A randomized trial assessing the Five-Day Plan for smoking cessation

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ABSTRACT

Aim To evaluate the effectiveness of the Five-Day Plan (FDP) in helping smokers to stop smoking.

Design Randomized controlled trial comparing intervention and control groups. The primary outcome measure was 12 months continuous abstinence verified by expired air carbon monoxide concentration. Secondary outcome measures were self-reported abstinence at end of treatment, at 3 and 6 months.

Setting Six towns in France.

Participants 228 smokers, recruited by newspaper and radio advertisement, aged 18 years or over and willing to make an attempt to quit smoking.

Intervention The Intervention group (119 participants) received the FDP, which is a behavioural group-based treatment programme that has been in operation in France since 1965. It involves five consecutive evening behavioural therapy sessions. The Control group (109 participants) received a single session discussing the health effects of smoking.

Findings In the Intervention group, 67 participants (56%) quit smoking at the end of the FDP. After three months this number had been reduced to 30 (25%) and to 19 (16%) by the end of one year. In the Control group these numbers were 14 (13%) and 12 (11%), respectively, after three and 12 months. When considering the rate of cessation without lapse after one year a significant difference was observed with a 13% rate in the Intervention group and 3% in the Control group ($P = 0.004$).

Conclusions The FDP may be considered as an aid for smokers who want to quit.

KEYWORDS Five-Day Plan, group behavioural therapy, smoking cessation, 12-month quit rates.

INTRODUCTION

Smoking is the most important preventable cause of morbidity and mortality in our society today. A life-long smoker's chance of reaching the age of 73 years is half that of a non-smoker (Phillips *et al.* 1996). International organizations such as the World Health Organization (World Health Organization Europe 2000) and national institutions such as the Surgeon General of the United States (United States Department of Health and Human Resources 2000), the Health Education Authority in England (West, McNeil & Ra 2000) and the Health Ministry in France (ANAES 1998) have therefore stressed the importance of curbing the prevalence of smoking among their populations in order to avoid a predicted world health catastrophe (Peto *et al.* 1994). Several strategies have been proposed and implemented, such as frequent increases in tobacco prices (Chaloupka 1999), the banning of tobacco advertisements (Emery, Choi & Pierce 1999), smoking prevention programmes and use of smoking cessation treatment programmes (TUDC 2000). For the latter, two elements can be distinguished: one based on pharmacotherapeutic methods, the other based on behavioural approaches. A recent review from the

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World Health Organization (World Health Organization Europe 2001) published findings supporting the evidence-based efficacy of both pharmacological and behavioural treatments. At present evidence has revealed that a combination of cognitive–behavioural techniques with pharmacological treatments can significantly increase the rate of smoking cessation (Garcia-Vera 2004).

Group behavioural treatments are recognized as effective methods for smoking cessation (Kottke, Battista & DeFriese 1988), with success rates at the 12-month follow-up ranging between 20 and 40% (depending in part on the outcome criteria). Historically these treatments were adopted as the first approach and included a variety of methods (TUDC 2000). One of the first behavioural methods, developed in the 1950s and called the Five-Day Plan (FDP), gained a reputation as a group-based therapy used widely in several countries (McFarland *et al.* 1964). Assessment of the FDP has shown that abstinence rates 1 year after treatment range between 20 and 35% in several European countries such as England (Riches 1978), Italy (Serraino *et al.* 1993), France (Romand 1995) and Switzerland (Frikart *et al.* 2003). However, there have been no adequately powered controlled trials. One very small study with less than 30 subjects in control and FDP groups concluded that the effectiveness of the FDP was limited to a duration of less than 6 months (Schlegel *et al.* 1984).

A French consensus conference (ANAES 1998) recognized the effectiveness of nicotine replacement therapy as an aid to smoking cessation. Bupropion has also been found to be effective (Dale *et al.* 2001) and, in France at least, has been added recently to the arsenal of smoking cessation. Although the FDP implemented by the Ligue Vie et Santé was mentioned during this conference, it remains a therapeutic method whose usefulness is not yet wholly acknowledged owing to the lack of rigorous supporting evidence. The goal of this present study was to test the potential of the FDP at 1 year against a control group, employing biological validation as a complementary means of evaluation. For this study we did not intend to test a particular component of this programme. Other relevant questions of interest were also considered: the usefulness of FDP for heavy as well as light smokers (Serraino *et al.* 1993) and the potential influence of motivation upon the cessation rate.

The research question was: is the FDP effective up to 1 year in helping people that quit smoking?

METHODS

Participants

The sample consisted of male and female smokers aged 18 years and over who were motivated to quit smoking. Accordingly, a cohort of smokers who were willing to quit was recruited by local newspapers and radio announcements in six different French towns between March 2000 and June 2001.

Each smoker attending the initial information session was listed following signed and approved consent. The participants were informed that each would be assigned at random to one of two groups: the intervention group, which would receive the FDP and the control group, which would only receive general information on tobacco-related health problems.

Interventions

The control group received general educative advice for 1 hour on health problems related to smoking while the intervention group was first informed as to how the FDP would be conducted and then given appointments to start the therapy (usually a few days following the information session). The two groups were not allowed to use nicotine replacement therapy, bupropion or other therapies during the course of the study (although it was difficult to prevent smokers who really wanted to stop smoking to use these supports for the duration of the experiment).

The FDP is a behavioural group therapy programme that takes into account the two principal aspects of tobacco addiction, physical and behavioural dependence (Shadel *et al.* 2000). The programme offers an opportunity to learn behavioural techniques to aid smoking cessation and continuing abstinence and to encourage other members of the group. The FDP is a multi-component therapeutic approach to smoking cessation with health-related advice to prevent weight gain. It employs elements of psycho-educative information, behavioural skills training and cognitive therapy (Sutherland 2003; Manske *et al.* 2004). Most of these elements were recommended by the United States Department of Health and Human Service (TUDC 2000). The practical aspects of this programme have been described by Frikart *et al.* (2003).

The FDP comprises an information session followed by five consecutive evening behavioural therapy sessions. These initial sessions are followed 1 or 2 weeks later by supplementary evening sessions. During these sessions, the physiopathological and psychological–cognitive aspects of tobacco-related problems are discussed with participants. Support is provided every evening by two professionals, e.g. a trained psychologist and a qualified health adviser.

Psychoeducative information was provided to motivate the subjects to quit smoking (Rundmo, Smedslund & Gotestam 1997; TUDC 2000) and on the role of smoking-related beliefs and peer psychosocial factors as ante-

cedents. Information was also given on the neural basis of addiction, the consequences of continuous smoking on the cardiovascular and pulmonary systems and other health-related problems. The subjects received encouragement through explanations of the benefits gained from quitting (Tonstad 2003). Behavioural skills training during the therapy emphasized coping with the physical and behavioural effects of nicotine dependence and the consequent smoking urge, risk-tendency and stress management with relaxation, as well as dealing with smoker gesticular habits. Non-smoking attitudes in the social environment and drug refusal techniques were also implemented (Morgan, Ashenberg & Fisher 1988; Suedfeld 1990). Mutual support between sessions (buddy system) was strongly encouraged (West, Edwards & Hajek 1998). Cognitive therapy emphasizes changes in motivation to quit smoking, control of thoughts while coping with the side-effects of abstinence and stressful situations and accumulation of confidence in the ability to quit smoking long-term (Hall *et al.* 1984; Shiffman 1989). With health-related advice subjects were strongly encouraged to adopt a more active life-style (King *et al.* 1996; Marcus *et al.* 1999). Dietary information provided was also important, as smoking cessation is often followed by weight gain (Klesges *et al.* 1989; Williamson *et al.* 1991). A diet adapted to low calorie intake was suggested (Gao *et al.* 1993; Danielsson *et al.* 1999), while low fat diet (Siguel & Lerman 1996) was recommended following the end of therapy. Counselling was also provided, e.g. asking subjects to refrain from alcohol consumption during the first week of the FDP (Miller & Gold 1998).

Outcomes

The principal outcome was an assessment of the effectiveness of smoking cessation up to 1 year following the FDP and analysis of the effectiveness of the FDP with respect to the intensity of dependence and the motivation to quit of the subjects under study.

Questionnaires were distributed to all participants and the results are presented for 3, 6 and 12 months following the FDP. The participation rates are given in Fig. 1.

Demographic information (age, gender, level of education, professional activity and marital status), smoking history (age at which the participant first began smoking and subsequent smoking frequency), current smoking exposure (number of cigarettes smoked daily, tobacco type, tobacco flavour, time of the first cigarette on the day, smoke inhalation), quitting history (number of previous attempts to quit and by which methods, length of non-smoking period and the consequences of these arrests on further smoking habits) were collected during the initial information session (Fig. 1, Q1).

At the same time, tests were used to evaluate tobacco dependence, anxiety and depression levels and the motivation towards quitting. Tobacco dependence was evaluated by the six-item questionnaire derived from the Fagerström model (Heatherton *et al.* 1991). The anxiety level and depression history (or current depression) were evaluated by assessment of two questionnaires completed by the participants: the Hospital Anxiety Depression score (HAD) (Zigmond & Snaith 1983; Bjelland *et al.* 2002) and the Befindlichkeits Scale (BfS) (Bobon, LaPierre & Lottin 1981).

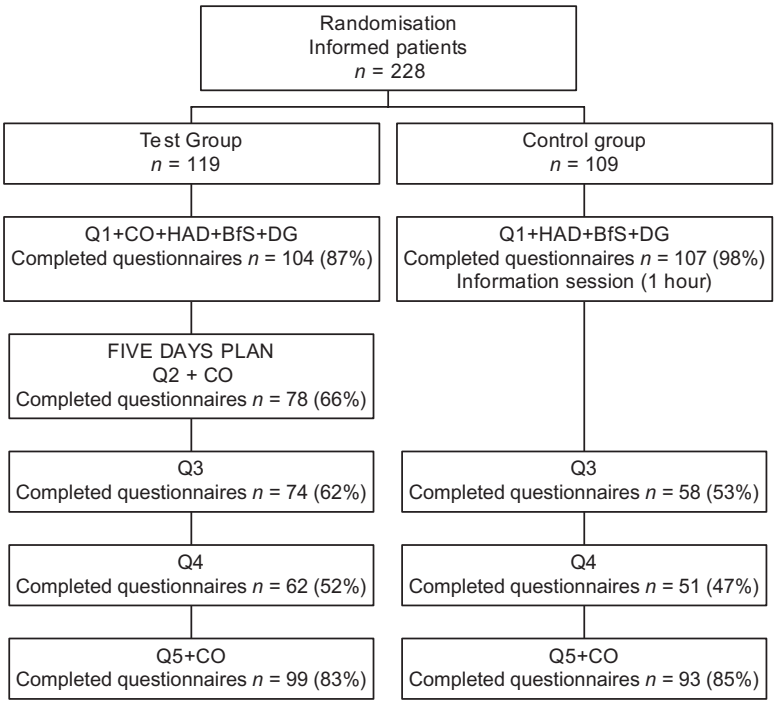

Figure 1 Flow of participants. Q1, 2, 3, 4, 5: questionnaires 1, 2, 3, 4, 5; HAD: Hospital Anxiety Depression scale; BfS: Befindlichkeits Scale for the evaluation of depression; DG: Demaria–Grimaldi test; CO: carbon monoxide test

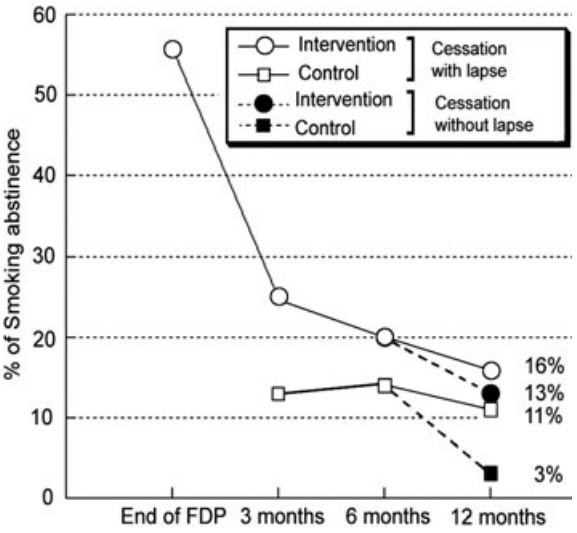

Figure 2 Follow-up of smoking abstinence rate between the intervention and control groups. The full lines versus the broken lines depict the percentage of self-reported abstinence for smokers who stopped smoking with or without relapse in the intervention and control groups, respectively.

The motivation to quit was measured by self-report based on the Demaria–Grimaldi scale (Demaria, Grimaldi & Loufrani 1987).

After the intervention, postal questionnaires were distributed in order to follow the smoking status of individuals of both groups and to evaluate a number of smoking-related variables at the end of FDP (Q2) and at 3-, 6- and 12-month intervals (Fig. 1, Q3, Q4, Q5). Smoking-related variables were: type of difficulties related to quitting smoking, time of day at which the craving is the strongest, change in brand of cigarettes, intention of planning to stop smoking in the future and reason for lapse. The majority of completed questionnaires were collected mainly by post or their information transferred by telephone, although some were collected by personal visits to those who had not responded to previous enquiries. Particular attention was paid to the recovery of the questionnaires at 12 months.

A biological measurement was used to validate smoking cessation. Carbon monoxide was measured using a CO-Tester (FIM Medical, Lyon, France) calibrated less than 6 months prior to the test. All participants from both groups who claimed to have quit smoking were verified by a measurement of CO exhalation (<10 p.p.m.).

Sample size determination

Sample size calculations were based on the hypothesis for a 1-year cessation rate of 10% for the control and 30% for the intervention group, with 95% power and $\alpha = 0.05$.

Randomization

A stratified random design, balanced every four individuals, was used to allocate participants to either the intervention or the control group. The stratification factor was town of inclusion. Recruitment was less successful than predicted and we were obliged to add new towns to recruit the necessary sample size.

Statistical analysis

Data were summarized by frequencies and percentages for categorical variables and by median and range for quantitative variables. The characteristics of each group were compared using the χ^2 test for categorical variable (Fisher's exact test for small sample size) and Student's *t*-test for continuous variables. People who did not answer the intermediate questionnaires at 3 and 6 months following the FDP and those who proved impossible to contact at 1 year were pooled with those subjects deemed unsuccessful in their attempt to quit. Analysis was undertaken using the intention to treat including subjects who neither completed any questionnaire nor attended the FDP as failures, whatever their group.

A *P*-value of less than 0.05 was considered statistically significant.

RESULTS

Baseline characteristics

The 228 participants in this trial were assigned randomly to either the control group (109) or the intervention group (119). Two participants (1.8%) from the control group and 15 participants (13%) from the intervention group did not complete the first questionnaire, Q1. However, no significant difference was observed between the two groups in terms of the rates of response for each questionnaire (Fig. 1). The median age of the control group (43 years; range = 18–66 years) was not significantly different from that of the intervention group (40 years; range = 19–64 years; $P = 0.49$). No statistical difference was observed between the two groups for other demographic parameters such as gender, level of education, professional activity or marital status (Table 1).

Psychological state evaluation

Using the BfS, which evaluates tendencies towards depression, no significant difference was observed between the two groups in terms of the number of participants who were depressed on entry to the study ($P = 0.114$), although 6% of subjects from the intervention group and 11% from the control group presented a strong tendency to be depressed (Table 1). However, only

43% of participants returned the BfS questionnaire, and many of the returned questionnaires were incomplete. The control group returned more incomplete questionnaires (74%) than the intervention group (39%; $P < 0.001$). For the HAD test, no significant difference was observed either for anxiety or depression scores between the intervention and control groups (Table 1). In the intervention group, 31% of participants had previ-

Table 1 Comparison of intervention and control groups.

	Intervention group		*Control group*		
	n = 119	*%*	*n = 109*	*%*	*P**
Demographic					
Females	64	54	58	54	0.99
Education high school graduate	69	62	69	66	0.53
Employed	86	78	82	78	0.99
Marital status (not alone)	92	82	84	81	0.79
Psychological tests					
Depressed at the time of test (BfS scale)**	15	21	10	36	0.114
HAD Scale					
Anxiety score > 10	30	28	7	20	0.38
Depression score > 10	31	29	5	14	0.09
Smoking habits					
Smoking start before year 20	105	90	95	90	0.99
Median number of cigarettes smoked daily					
Median (range)	20 (4–90)		20 (1–50)		0.096
25th percentile	15		15		
75th percentile	30		25		
Tobacco type					
Blond	90	82	79	84	
Brown	20	18	15	16	0.67
Tobacco flavour					
Mild	41	53	40	56	
Full flavour	37	47	32	44	0.71
Use of filter (yes)	42	81	35	90	0.24
Inhalation of smoke (yes)	107	91	100	93	0.44
Time of first cigarette					
At wake-up	40	35	31	29	
At breakfast	50	48	62	58	
Later	19	17	14	13	0.35
Smoking habits					
Same quantity	70	65	82	80	
Variable quantity	38	35	21	20	0.017
Modified 'Fagerström test' score					
Low (0–3)	30	25	24	27	
Medium (4–6)	55	47	39	45	
High (7–10)	33	28	25	28	0.94
Quitting history					
Number of previous attempts to quit					
No	20	17	11	11	
1	31	28	20	19	
2	31	28	30	29	
>3	30	27	42	41	0.084
Previous methods used***					
Patch	33	34	27	28	0.40
Acupuncture	26	27	20	21	0.35
Gum	15	15	18	19	0.52
Group therapy	12	12	11	11	0.86

Difference of percentage due to missing value. *χ^2 Test, between non-smokers/smokers + lost of follow up. **Depressed (15% versus 25%) + strongly depressed (6% versus 11%). ***Some subjects may have used several methods.

ously been treated for depression compared with 11% in the control group ($P < 0.001$).

According to the Demaria–Grimaldi scale there was no statistical difference between the two groups in their motivation to quit smoking. Six per cent of each group could be described as being indifferent toward stopping.

Smoking habits

No significant difference between the two groups was found for the various behavioural traits associated with smoking except that there was greater variability in the number of cigarettes smoked per day by the intervention group than by the control group (Table 1).

For both groups, 90% of individuals started to smoke before the age of 20 years, the median number of cigarettes smoked daily was 20 and 92% of subjects inhaled smoke (Table 1). Subjects within the age range of 18–35 years smoked more during the weekend than older subjects ($P = 0.003$).

Quitting history

The two groups presented a similar cessation history: 83% and 89% from the intervention and control groups, respectively, had tried at least once to quit smoking and 27% and 41% had tried three or more times (Table 1). The following methods had been previously employed: patch, acupuncture, gums, group therapies, medical consultations and laser (Table 1). Participants from the control group had tried more often to quit without seeking external help than those from the intervention group (67% versus 53%; $P = 0.053$).

For the intervention and control groups, respectively, similar numbers of subjects had received encouragement from families (78% versus 70%), friends (44% versus 39%) and colleagues (18% versus 10%). However, more intervention group members received support from medical practitioners than did control group members (32% versus 13%; $P = 0.004$).

The principal reasons given for wishing to quit smoking were due to health worries (92%), increasing prices (52%) and passive smoking (48%). No statistical difference was observed between the two groups with regard to these factors.

Evaluation at the end of FDP

From the 119 participants of the intervention group, 104 subjects (87%) replied to the Q1 questionnaire. Of these, 78 participants (75%) answered the Q2 questionnaire at the end of the FDP and 63 participants (81%) followed the entire 5 days of the FDP; the others missed one or two sessions. Of those that replied, 67 participants (86%) stopped smoking. Considering the group as a whole, 56% stopped smoking. Of these, a total of 35 participants (47%) indicated they had overcome an obstacle to quit smoking during the FDP such as working stress (15 participants; 20%), lack of motivation (12 participants; 16%) and family environment (11 participants; 15%).

Of the seven aspects proposed by the FDP 83% of participants reported having been helped by three or more components of the FDP and 50% by four or five aspects.

The most effective help was indicated as: leader support (57 participants; 77%), group therapy effect (54 participants; 73%), psychological and behavioural counselling (48 participants; 65%), health- and dietetic-related information (46 participants; 62%), physiological information (41 participants; 55%) and respiratory counselling (26 participants; 35%).

Smoking cessation trends

Considering those that did not complete the questionnaire as failures, we observed that 56% of the intervention group stopped smoking just after the FDP, 25% at 3 months, 20% at 6 months and 16% at 12 months. The corresponding percentages in the control group were 13%, 14% and 11% at 3, 6 and 12 months, respectively. Continuous abstinence at 1 year was 13% in the intervention group and 3% in the control group ($P = 0.004$; Table 2). All reports of abstinence were validated by carbon monoxide testing.

For the participants of the intervention group, the main causes of lapsing were: decreasing motivation (30%), nervousness (25%) and either familial (23%) or professional (20%) environment. Other causes were also reported such as stress (37.5%), circumstances such as holidays or a meal (31.2%), missing support (12.5%), accidents (6.3%), weight gain (6.3%), loss of job and divorce (6.3%).

In contrast, in the control group two participants quit smoking with nicotine patch, three others with FDP and seven without aid. All but three of these lapsed within 12 months (Table 2)

Of the participants who had lapsed or were still smoking, 84% in the intervention group and 80% in the control group wanted to try to quit again. Of these, 50% in the intervention group and 68% in the control group wanted to use the FDP when trying to quit again ($P = 0.04$).

DISCUSSION

Potential sources of bias in this study should be mentioned. The sample is unlikely to be representative of a population of smokers who want to quit as they were

Table 2 Evaluation of smoking cessation during follow-up.

	Intervention group		*Control group*		
	n = 119	%	*n* = 109	%	*P**
End of FDP					
Non-smoker	67	56	–	–	
Smokers	11	9	–	–	
Lost of follow-up	41	35	–	–	–
3 months					
Non-smoker	30	25	14	13	
Smokers	44	37	44	40	
Lost of follow-up	45	38	51	47	0.018
6 months					
Non-smoker	24	20	15	14	
Smokers	38	32	36	33	
Lost of follow-up	57	48	58	53	0.199
With or without relapse					
12 months					
Non-smoker	19	16	12	11	
Smokers	80	67	81	74	
Lost of follow-up	20	17	16	75	0.275
Without relapse					
12 months					
Non-smoker	16	13	3	3	
Smokers	83	70	90	82	
Lost of follow-up	20	17	16	15	0.004

*χ^2 Test, between non-smokers/smokers + lost of follow-up.

recruited only through newspaper and radio advertisements. This study was not blind because participants knew their treatment group from the beginning of the experiment. The control group tried to stop smoking during the course of the experiment with other methods such as nicotine patches (two participants) or with other FDP (three participants) in nearby towns. The use of other methods by control subjects may have increased the smoking cessation rate and led to a decrease in the difference between the two groups.

None the less, our results underline the relative effectiveness of FDP as described by several earlier observations, which did not include either control groups or biological validation (Serraino *et al.* 1993; Romand 1995; Picardi, Bertholdi & Morosini 2002; Frikart *et al.* 2003). The main difference between these previous observations and those of the current study is the reduced success rate observed at 1 year, although an earlier study in the United States presented a similar result with a 16% success rate at 10 months (Thomson & Wilson 1966).

Comparison of our success rate with other behavioural or cognitive therapy programmes is difficult due to the heterogeneity of methods. However, a recent meta-analysis, despite large variations in method, yielded a success rate between 14.2 and 33.7% (OR = 1.42–3.37) (Stead & Lancaster 2003). These authors concluded that there was no evidence that any particular component of group behaviour therapies was effective, except the support and skills training. As stated before, the FDP is a multi-component programme that is well codified (Bailey 1985), and we believe that a single component, e.g. enhancing motivation at the beginning of the therapy or health/illness problems, would not be found effective when tested apart from the general programme. The majority of participants who remained non-smokers after 1 year reported that they had been helped by three or more components of the FDP, and that social interactions between participants as well as psychological support from the leaders were the most important parameters.

When compared with pharmacological cessation methods, the FDP yields at least a comparable result. A recent meta-analysis gave a cessation rate of 10–15% at 1 year (Silagy *et al.* 2004), similar to that for bupropion (Jorenby, Leischow & Nides 1999; West 2003). However, the combination of different nicotine replacement therapies (NRT; Bohadana *et al.* 2000) and NRT with bupropion may yield a greater success rate (Jorenby, Leischow & Nides 1999).

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