche AG were supported by the same healthcare advisors at a single location, Novartis Pharma AG outsourced study management to five different subcentres with changing healthcare advisors.

Recruitment

An additional, standardized, and confidential pre-screening questionnaire was sent to all 4,449 employees of the University Hospital Basel in February 2005, with the objective of studying the smoking history of employees, assessing their former and current smoking status, daily nicotine consumption, number of pack-years, prior attempts to quit, willingness to stop smoking, barriers to smoking cessation and motivation to participate in the programme. In addition, the conduct and purpose of the study were explained more in-depth. Returned

questionnaires were analyzed and smoking employees interested in quitting to smoke were contacted by telephone through an occupational healthcare advisor and, if they desired, an enrolment visit was planned. Of the 4,449 pre-screening questionnaires mailed out, 2,555 (57 %) were returned within 1 month. Of those, 1,455 (57 %) were from non-smokers, 791 (31%) from former, and 333 (13%) from active smokers. Of the 333 active smokers, 253 (76%) were eligible for enrollment and signed an informed consent in writing.

Informed Consent, Incentives, Ethical Review, and Regulatory

Considerations

Patients had to provide informed consent in writing stating that they agreed to participate in the study. The document explained the aim of the study, required visits, and procedures. It also contained a statement that the consent was freely given, and that withdrawal from the study was allowed at any time. No financial incentives to quit smoking were offered, but the financial costs of the programme, including pharmacological support, were either entirely covered by the employer or offered for a symbolic contribution, i.e. about 100 Swiss francs per employee.

This study was conducted in accordance with the ethical principles stated in the most recent version of the Declaration of Helsinki or the applicable International Conference on Harmonization (ICH) Guidelines on Good Clinical Practice, whichever represented the greater protection of the individual [2].

Assessment

All clinical data from the three study centres were recorded using an original, web-based, structured, and standardized e-CRF. Demographic information included age, gender, date of birth, educational level in four categories (university degree, technical school, apprenticeship, or basic education) and marital status (single, married, divorced, widowed).

Health risk factors besides cigarette smoking were screened with individualized, non-standardized questions for unhealthy dietary intake (“How often do you eat meals rich in fat?”, “Do you regularly eat fruit and vegetables?”) and for a sedentary lifestyle (asking for regular physical activity/sports of any kind, duration, and frequency).

A general physical examination was performed by a study physician at each centre, including questions for respiratory symptoms (cough, sputum production, wheezing, breathlessness at rest, exertional dyspnoea), comorbidities and concomitant medication. Spirometry was performed with an EasyOne Spirometer (ndd Medizintechnik AG, Zurich, Switzerland).

Forced expiratory manoeuvres were repeated until two readings of forced expiratory volume in 1s (FEV₁) within 100 ml of one another were obtained; the higher value was used in the analyses. Values for FEV₁ and FVC were recorded as a percentage of the predicted values according to ATS Guidelines [3]. Carbon monoxide (CO) concentration in exhaled air was measured by a Micro Smokerlyser (Bedfont, Kent, UK) [4]. Smoking-related assessment was started with general questions on the the subject’s history of smoking (“How many smokers live in your household?”, “How many of your colleagues at your place of work are active smokers?”, “How old were you when you started smoking?”, “How many years did you smoke?”, “When did you start smoking?”, “On how many days of the week are you smoking?”). History of past attempts to quit listed the number of prior attempts to quit, duration of the longest nicotine abstinence and previous methods of cessation support (any kind of nicotine replacement therapy, bupropion, hypnosis, acupuncture, others) and reasons for the renewed smoking relapse (free answers).

Standardized motivation to quit smoking was estimated by both the employee and the study physician on a visual analogue scale (0 = no motivation; 100 = very high motivation).

Severity of nicotine dependence was assessed by the Fagerstroem Score (FTND) consisting of six items about smoking behaviour and Craving Score (VAS). Following the literature, FTND scores were considered as mild (0-3 points), moderate (4-7 points), and high dependence (8-10 points) [5]. Intensity of craving was assessed by a visual analogue scale (0-100), with 0 representing a strong feeling of disgust and 100 a strong desire to smoke cigarettes. Individual quality of life was measured by the Satisfaction with Life Scale (Qol), consisting of 5 items of life satisfaction which were classified on a rating scale of 1 ("is not correct at all") to 5 ("is completely correct"). Values between 31 and 35 units reflect a high and 5-10 units a low satisfaction with life [6].

Pharmacological Support

Pharmacotherapy was not mandatory and participants could choose according to their own preferences between either a monotherapy or a combination of NRT (nicotine replacement therapy). NRT consisted either of a 16-hour transdermal patch, 2 or 4 mg nicotine chewing gum, 10 mg nicotine inhaler, or 1 mg or 2 mg nicotine lozenges. Combinations of nicotine patches and either nicotine chewing gum, nicotine inhaler, or nicotine lozenges were allowed for double NRT. Bupropion could be added to NRT or was used as monotherapy. Bupropion was prescribed at a total daily dose of 150 mg for the first 7 days and increased to 300 mg/bid thereafter. Prescription of pharmacological treatment, doses, and delivery systems were based on daily cigarette consumption and severity of nicotine dependence following recommendations of manufacturers and the respective literature [7, 8]. Participants were instructed to start with a pharmacological support therapy 7 days prior to the individual quit date.

References

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