A Self-Determination Multiple Risk Intervention Trial to Improve Smokers' Health

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BACKGROUND: Little is known about how interventions motivate individuals to change multiple health risk behaviors. Self-determination theory (SDT) proposes that patient autonomy is an essential factor for motivating change.

OBJECTIVE: An SDT-based intervention to enhance autonomous motivation for tobacco abstinence and improving cholesterol was tested.

DESIGN: The Smokers' Health Study is a randomized multiple risk behavior change intervention trial.

SETTING: Smokers were recruited to a tobacco treatment center.

PATIENTS: A total of 1,006 adult smokers were recruited between 1999 and 2002 from physician offices and by newspaper advertisements.

INTERVENTIONS: A 6-month clinical intervention (4 contacts) to facilitate internalization of autonomy and perceived competence for tobacco abstinence and reduced percent calories from fat was compared with community care. Clinicians elicited patient perspectives and life strivings, provided absolute coronary artery disease risk estimates, enumerated effective treatment options, supported patient initiatives, minimized clinician control, assessed motivation for change, and developed a plan for change.

MAIN OUTCOME MEASURES: Twelve-month prolonged tobacco abstinence, and change in percent calories from fat and low-density lipoprotein-cholesterol (LDL-C) from baseline to 18 months.

RESULTS: Intention to treat analyses revealed that the intervention significantly increased 12-month prolonged tobacco abstinence (6.2% vs 2.4%; odds ratio [OR] = 2.7, P = .01, number needed to treat [NNT] = 26), and reduced LDL-C (-8.9 vs -4.1 mg/dL; P = .05). There was no effect on percent calories from fat.

CONCLUSIONS: An intervention focused on supporting smokers' autonomy was effective in increasing prolonged tobacco abstinence and lowering LDL-C. Clinical interventions for behavior change may be improved by increasing patient autonomy and perceived competence.

I n 1997, the NIH solicited intervention studies to compare theories related to mechanisms involved in health behavior change, or to assess the utility of a particular theoretical model for changing 2 or more health-related behaviors.[1] This is the primary outcome report describing the effectiveness of a self-determination theory (SDT)[2–4]-based intervention for tobacco use and hyperlipidemia. Both risk factors commonly interact to cause heart disease.[5–8] Tobacco kills 435,000 Americans annually.[9] The Public Health Service (PHS) Guideline *Treating Tobacco Use and Dependence*[10] recommends that practitioners provide 5 to 10 minutes counseling and referral for intensive treatment (4 to 8 contacts) for all willing smokers.

Self-determination theory is the only theory of motivation and behavior change in which the importance of patient autonomy, including methods for assessing it, is emphasized.[3] Self-determination theory proposes that patient autonomy is essential for motivating change. Autonomy involves experiencing a sense of choice as one behaves in a manner congruent with one's values. Theorists of SDT suggest that supporting patient autonomy by acknowledging patient perspectives, providing choice, supporting initiations, and providing relevant information will increase autonomous motivation over time.

Research has linked autonomous motivation to maintained weight loss,[11] medication adherence,[12] reduced adolescents' tobacco use,[13] and diabetic control.[14,15] Thus, autonomous motivation consistently predicts change in health behaviors. A previous randomized trial of physicians providing a brief intervention for tobacco abstinence linked autonomy to long-term abstinence from tobacco,[16] but this less intensive intervention failed to increase patient autonomy or abstinence. A more intensive intervention was needed.

Self-determination theory also proposes that perceived competence is necessary for behavior change. Perceived competence is similar to self-efficacy[17] and represents the degree to which people feel able to achieve desired outcomes. Perceived competence predicts smoking and diabetes outcomes.[14–16] Supporting patient autonomy increases perceived competence for change.[15,16] The process of increasing autonomy and perceived competence is termed "internalization" in SDT.[3]

Smokers were recruited to a cessation-induction trial about improving smokers' health whether or not they were ready to stop.[18] The intervention tested was based on SDT and the USPHS intensive interventions.[10,18] A previous report related to this trial demonstrated greater 6-month tobacco abstinence for the intervention group.[19] The hypotheses for this report were: (1) smokers randomized to the SDT tobacco intervention would have greater prolonged abstinence from tobacco 18 months after randomization and (2) for smokers with hyperlipidemia, SDT dietary intervention patients would have greater reduction in intake of percent calories from fat and lower low-density lipoprotein-cholesterol (LDL-C) 18 months after randomization.

METHODS

Study Design

The study design, recruitment, and a detailed description of the intervention were reported previously.[18,19] Eligible subjects were currently smoking 5 or more cigarettes per day, were 18 years of age and older, read and spoke English, had no history of a psychotic illness (depression and anxiety were allowed), and had a minimum life expectancy of 18 months. Subjects were recruited through newspaper ads and signs in physician offices to participate in a study about smokers' health. Subjects were paid $75. Thirty percent of patients were randomly assigned to community care (CC) and 70% to intensive tobacco treatment. The protocol was approved by the University of Rochester Human Subject Protection Program.

Randomization

The randomization was stratified by whether a dietary intervention was indicated based on the National Cholesterol Education Program's (NCEP's) LDL-C goals.[20] Patients who were at LDL-C goal were randomized to tobacco intervention or CC. Patients not at LDL-C goal were randomized to (1) tobacco and dietary intervention, (2) tobacco intervention and dietary CC, or (3) community care for both tobacco and diet. The results of a stratified permutated blocked randomization were placed in numbered double-sealed security envelopes. After obtaining informed consent, research assistants explained the intervention or CC condition based on assignment.

Community Care Condition

Patients randomized to CC completed questionnaires and then received the National Cancer Institute booklet "You Can Quit Smoking,"[21] a copy of their cholesterol test results, the American Dietetic Association booklet on elevated cholesterol "The New Cholesterol Countdown,"[22] and a list of active area smoking cessation programs. They were encouraged to enroll in a cessation program and to meet with their physician.

Intervention Condition

Intervention patients were given the same materials and encouragements as those in CC. Participants at LDL-C goal were encouraged to meet at least 4 times with a counselor in person during the subsequent 6 months, although telephone follow-up was permitted. Participants with elevated LDL-C were asked to meet 4 times with a counselor and 2 times with a dietician. The patients were provided a choice of a study physician or their own physician to prescribe medications. There was no limit on the number of contacts, as long as they occurred within the 6-month intervention period.

The counselor met with the patient for 50 minutes initially and for 20-minute follow-up visits. Counselors were trained to support patients in making clear and autonomous choices about whether or not they wanted to stop smoking or to change their diet to reduce their cholesterol. Patients were informed if their cholesterol exceeded the NCEP goals.[20] Counselor autonomy support was operationalized by eliciting and acknowledging patients' perspectives about their diet and tobacco use, providing information about the health risks of elevated cholesterol and smoking along with the benefits of change in diet and abstinence from tobacco, supporting patients' initiatives, listing effective options for those wanting to change, and minimizing controlling behavior by the counselor (e.g., pressuring patients to do what we say). Counselors asked about patients' life strivings, and how their tobacco use and current dietary patterns either helped or interfered with achieving their strivings. Next, patients' 10-year risks for developing cardiovascular disease were reviewed,[23] and patients were informed that lowering their cholesterol and stopping smoking could cut that risk by more than 50% within 12 months.[24] Patients were then asked if they wanted to make a change in their diet, or stop smoking, or both.

Follow-up visits for those not wanting to stop smoking or change their diet involved counselors reviewing the patients' strivings. For patients who wanted to stop, or alter their diet, counselors would support their competence by establishing a plan for change, reviewing, and acknowledging any attempts to change, and reframing failures as short successes.[10,25]

Baseline Assessments

Patients completed questionnaires (approximately 50 minutes), including demographic information, medical history, smoking history, the Fagerstrom Addiction Severity Scale (FAS[26]), the treatment self-regulation questionnaire (TSRQ-S) for autonomous motivation, the perceived competence scale (PCS-S), and their intention to quit smoking in the next 30 days. The TSRQ for diet (TSRQ-D), and Perceived Competence for Diet (PCS-D) were also assessed. Low-density lipoprotein-cholestrol was determined from the mean of 2 fasting serum samples drawn a week apart before randomization. Blood pressures were recorded. Items from the previously validated motivation scales[11,14,16,27] were answered on 7-point Likert-type scales and can be seen at http://www.psych.rochester.edu/SDT/measures/index.html.

Dietary Recalls

Three 24-hour dietary recalls (2 weekdays and 1 weekend day) were collected at baseline and at 18 months using the Nutrition Data System for Research (NDS-R), Version 4.05_33 (Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN). Telephone dietary recalls were conducted by the Pennsylvania State University Diet Assessment Center (University Park, PA) using a multiple-pass technique to facilitate dietary recall and improve accuracy.[28] The 2-dimensional (2D) Food Portion Visual (Nutrition Consulting Enterprises, Framingham, MA) of cups, spoons, bowls and various shapes and thicknesses were given to participants to estimate portion sizes. Nutrient data were generated and sent to the University of Rochester for analysis.

One-Month Assessments

A mailed questionnaire assessed patient perceptions of the health care climate (HCCQ, 15 items), particularly the practitioner autonomy support of patient decisions.[19] Three phone calls were made to non-respondents, and then a second questionnaire was mailed.

Six-Month Assessments

A mailed questionnaire assessed autonomous motivation for tobacco abstinence and dietary change, perceived competence

for tobacco abstinence and dietary change, and their 7-day point-prevalence tobacco abstinence at 6 months with the question "Have you smoked a cigarette, even a puff in the past 7 days?" Those answering "No" were instructed to have a blood sample to verify their reported abstinence. Serum cotinine validated the point prevalence report.[29] Six-month treatment intensity was determined by adding the self-reported patient contact time with health care practitioners regarding tobacco or diet outside the study, to the number of contact minutes with study practitioners.

Eighteen-Month Outcomes

As recommended by the Society for Research on Nicotine and Tobacco,[30] the primary abstinence outcome reported is 12-month prolonged abstinence. This is defined as self-report of not smoking at all in the past 12 months following a 2-week grace period from the end of the 6-month intervention. Patients also reported the number of serious quit attempts they made during the study, which smoking cessation medications they used and for how many days, and the number of days since their last cigarette. For patients with elevated cholesterol at baseline, 2 fasting LDL-C samples and 3-day dietary recalls were obtained.

Statistical Methods

The data were analyzed using SPSS statistical software.[31] Autonomy support at 1 month, change in autonomous motivation, and change in perceived competence were analyzed using t-tests and analysis of covariance (ANCOVA). A χ^2 test was used for the effect of the intervention on 12-month prolonged tobacco abstinence. Intention-to-treat analysis was used. Subjects lost to follow-up were assumed to be smoking from the point of last contact, and the autonomy and perceived competence scores were assumed to be unchanged from last measurement. The effects of autonomy support, change in autonomous motivation, change in perceived competence, and treatment intensity on 12-month prolonged tobacco abstinence and medication taking were tested using logistic regression. Linear regression was used to test these effects on dietary change and LDL-C.

A sample size of 1,056 was estimated to have 80% power to detect a 7% difference in the 6-month quit rate between the intensive intervention (15%) versus the CC (8%) condition with a 2-sided α of 0.05.

RESULTS

Between January 2000 and July 2002, 2,681 smokers were screened for eligibility, and 2,037 (76%) were eligible and provided phone consent for having 2 fasting lipid profiles (FLP). One thousand and six (49%) of those eligible came to an initial appointment, provided full informed consent, completed the baseline questionnaires, and were randomized. Fifty-seven subjects who did not have FLPs drawn were excluded from consideration for the dietary study. The 383 participants above LDL-C goal were randomized to diet intervention ($N=174$, 45.4%) or to diet CC ($N=209$, 54.6%).

The randomization was effective as the groups did not differ significantly on key demographic characteristics (see Table 1). Compared with our community, our study population had a lower average household income ($34,600 vs a county-wide $44,900) and fewer had graduated from college (26% vs 33% of those over 24 years). During the 18 months following randomization, 78 individuals withdrew from the study, 6 died (no deaths were related to the study), and 285 were lost to follow-up (see Fig. 1).

Tobacco Abstinence and Motivational Outcomes

The primary outcome of 12-month prolonged abstinence was significantly higher in the intervention condition (6.2% vs 2.4%, $P=.01$, Number Needed to Treat [NNT]=26.3). The mean days since last cigarette (37.30 vs 17.58, $P=.01$) and the longest time not smoking (59.05 vs 28.88 days, $P<.001$) were greater for the intervention group. The intensive treatment patients perceived greater autonomy support at 1 month ($P<.001$ by t-test), and internalized greater autonomous motivation for cessation ($P<.05$ by ANCOVA), for taking

Table 1. Baseline Characteristics

Characteristics	Community Care Group (n=292)	Intensive Treatment Group (n=714)	All (n=1006)	Range	P-Value	Cronbach's α
Sex (% female)	67.0	62.9	63.9	—	.22	—
Age	44.8	45.7	45.5	18 to 82	.23	—
Marital status (% married or living as married)	46.7	47.1	47.0	—	.91	—
Ethnicity (% white)	81.1	82.2	81.6	—	.69	—
Cigarettes per day	20.9	20.3	20.5	2 to 60	.43	—
Fagerstrom AS	5.0	5.0	5.0	0 to 10	.74	.63
Baseline variables						
Intention to quit in 30 days (%)	44.3	48.1	47.0	—	.37	—
Autonomous motivation for cessation	6.0	6.1	6.1	1.17 to 7.00	.12	.87
Autonomous motivation for medication taking	5.2	5.3	5.3	1.00 to 7.00	.40	.87
Perceived competence	4.3	4.4	4.4	1.00 to 7.00	.50	.90
Baseline LDL-C* (mg/dL)	152.5	154.4	—	30.00 to 258.5	.47	—
Baseline %* calories from fat	33.3	32.1	—	13.52 to 50.82	.10	—

A factor analysis was conducted on the autonomous motivation and perceived competence items at both baseline and 1-month. In each case, the items loaded cleanly on 2 factors with Eigen values exceeding 1.00.

*Values are for diet intervention versus diet community care.

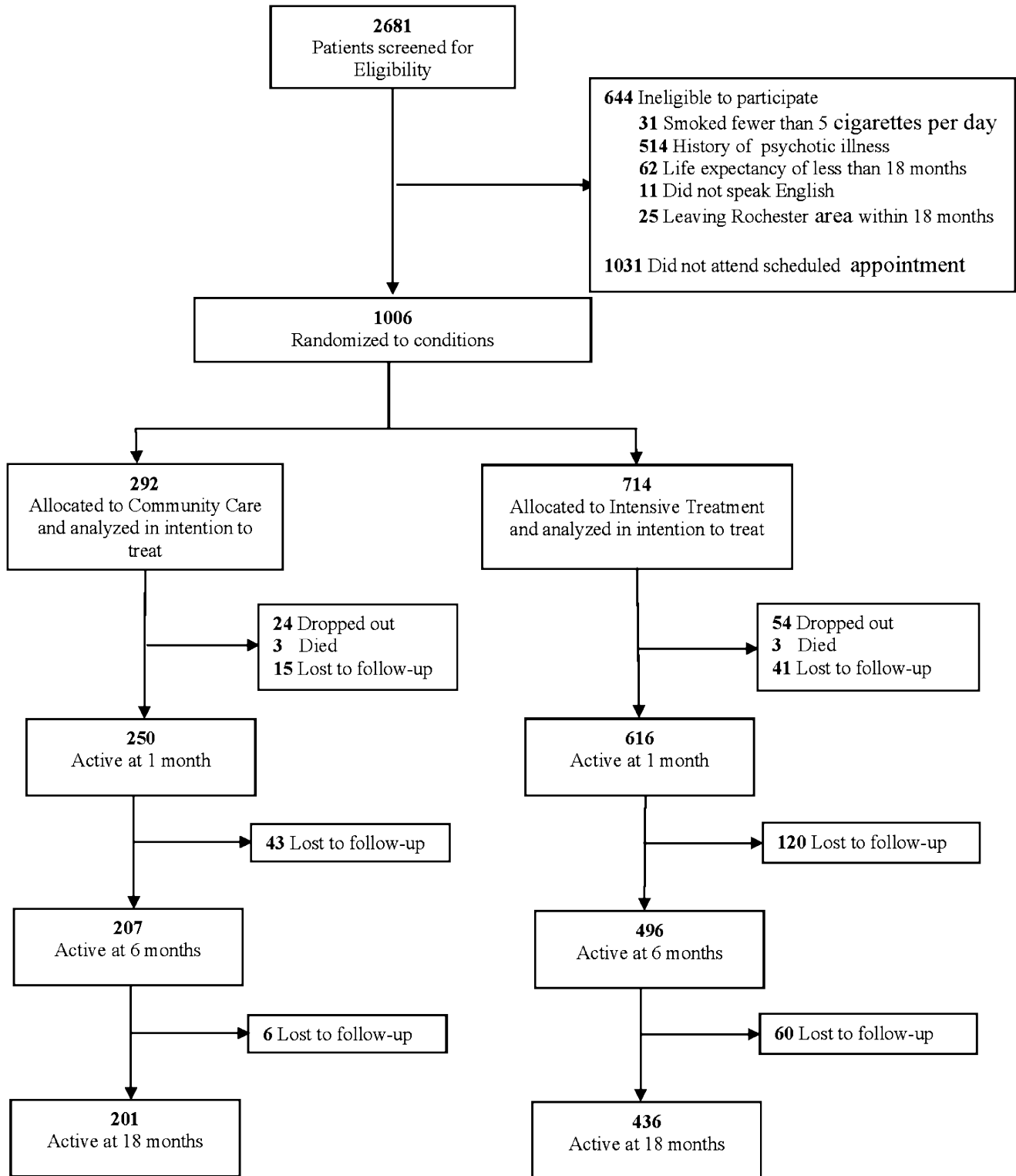*AS, addiction severity; LDL, low-density lipoprotein.*

2681
Patients screened for
Eligibility

644 Ineligible to participate
   31 Smoked fewer than 5 cigarettes per day
   514 History of psychotic illness
   62 Life expectancy of less than 18 months
   11 Did not speak English
   25 Leaving Rochester area within 18 months

1031 Did not attend scheduled appointment

1006
Randomized to conditions

292
Allocated to Community Care
and analyzed in intention to
treat

714
Allocated to Intensive Treatment
and analyzed in intention to treat

24 Dropped out
3 Died
15 Lost to follow-up

54 Dropped out
3 Died
41 Lost to follow-up

250
Active at 1 month

616
Active at 1 month

43 Lost to follow-up

120 Lost to follow-up

207
Active at 6 months

496
Active at 6 months

6 Lost to follow-up

60 Lost to follow-up

201
Active at 18 months

436
Active at 18 months

FIGURE 1. Smokers' Health Study recruitment and retention of participants.

medications (*P*=.001), and greater perceived competence (*P*<.001) from baseline to 6 months (Table 2).

Demographic variables, cigarettes per day, and addiction severity were excluded from the logistic regression model examining factors associated with 12-month prolonged absti-

nence, as none significantly predicted the outcome. Abstinence rates were the same for the smoking intervention alone compared with the smoking and diet intervention, so all smoking intervention patients were analyzed together. In addition to group assignment, 12-month abstinence was significantly pre-

Table 2. Treatment and Motivational Outcomes

Outcome	Community Care (N=292)	Intensive Intervention (N=714)	Odds Ratio	Confidence Interval	P-Value
12-month prolonged abstinence	2.4%	6.2%	2.67	1.19, 6.01	.001
Validated 6-month PP (%) 6-month PP (%)	4.1%	11.8%	3.11	1.67, 5.79	.001
Serious quit attempt by 6 months (%)	39.0%	49.7%	1.54	1.17, 2.04	.002
Used medication (%)	15.8%	30.8%	2.38	1.67, 3.39	.001
Days on medications	7.80	29.90	—	13.74, 30.47	.001
6-month treatment intensity (minutes)	15.87	155.04	—	—	.001
1-month autonomy support	5.66	6.12	—	—	.001
BL to 6M change in* autonomous motivation for cessation	6.12	6.22	—	—	.05
BL to 6M change in* autonomous motivation for medication taking	5.08	5.38	—	—	.001
BL to 6M change in* perceived competence	4.19	4.58	—	—	.001
	N=209	N=174			
18-month LDL-C†	148.9	144.6	—	—	.05
18-month % calories from fat†	33.2	33.3	—	—	.39

*Values are estimated means in the 6-month variables controlling for baseline values.

†Values are for diet intervention versus diet community care, and are means of the 18-month variables controlling for the baseline values.

PP, point prevalence; BL, baseline; LDL, low-density lipoprotein; 6M, 6-month.

dicted by: 1-month autonomy support (odds ratio [OR]=1.69; 95% confidence interval [CI]: 1.15, 2.49), change in autonomous motivation for cessation (OR=1.65; 95% CI: 1.05, 2.58), change in perceived competence (OR=2.89; 95% CI: 2.13, 3.93), and the days of medication use in 6 months (OR=1.01; 95% CI: 1.010, 1.012). Change in autonomous motivation for taking medications from baseline to 1 month predicted 12-month abstinence (OR=1.39; 95% CI: 1.07, 1.82), but change to 6 months did not. Table 3 displays similar outcomes for the logistic regression analysis of the subgroup of 528 patients who did not want to quit smoking at baseline. Thus, each construct in the self-determination model consistently predicted prolonged abstinence.

Diet and Diet-Specific Motivational Outcomes

There was no difference in change in percent calories from fat from baseline to 18 months between the groups (+0.92% vs +0.17%, P=.39). However, reduction in LDL-C from baseline to 18 months was significantly greater in the intervention compared with CC group (–8.9 vs –4.1 mg/dL; P=.05).

There was no effect of the diet intervention on the motivation variables, and thus the intervention and CC groups were combined for further analyses. Linear regression analyses revealed a marginally significant effect of autonomy support on change in percent calories from fat from baseline to 18 months (P=.09), and change in autonomous motivation for diet from baseline to 6 months negatively predicted change in percent calories from fat from baseline to 18 months (β=– 0.18, P<.05). Change in perceived competence for dietary change did not predict change in the percent calories from fat (P=.19). There was no predictive effect of autonomy support (P=.18), change in autonomous motivation (P=.29), or change in perceived competence (P=.13) on 18-month change in LDL-C. Thus, only change in autonomous motivation for diet predicted reduction in percent calories from fat (Table 2).

Treatment Intensity, Motivation, and Outcomes

Treatment intensity (in minutes) was significantly different between conditions at 6 months (155.04 vs 15.87 minutes, P<.01). Linear regression analyses revealed that 6-month treatment intensity significantly predicted 1-month autonomy support (β=0.26, P<.01), as well as baseline to 6-month change in autonomous reasons for taking medications (β=0.15, P<.01), change in autonomous reasons for cessation (β=0.07, P<.01) and perceived competence (β=0.19, P<.01). Six-month treatment intensity also significantly predicted 12-month prolonged tobacco abstinence (OR=1.01;

Table 3. Treatment and Motivational Outcomes for Those Who Did Not Want to Quit (N=528)

	Community Care	Intensive Intervention	Odds Ratio	Confidence Interval	P-Value
12-month prolonged abstinence	0.6%	5.2%	8.74	1.16, 65.82	.012
Validated 6-month PP (%)	3.7%	9.8%	2.81	1.16, 6.81	.02
Serious quit attempt (%)	32.3%	46.9%	1.85	1.25, 2.73	.002
Used medication (%)	9.9%	29.7%	3.83	2.18, 6.72	.001
Days on medications	3.75	27.83	—	13.71, 34.44	.001
1-month autonomy support	5.63	6.11	—	—	.001
BL to 6M change in* autonomous motivation for cessation	5.89	6.01	—	—	.12
BL to 6M change in* autonomous motivation for medication taking	4.73	5.15	—	—	.002
BL to 6M change in* perceived competence	3.73	4.22	—	—	.001

*Values are estimated means for 6-month variables controlling for baseline values.

PP, point prevalence; BL, baseline; LDL, low-density lipoprotein; 6M, 6-month.

95% CI: 1.003, 1.007), but did not predict 18-month reduction in LCL-C from baseline ($P=.42$).

DISCUSSION/CONCLUSIONS

This study demonstrated that an intensive SDT-based intervention for smokers was effective in increasing prolonged abstinence from tobacco and reducing LDL cholesterol for smokers with elevated cholesterol, compared with CC. This intervention is the first to yield a measurable increase in patient perception of autonomy support, patient autonomy for medication use and tobacco abstinence, and perceived competence, thus demonstrating that the intervention facilitated internalization of motivation. These tobacco motivation and outcome effects resulted from increased treatment intensity (minutes of contact). The trial is also important because smokers not ready to quit were motivated to remain abstinent over 12 months.[32,33]

The diet intervention was not effective in reducing dietary intake of percent calories from fat, but change in autonomous motivation did explain change in percent calories of fat. While LDL-C was reduced in the dietary intervention group, the motivation mediators for dietary change were not changed by the intervention. Low-density lipoprotein-cholesterol may have been lowered by an alternate motivation pathway (e.g., for using cholesterol medications), and this deserves further study.

Practitioners are bound by biomedical ethics[34] and principles of professionalism[35] to support patient autonomy by fully informing patients regarding their prognosis and their options for treatment.[36] This self-determination intervention was focused on supporting patients in making an informed choice about whether or not they wanted to stop smoking, and if indicated, to lower their cholesterol, in part by eliciting the intervention patients' broader values and informing them of an important risk (10-year risk of CAD). The results show that intervention patients became more motivated to abstain from tobacco, that almost twice as many people chose to take medications, and that more than twice as many were successful in achieving prolonged abstinence. Thus, it provides a benchmark by which informed decision making can be measured.[36,37]

Primary care practitioners (PCPs) usually do not provide this intensity of treatment due to time constraints. However, PCPs could reasonably provide the 13 minutes of physician counseling that patients received in this intervention along with referral for behavioral counseling as recommended by the USPHS.[10,38] The effect of this intervention was modest, yet an NNT of 26 is clinically important because smokers who abstain for 12 months are not as likely to relapse.[39] Tobacco interventions are clinically important relative to many other primary care interventions,[40,41] because of the substantial health benefit associated with prolonged abstinence.[42]

The limitations of this study are that the absolute effect of the tobacco and cholesterol intervention was modest. The use of a CC comparison group precludes us from determining which of the elements of the intervention beyond treatment intensity accounted for the changes in motivation and health outcomes. Furthermore, the results cannot be generalized to the population of patients with severe mental illness for whom tobacco dependence is devastating.[43]

In summary, an intensive clinical intervention, based on the USPHS Guideline for Treating Tobacco Dependence and SDT, works in part because it facilitates internalization of autonomous and perceived competence for stopping smoking. Autonomous motivation and perceived competence are 2 of the psychological variables that result from the counseling and behavioral therapies found by the Public Health Service meta-analysis to result in higher abstinence rates.[10] The SDT intervention integrated with recommendations from the National Cholesterol Education Program[20] also resulted in a lowering of LDL-C for those smokers with elevated cholesterol. Placing patient needs for autonomy and competence at the center of the therapeutic focus facilitates the natural process of internalization which, in turn, is likely to improve health outcomes.

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