

Cannabis and Young Users—A Brief Intervention to Reduce Their Consumption (CANABIC): A Cluster Randomized Controlled Trial in Primary Care

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ABSTRACT

PURPOSE Brief intervention to reduce cannabis is a promising technique that could be adapted for use in primary care, but it has not been well studied in this setting. We tested the efficacy of a brief intervention conducted by general practitioners among cannabis users aged 15 to 25 years.

METHODS We performed a cluster randomized controlled trial with 77 general practitioners in France. The intervention consisted of an interview designed according to the FRAMES (feedback, responsibility, advice, menu, empathy, self-efficacy) model, while the control condition consisted of routine care.

RESULTS The general practitioners screened and followed up 261 young cannabis users. After 1 year, there was no significant difference between the intervention and control groups in the median number of joints smoked per month among all users (17.5 vs 17.5; $P = .13$), but there was a difference in favor of the intervention among nondaily users (3 vs 10; $P = .01$). After 6 months, the intervention was associated with a more favorable change from baseline in the number of joints smoked (-33.3% vs 0% , $P = .01$) and, among users younger than age of 18, smoking of fewer joints per month (12.5 vs 20, $P = .04$).

CONCLUSIONS Our findings suggest that a brief intervention conducted by general practitioners with French young cannabis users does not affect use overall. They do, however, strongly support use of brief intervention for younger users and for moderate users.

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INTRODUCTION

Cannabis is the first illegal substance used by young people worldwide.¹ Across continents, 7% to 12% of adolescents and teenagers younger than 18 years and 6.6% to 25% of young adults aged 18 to 25 years are monthly users.¹⁻⁴ In Europe, France has the highest consumption of cannabis.³ As of 2014, 25.5% of French adolescents (aged 15 to 17 years) and 17% of young adults (aged 18 to 25 years) were monthly users of cannabis.^{5,6}

Current data are clear about the risks of cannabis use,⁷ which include social and psychiatric risks (eg, anxiety, depression, and an increased incidence of schizophrenia in vulnerable individuals),^{8,9} risks of lung and otorhinolaryngeal cancers,^{10,11} and cardiovascular risk.¹²⁻¹⁴ Use before driving increases the likelihood of motor vehicle collision-related morbidity and mortality.¹⁵⁻¹⁸ During adolescence, cannabis use causes cerebral microstructural changes that are not always reversible and have been implicated in cognitive and psychiatric disorders.¹⁹

In France, 80% of youth aged 15 to 25 years have visited their general practitioner in the preceding year.⁵ These visits could represent a privileged opportunity to identify young cannabis users and intervene to reduce their consumption. Motivational interviewing is a method of interaction centered on the patient and intended to modify behavior.^{20,21} Brief intervention is a

motivational interviewing technique that is characterized by its short duration.²² It is well accepted by both adolescent²³ and young adult²⁴ cannabis users.

Many randomized controlled trials have tested the efficacy of a brief intervention addressing cannabis use in adolescents, young adults, or both. These trials involved specific populations: students attending high schools,²⁵⁻²⁸ students attending universities,²⁹⁻³¹ people visiting addiction centers,³² people contacting the emergency services,^{33,34} or the general public following media calls for participation.³⁵⁻⁴⁰ The initial levels of consumption varied greatly, from once a year¹⁹ to weekly^{11,13,14,16} to monthly,^{20-22,25} and qualitative data suggested motivation ranged from a desire to stop²³ to having dependency symptoms.^{18,24} Furthermore, the measured impact on use varied considerably, with some of the trials reporting a reduction in use^{13,16,21-23} or an increase in the number of abstainers,^{12,20,23} but others showing no effect.^{11,14,15,17-19,24}

Few primary care–based studies of intervention exist in the published literature. Two trials involving US adolescents demonstrated a decrease in cannabis use (in excessive users)³⁷ or in the desire to use (irrespective of their initial level of consumption).³⁸ These studies were carried out in a primary care setting, but the brief intervention was not performed by a general practitioner; instead, it was carried out, for example, by a therapist with a computer or a case manager. A trial conducted among young Swiss patients who were excessive cannabis users did not find a brief intervention conducted by a general practitioner to be efficacious.³⁹

More research is therefore needed to assess the efficacy of a brief intervention for the reduction of cannabis use in primary care.^{40,41} We hypothesized that a brief intervention conducted in primary care by general practitioners among young users aged 15 to 25 years, regardless of their initial level of consumption, would lead to a decrease in their consumption at 1 year relative to usual care.

METHODS

Study Design

We used a pragmatic cluster randomized trial to test the efficacy of a brief intervention, conducted by general practitioners in primary care practices, in reducing the consumption of cannabis among young users. Cluster randomization was appropriate for limiting contamination bias,⁴² as allocating patients from the same practice into 2 different experimental groups could introduce bias. After being trained in the motivational interview method, a general practitioner was deemed unable to have a neutral visit with patients, and so could not care for patients in the control

group. The design and study protocol have been published previously.⁴³

Setting and Participants

All general practitioners working in general practices in 3 areas of France (Auvergne, Rhône-Alpes, and Languedoc-Roussillon) were personally invited by mail to take part in the trial. Their addresses were sourced from the National Institute for Statistics and Economic Studies. General practitioners who had specialized training in addiction treatment (eg, a university degree, qualification, or university course) were excluded from the trial.

All cannabis users aged 15 to 25 years who had consumed at least 1 joint per month for at least 1 year were eligible for inclusion in the study. We excluded patients who had severe mental disorders (that had been diagnosed by a psychiatrist before the study); had previously been treated for withdrawal from addiction; had a poor command of the French language; or had participated in a preliminary study of adolescent cannabis users.⁴⁴

Randomization and Blinding

CANnabis and Adolescents, a Brief Intervention to Reduce Their Consumption (CANABIC) was a cluster randomized controlled clinical trial in which the general practice was the unit of randomization. The unit of observation of the outcome was the patient enrolled in the study. General practitioners from the same practice were allocated to the same group to avoid contamination bias. All patients of a given general practitioner were assigned to his or her group. Randomization and allocation were carried out by an independent statistician in each area using Stata version 13 (StataCorp LP).

Study Procedure

The study was proposed to general practitioners between October and December 2011. From those who were eligible and volunteered, we randomly selected 50 per region. They were randomized into the intervention group or the control group. In the intervention group, we trained the general practitioners in conducting the brief intervention; in the control group, they simply received a briefing on the study. All general practitioners then had 1 year during which to enroll the first 5 eligible patients seen in their practice, regardless of the reason for the visit. Patients were seen alone during the visit. During this initial enrollment visit, the general practitioners in the intervention group conducted the brief intervention. In both groups, the general practitioners conducted follow-up visits at 3, 6, and 12 months. Those in the intervention group carried out the brief intervention at each visit, whereas those in the

control group gave routine care. In both groups, general practitioners were paid €80 per patient enrolled; patients were not paid.

Intervention and Control Groups

The general practitioners in the intervention group conducted an interview according to the brief intervention model, defined by the acronym FRAMES (feedback, responsibility, advice, menu, empathy, self-efficacy).²² During feedback, they related to the patient the quantity of their consumption and its consequences, then focused on their personal responsibility to change. The general practitioners gave advice about moderation and established a menu of alternative change options with the patient. They adopted an empathetic style, without judgment. Finally, they encouraged patient self-efficacy.

The general practitioners were trained to carry out the brief intervention through a training day that was held in collaboration with an addiction specialist and a psychologist specializing in addiction, and was approved by the Collège National des Généralistes Enseignants (National College of General Teachers). It aimed to update general practitioners' knowledge about cannabis, remove communication barriers, and train them in the brief intervention. Learning activities included discussion of the results of preliminary studies and role-play exercises about the brief intervention. The general practitioners had the flexibility to adapt the brief intervention according to their patients' needs. The study team did not monitor the brief intervention conducted by the general practitioners.

In the control group, after assessing patients' cannabis use, the general practitioners administered routine care. General practitioners and patients were told that they were participating in an observational descriptive study about cannabis use.

Measures

At each patient visit, general practitioners recorded the number of joints and bongs smoked, the quantity of alcohol and cigarettes consumed, and experimentation with other drugs. At baseline and at the end of the trial, all patients completed an anonymous self-administered questionnaire. They provided the same information as given to the general practitioner, but also details about how they used marijuana and their perception of their consumption. At baseline, the self-administered questionnaire contained questions from the Cannabis Abuse Screening Trial (CAST) tool⁴⁵ to identify at-risk users.

Outcomes

The trial's primary outcome was the number of joints consumed per month at 1 year. The secondary out-

comes were the number of joints consumed per month at the intermediate time points, and the quantities of cigarettes and alcohol concomitantly consumed. We also compared outcomes for those who were, and were not, daily users initially, as well as for patients aged younger than 18 years and those aged 18 years and older.

Sample Size

The sample size estimation and statistical analyses have been previously reported.⁴³ To establish the significance of any differences in outcomes between the 2 groups, we required 250 patients, as detailed below. The working hypotheses of this study were (1) that the intervention would reduce by 30% the stated consumption of cannabis at 12 months (ie, 5 joints per month) and (2) that a Hawthorne effect would occur, whereby simply participating in the study would reduce use.⁴⁶ Our projection was that patients in the control group would reduce their consumption by 15%.

Various simulations were carried out according to the standard deviation (SD) of joint consumption (an SD of 1.5, 2, 3, 4, or 5 joints) and clustering by practice (an intraclass correlation coefficient [ICC] of 0.05 to 0.2). Considering the results of these simulations—a 2-sided type I error of $\alpha = 0.05$, a statistical power equal to 90%, a 10% general practitioner dropout rate, and a 20% patient dropout rate—we calculated that a minimum of 250 patients were required to detect a relative difference in the reduction in joint consumption of 50% between the 2 groups (30% vs 15%). As each general practitioner had to enroll 5 adolescents and young adults, a total of 50 general practitioners were needed to attain our goal of 250 patients.

Statistical Methods

All statistical analyses were performed using Stata version 13. The tests were 2-sided with type I error set at $\alpha = 0.05$. Baseline characteristics were presented as means \pm SDs or medians (interquartile ranges) according to the statistical distribution of continuous data, and as number of patients and percentages for categorical parameters. At baseline, we compared patient characteristics between the randomized groups using the Student *t* test, or the Mann-Whitney test if the conditions of the *t* test were not met (normality and homoscedasticity determined using the Fisher-Snedecor test). For categorical variables, comparisons between groups were performed using the χ^2 test or, when appropriate, the Fisher exact test. Hierarchical linear regression models (mixed models) with levels per practice, individuals within practices, and repeated measurements per individual were generated to estimate the effects of the intervention on the number

of joints smoked per month at various follow-up time points. We assessed the normality of the residuals using the Shapiro-Wilk test. According to the skewness of the statistical distribution of the primary outcome, these models were run using the logarithm of the number of joints (to achieve the normality of the dependent variable). These models included an interaction between the randomization group and time point, and were adjusted for the number of joints smoked per month at baseline, age of first consumption, sex, CAST score at baseline, socioeconomic status, and general practitioner characteristics. ICCs were calculated by group. Subgroup analyses with the relevant age and level of initial consumption were performed after the assessment of a fixed-effect interaction (subgroup \times randomization group). When appropriate ($P < .05$), a subgroup analysis was performed. We took into account missing data by using estimation methods.⁴⁷ We chose to report all the individual P values without carrying out any mathematical correction for distinct tests comparing groups.⁴⁸ In particular, we focused on the magnitude of differences and their clinical relevance.⁴⁹ The self-administered questionnaire allowed us to determine the number of joints consumed per month anonymously; therefore, it was possible to calculate the Lin concordance⁵⁰ with our data for the principal criteria.

Ethics Considerations

The trial protocol was approved by the Comité de Protection des Personnes SUD-EST VI (South-East VI Committee for the Protection of Persons) of Clermont-Ferrand. The patients were given written information about the study. Enrollment was voluntary, anonymous, and within medical confidentiality, and it ensured an unconditional right to withdrawal. In accordance with French law, general practitioners have signed a form of nonopposition of patients, allowing minors to participate without parental consent.

RESULTS

Recruitment and Follow-up

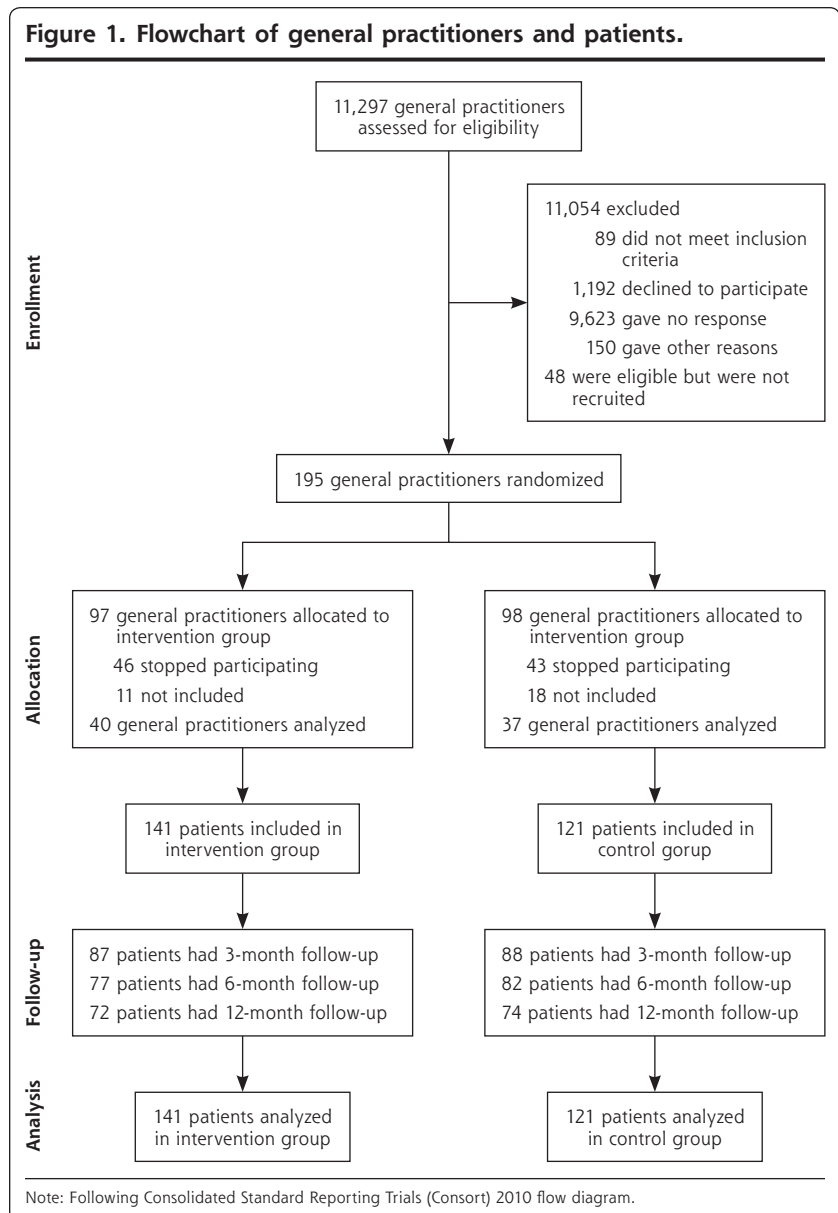
Figure 1 shows recruitment and flow of trial participants. In all, 77 general practitioners enrolled 262 patients and followed them up between March 2012 and March 2014.

Baseline Characteristics

Baseline characteristics of the 77 general practitioners in the intervention and control groups were similar (Table 1). They were 48 years old, on average; a slight majority were male, and most worked in urban or semirural areas.

The sociodemographic characteristics of the patients in the 2 groups were also generally comparable (Table 1). The intervention group contained more bong users than the control group (19.2% vs 9.9%; $P = .04$).

Figure 1. Flowchart of general practitioners and patients.



On the self-administered questionnaire at baseline, the median number of joints smoked per month was 20 joints for the patients overall (range, 5 to 50). This number was essentially the same as the 20 (range, 6 to 60) reported by patients to their physician, with a Lin concordance coefficient of 0.9.

Delivery and Receipt of the Intervention

Of the 262 patients enrolled, 175 of them (66.8%) had follow-up at 3 months, 159 (60.7%) at 6 months, and 146 (55.7%) at 12 months. On average, each patient had 2.8 (± 1.2) visits.

Primary Outcome

The brief intervention and control groups did not differ significantly at any of the time points with respect to the primary outcome of number of joints smoked per month (Figure 2). After 1 year, the median number of joints consumed monthly was identical at 17.5 (2 to 60) in the intervention group and 17.5 (4 to 40) in the control group ($P = .13$). Additionally, when all time points were combined, there was no global effect ($P = .11$).

The intervention group did, however, have a significant reduction from baseline in the number of joints consumed at both 6 months ($P = .01$) and 12 months ($P = .02$). Furthermore, the number of joints consumed at 6 months fell in the intervention group but remained unchanged in the control group (-33.3% vs 0% ; $P = .01$).

The ICC was 0.02 overall (0.12 in the intervention group, 0.01 in the control group). In the per-protocol analysis, monthly joint consumption at baseline was greater among the 72 patients in the brief intervention group (30 [7 to 85]) than among the 74 patients in the control group (18 [5 to 32]) ($P = .04$), but there was no significant difference at 12 months (17.5 [2 to 60] vs 17.5 [4 to 40]) ($P = .47$).

Secondary Outcomes

Subgroup Analyses

In a subgroup analysis according to frequency of cannabis use at baseline, among nondaily cannabis users,

Table 1. Characteristics of General Practitioners and Patients

Characteristic	Overall	Group		P Value
		Intervention	Control	
General practitioners, No.	77	40	37	
Men, No. (%)	42 (54.6)	23 (57.5)	19 (51.3)	.59
Age, mean (SD), y	48.3 (9.2)	47.8 (9.0)	48.9 (9.5)	.60
Group practice, No. (%) ^a	51 (66.2)	27 (67.5)	24 (64.9)	.81
Self-employed, No. (%)	65 (85.5)	32 (82.1)	33 (89.2)	.38
Teaching role, No. (%) ^b	32 (41.6)	18 (45.0)	14 (37.9)	.52
Work setting				
Rural, No. (%)	9 (11.7)	4 (10.0)	5 (13.5)	.73
Semirural, No. (%)	37 (48.0)	18 (45.0)	19 (51.4)	
Urban, No. (%)	31 (40.3)	18 (45.0)	13 (35.1)	
Number of patients enrolled, mean (SD)	3.4 (2.1)	3.5 (2.2)	3.3 (2.0)	.60
Patients, No.	262	141	121	
Men, No. (%)	169 (64.5)	89 (63.1)	80 (66.1)	.61
Age				
Mean (SD), y	20.60 (2.6)	20.88 (2.7)	20.28 (2.6)	.07
<18 y, No. (%)	47 (18.0)	20 (14.3)	27 (22.3)	.09
Marital status, No. (%)				
Single	211 (81.2)	108 (77.7)	103 (84.3)	.31
Married	49 (18.9)	31 (22.3)	18 (14.9)	
Divorced/separated	2 (0.8)	1 (0.7)	1 (0.9)	
Lodging status, No. (%)				
Cohabiting	202 (77.1)	106 (75.2)	96 (79.3)	.42
Living alone	63 (24.1)	37 (26.2)	26 (21.5)	.37
Employment status, No. (%)				
Working	147 (56.1)	82 (58.2)	65 (53.7)	.07
No occupation	7 (2.7)	5 (3.6)	2 (1.7)	
Student	108 (41.2)	54 (38.3)	54 (44.6)	
Psychotropic medication use, No. (%) ^c	10 (3.8)	6 (4.3)	4 (3.3)	.69
Cannabis use				
Joints per mo, median (IQR)	20 (6-60)	30 (6-80)	20 (5-40)	.08
≥ 30 joints per mo, No. (%)	121 (46.2)	73 (51.8)	48 (39.7)	.05
Use bongos, No. (%)	39 (14.9)	27 (19.2)	12 (9.9)	.04
Age at first use, mean (SD), y	15.15 (1.9)	15.24 (2.1)	15.04 (1.6)	.40
Alcohol use				
Used in past month, No. (%)	204 (77.9)	110 (78.0)	94 (77.7)	.94
Quantity: glasses/wk, median (IQR)	6 (2-10)	5 (2-10)	7.5 (3-14)	.02
Tobacco use				
Used in past month, No. (%)	240 (91.6)	124 (87.9)	116 (95.7)	.02
Quantity: cigarettes/wk, median (IQR)	60 (30-82)	60 (35-100)	60 (28-78)	.60
Experimented with other drugs, No. (%)	111 (42.4)	59 (41.8)	52 (43.0)	.85

IQR = interquartile range.

^a Any practice other than solo practice.

^b Taught students in his or her practice.

^c Anxiolytics prescribed by the general practitioner.

median monthly joint consumption after 1 year was significantly lower in the brief intervention group than in the control group (3 vs 10 joints; $P = .01$) (Table 2). In contrast, the difference among daily users was not significant (55 vs 30; $P = .40$). The results of the multivariate analysis, adjusted for sex and age, confirmed these results.

The subgroup analysis according to age, with a multivariate model considering the interaction age \times group, showed that among users younger than 18 years, those in the brief intervention group had significantly lower monthly cannabis use than peers in the control group at 6 months (12.5 vs 20 joints; $P = .04$) (Figure 3). Also, in this subset, the proportion of daily users at 12 months was lower in the intervention group (4 [26.7%]) than in the control group (10 [55.6%]) ($P = .04$), whereas there was no difference among users aged 18 years or older (27 [47.4%] vs 21 [37.5%]) ($P = .46$).

Use of Other Substances

The lower proportion of tobacco smokers at baseline in the brief intervention group vs the control group persisted at 12 months (77.8% vs 90.5%; $P = .03$). There was no significant difference between groups in the number of glasses of alcohol consumed per week at 12 months (4 [2 to 7] vs 6 [2 to 10]; $P = .17$).

DISCUSSION

Main Findings

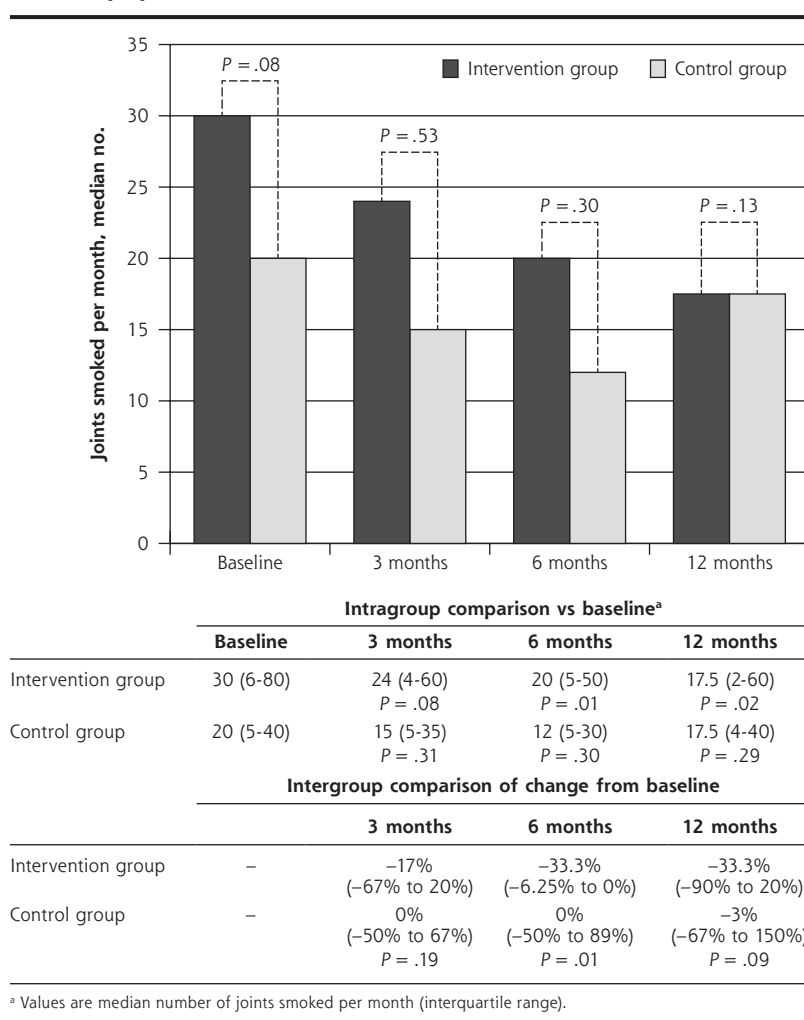
Our trial is one of only a handful to test a brief intervention performed by general practitioners for young cannabis users in primary care. The main results can be summarized as follows: (1) after 1 year, the intervention was associated with a decrease in the median number of joints smoked per month, but without significant difference relative to routine care; (2) among nondaily users, the intervention significantly reduced use of cannabis compared with routine care; (3) after 6 months, the change in median number of joints smoked per month was larger with the intervention than with routine care; and (4) among cannabis

users younger than 18 years, the intervention reduced the quantity used compared with routine care.

Comparison With Published Data

In our study, cannabis use fell in both groups, without statistical difference. A Swiss cluster randomized trial in primary care had the same result.³⁹ The Hawthorne effect may partially explain these findings.⁴⁶ Seeing a patient regularly during a study can modify the behavior of both the patient and the general practitioner.^{51,52} In our study, we observed a significant decrease in cannabis use in both the intervention group and control group among patients aged 18 years and older. Among patients younger than 18 years, however, consumption decreased in the intervention group but increased in the control group, with a significant difference at 6 months, consistent with another trial conducted in primary care.⁴³

Figure 2. Median number of joints smoked per month at baseline and at 3, 6, and 12 months.



This pattern suggests that brief intervention may be effective in slowing or preventing increases in use, which often occur between 15 and 25 years of age.⁵³ The impact on adolescents can be explained by their ambivalence in this period. The general practitioner is perceived both as a potential informer and as a benevolent authority.⁴⁴

Our brief intervention also had an effect on non-daily users, consistent with findings of another study conducted in primary care.³⁸ Brief intervention has likewise proven effective in nonexcessive drinkers.^{54,55} There may be a neurophysiologic explanation. The effectiveness of brief interventions is based on patients' ability to change after realizing the adverse effects

related to a substance. It appeals to their executive functions. In cases of dependency, increased salience and difficulty in accepting the adverse effects may necessitate longer motivational methods.⁵⁶

Table 2. Comparison of Intervention and Control Groups According to Frequency of Cannabis Use at Baseline

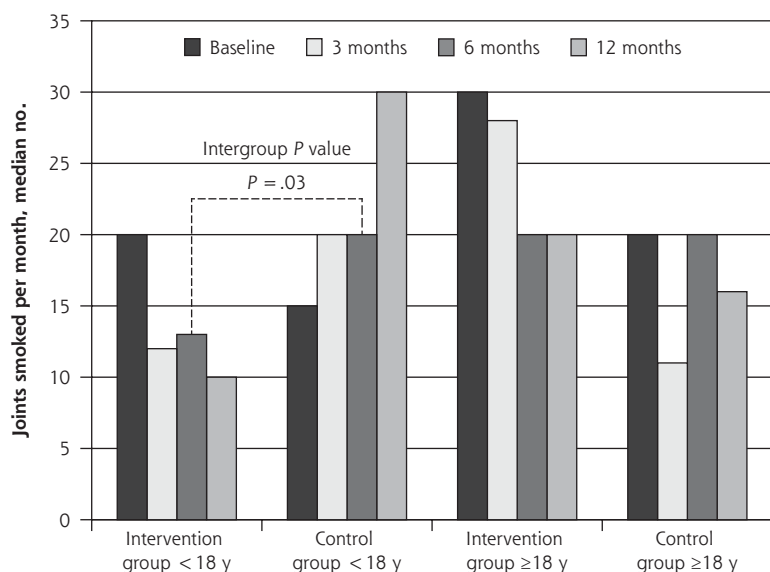
Time Point	Nondaily Users ^a			Daily Users ^b		
	Intervention	Control	P Value	Intervention	Control	P Value
Baseline	6 (4-14)	10 (4-15)	.29	70 (40-120)	50 (30-95)	.11
3 months	4 (2-20)	10 (5-21)	.19	40 (20-95)	35 (10-60)	.41
6 months	5 (1-10)	10 (5-20)	.002	40 (23-100)	30 (10-68)	.17
12 months	3 (0-15)	10 (3-30)	.01	55 (10-100)	30 (15-60)	.40

Note: Values are median number of joints smoked per month (interquartile range).

^a Smoked <30 joints per month at baseline.

^b Smoked ≥30 joints per month at baseline.

Figure 3. Median number of joints smoked per month at baseline and at 3, 6, and 12 months, according to age-group.



Intragroup comparison of change from baseline^a

	Intervention group <18 y	Control group <18 y	Intervention group ≥18 y	Control group ≥18 y
Baseline	20 (4 to 35)	15 (10 to 30)	30 (8 to 90)	20 (5 to 50)
3 months	12 (4 to 30) P = .83	20 (10 to 33) P = .45	28 (4 to 60) P = .005	11 (5 to 35) P = .03
6 months	13 (1 to 30) P = .10	20 (12 to 60) P = .19	20 (7 to 60) P = .003	10 (5 to 30) P = .006
12 months	10 (0 to 30) P = .11	30 (3 to 40) P = .78	20 (2 to 70) P = .001	16 (5 to 35) P = .03

^a Values are median number of joints smoked per month (interquartile range).

Strengths and Limitations

Of the 195 randomized general practitioners, only 77 ultimately enrolled patients. Those who did not were not significantly different from those who did, so such differences were unlikely to cause major recruitment bias. The power of the study may have been affected, although the required number of patients was reached. The rate of follow-up was lower than that of the Swiss trial.³⁹ Administrative burden and a lack of time were the main obstacles reported by general practitioners to enrollment and follow-up of patients,⁵⁷ and also to their identification.⁵⁸

In our trial, the general practitioners conducted screening, enrollment, intervention, and data collection, which may have introduced bias, but these practices reflect the real-life course of patient care, and the situation was the same in both groups. The double collection of data (both by the physician during the visit and by anonymous self-report) ensured good reliability. For the same reasons, performance of the general practitioners in delivering the brief intervention was not evaluated.

This study contributes to the discussion on intravariability and intervariability of general practitioners in response to an intervention, as well as on the effects of interventions on individuals, the

study of whom requires mixed methods: qualitative and quantitative.⁵⁹ The impact of an intervention could be unexpected (worse than expected or even harmful).⁶⁰ It would be pertinent to analyze the behavior within each group to understand such changes, as was done in a recent cluster study.⁶¹ We integrated characteristics of the general practitioners into our analysis, and are further evaluating patients' behavior according to these characteristics and the practitioners' practices. This analysis of behavior of each cluster in a clustered response test is one of the challenges of research in primary care.⁵⁹

Implications

In conclusion, our study did not show an effect on cannabis use of a brief intervention conducted by general practitioners with French adolescents and young adult cannabis users overall. Our results do, however, strongly support use of brief interventions for users who are younger than age 18 and for moderate, nondaily users.

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Key words: general practice; addiction; marijuana; brief intervention; public health; primary care; practice-based research

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