RANDOMIZED TRIAL OF TELEPHONE COUNSELLING IN ASSOCIATION WITH THE *GUIDE YOUR PATIENTS TO A SMOKE-FREE FUTURE* PROGRAM

by

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A thesis
presented to the University of Waterloo
in fulfillment of the
thesis requirement for the degree of
Doctor of Philosophy
in
Health Studies

Waterloo, Ontario, Canada, 1997

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ABSTRACT

"Randomized Trial of Telephone Counselling in Association with the *Guide Your Patients to a Smoke-Free Future* Program"

Objective: To evaluate the incremental benefit of telephone counselling in association with the *Guide Your Patients to a Smoke-Free Future* program.

Design: Clinical trial with stratification (by gender & degree of nicotine dependence) and random assignment to Guide Your Patients (GYP) or Guide Your Patients + Telephone Counselling (GYP+TC) group.

Setting: Smoking Cessation Clinic at the Ottawa Heart Institute.

Participants: Volunteer sample of 396 smokers (≥ 15 cigarettes/day), free of major health problems, interested in quitting smoking within 30 days.

Interventions: Physician advice on three occasions according to the *Guide Your Patients* handbook, self-help materials and 12 weeks of nicotine replacement therapy, with (Guide Your Patients + Telephone Counselling group), or without (Guide Your Patients group) nurse-mediated telephone counselling two, six, and 13 weeks after a target quit date.

Main Outcome Measures: Smoking status (point-prevalent abstinence, continuous abstinence, and time to relapse) at 26-week follow-up; processes of change, self-efficacy, and perceived stress at baseline, four and 12 weeks after target quit date.

Results: There was no difference in the 26-week point prevalent abstinence rate (29.6% vs. 26.9%; P-Value=.54) or continuous abstinence rate (25.6% vs. 25.4%; P-Value=.96) between the Guide Your Patients and Guide Your Patients + Telephone Counselling groups, respectively. Survival analysis showed no difference between the relapse curves for the two groups (median time to relapse = 110 vs. 92 days; P-Value=.10). Survival analysis within subgroups revealed an unexpected reduction in the survival function for low nicotine-dependent males receiving telephone counselling (median time to relapse = 99 vs. 187 days; P-Value=.01).

Repeated measures ANOVA analysis of process of change data revealed significant increases in the use of consciousness raising, self-liberation, counterconditioning, stimulus control, reinforcement management, and helping relationships over time, but no significant interactions between treatment condition and changes in use of processes of change. Successful quitters endorsed significantly less use of self-reevaluation and greater use of counterconditioning and helping relationships.

Repeated measures ANOVA analysis of self-efficacy data revealed significant increases in total confidence and confidence in social, negative affect and habitual situations over time during treatment, but no effect of treatment condition. Successful quitters had significantly higher levels of total confidence and confidence in social, negative affect and habitual situations over time during treatment.

Perceived stress during treatment was unaffected by the treatment group assignment. Successful quitters had significantly lower levels of perceived stress at baseline and four and 12 weeks after the target quit date.

Logistic regression analysis revealed three significant univariate baseline predictors of cessation: level of nicotine dependence; education level; and perceived stress. The odds of being abstinent at 26-week follow-up were increased by having more than a high school education (OR; 95% CI = 2.3; 1.44, 3.68). The odds of being abstinent were reduced by having a Fagerstrom Tolerance Questionnaire Score ≥ 7 (OR; 95% CI = 0.63; 0.40, 0.99) or a Perceived Stress Score ≥ 8 (OR; 95% CI = 0.39; 0.22, 0.69).

Conclusions: Physician assistance, using the *Guide Your Patients* program, and incorporating nicotine replacement therapy, is enough to help many smokers. Quit rates are not improved by additional nurse-mediated telephone counselling. Telephone counselling may be counterproductive in low nicotine-dependent males. Telephone counselling did not incrementally enhance the stage-appropriate use of processes of change or the development of self-efficacy. This study does not rule out the possibility that telephone counselling may benefit smokers in earlier stages of preparedness to quit, smokers receiving less intense intervention or less than optimal assistance from their physician, or smokers who self-select telephone counselling. This study also does not rule out the possibility that a different telephone intervention or altered timing of the calls could have yielded different results.

Keywords: Smoking Cessation, Nicotine Replacement Therapy, Physician's Role, Telephone, Counselling

ACKNOWLEDGMENTS

This research was supported by the National Cancer Institute of Canada with funds from the Canadian Cancer Society (Grant in Aid of Research 006062).

Nicotine replacement therapy was provided by McNeil Consumer Products.

The author thanks Mariana Herskovitz, MD, Arlene Pagtakhan, MD, and Joie Zeglinski, MD who served as study physicians; and Sue Tracey, Vivian Welch, and Karin Boucher for their assistance in data collection during this trial.

The guidance and encouragement of Andrew Pipe, MD and William Dafoe, MD, FRCP (C) are gratefully acknowledged.

Special thanks to Roy Cameron, Ph.D. Janice Husted Ph.D, and Steve Brown, Ph.D. for serving as internal reviewers, and for their advice and support throughout the study.

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1.0 PURPOSE AND OBJECTIVES

1.1 PURPOSE

The purpose of this study was to evaluate the incremental benefit of telephone counselling in association with the *Guide Your Patients to a Smoke-Free Future* program.

1.2 OBJECTIVES

1. To evaluate the incremental benefit of telephone counselling in association with the *Guide Your Patients to a Smoke-Free Future* program.

2. To explore the impact of proactive telephone counselling on:

   a) the use of processes of change during smoking cessation; and

   b) the development of self-efficacy during smoking cessation.

1.3 RESEARCH HYPOTHESES

1. Proactive telephone counselling on three occasions during the process of cessation would increase the quit rate observed at 26-week follow-up;

2. Proactive telephone counselling would:

   a) result in increased usage of stage-appropriate processes of change during smoking cessation; and

   b) enhance the development of self-efficacy during smoking cessation.

2.0 INTRODUCTION

Cigarette smoking is a known cause of cancer, heart disease, stroke and chronic obstructive pulmonary disease (Agency for Health Care Policy and Research Smoking Cessation Guideline Panel, 1996). Smoking cessation remains a critical public health challenge. Grover, Gray, Joseph, Abrahamowicz and Coupal (1994) estimate that smoking cessation would increase life expectancy from 2.6 to 4.4 years among Canadian men and from 2.6 to 3.7 years among Canadian women.

Cessation interventions are some of the most cost-effective of all current health care interventions (Tsevat, 1992). Brief physician counselling about quitting smoking during a single office visit costs $1300 to $1850/ Year of Life Saved (YLS) in men and $2300 to $3900/YLS in women based on randomized trials showing a 2.7% cessation rate at one year (Cummings, Rubin, and Oster, 1989). Nicotine gum for 4 months costs $7750 to $17850/YLS assuming a 6.7% quit rate, no relapse after a 12 month abstinence and a life expectancy increase of 1 to 5 years depending on age and sex (Oster, 1986). A nurse-counselling program targeted at post-MI patients was shown to have a cost-benefit ratio of $250/YLS assuming a 26% quit rate and 1.7 years of life saved (Krumholz, Cohen, Tsevat, Pasternak, and Weinstein, 1993).

Comparing the cost-benefit ratios obtained for smoking cessation interventions to the cost-benefit of other primary prevention strategies is informative. Cost-benefit ratios (updated to 1996 dollars) for pharmacologic lipid treatment in primary prevention range from $43,700 to $1,530,000/YLS depending on medication, age, gender and co-existing risk factors (Kupersmith, et al., 1995). Treatment of hypertension costs $13,100 to $49,200/YLS and is most cost-effective when there are co-existing risks (Kupersmith, et al., 1995).

Physician-based interventions are an important way of offering assistance to smokers. Such techniques can help smokers recognize and cope with problems encountered in quitting and provide social support as part of a treatment program (Agency for Health Care Policy and Research Smoking Cessation Guideline Panel, 1996). The Canadian Council on Smoking and Health (1992) has developed a health professional training program entitled *Guide Your Patients to a Smoke-Free Future* to assist physicians and other health professionals acquire skills in providing cessation assistance to patients, within a regular medical practice setting. More than 7000 Canadian physicians have received training in the delivery of this intervention (Townsend, 1995). While a preliminary evaluation of the impact of this program on physician knowledge and practice

behaviour has been reported (Coambs, Wilson, and Pederson, 1994), there have been no reports of patient cessation rates.

The use of transdermal nicotine replacement therapy (NRT; "the nicotine patch") is an integral part of the *Guide Your Patients* program. The nicotine patch is a highly effective aid to smoking cessation, doubling or tripling quit rates over placebo treatment (Fiore, Smith, Jorenby, and Baker, 1994; Gourlay, 1994; Po, 1993; Silagy, Mant, Fowler, and Lodge, 1994; Tang, Law, and Wald, 1994). Despite the relative efficacy of the patch (quit rates are typically 15-20% at one-year follow-up), there is uncertainty about whether health professionals can do more to enhance quit rates.

The purpose of the current study was to evaluate the incremental benefit of telephone counselling in association with the *Guide Your Patients to a Smoke-Free Future* program. The following subsections will examine in more detail the present state of knowledge with respect to methods of smoking cessation, telephone counselling, the transtheoretical model of smoking cessation and its use in the current study, and factors known to affect outcomes in smoking cessation studies.

2.1 METHODS OF SMOKING CESSATION

In evaluating the incremental benefit of telephone counselling, it is helpful to establish a sense of quit rates typically observed in cessation studies. In this section, evidence about the efficacy of no intervention and intervention components comprising the *Guide Your Patients* program (i.e., self-help methods, person-to-person contact, and nicotine replacement therapy) is reviewed. This evidence was assembled from previously published reviews of smoking cessation programs and interventions (Agency for Health Care Policy and Research Smoking Cessation Guideline Panel, 1996; Fiore, Novotny, and Lynn, 1987; Fiore, Novotny, and Pierce, 1990; Lichtenstein and Glasgow, 1992; Schwartz, 1987; Schwartz, 1992; US Department of Health Education and Welfare, 1990) and is summarized in Table 1.

2.1.1 No Intervention

Viswesvaran and Schmidt (Viswesvaran and Schmidt, 1992) used meta-analysis to assess the results from 633 studies of smoking cessation, involving 71,806 volunteers and subjects recruited through population-based sampling techniques such as random-digit dialing. Cumulation of quit rates from all available control groups indicated that, on average, 6.4% of the smokers involved in

cessation studies could be expected to quit smoking without any intervention. This figure must be subtracted from the raw success rate to obtain a true estimate of the efficacy of each intervention.

2.1.2 Self-Help Methods

About 90% of successful quitters use self-help methods rather than organized smoking cessation programs (Curry, 1993) and smoking cessation interventions delivered by means of self-help materials increase cessation rates relative to no intervention (Agency for Health Care Policy and Research Smoking Cessation Guideline Panel, 1996). The advantages of self-help treatment include: ease of delivery, facility for wide-spread dissemination, smoker preference, and low cost; the disadvantages are low effectiveness, poor adherence to suggested quitting activities, and difficulty in tailoring to the needs of individual smokers (Abrams, Orleans, Niarura, Goldstein, Velicer, and Prochaska, 1993).

For healthy populations, point prevalence quit rates at one-year follow-up after self-help programs are in the 10-15% range, while continuous quitting is in the range of 3-5% (Curry, 1993).

2.1.3 Person-to-Person Contact

There is a strong dose-response relationship between the intensity of person-to-person contact and successful cessation outcome, i.e., as the intensity of person-to-person contact increases, efficacy also increases. Furthermore, smoking cessation interventions utilizing counselling sessions lasting more than 10 minutes markedly increase cessation rates relative to no-contact interventions (Agency for Health Care Policy and Research Smoking Cessation Guideline Panel, 1996).

In general, the greater the number of weeks over which person-to-person counselling or treatment is delivered, the more effective it is (Agency for Health Care Policy and Research Smoking Cessation Guideline Panel, 1996). Ideally, smoking cessation interventions should last as many weeks as feasible. Person-to-person treatment delivered over four to seven sessions appears especially effective in increasing cessation rates. The trend for increasing efficacy with increasing duration of treatment remains even after for controlling for the intensity of person-to-person contact (Agency for Health Care Policy and Research Smoking Cessation Guideline Panel, 1996).

Quit rates at one-year follow-up are in the 10 to 18% range, depending on the intensity and duration of person-to-person contact.

Interventions	No. of Study Arms	Estimated Odds Ratio	Estimated Quit Rate
Treatment Formats			
No intervention (reference group)	23	1.0	7.6
Self-help	8	1.2 (1.0-1.6)	9.3 (7.3-11.4)
Individual counselling	26	2.2 (1.9-2.4)	15.1(13.6-16.5)
Group counselling	15	2.2 (1.6-3.0)	15.3 (11.4-19.2)
Types of Self-Help Intervention			
No self-help (reference group)	8	1.0	7.9
Hotline/Helpline	3	1.4 (1.1-1.8)	11.1 (8.7-13.4)
Video- or audiotapes	5	1.3 (0.6-2.9)	10.9 (3.6-18.2)
List of community programs	2	1.1 (0.8-2.5)	8.8 (6.9-10.8)
Pamphlets/booklets/manuals	22	1.0 (0.8-1.2)	8.1 (6.7-9.5)
Intensity of Person-to-Person Intervention			
No contact (reference group)	49	1.0	8.8
Minimal contact (< 3 min)	14	1.2 (1.0-1.5)	10.7 (8.9-12.5)
Brief counselling (3 to 10 min)	26	1.4 (1.2-1.7)	12.1 (10.0-14.3)
Counselling (> 10 min)	60	2.4 (2.1-2.7)	18.7 (16.8-20.6)
Person-to-Person Treatment: Duration of Sessions			
< 2 w (reference group)	101	1.0	10.4
2 to < 4 w	14	1.6 (1.3-2.0)	15.6 (12.9-18.3)
4 to 8 w	12	1.6 (1.2-2.1)	16.1 (12.4-19.7)
> 8 w	15	2.7 (2.2-3.2)	23.8 (20.6-27.1)
Person-to-Person Treatment: Number of Sessions			
1 session (reference group)	96	1.0	10.4
2-3 sessions	15	2.0 (1.6-2.4)	18.8 (15.8-21.9)
4-7 sessions	25	2.5 (2.2-2.9)	22.6 (19.9-25.3)
> 7 sessions	12	1.7 (1.2-2.5)	16.7 (11.4-22.0)
Type of Clinician			
No provider (reference group)	38	1.0	8.2
Multiple providers	14	3.8 (2.6-5.6)	25.5 (18.1-32.7)
Non-medical health care provider	23	1.8 (1.5-2.2)	14.1 (12.0-16.3)
Physician provider	36	1.5 (1.2-1.9)	12.0 (9.6-14.3)
Non-physician medical health care provider	20	1.4 (1.1-1.8)	11.5 (9.0-14.0)
Smoking Cessation Pharmacotherapy			
Control (reference group)	66	1.0	11.5
Nicotine gum	50	1.5 (1.4-1.6)	17.7 (16.9-18.2)
Nicotine patch	16	2.3 (2.1-2.6)	26.0 (24.1-29.9)

* Minimum 6-month follow-up, with biochemical confirmation.

Table 1: Estimates of the Efficacy of Various Interventions to Help People Stop Smoking (adapted from Agency for Health Care Policy and Research Smoking Cessation Guideline Panel, 1996).

2.1.4 Type of Provider

Smoking cessation interventions delivered by a variety of clinicians and health care personnel can increase cessation rates (Agency for Health Care Policy and Research Smoking Cessation Guideline Panel, 1996). Provider type or number (i.e., single vs. multiple providers) does not appear to affect outcome.

In the current study, family physicians were used to provide individual counselling to study participants, and registered nurses provided telephone counselling to participants assigned to the experimental group.

Interventions employing physician providers and/or non-physician medical health care providers typically produce quit rates in the 10 to 15% range, at one-year follow-up.

2.1.5 Nicotine Replacement Therapy

Five separate meta-analyses have concluded that the nicotine patch is a highly effective aid to smoking cessation, doubling or tripling quit rates over placebo treatment (Fiore, et al., 1994; Gourlay, 1994; Po, 1993; Silagy, et al., 1994; Tang, et al., 1994). Despite the relative efficacy of the patch, absolute cessation rates remain modest, typically 15-20% at one-year follow-up (Agency for Health Care Policy and Research Smoking Cessation Guideline Panel, 1996).

One possible reason for the modest long-term abstinence rates produced by the patch is that studies have not yet identified which adjuvant treatments, when combined with the nicotine patch, produce the highest long-term quit rates. Reported trials have used a variety of adjuvant treatments, including minimal contact, brief individual counselling, and weekly group smoking cessation therapy.

A meta-analysis by Fiore, Smith, Jorenby and Baker (1994) indicated that more intense adjuvant treatments produced higher absolute rates of smoking cessation. However, the most robust evaluation of different types of adjuvant treatment requires that participants be assigned randomly to different treatments within the same study. Only two studies involving the nicotine patch have been specifically designed to test their combined effect with other behavioural treatments (Cinciripini, Cinciripini, Wallfisch, Haque, and Van Vunakis, 1996; Jorenby, Smith, Fiore, Hurt, Offord, Croghan, et al., 1995).

Jorenby, Smith, Fiore, Hurt, Offord, Croghan, Taylor-Hays, Lewis and Baker (1995) combined the nicotine patch with one of three different levels of adjuvant therapy intensity: minimal counselling consisting of a single self-help cessation pamphlet; four brief (< 15 min.) individual counselling sessions; and nine counselling sessions, eight of which involved hour-long group smoking cessation counselling. They found that, despite dramatic differences in the length and intensity of counselling, there were no differences in abstinence at 26-week follow-up as a function of counselling intensity. Point-prevalent abstinence rates of 26%, 34%, and 26% were observed at six-month follow-up in participants assigned to minimal counselling, individual counselling and group counselling, respectively.

Cinciripini, Cinciripini, Wallfisch, Haque and Van Vunakis (1996) compared the outcome of a smoking cessation program using intensive group behaviour therapy (BT) alone or intensive group behaviour therapy plus the nicotine patch (BTP) in 64 volunteer participants. Abstinence was significantly higher for the BTP group versus the BT group from the end of behavioural treatment (79% vs. 63%) through the three-month follow-up ($p<.01$), with the effects weakening at the six- ($p=.06$) and 12-month marks ($p=.10$).

Cessation rates from the studies by Jorenby et al (1995) and Cinciripini et al (1996) along with studies by Tonnesen, Norregaard, and Simonsen (1991) and Sachs, Sawe, and Leischew (1993) which utilized the same nicotine patch as in the current study are summarized for comparison in Table 2.

Authors	Intervention	Observed Cessation Rate
Tonnesen, et al., 1991	Patch + Minimal Contact	17%
Sachs, et al., 1993	Patch + Self-Help + Individual Counselling	25%
Jorenby, et al., 1995	Patch + Minimal Contact	26%
	Patch + Individual Counselling	34%
	Patch + Group Counselling	26%
Cinciripini, et al., 1996	Behaviour Therapy Alone	22%
	Patch + Behaviour Therapy	38%

*Cessation Rate at one-year follow-up, except for Jorenby et al where cessation rate is at six-month follow-up.

Table 2: Comparison of Cessation Rates in Studies of the Nicotine Patch With Participants Randomly Assigned to Various Adjuvant Treatments and in Two Studies Which Utilized the Same Nicotine Patch as the Current Study.

2.2 TELEPHONE COUNSELLING

The major focus of the current study was to evaluate the incremental benefit of telephone counselling in association with the *Guide Your Patients to a Smoke-Free Future* program. For smokers, the primary advantages of telephone counselling are accessibility and convenience. Since telephone counselling can be received in the privacy of one's own home, it is accessible to people who would be unlikely to attend counselling in-person. Smokers living in remote areas without specialized support can also be reached by telephone counselling. Telephone counselling eliminates travel time and costs associated with in-person visits and allows greater flexibility in the scheduling of professional assistance.

This section will review general principles of telephone counselling, its use in previous smoking cessation interventions, and gaps in the knowledge about telephone counselling to be addressed in this study.

2.2.1 General Principles of Telephone Counselling

The telephone counselling scripts used in this study (see Appendix I) were adopted with permission from scripts previously used by Orleans, Shoenbach and Wagner (1991). The scripts were designed to incorporate a number of principles and allow the telephone counsellors to:

1. *Provide positive, non-judgmental feedback and encouragement appropriate to the quitter's particular stage of change.* In this study, the relevant stages were the preparation and action stages of change.

2. *Address personal quitting barriers.* Many people are concerned about how they will deal with urges to smoke, stress and tension, and weight gain during the process of smoking cessation (Glynn, Boyd, and Gruman, 1990). Information and support were provided to help people address these barriers.

3. *Elicit statements of intentions to comply with stage-appropriate quitting processes.* This included intentions to review self-help materials, make a quit attempt on the established quit date, try out alternatives to smoking, manage triggers and cues in the environment, solicit social support, and reward oneself for progress. If relapse did occur, attempts were made by the counsellors to get people to establish a new quit date and to try again.

4. *Enhance self-efficacy and retrain attributions for progress in quitting.* Personal experience and successes are potent sources of self-efficacy expectations (Bandura, 1991). Counsellors were instructed to praise the attainment of sub-goals of the larger goal of smoking cessation, and provide examples of how other people had regained control after setbacks. The counsellors also attempted to attribute success to internal factors and failures or setbacks to external factors. Marlatt and colleagues have suggested that internal attributions for abstinence failures promote guilt and other negative emotions, and that external, unstable, specific and controllable attributions are optimal for relapse prevention (Curry, Marlatt, and Gordon. 1987; Marlatt, 1985).

5. *Remind people about useful coping activities.* Even when people know what actions can help them to gain control over their smoking and feel themselves capable of taking these actions, they still may require reminders about useful coping activities.

6. *Effectively increase the length of time that patients are in contact with a program.* Kottke, Battista and DeFriese (1988) found that the number of months that a subject was in contact with a smoking cessation program was the strongest predictor of 12-month abstinence.

2.2.2 Previous Studies of Telephone Counselling in Smoking Cessation

Outreach telephone counselling has been used previously in attempts to increase the success rate associated with smoking cessation interventions. Orleans at al (1991) and Ossip-Klein, Giovino, Megahed, Black, Emont, Stiggins, Shulman and Moore (1991) found that telephone counselling improved the success rate associated with the use of self-help materials in motivated volunteers. On the other hand, Lando, Hellerstedt, Pirie and McGovern (1992) reported only a short-term benefit to telephone counselling, with the long-term outlook no better than for self-help materials alone, in a sample of smokers identified through random digit dialing who were interested in treatment. In the Lando study, smokers were randomly assigned to an intervention consisting of two 15-minute telephone calls approximately one to three weeks apart or to a nonintervention control. At the six-month follow-up, a significant overall effect was found in favor of the intervention condition for both self-reported and cotinine-validated quitting. Differences between intervention and control conditions were no longer significant at 18 months.

Curry, McBride, Grothaus, Louie and Wagner (1995) examined the incremental effect of (a) a self-help booklet alone, (b) self-help booklet with computer-generated personalized feedback, and (c) self-help booklet, personalized feedback and outreach telephone counselling in a population-based sample of smokers recruited through random digit dialing. Telephone counselling increased smoking cessation at three-month follow-up (11% in telephone group vs. 6% overall; p=.02) but not at 12- or 21-month follow-up in the overall group. Improvements in the 12-month quit rate occurred only among smokers who were precontemplative at baseline (16% in telephone group vs. 7% overall; p=<.01). Comparative quit rates (telephone group vs. overall) for smokers in other stages were: 3% vs. 9% (p=.22) for contemplators, and 23% vs. 16% (p=.35) for preparers.

Zhu, Stretch, Balbanais, Rosbrook, Sadler and Pierce (1996) examined the effects of two levels of telephone counselling (1 call or 6 calls) with self-help materials and compared them with the effects of self-help alone in 3030 smokers who had called a helpline during an anti-smoking campaign. Both levels of telephone counselling achieved significantly higher levels of continuous abstinence for 12 months (5.4% for self-help, 7.5% for single counselling, and 9.9% for multiple counselling).

A few studies have used telephone counselling to provide follow-up to cessation programs initiated during hospitalization.

Taylor et al (1990) randomly assigned 173 patients who had been smoking in the six months prior to their hospitalization for myocardial infarction. A major component of the intervention was nurse-mediated telephone counselling once per week for the first two to three weeks and then monthly for the next four months. In addition, physicians provided standardized counselling for less than two minutes and nurses counselled patients on how to manage high risk situations (i.e., those in which they reported less than 70% confidence). Patients also received a relapse prevention manual and a relaxation audiotape. Patients who relapsed were offered one additional visit with the nurse for further counselling. Nicotine gum or patches were provided to highly addicted patients who relapsed after hospital discharge, The experimental intervention had a confirmed quit rate at one-year follow-up of 61% compared to 32% in the usual care group. Smoking-related disease such as coronary artery disease have a powerful effect on the cessation process.

These same procedures were used again in the MULTI-FIT trial of DeBusk et al (1994). One year after infarction, a quit rate of 71% was observed in the special intervention group as compared to 53% for usual care.

Ockene et al (1992) evaluated an intervention similar to that used by the Taylor group with patients following coronary angiography. Intervention began in the hospital and continued with four telephone calls after hospitalization. Marginally significant results were observed between the experimental intervention and advice only at six-month follow-up (45% vs. 34% validated), but not at 12-month follow-up (35% vs. 28% validated). Secondary analysis of this data using logistic regression analysis showed that the experimental intervention was most effective with patients with severe coronary artery disease.

Lichtenstein, Glasgow, Lando, Ossip-Klein and Boles (1996) published a meta-analytic review of the evidence for telephone counselling for smoking cessation. They examined 13 randomized trials of proactive phone counselling and found that most showed significant short-term (three to six month) effects, and four found long-term differences between intervention and control conditions. A meta-analysis using a best-evidence synthesis showed pooled odds ratios of 1.34 (1.19 - 1.51) and 1.20 (1.06 - 1.37) in favour of telephone counselling compared with control conditions at short and long-term follow-up, respectively. They concluded that phone counselling is most effective when used as the sole intervention modality or when augmenting programs initiated in hospital settings.

Estimates of the cessation rate and incremental benefit from studies showing a long-term benefit of telephone counselling are shown in Table 3.

Author and Intervention	Type of Subjects	Cessation Rate (%)	Incremental Benefit (%)
Orleans, et al., 1991	2021 Volunteers from an HMO		
Telephone Counsel & Social Support Instruction vs. Untreated Control Group		23.0 vs. 16.0**	7.0
Telephone Counsel & Social Support Instruction vs. Self-Help Guide Alone		23.0 vs. 14.7**	8.3
Telephone Counsel & Social Support Instruction vs. Self Help Guide and Social Support Instruction		23.0 vs. 14.2**	8.8
Curry, et al., 1995	1137 Subjects, Population-Based Sample		
Telephone Counsel & Self- Help Guide vs. Untreated Control Group	*Precontemp.*	16.0 vs. 7.0**	9.0
	Contemplators	3.0 vs. 9.0	- 6.0
	Preparers	23.0 vs. 16.0	7.0
Zhu, et al., 1996	3030 Volunteers from callers to a smoker's help-line		
Multiple (6) Telephone Counselling Sessions & Self-Help Kit vs. Single Telephone Counsel Session & Self-Help Kit		9.9 vs. 7.5**	2.4
Multiple (6) Telephone Counselling Sessions & Self-Help Kit vs. Self-Help Kit Alone		9.9 vs. 5.4**	4.5
Single Telephone Counsel Session & Self-Help Kit vs. Self-Help Kit Alone		7.5 vs. 5.4	2.1

* minimum 12-month follow-up, with biochemical confirmation; ** $p < .05$.

Table 3: Estimates of the Incremental Benefit in Randomized Trials Showing a Long-Term Benefit of Telephone Counselling.

2.2.3 Gaps in Knowledge Addressed in the Present Study

There are some apparent advantages to telephone counselling and a number of theoretical principles that can be used in the design of telephone-based interventions. There is currently insufficient evidence to judge the incremental benefit of telephone counselling in combination with a powerful intervention like the *Guide Your Patients* program, incorporating physician advice and NRT. Previous studies of telephone counselling have combined it with only self-help materials, personalized feedback, and/or social support instruction.

The effect of telephone counselling on potentially important mediating variables such as the use of processes of change and the development of self-efficacy has not been reported. If telephone counselling could remind people to use behavioural processes of change, convince relapsers to try again, and/or increase self-efficacy during treatment, then it might be an efficacious and efficient way to boost quit rates. The methods evaluated in the current study are intended to work by changing the psychological processes that mediate behaviour change. In this case, knowledge of the impact of the interventions with respect to the use of various processes of change can help to clarify how different effects are being achieved.

Predictors of successful quitting and relapse can also be determined from the prospective design used in this study, providing valuable information about the types of smokers most and least likely to benefit from these interventions.

2.3 TRANSTHEORETICAL MODEL OF SMOKING CESSATION

Prochaska and his colleagues have proposed a transtheoretical model of behaviour change to explain the process of smoking cessation (DiClemente, Prochaska, and Gibertini, 1985; DiClemente and Prochaska, 1985; Prochaska and DiClemente, 1983; Prochaska and DiClemente, 1992; Prochaska, DiClemente, and Norcross, 1992; Prochaska, Velicer, DiClemente, Guadagnoli, and Rossi, 1991; Prochaska, Velicer, Rossi, Goldstein, Marcus, Rakowski, et al., 1994). In this model, stages of change, decisional balance, processes of change and self-efficacy are intertwined and interacting variables in the modification of smoking behaviour. A brief review of each of these variables is provided in the accompanying subsections.

2.3.1 Stages of Change

Quitting smoking has been characterized as a process involving five distinct stages: precontemplation (not thinking about quitting); contemplation (seriously thinking about quitting in the next six months); preparation (planning to quit in the next 30 days, with the additional characteristic that a person has made a 24-hour quit attempt in the past year); action (having quit smoking within the past six months); and maintenance (having quit for more than six months). Each stage represents a specific constellation of attitudes, intentions, and behaviours that are relevant to an individual's status in the process of change (Prochaska and DiClemente, 1992). A number of studies have shown that people in the later stages of change have significantly greater levels of abstinence at one-year follow-up with or without treatment (Prochaska and DiClemente, 1992; Prochaska, et al., 1992; Prochaska, et al., 1994; Rohren, Croghan, Hurt, Offord, Marusic, and McClain, 1994).

2.3.2 Decisional Balance

A decision to change smoking behaviour is partially based on a person's appraisal of the pros and cons of smoking (Prochaska, DiClemente, Velicer, Ginpil, and Norcross, 1985). The relative weighting of the pros and cons are particularly relevant for people in the stages of precontemplation, contemplation and preparation. In precontemplation, pros for smoking are high and cons for smoking are low. This balance shifts as people move from precontemplation to the later stages. Contemplators appear to struggle with their positive evaluations of their smoking habit and the amount of effort, energy, and loss it will cost to quit. As people move through the preparation stage, the cons begin to outweigh the pros. As people move into the action phase, the cons clearly outweigh the pros of continued smoking.

2.3.3 Processes of Change

Movements between the stages of change are mediated by processes of change. Prochaska and DiClemente (1992) describe processes of change as "covert and overt activities and experiences that individuals engage in when they attempt to modify problem behaviours." The processes underlie a large number of coping activities. Processes of change allow an understanding of how movements between various stages of change occur.

A total of 10 processes of change have been identified in smokers attempting to quit. A brief description of each of these processes is provided in Table 4. These processes are: consciousness raising; social liberation; self reevaluation; environmental reevaluation; dramatic relief; self-liberation; counterconditioning; stimulus control; reinforcement management; and, helping relationships. The first five processes generally involve an experiential restructuring component and are labeled as experiential (cognitive) processes. The second five factors involve more specific and observable behaviours and have been labeled as behavioural processes. Most processes reflect both and the label merely describes the most dominant theme (Prochaska, Velicer, DiClemente, and Fava, 1988).

The processes of change appear to be potent predictors of change for both therapy changers and self-changers (Ahijevych and Wewers, 1992; Prochaska and DiClemente, 1983; Prochaska, et al., 1992; Prochaska, et al., 1988). Ahijevych and Wewers (1992) conducted a cross-sectional study of the ways 190 randomly selected smokers and ex-smokers had modified their smoking behaviour. They found significant differences in the use of processes of change by smokers and ex-smokers in various stages of smoking cessation in the natural environment. Recent quitters' very high use of self-liberation was theorized to be a key to their cessation success. The processes that long-term quitters reported using most frequently were environmental reevaluation and counterconditioning, with low use of other processes. According to DiClemente and Prochaska (1985), cognitive/experiential processes are more salient in the early stages and behavioural processes become increasingly more important during the action and maintenance stages. Prochaska and DiClemente (1983) found that self-liberation, counterconditioning, stimulus control, reinforcement management, and helping relationships were emphasized during the action stage.

It has been suggested that the timing of the use of the various processes of change may be more critical to success in quitting than the total volume of activity. In the current study, it was

hypothesized that telephone counselling should have its effect by inducing participants to make increased use of the processes most appropriate to the action stage (i.e., behavioural processes).

Process of Change	Description
1. Consciousness Raising	Recalling information about quitting smoking.
2. Social Liberation	Awareness of social and policy changes about non-smoking behaviour.
3. Self-Reevaluation	Perception of self in relation to one's personal smoking habit.
4. Environmental Reevaluation	Assessment of the harmfulness of smoking on the environment.
5. Dramatic Relief	Emotional responses such as fear, anger, sadness to warnings about the hazards of smoking.
6. Self-Liberation	Making an active choice not to smoke.
7. Helping Relationships	Willingness of someone with whom to discuss smoking concerns.
8. Counterconditioning	Substitution of other thoughts or acts for smoking behaviour.
9. Stimulus Control	Alteration of surroundings to reduce the presence of smoking reminders.
10. Reinforcement Management	Rewards from self or others for non-smoking behaviour.

Table 4: Description of 10 Processes of Change (adapted from Prochaska, et al., 1992)

2.3.4 Self-Efficacy

Self-efficacy is a central construct to cognitive-behavioural approaches to human behaviour, including the transtheoretical model. Perceived self-efficacy is defined as people's beliefs in their capabilities to motivate themselves and to mobilize the cognitive resources and actions needed to meet situational demands (Bandura, 1991). Self-efficacy beliefs affect what people choose to do, how much effort they will expend in a given endeavour, how long they will persevere in the face of difficulties and setbacks, whether their thought patterns are encouraging or hindering to their

actions, and the amount of stress they experience in coping with environmental demands (Bandura, 1991).

The relationship of self-efficacy and stages of change in smoking cessation has been evaluated previously (DiClemente, 1986; DiClemente, et al., 1985; Prochaska and DiClemente, 1992). Self-efficacy increases during successful treatment and therapy of different types enhances self-efficacy expectations (Candiotte and Lichtenstein, 1981; Coelho, 1984). As individuals move toward and into the action stage, efficacy tends to increase rather dramatically. At the end of treatment, subjects who have been able to stop smoking have significantly greater self-efficacy expectations than those who have not. Post-treatment self-efficacy evaluations are significant predictors of maintenance of smoking cessation, at least in the short-term of three to six months after treatment (Coelho, 1984; McIntyre, Lichtenstein, and Mermelstein, 1983).

2.3.5 Critical Commentary on the Transtheoretical Model

Some authors have offered critical commentary on the transtheoretical model. The model has been criticized by Bandura (1995) as causing "fractionation of predictors" and "theoretical disconnectedness"..."The behavioristic, psychodynamic and existential theories on which the transtheoretical model is based lead to contradictory prescriptions on how to change human behaviour."

Categories in the stage of change scheme have been described by Bandura (1995) as arbitrary "pseudo-stages" rather than genuine stages, i.e., in a true stage model, the characteristics of one stage should be transformed into qualitatively different characteristics at the next stage. In the transtheoretical model, the action and maintenance stages are arbitrary subdivisions based on whether people have quit smoking for less or more than six months.

Another criticism of the transtheoretical model is that most of the stages are defined in terms of the very behaviour to be explained. This creates circularity of explanation and prediction. The stages mainly describe behaviours rather than specify determinants. The stage of change scheme converts the standard change processes to descriptive categories stripped of their underlying knowledge base. Bandura (1995) describes this change as regressive.

Fisher, Lichtenstein and Haire-Joshu (1993) caution that stage theories often ignore the extrinsic influences on human behaviour, concentrating instead on an intrinsic sequence of events which appears to play itself out independent of the events surrounding it. Like Bandura, they also

emphasize the risk of circular explanations, as characteristics of a certain stage are described as being caused by that stage.

2.3.6 Use of the Transtheoretical Model in the Present Study

In the current study, the transtheoretical model was used to: design the recruitment advertising (see Appendix A); structure information presented in the self-help materials; define the type of assistance provided during the telephone counsellor calls (Appendix I); and identify intermediate treatment outcomes that could demonstrate how telephone counselling affects participants during treatment.

Participants in this study were in either the contemplation or preparation stage at study entry. Contemplators are smokers who are seriously considering quitting in the next six months. Preparers are those individuals who are also planning to quit in the next 30 days, with the additional characteristic that they have made a 24-hour quit attempt in the past year. The intervention portion of this study involved participants moving to the action stage and involved the overt modification of their smoking behaviour. The self-help materials, physician contacts, and telephone counselling were designed to provide participants with the skills to use key behavioural processes of change such as counterconditioning, stimulus control, contingency management and helping relationships.

A priori, it was hypothesized that proactive telephone counselling would: (a) result in increased usage of stage-appropriate processes of change (i.e., the use of behavioral processes of change during the action stage); and (b) enhance the development of self-efficacy during treatment. If these intermediate outcomes were positively influenced by the telephone counselling intervention, it was hypothesized that this would result in an increase in the quit rate observed at 26-week follow-up.

2.4 FACTORS AFFECTING OUTCOMES IN SMOKING CESSATION

There are a number of patient-related factors that have been shown to predict cessation outcomes in previous studies of smoking cessation. Efforts were made to control for these potentially confounding factors in the design of the study and in the analysis of data.

2.4.1 Level of Nicotine Dependence

Smokers who are more physically dependent on cigarettes have greater difficulty in successfully quitting than less addicted smokers (Killen and Fortmann, 1994). The strength of a smoker's nicotine addiction may be reflected by the smoker's daily consumption level and their Fagerstrom Tolerance Questionnaire (FTQ) score.

The FTQ is a widely-used eight-item paper-and-pencil test of nicotine dependence. The FTQ correlates with other measures of nicotine dependence, including carbon monoxide, blood nicotine and cotinine levels (Fagerstrom, 1980; Fagerstrom, 1991; Fagerstrom and Schneider, 1989). The FTQ has a scoring range of 0-11 points, with a score of 0 assumed indicative of minimum nicotine dependence and a score of 11 indicative of maximum nicotine dependence. The mean score is usually within the range of 5-7 points, with a standard deviation of about 2.

Smoking habit factors associated with a better prognosis for cessation include: a lower smoking rate and nicotine intake (e.g., fewer than 25 cigarettes/day) (Killen and Fortmann, 1994); lower nicotine dependence (e.g., FTQ score < 7, first cigarette at least 30 minutes after waking, few past difficulties with withdrawal after quitting) (Fagerstrom, 1980; Fagerstrom, 1991; Fagerstrom and Schneider, 1989); shorter smoking history; past success quitting for 6 months or longer; and less dependence on smoking to regulate negative affect (Carmody, 1992).

In the current study, the FTQ was used to determine baseline level of nicotine dependence. Participants were stratified into high and low nicotine-dependent groups using this factor prior to randomization (see Figure 1). The FTQ is embedded within the Participant Intake Questionnaire (Appendix D, Section E; see page 95).

2.4.2 Gender

There are gender differences in tobacco consumption and cessation (Millar, 1988). Males are more likely than females to attempt to quit smoking over a fixed observation period (US Department of Health Education and Welfare, 1990). Women are more likely than men to seek assistance in the quitting process (US Department of Health Education and Welfare, 1990). Female smokers seem to have more difficulty maintaining abstinence after cessation (Blake, Klepp, and Pechacek, 1989). While men and women do not differ significantly in the types of reasons that they give for quitting (US Department of Health Education and Welfare, 1990), women may react more adversely to unwanted changes accompanying quitting, especially temporary moodiness and weight gain, because they find such changes to be greater social liabilities (Blake, et al., 1989).

In the current study, gender was controlled for by stratifying patients using this factor prior to randomization (see Figure 1).

2.4.3 Processes of Change

Efficient behaviour change depends on doing the right things (processes) at the right time (stages). The use of various processes of change have been identified as potent predictors of smoking behaviour change (Prochaska, et al., 1985; Wilcox, Prochaska, Velicer, and DiClemente, 1985). A cross-sectional analysis of smokers in different stages of change demonstrated that the use of various processes of change was clearly related to stage status (Prochaska and DiClemente, 1992). Successful quitters demonstrate a pattern of how change processes can be used most effectively over time. Cross-sectional evidence suggests that those in the contemplation and preparation stages tend to use cognitive processes such as self-reevaluation and consciousness raising, whereas those in the action and maintenance stages use behavioural processes such as stimulus control and counterconditioning (Prochaska and DiClemente, 1992).

Processes of change were measured at baseline so that they could be used as covariates during the analysis of data.

2.4.4 Self-Efficacy

People do not attempt to change their smoking behaviour unless they believe they have "what it takes" to successfully quit. Post-treatment self-efficacy scores have predicted successful completion of treatment programs, post-treatment relapse, and subjects' smoking rates after

treatment. In her review of self-efficacy and relapse in smoking cessation. O'Leary (1985) reported that self-efficacy was a better predictor of outcome than health locus of control, confidence in treatment rationale, or expectations about the positive effects of smoking cessation. Self-efficacy is a better predictor of treatment outcome than the degree of nicotine dependence (Killen, Maccoby, and Taylor, 1984; McIntyre, et al., 1983).

Self-efficacy was measured at baseline so that it could be used as a covariate during the analysis of data.

2.4.5 Perceived Stress

The anxiolytic effects of nicotine suggest that stress reduction is a factor that supports regular smoking (Leventhal and Cleary, 1980; Pomerleau and Pomerleau, 1987). Stress is variously defined as an appraisal (perception), an aversive event, a set of biologic responses, or a set of behavioural or affective responses. Perceived stress represents a person's appraisal of whether the demands in their lives exceed their capacity to cope (Cohen and Williamson, 1988).

Persons who quit smoking and subsequently relapse often report that their relapse was triggered by a stressful experience or negative affect state (Baer and Lichtenstein, 1988; Cummings, Jaen, and Giovino, 1985; Shiffman, 1982). Smokers often view smoking as an effective means of coping with the emotions elicited by stressful events and are presumed to have strong urges to return to such a well-established response when confronted with stressors (Ockene, Nuttall, Benfari, Hurwitz, and Ockene, 1981; Wills and Shiffman, 1985).

Cohen and Lichtenstein (1990) examined the dynamic relations between perceived stress and smoking status using a four-item version of the Perceived Stress Scale (Cohen, Kamarck, and Mermelstein, 1983). They found a strong relation between perceived stress and smoking. Those who failed to quit smoking for more than 24-hours during the trial period maintained a relatively high and consistent level of stress over the entire six-month trial period. For those who remained continuously abstinent over the course of the study, stress decreased as duration of abstinence increased.

Perceived stress was measured at baseline so that it could be used as a covariate during the analysis of data.

3.0 METHODS

3.1 SETTING

This study was conducted at the Smoking Cessation Clinic at the University of Ottawa Heart Institute at the Ottawa Civic Hospital. The Heart Institute serves primarily the National Capital Area and is also a referral centre for Eastern and Northern Ontario. Approximately 1.5 million people live within one hour of the Heart Institute.

3.2 SUBJECTS

Volunteers were recruited by radio advertisements in the Ottawa area. A transcript of this advertisement is provided in Appendix A. Smokers aged 18 years or more were eligible if they had smoked at least 15 cigarettes per day during the past year, were interested in quitting smoking completely within 30 days , were willing to attend a pre-screening session, and were willing to provide informed consent. Women of child-bearing age had to be using a reliable method of birth control to be eligible.

Exclusion criteria were: myocardial infarction within the past six months; Class III or greater angina (NYHA); Class III or greater congestive heart failure (NYHA); variant angina: active and untreated arrhythmias; Buerger's Disease; pregnancy or lactation; alcoholism or a history of other drug abuse; coexisting psychiatric illness; chronic dermatological disorders; diabetes requiring insulin; and kidney or liver disease. Exclusion factors were determined during pre-screening procedures over the phone and during a pre-screening evaluation by a study physician. Operational definitions for each of the exclusion factors are shown in Appendix B.

A total of 453 people responded to the radio advertisements and were scheduled to attend a pre-screening session. (Details of the pre-screening session are provided in Section 3.3.2). Of those scheduled to attend the prescreening session, 408 (90%) attended. Of those attending the pre-screening session, 12 (2.9%) were ineligible because of abnormal tests of liver and kidney function, alcoholism or a history of other drug abuse. Three hundred and ninety-six eligible participants were enrolled.

Recruitment to the study was completed in two waves. The first wave of recruitment was in September 1995 and the second wave of recruitment was in January 1996. Due to the logistics of providing treatment, each recruitment wave was divided into two treatment cohorts. The time lag

between recruitment and the initiation of treatment varied from two weeks to six weeks. Participants were not paid for their participation, but received a 12-week supply of the nicotine patch (approximate value = $400) at no cost during the treatment period.

3.3 DESIGN AND PROCEDURES

3.3.1 Study Design

This study employed a parallel, two-group design with stratification by level of nicotine dependence and random assignment to either a Guide Your Patients (GYP) or a Guide Your Patients + Telephone Counselling (GYP+TC) treatment group (see Figure 1). Measures included smoking status variables, processes of change, self-efficacy, and compliance with the treatment protocol. Demographic and medical history data were collected for screening and descriptive purposes. The dependent variable of primary interest was the quit rate at 26-week follow-up. Dependent variables of secondary interest included processes of change, self-efficacy and compliance. The independent variable was the treatment group: GYP or GYP+TC.

All procedures were in accordance with the ethical standards of the Research Ethics Committees of the Ottawa Civic Hospital and the University of Waterloo, and with the Helsinki Declaration of 1975, as revised in 1983. Table 5 provides an overview of the flow of recruitment, pre-screening, medical screening, stratification, assignment, treatment and follow-up procedures.

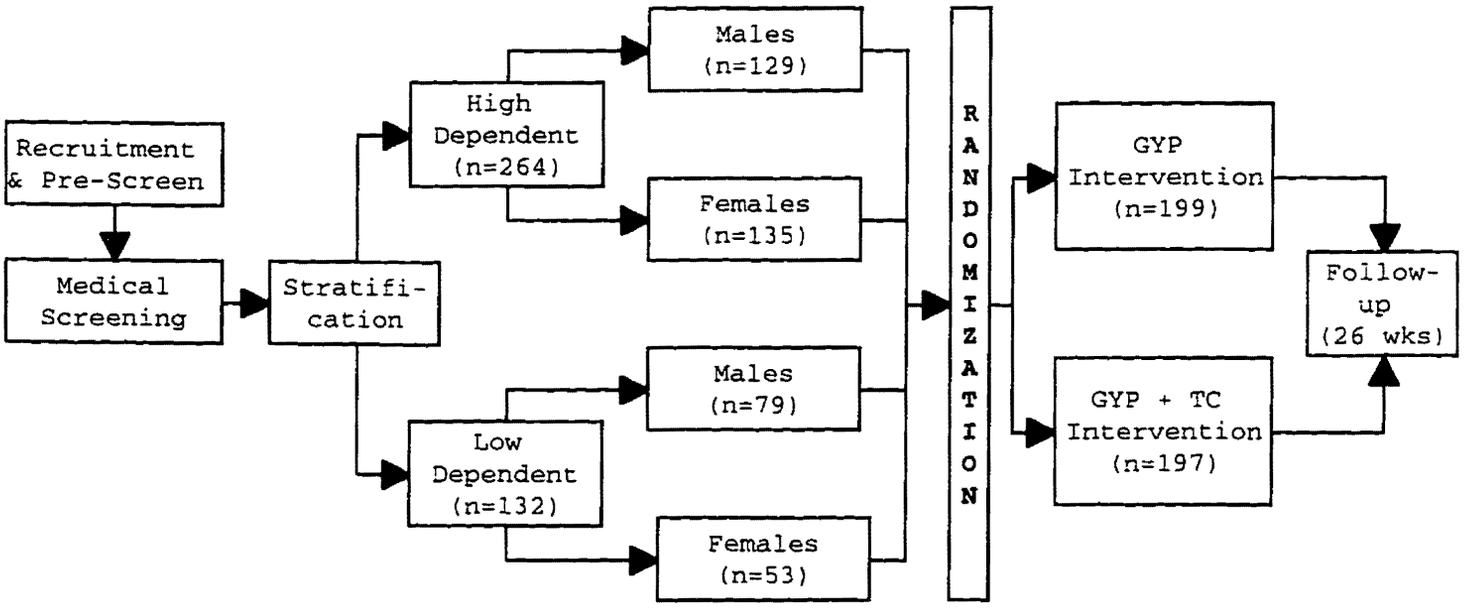

Figure 1: Overview of experimental design.

Contact Point	1	2	3	4	5	6	7	8	9	10
Weeks Baseline (Time 0 = target quit date)	-4	-3	-2	-1	4	6	12	18	38	52
Pre-screening interview by telephone	X									
Sign informed consent		X								
Complete questionnaires										
- Smoking status		X			X		X		X	X
- Stage of change		X			X		X		X	X
- Decisional balance		X								
- Processes of change		X			X		X			
- Self-efficacy		X			X		X			
- Temptations		X			X		X			
- Perceived stress		X			X		X			
- Medical and smoking history		X								
Laboratory tests										
- hematology/biochemistry		X								
- anthropometric measures		X			X		X			
Medical Examination										
- Inclusion/exclusion criteria			X							
- Medical history			X							
- Blood pressure, pulse			X		X		X			
- Systems review			X							
Physician Counselling										
- Review previous attempts			X							
- Establish Target Quit Date			X							
- Review use of nicotine patch			X		X		X			
- Review progress					X		X			
- Review relapse prevention strategies					X		X			
Self-Help Materials										
- Provide booklet and video tape			X							
Nicotine Replacement Therapy										
- Dispensing			X		X					
- Patch count					X		X			
Carbon Monoxide Monitoring			X		X		X		X	X
Telephone Counselling										
- (for participants in GYP+TC group only)				X		X		X		

Table 5: Overview of Timeline of Screening, Data Collection, Intervention and Follow-up Procedures.

3.3.2 Pre-Screening and Assessment

During the pre-screening session, the nature of the experiment was explained, and eligibility criteria were outlined by the investigator. All potential participants received advice on the importance of smoking cessation and provided informed consent (Appendix C) prior to any data being collected. Participants completed a detailed medical and smoking history (Appendix D), and had blood drawn by a study nurse for routine chemistry tests. Participants were then scheduled for a subsequent visit, during which one of the three study physicians completed a standardized medical exam, and reviewed all medical history and laboratory data collected during the pre-screening session (Appendix E).

3.3.3 Allocation to Treatment

Two factors, gender and degree of nicotine dependence, were identified as potentially important confounders in this study. Based on information collected during the pre-screening session, participants were placed into one of four strata based on gender and level of nicotine dependence (low nicotine-dependent women, low nicotine-dependent men, high nicotine-dependent women, and low nicotine-dependent men). High dependent smokers were defined as those with FTQ scores ≥ 7 (Fagerstrom and Schneider, 1989). Random assignment to one of two treatment groups, GYP or GYP+TC, was then performed within strata. For the purposes of randomization, a table of random numbers, in blocks of four, was generated by the Coordinator of Nursing Research, independent of the study administration. The treatment assignments were opened by a study coordinator after the pre-screening and medical assessment.

Participants were assigned randomly to physicians, and physicians were blinded with respect to the treatment allocation of subjects under their care. Participants were reminded at each visit by the study coordinator to not discuss their treatment group allocation with their study physician. However, there were no attempts made to determine whether the blinding of physicians was maintained. An analysis of outcomes, stratified by physician, was conducted to ensure that there were no differences in outcomes as a function of the physician.

3.3.4 Treatments

3.3.4.1 Guide Your Patients (GYP) Group

The GYP group received NRT and smoking cessation guidance from one of the study physicians in a manner consistent with the recommendations of the *Guide Your Patients to a Smoke-Free Future* program over a series of three treatment visits. The first treatment visit occurred immediately following the physician examination and allocation to treatment, approximately two weeks prior to the attempted quit. The second treatment visit occurred four weeks after a quit date negotiated by the participant and the physician. The third and final treatment visit occurred 12 weeks after the quit date. The same physician completed all three visits with each participant.

The three study physicians participated in a four-hour training session regarding the *Guide Your Patients* program. During this training session, study physicians reviewed the process of Ask, Advise, Assist and participated in role-playing exercises simulating typical interactions between participants and physicians. This training session was conducted by the Investigator with the assistance of Dr. Andrew Pipe. During the trial, all interactions between the physician and the subject were structured through the use of an checklist (Appendix F, G), suggesting the flow of questions and appropriate responses during each of the three treatment visits. During a pilot study conducted prior to start of the current study, the Investigator had an opportunity to directly observe and provide feedback on the performance of study physicians in their interactions with participants.

The purpose of the initial treatment visit with the physician was to reinforce the decision to quit, to assist the participant to set a target quit date, and to explain the proper use of transdermal NRT. During the trial, participants received NRT for a total of 12 weeks: eight weeks at 15 mg/16 hours, two weeks at 10 mg/16 hours, and two weeks at 5 mg/16 hours. NRT was provided free to participants, courtesy of McNeil Consumer Products. Participants were instructed to apply a new patch each morning to a clean, non-hairy area of intact skin, which has not been used as a patch application site within the last week, and to remove the patch prior to retiring at night. The physician explicitly reminded the participant to stop smoking and apply the NRT first thing on target quit date morning.

At the initial treatment visit, the physician also provided the participant with the "*Stop Smoking Now!*" video tape and self-help booklet developed by the University of Ottawa Heart Institute (Reid, 1994). The physician instructed the participant to use the self-help materials before the target quit date to develop an individual action plan and to review coping strategies in preparation for the quit day. The self-help materials incorporated the stages and processes of change outlined by Prochaska and DiClemente (1992) into a step-by-step guide to quitting. Materials were

available in both French and English. The workbook and the video emphasized the processes of self-evaluation, self-liberation, reinforcement management, counterconditioning and stimulus control. These processes of change have been identified as particularly important during the preparation and action stages of smoking cessation (Ahijevych and Wewers, 1992; DiClemente and Prochaska, 1985; Kristeller, Rossi, Ockene, Goldberg, and Prochaska, 1992; Prochaska, et al., 1992).

During the second and third treatment visits, four and 12 weeks after the target quit date respectively, the physician provided follow-up advice to the participant in accordance with the *Guide Your Patients* program. Each physician visit lasted approximately 15 minutes. During each treatment visit, prior to the participant meeting with the physician, a research nurse had the participant complete any necessary questionnaires (Appendix H), monitored patch compliance, measured vital signs, including weight, and determined the exhaled carbon monoxide level to verify smoking status. The research nurse was blinded with respect to the treatment allocation of the study participant.

3.3.4.2 Guide Your Patients + Telephone Counselling (GYP+TC) Group

The GYP+TC Group received NRT, self-help materials, and physician advice in a manner identical to that provided to the GYP Group. In addition, the GYP+TC Group had their treatment augmented by the addition of telephone counselling two, six, and 13 weeks after the target quit date. One of two trained nurse-counsellors initiated telephone calls, which followed a scripted intervention. The telephone scripts (see Appendix I) were adapted with permission from scripts used previously by Orleans et al (1991). To ensure that treatment and data collection were kept separate, telephone counsellors did not confer with the study coordinator on the progress of participants in the study. Following each call, the telephone counsellor mailed a personalized letter along with additional fact sheets that had been developed to address concerns expressed by the user during the call. Five fact sheets were available for distribution: Managing Withdrawal Reactions, Urges and Cravings; Dealing with Weight Gain/Increased Appetite; Stress and Negative Emotions; Developing Social Support; and Handling Relapse.

Prior to the study, the telephone counsellors received three days of training on the telephone counselling procedures from the investigator. They also had an opportunity to practice using these procedures during a pilot study involving 119 participants that used methods identical to those used in the current study (Reid, Pipe, Tracey, and Welch, 1996). During each telephone call, the telephone counsellors completed a telephone contact sheet that summarized the participant's

responses and remarks during the telephone conversation. The telephone counsellors also recorded the start and finish time of the telephone call.

3.3.5 Follow-up Data Collection

All GYP and GYP+TC participants were surveyed by questionnaire 26 weeks after their target quit date. Questionnaires (Appendix J) were initially mailed to participants. If they did not return the questionnaire within 14 days, they were sent a second copy by courier. If the second copy was not returned within 14 days they were called by the study coordinator and asked to complete the questionnaire by telephone.

Participants who were unreachable within a four-week window (24-28 weeks after target quit date) or who declined to be surveyed were considered to be smoking. An attempt was made to collect a breath sample for carbon monoxide determination from all participants who reported not smoking at the 26-week follow-up. Participants were offered a variety of convenient times and locations for providing a sample. If there were scheduling problems, the study coordinator offered to collect the sample at the participant's home or workplace.

3.4 MEASURES

3.4.1 Smoking Status

Smoking status was determined 26 weeks after the target quit date. For the primary analysis, point prevalent abstinence (PPA) was used. PPA was defined as patient self-report of no smoking (not even a puff) in the preceding seven days (Ossip-Klein, Bigelow, Parker, Hall, and Kirkland, 1986). An expired carbon monoxide level of ≤ 9 ppm was considered as confirmatory for nonsmoking (Velicer, Prochaska, Rossi, and Snow, 1992).

Continuous abstinence (CA) from the target quit date was also assessed. CA, while difficult to establish objectively, inspires confidence in the durability of the quit attempt. CA was defined as no smoking, not even a puff, from the target quit date (Ossip-Klein, et al., 1986).

Participants were asked to keep a diary to record any cigarette use after the target quit date. Time to relapse, or survival time, was determined from this information. For the purpose of the survival analysis, time to relapse was defined as seven consecutive days smoking at least one cigarette each day (Ossip-Klein, et al., 1986).

The smoking status questions are shown in the Participant Follow-up Questionnaire in Appendix J.

3.4.2 Processes of Change

Processes of change were measured using a 20-item questionnaire (Prochaska, et al., 1988), which included two items for each of the 10 processes of change answered on a Likert scale of frequency of use from never (1) to frequently (5). A score for each of the 10 processes of change was calculated as the unweighted sum of responses for its two items. The possible range of scores for any given process of change was 2 to 10. A higher score indicated increased use of a particular process of change.

The validity of this scale for distinguishing successful and unsuccessful subjects for each of the stages of change has been demonstrated cross-sectionally (Prochaska and DiClemente, 1983) and longitudinally (Prochaska, et al., 1985). Processes of change were measured at the baseline screening as well as during clinic visits at four and 12 weeks after the target quit date.

The processes of change (Impacts on Smoking) questions are shown in the Participant Follow-up Questionnaire in Appendix J.

3.4.3 Self-Efficacy

Self-efficacy was measured using a 20-item questionnaire (Velicer, Prochaska, Bellis, DiClemente, Rossi, Fava, et al., 1993), to measure confidence in not smoking across a wide variety of daily situations. Each question was answered on a Likert scale of confidence in not smoking from not at all confident (1) to extremely confident (5). The range of possible scores for total confidence was from 18 to 90, with higher scores indicating increased confidence in not smoking.

This questionnaire has been tested by DiClemente and his co-investigators and is reliable and has been replicated using different samples, problems and response formats (DiClemente, 1986; DiClemente, et al., 1985). The confidence scale also incorporates three subscales: confidence in social situations (possible range 6 to 30); confidence in affective situations (possible range 6 to 30); and confidence in habitual situations (possible range 6 to 30). Self-efficacy was measured at the baseline screening as well as during clinic visits at four and 12 weeks after the target quit date.

The self-efficacy (Confidence in Not Smoking) questions are shown in the Participant Follow-up Questionnaire in Appendix J.

3.4.4 Perceived Stress

Perceived stress was measured using the four-item version of the Perceived Stress Scale (PSS-4) designed by Cohen, et al.(1983). The PSS is designed to determine the degree to which respondents find their lives unpredictable, uncontrollable, and overloading. For each item, respondents indicate on a scale ranging from never (0) to very often (5) how often they have felt that way during the past month. High scores on the PSS-4 have been associated with elevated life events, psychological distress, physical symptomatology and use of health services (Cohen and Williamson, 1988).

The perceived stress questions are shown in the Participant Follow-up Questionnaire in Appendix J.

3.4.5 Participation in the Intervention

Participation was tracked throughout the study. For physician counselling, the study coordinator recorded attendance by participants at each of the counselling visits. The study physicians also completed a physician contact sheet during each counselling visit.

To assess use of the nicotine patch, participants were asked to record in their daily diary the time of day they applied and removed the patch, and the site of application. At each treatment visit, the participant was supplied with sufficient patches to cover the interval until the next visit. All unused patches were collected by the study coordinator during the study visits.

To determine the participation rate in the telephone counselling portion of the intervention, telephone counsellors completed a detailed call record during and after each telephone call.

3.5 ANALYTIC METHODS

Data were analysed using SPSS software. All eligible participants, regardless of their compliance with the protocol, were included in the analysis. Baseline subject characteristics in the two groups (GYP vs. GYP+TC) were compared using two-tailed independent-group *'t '* tests for continuous variables and Pearson chi-square tests for categorical variables.

The primary analysis compared the two treatments for their effect on PPA rates observed at 26-week follow-up using chi-square analysis. Initially, differences in abstinence were evaluated using all participants in the study. A stratified analysis of abstinence rates between the treatments was then completed using gender and degree of nicotine dependence as stratification variables. All analyses were repeated using CA as the dependent variable.

Survival analysis was used to compare the time to relapse between the two treatment groups. For the purposes of this analysis, Time 0 was assumed to be the Target Quit Date and relapse to smoking was defined as having smoked at least one cigarette on seven consecutive days (Ossip-Klein, et al., 1986). The Log-Rank (Mantel-Cox) Test was used to compare the survival curves (Matthews and Farewell, 1988). If a participant was observed for the full 26 weeks of follow-up and relapse to smoking did not occur during this time, then these individuals were considered to have a censored survival time. Participants who were lost to follow-up were considered to have relapsed to smoking at the mid-point between their last verified visit and the follow-up point. A stratified (by gender and degree of nicotine dependence) analysis of survival time was also completed.

The data collected with respect to processes of change, self-efficacy and perceived stress were analysed using ANOVA with repeated measures. In the analysis, the within factor was the process of change, self-efficacy or perceived stress score measured at different time points, i.e. baseline, four and 12 weeks. The between factor was the treatment condition. For the ANOVA, missing values were replaced using linear interpolation. The last valid value before the missing value and the first valid value after the missing value were used for interpolation.

4.0 RESULTS

4.1 SUBJECT CHARACTERISTICS

Baseline characteristics of subjects are shown in Table 6. Smoking history variables (cigarettes/day, number of years smoking, FTQ score) indicate that participants in this study were relatively heavy smokers with extensive smoking careers. The majority of participants were in the high nicotine-dependent category (i.e., FTQ ≥ 7). Just under 19% of participants were in the contemplation stage of change. The remaining 81% were in the preparation stage. There were no differences between the groups at study entry for: age, percentage of male participants, number of cigarettes per day, number of years smoking, FTQ score, percentage of smokers with FTQ score ≥ 7, number of quit attempts lasting more than 24 hours in the year prior to the study, perceived stress, decisional balance, or percentage of participants in the preparation stage of quitting.

	GYP Group n = 199		GYP+TC Group n = 197		
Baseline Variable	Mean	SD	Mean	SD	P-Value
Age at Study Entry (yrs.)	37.5	7.9	38.4	8.2	.24
Percent Male	52.3		52.8		.92
Number of Cigarettes/Day	22.8	6.9	24.2	8.5	.07
Number of Years Smoking	21.3	8.1	21.9	8.2	.51
FTQ Score	7.1	1.7	7.2	1.9	.65
Percent FTQ ≥ 7	65.2		69.0		.44
Quit Attempts ≥ 24 hr in past year	1.4	2.0	1.6	2.0	.35
Perceived Stress	5.0	2.7	5.1	2.7	.70
Decisional Balance (Pros-Cons)	- 0.8	3.6	- 1.0	3.8	.60
Percent in preparation stage	82.4		80.2		.57

Table 6: Baseline Characteristics of Study Participants.

4.2 PARTICIPANT FLOW AND FOLLOW-UP

Figure 2 provides a summary of progress through the various stages of the trial. A total of 396 participants were allocated to the intervention groups: 199 to the GYP group and 197 to the GYP+TC group.

Participation rates for various components of the two interventions are shown in Table 7. In the GYP group, 171 subjects participated in ≥ 80% of the prescribed intervention. In the GYP+TC group, 163 participants participated in ≥ 80% of the prescribed intervention. There was no differential rate of participation between the two groups.

Follow-up data at 26 weeks were available for 337 (85.1%) of the 396 smokers originally assigned to treatment. Two hundred and thirteen participants (54%) returned their questionnaires by mail and 124 participants (31%) had data collected by telephone. Carbon monoxide samples were collected from 83 (81%) of the 112 participants who reported not smoking at the follow-up point. There was no difference in the proportion of participants providing carbon monoxide samples between the two treatment groups (82% in the GYP group vs. 80% in the GYP+TC group; $p = .73$). Of the carbon monoxide samples collected, only one reading exceeded 9 ppm. The participant with the elevated carbon monoxide level, a male assigned to the GYP group, worked in a garage where cars were regularly run indoors, and had a carbon monoxide level of 16 ppm. For the purposes of analysis, only the self-reported smoking status was used, i.e., abstinence rates were not corrected for carbon monoxide validation.

Of the 59 (14.9%) withdrawals from the trial, six people dropped out during treatment, four changed address and could not be located through directory assistance, and 49 were unable to be contacted during the follow-up period. When there was no initial answer, up to five attempts were made to call back, at various times of days and days of the week. There was no differential withdrawal rate between the GYP and GYP + TC groups (15.2% vs. 14.6%, respectively; $p=.88$). Withdrawals were treated as smokers in the analysis.

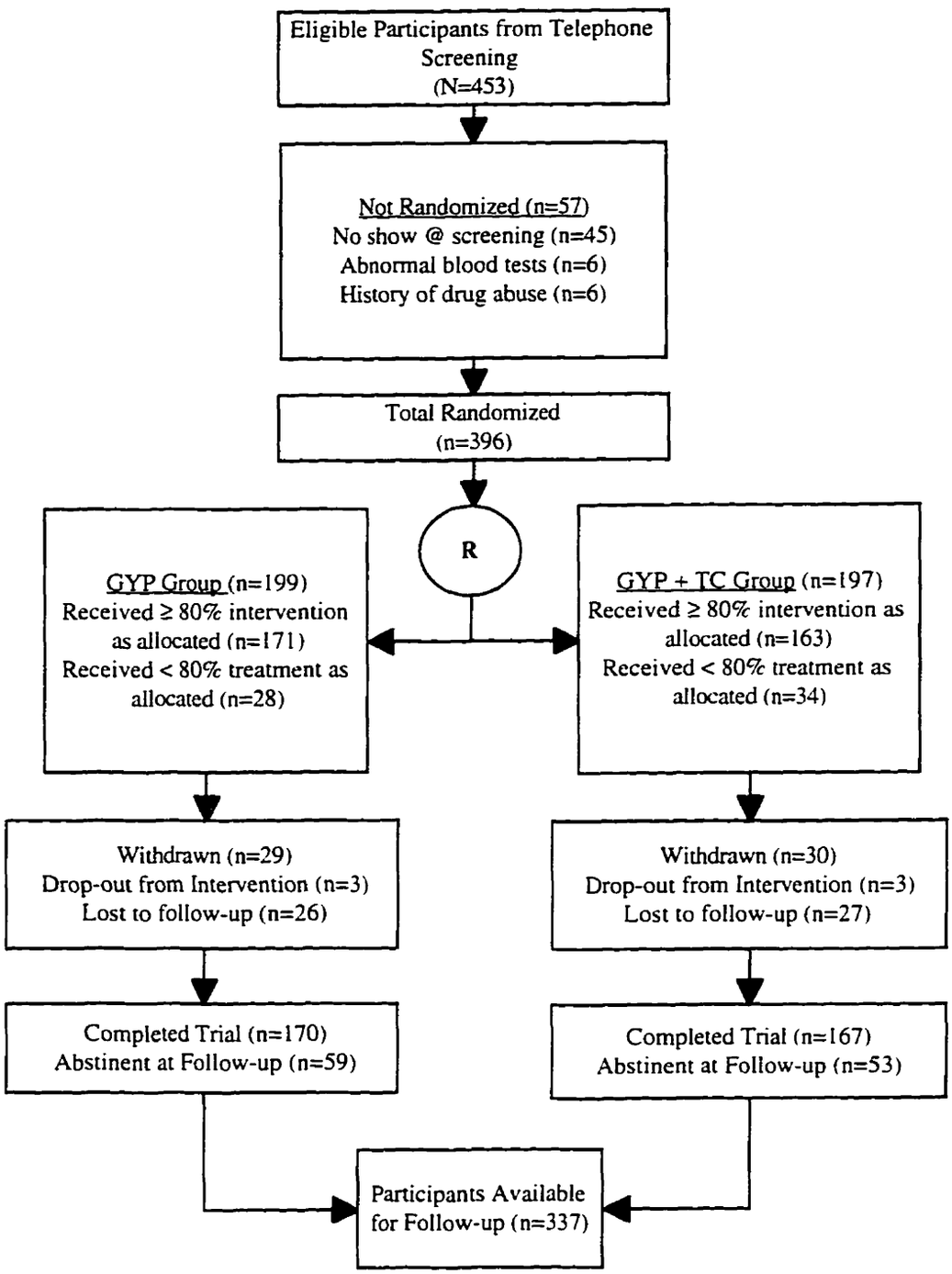

Figure 2: Participant Flow and Follow-up

4.3 PARTICIPATION IN THE INTERVENTION

Participation rates were tracked throughout the study (Table 7) and ranged from a high of 100% for pre-screening and assessment procedures as well as the first physician counselling visit, to a low of 78% for use of the nicotine patch. Patch use was dependent on smoking status. Participants were provided with a total of 84 patches and, on average, returned 18.8 (+/- 15.7) unused patches at the 12-week visit. Participants who were abstinent at this point returned fewer unused patches than those who were smoking (4.3 vs. 22.5 patches, p=<.01). There were no differential rates of participation between the treatment groups for any of the common intervention components.

The main independent variable in this study was the telephone counselling provided on three occasions to participants assigned to the GYP+TC group. The completion rate and length of each call was obtained from records completed by the telephone counsellors. The completion rates for calls number one (two weeks), number two (six weeks), and number three (13 weeks) were 96.4%, 87.7%, and 78.5%, respectively. The average call length was 19.5 +/- 6.2 minutes for call number one, 12.0 +/- 4.9 minutes for call number two, and 9.5 +/- 3.6 minutes for call number three. (Average call length was calculated using only completed call data). Some variability in the length of the telephone calls was expected since the content of the calls varied and counsellors altered their advice depending on the participant's particular stage (i.e., preparation, action, relapse). Differences were noted in the length of both call one and call two between the two counsellors (14.4 vs 21.8 minutes, p<.01; and 12.8 vs. 10.5 minutes, p=.02, respectively). There was no difference between counsellors for call three.

Intervention Component (Timing)	Participation Rate (%)
Pre-screening and assessment (- 4 wks)	100
Physician Counselling	
Visit #1: (- 2 wks)	100
Visit #2: (+ 4 wks)	91
Visit #3: (+ 12 wks)	86
Telephone Counselling	
Call #1: (+ 2 wks)	96
Call #2: (+ 6 wks)	88
Call #3: (+ 13 wks)	79
Patch Use (0 - 12 wks)	78

Table 7: Completion Rates for Components of the Smoking Cessation Intervention.

4.4 EFFICACY OF TELEPHONE COUNSELLING

The primary objective of this study was to compare abstinence from smoking at 26-week follow-up in the GYP and the GYP+TC groups. Abstinence was defined in a number of ways, including: point-prevalent abstinence, continuous abstinence, and time to relapse.

4.4.1 Point-Prevalent Abstinence

PPA rates at 26-week follow-up for the total sample and when stratified by level of nicotine dependence and gender are shown in Table 8. The overall PPA rate at 26-weeks was 28.3%. There was no difference in the PPA rate between the GYP and the GYP+TC groups (29.6% vs 26.9%; p=.54). When the analysis was stratified by level of nicotine dependence and gender, there were no differences in PPA between the treatment groups in any of the analysis stratum.

There was no difference in PPA for participants in the contemplation stage vs. preparation stage at baseline (23.0% vs. 29.5%; p =.26).

	GYP Group (n=199)	GYP + TC Group (n=197)	Total	
Analysis Stratum	Number (%; 95% CI) Abstinent	Number (%; 95% CI) Abstinent	Number (%; 95% CI) Abstinent	P-Value
All Participants (N = 396)	59 (29.6; 23.3, 35.9)	53 (26.9; 20.7, 33.1)	112 (28.3; 23.9, 32.7)	.54
Dependence X Gender				
Low Dependent Males (n = 79)	18 (43.9; 28.7, 59.1)	12 (31.6; 16.9, 46.3)	30 (38.0; 27.3, 48.7)	.26
High Dependent Males (n = 129)	18 (28.6; 17.5, 39.7)	18 (27.3; 16.6, 38.0)	36 (27.9; 20.2, 35.6)	.87
Low Dependent Females (n = 53)	9 (29.0; 13.1, 44.9)	6 (27.3; 8.7, 45.9)	15 (28.3; 16.2, 40.4)	.89
High Dependent Females (n = 135)	17 (21.9; 12.3, 31.5)	14 (23.9; 13.5, 34.3)	31 (23.0; 15.9, 30.1)	.78

Table 8: Number and Percent Point-Prevalent Abstinent (with 95% CI) in the GYP and GYP+TC Groups at 26-Week Follow-up.

4.4.2 Continuous Abstinence

CA rates at 26-week follow-up for the total sample and when stratified by level of nicotine dependence and gender are shown in Table 9. The overall CA rate at 26-weeks was 25.5%. There was no difference in the CA rate between the GYP and the GYP+TC groups (25.6% vs 25.4%; p=.96). When the analysis was stratified by level of nicotine dependence and gender, there were no significant differences in CA between the treatment groups in any of the analysis strata.

	GYP Group (n=199)	GYP + TC Group (n=197)	Total	
Analysis Stratum	Number (%; 95% CI) Abstinent	Number (%; 95% CI) Abstinent	Number (%; 95% CI) Abstinent	P-Value
All Participants (N = 396)	51 (25.6; 19.5, 31.7)	50 (25.4; 19.3, 31.5)	101 (25.5; 21.2, 29.8)	.96
Dependence X Gender				
Low Dependent Males (n = 79)	14 (34.1; 19.6, 48.6)	11 (28.9; 14.5, 43.3)	25 (31.6; 21.3, 41.9)	.62
High Dependent Males (n = 129)	15 (23.8; 13.3, 34.3)	17 (25.8; 15.3, 36.3)	32 (24.8; 17.3, 32.3)	.80
Low Dependent Females (n = 53)	9 (29.0; 13.0, 45.0)	5 (22.7; 5.2, 40.2)	14 (26.4; 14.5, 38.3)	.61
High Dependent Females (n = 135)	13 (20.3; 10.4, 30.1)	17 (23.9; 13.9, 33.9)	30 (22.2; 15.2, 29.2)	.61

Table 9: Number and Percent Continuously Abstinent (with 95% CI) in the GYP and GYP+TC Groups at 26-Week Follow-up.

4.4.3 Time to Relapse

Relapse curves were compared between the two groups using the generalized log rank statistic (see Table 10). The survival curves, when all 396 participants were considered, are shown in Figure 3. There was no difference in the median time to relapse between the GYP and the GYP+TC groups (110 vs. 92 days; p=.10).

	GYP Group (n=199)	GYP + TC Group (n=197)	
Analysis Stratum	Median Time to Relapse in Days (95% CI)	Median Time to Relapse in Days (95% CI)	P-Value
All Participants (N = 396)	110 (91, 129)	92 (77, 107)	.10
Nicotine Dependence X Gender			
Low Dependent Males (n = 79)	187 (156, 234)	99 (54, 144)	.01
High Dependent Males (n = 129)	86 (60, 112)	86 (56, 116)	.80
Low Dependent Females (n = 53)	126 (112, 140)	121 (62, 180)	.96
High Dependent Females (n = 135)	89 (66, 112)	74 (56, 92)	.80

Table 10: Stratified Analysis of Median Time to Relapse and Results of Significance Testing for Equality of Survival Curves. (P-Value refers to the significance of Mantel-Cox test comparing the GYP and GYP+TC groups.

Time to relapse was also evaluated with the sample stratified by gender and level of nicotine dependence.

Figure 4 and Table 10, show that telephone counselling resulted in a statistically significant reduction in time to relapse for men assigned to the GYP+TC group compared to those assigned to the GYP group (median time to relapse = 99 vs. 187 days; p=.01).

Figures 5, 6 and 7, and Table 10, show that telephone counselling did not alter time to relapse in high nicotine-dependent males, low nicotine-dependent females, or high nicotine-dependent females.

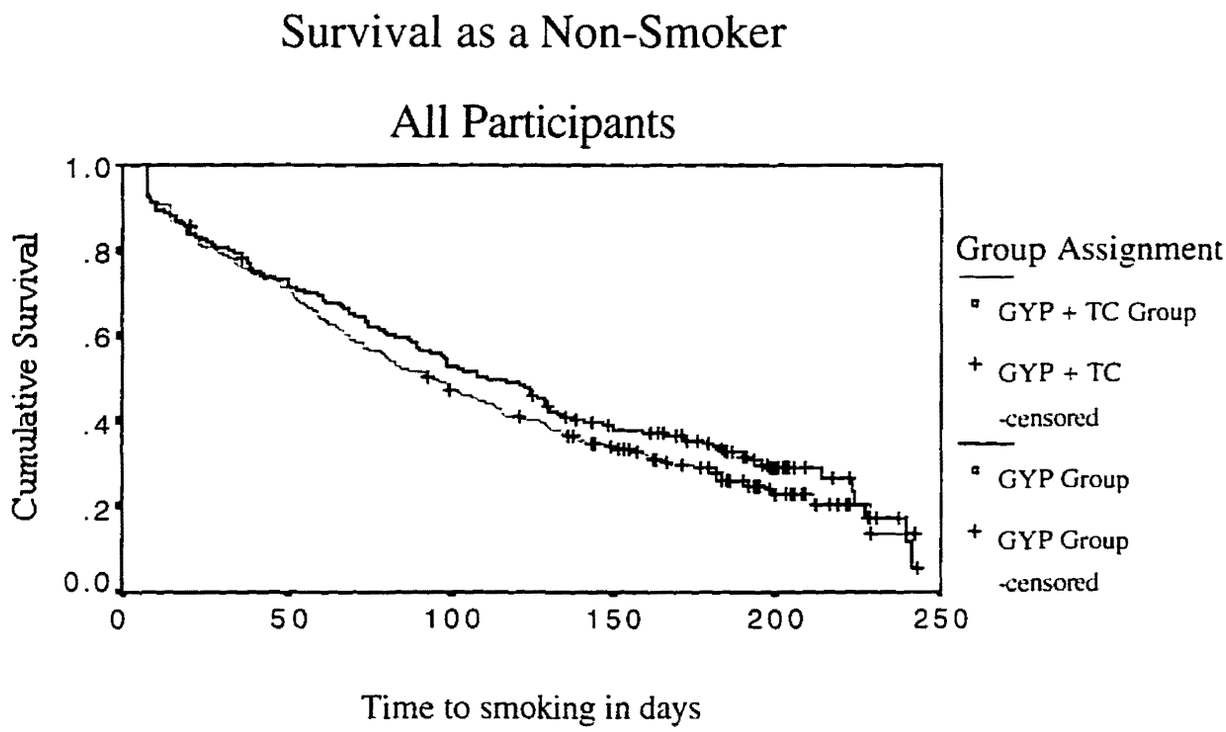

Figure 3: Time to Relapse in the GYP vs. GYP+TC Groups. (P=.10 by the log rank test. Time 0 corresponds to the target quit date. Longer follow-up times are reported for participants taken into the study at an earlier point in time).

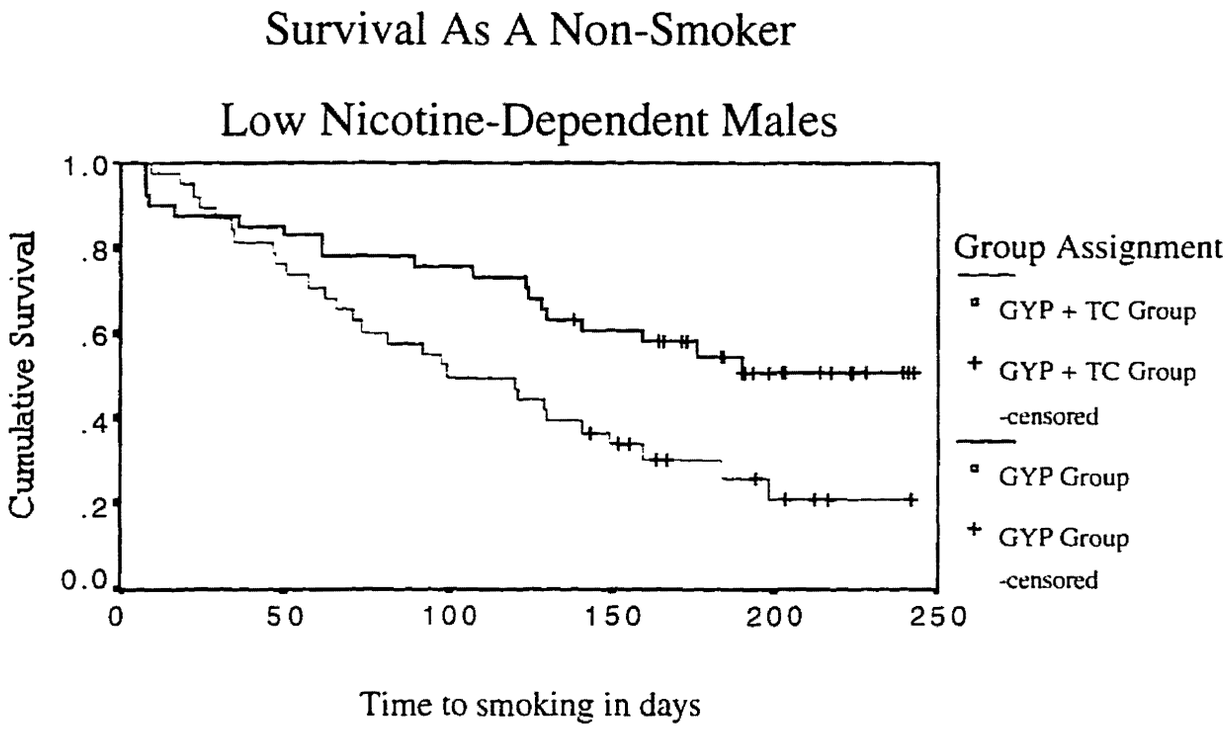

Figure 4: Time to Relapse for Low Nicotine-Dependent Males in the GYP vs. GYP+TC Groups. (P=.01 by the log rank test. Time 0 corresponds to the target quit date).

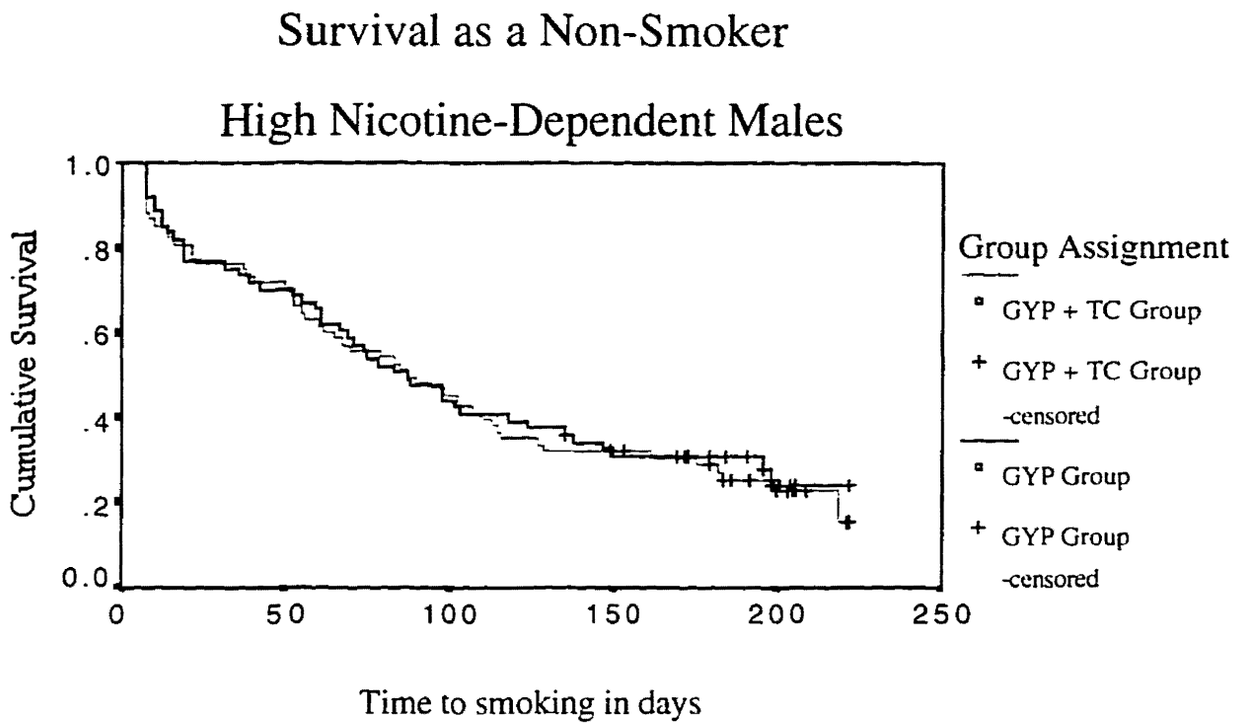

Figure 5: Time to Relapse for High Nicotine-Dependent Men in the GYP vs. GYP+TC Groups. (P=.80 by the log rank test. Time 0 corresponds to the target quit date).

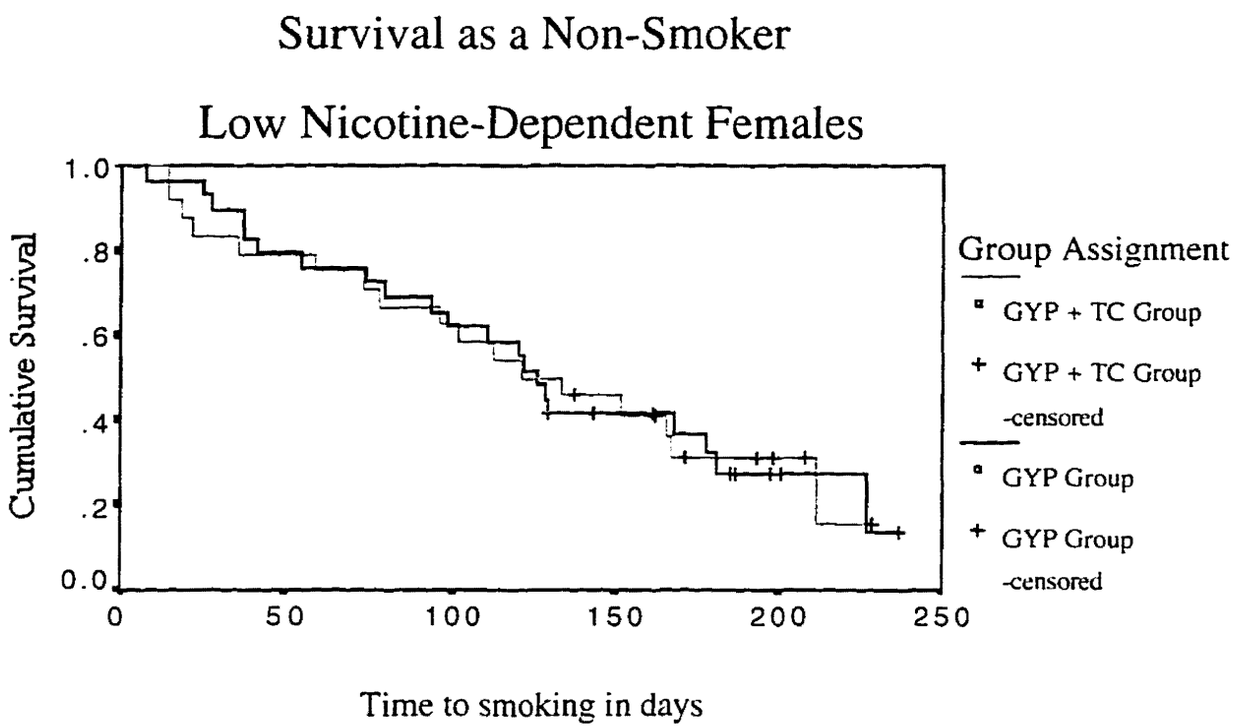

Figure 6: Time to Relapse for Low Nicotine-Dependent Females in the GYP vs. GYP+TC Groups. (P=.96 by the log rank test. Time 0 corresponds to the target quit date).

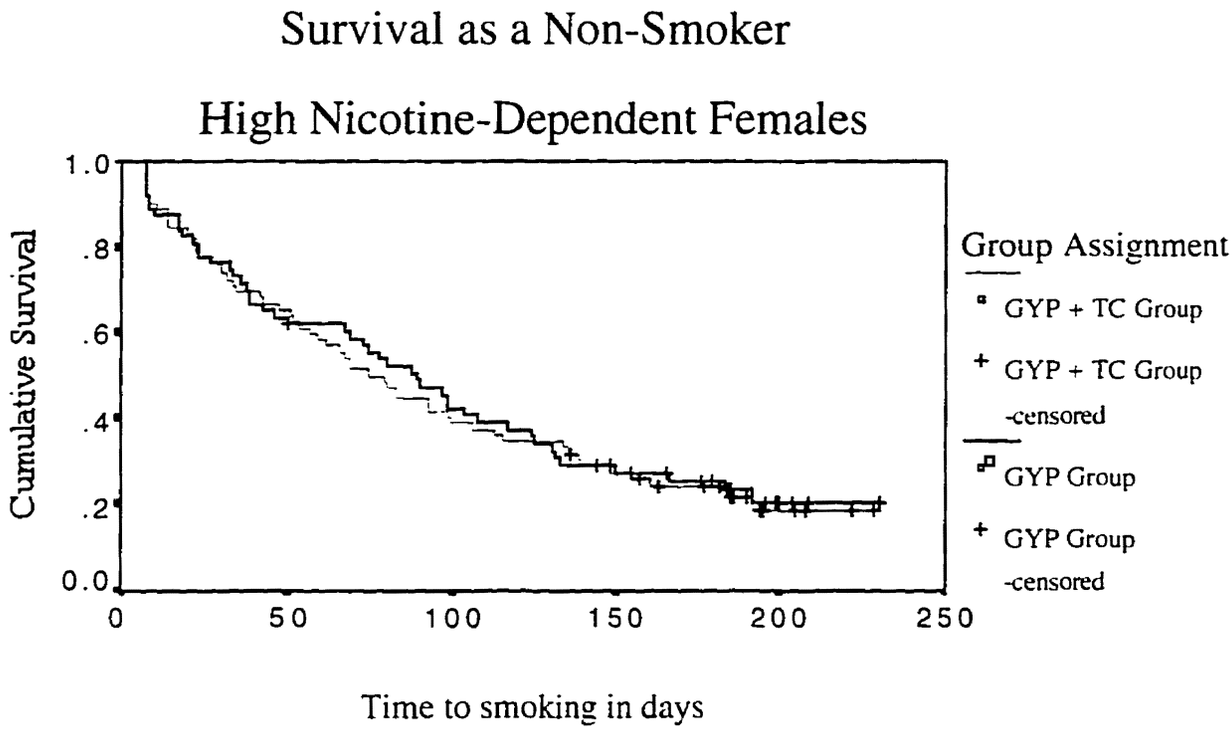

Figure 7: Time to Relapse for High Nicotine-Dependent Females in the GYP vs. GYP+TC Groups. (P=.80 by the log rank test. Time 0 corresponds to the target quit date).

4.5 PROCESSES OF CHANGE

The second objective of this study was to explore the impact of telephone counselling on the use of processes of change. Processes of change were measured at baseline, four weeks, and 12 weeks after target quit date using a 20-item questionnaire which included two items for each of the 10 processes of change (Prochaska, et al., 1988). The score for each of the processes of change was calculated as the unweighted sum of responses for its two items (maximum score = 10; range of possible scores two to 10); a higher score indicated increased use of the process of change.

4.5.1 Processes of Change at Baseline

Pre-treatment scores for the processes of change were compared using two-tailed independent-group *'t'* tests (see Table 11). Pre-treatment scores were similar between the two groups. The most frequently used processes of change at baseline were social liberation, self-liberation, and self-reevaluation. The least frequently used processes of change were stimulus control, counter conditioning and reinforcement management. Greater use of cognitive/experiential processes of change (such as social liberation and self-reevaluation) prior to treatment is consistent with participants being in the contemplation and preparation stages of quitting at baseline (Prochaska and DiClemente, 1992; Prochaska, et al., 1991).

	GYP Group n = 199		GYP+TC Group n = 197		
Baseline Variable	Mean	SD	Mean	SD	P-Value
Consciousness Raising	6.3	1.9	6.5	1.9	.41
Social Liberation	8.1	1.7	8.2	1.7	.51
Self-Reevaluation	7.1	2.0	7.3	2.0	.28
Environmental Reevaluation	5.2	2.4	5.2	2.4	.91
Dramatic Relief	5.7	2.2	5.7	2.2	.87
Self-Liberation	7.2	1.9	7.1	2.0	.60
Counter Conditioning	4.6	1.8	4.8	1.6	.37
Stimulus Control	3.6	1.8	3.4	1.7	.47
Reinforcement Management	4.6	2.4	4.4	2.4	.26
Helping Relationships	5.8	2.5	6.0	2.4	.46

Table 11: Comparisons of Baseline Process of Change Scores for Participants in the GYP vs. GYP+TC Groups.

4.5.2 Processes of Change X Treatment Group

Increased use of behavioural processes of change (i.e., self-liberation, counterconditioning, stimulus control, reinforcement management, and helping relationships) during the action stage of smoking cessation have been reported as a predictors of successful change and long-term abstinence (DiClemente and Prochaska, 1985; Prochaska and DiClemente, 1983; Prochaska and DiClemente, 1992; Prochaska, et al., 1991).

A priori, it was hypothesized that telephone counselling could lead to better quitting outcomes if it resulted in the increased use of behavioural processes of change during the action stage. To test this hypothesis, scores for each of the 10 processes of change were analysed using ANOVA with repeated measures. In these analyses, the within factor was the process of change score as measured at baseline, four weeks (mid-treatment), and 12 weeks (end-of-treatment) after the target quit date. The between factor was the treatment assignment, either GYP or GYP+TC. As described in Section 3.5, missing values were replaced using linear interpolation. The last valid value before the missing value and the first valid value after the missing value were used for interpolation. Complete processes of change data was available for 100%, 91% and 86% of participants at baseline, four weeks and twelve weeks after the target quit date, respectively.

A summary of the results of repeated measures ANOVA testing for the effects of treatment condition, time, and possible interactions between treatment condition and time are shown in Table 12. In reviewing the ANOVA summary, the initial interest was in the treatment by time interaction. If the presence of a significant interaction was established, no further hypothesis testing (for main effects of treatment or time) was conducted since the two variables jointly affect the dependent variable. If there was no significant interaction, the main effects variables (i.e., treatment condition and time) were tested individually.

Process of Change	Treat't Effect F-Value	P-Value	Time Effect F-Value	P-Value	Treat X Time F-Value	Treat X Time P-Value
Consciousness Raising	1.1	.31	6.8	<.01	0.0	.97
Social Liberation	0.6	.43	15.8	<.01	0.0	.96
Self-Reevaluation	0.0	.97	6.8	<.01	3.3	.04
Environmental Reevaluation	0.0	.92	1.6	.21	0.7	.48
Dramatic Relief	0.1	.75	0.6	.53	0.9	.40
Self-Liberation	0.1	.72	68.4	<.01	1.0	.37
Counter Conditioning	1.3	.26	394.3	<.01	0.0	.96
Stimulus Control	0.2	.64	258.5	<.01	1.2	.30
Reinforcement Management	1.0	.32	26.9	<.01	0.2	.82
Helping Relationships	0.3	.57	36.2	<.01	0.0	.74

Table 12: Summary data from repeated measures ANOVA for each of the processes of change.

There was one significant interaction, of unknown clinical significance, between treatment condition and time for the use of self-reevaluation during treatment (see Figure 9). Self-reevaluation decreased in the GYP group between the first and second treatment visit and then increased toward baseline levels between the second and the third treatment visits. In the GYP+TC group, the use of self-reevaluation also decreased between the first and second treatment visit, and continued to decrease between the second and third treatment visits.

No significant main effects for treatment condition on the use of any of the 10 processes of change were observed. Telephone counselling did not increase the use of behavioural processes of change relative to the control condition during the treatment period. In addition, there were no significant effects of the treatment condition on any of the five cognitive/experiential processes of change (consciousness raising, social liberation, self-reevaluation, environmental reevaluation, or dramatic relief).

Summary data shown in Table 12 indicated that there were significant changes on several of the processes of change over time (consciousness raising, self-reevaluation, social liberation, self-liberation, helping relationships, counterconditioning, reinforcement management, and stimulus control). Figures 8 through 15 illustrate these changes.

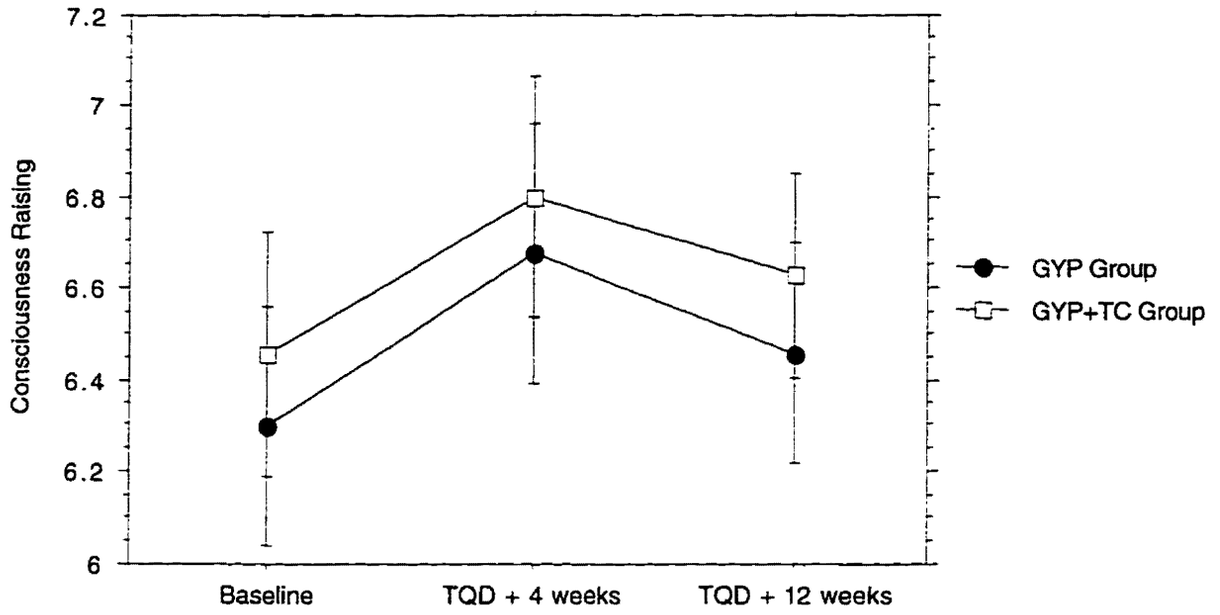

Figure 8: Changes in the Use of Consciousness Raising Over Time for Participants in the GYP and GYP+TC Groups (with 95% confidence intervals).

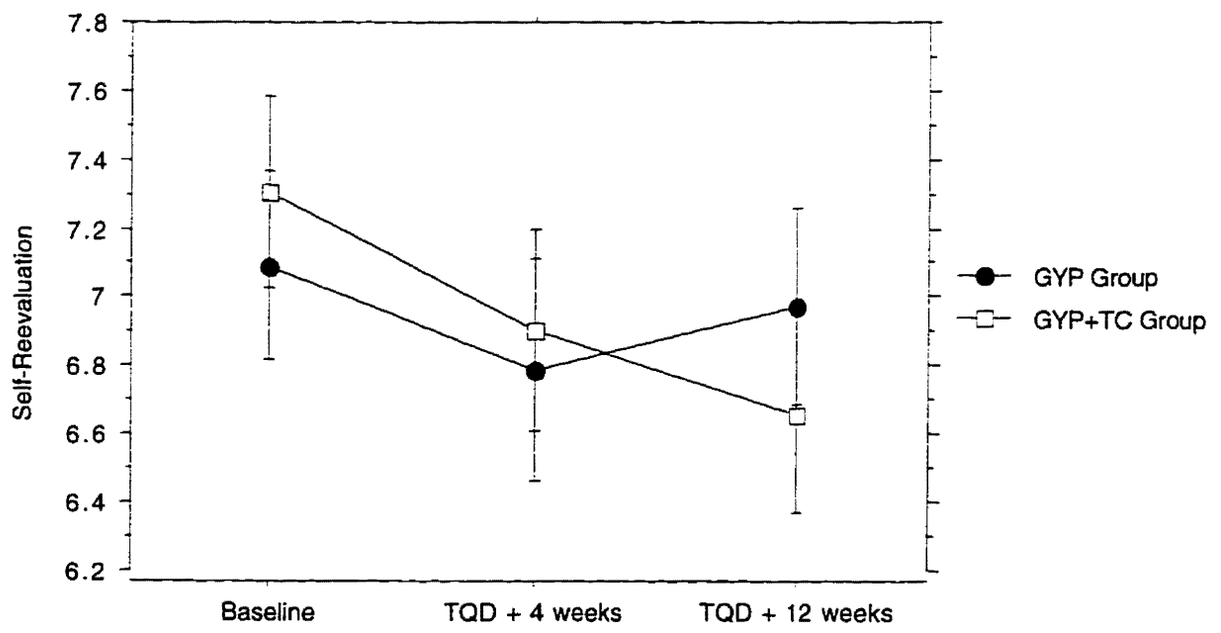

Figure 9: Changes in the Use of Self-Reevaluation Over Time for Participants in the GYP and GYP+TC Groups (with 95% confidence intervals).

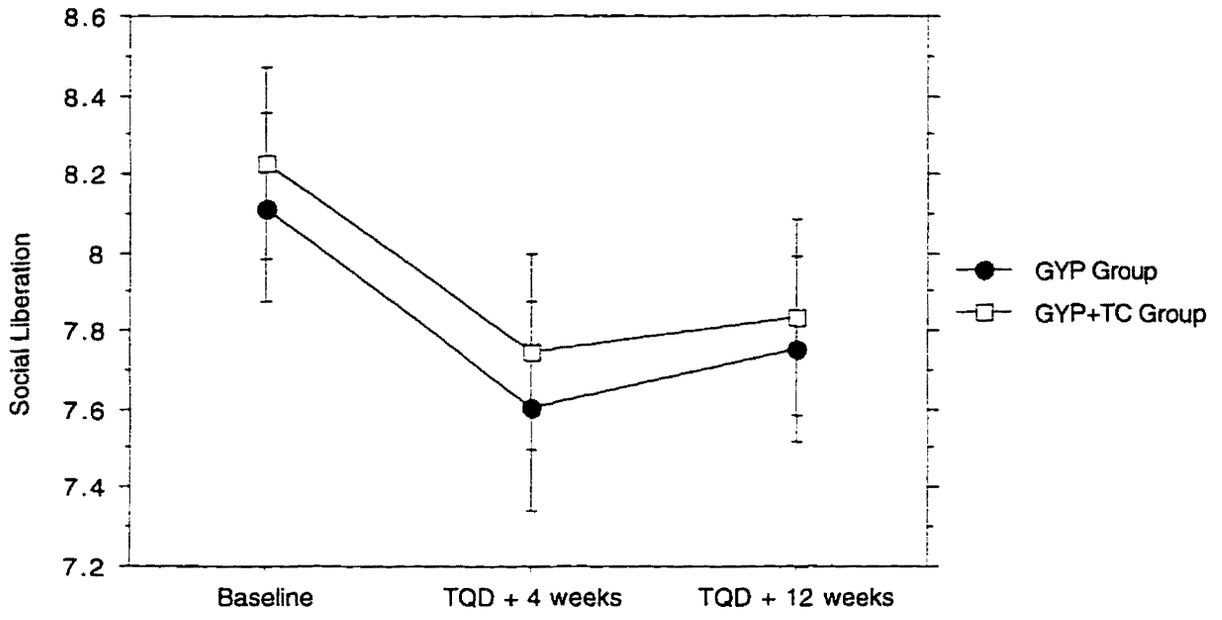

Figure 10: Changes in the Use of Social Liberation Over Time for Participants in the GYP and GYP+TC Groups (with 95% confidence intervals).

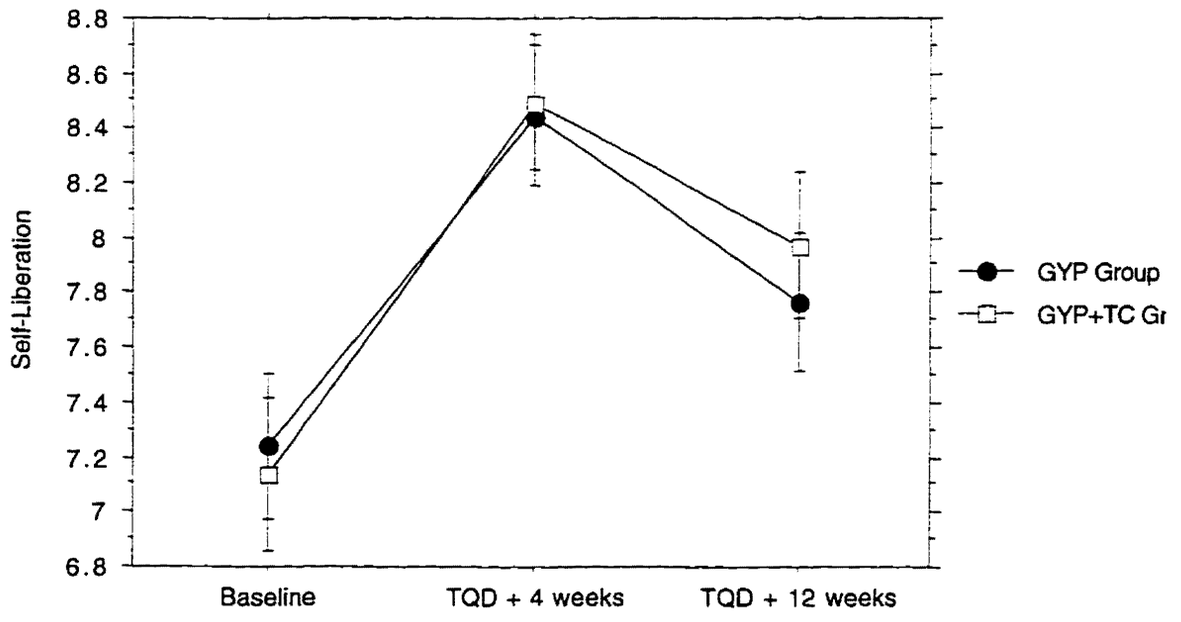

Figure 11: Changes in the Use of Self-Liberation Over Time for Participants in the GYP and GYP+TC Groups (with 95% confidence intervals).

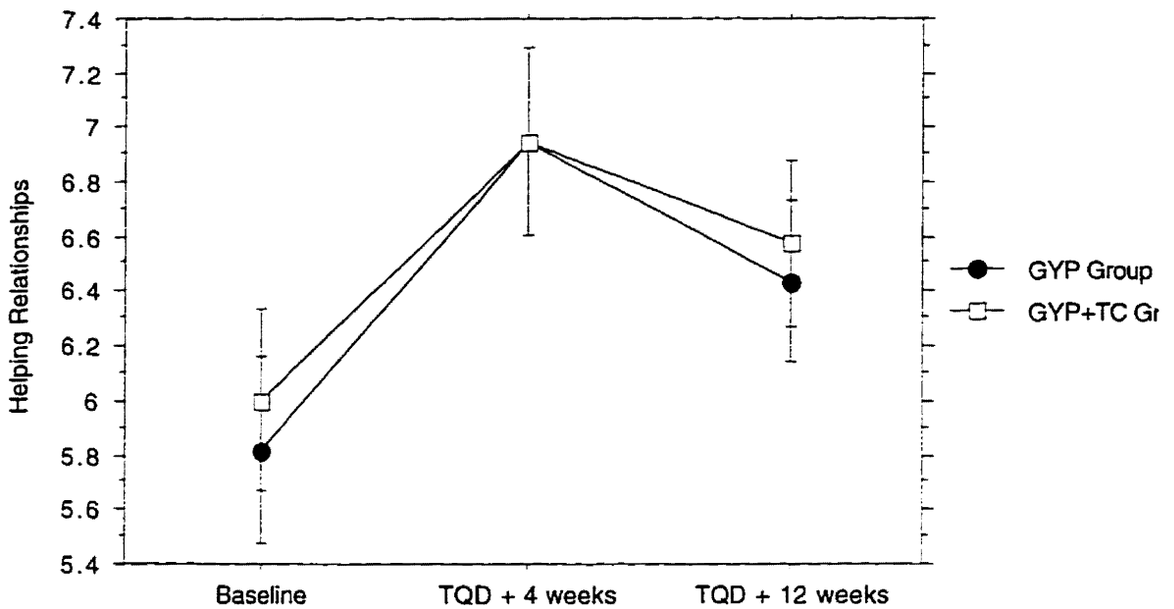

Figure 12: Changes in the Use of Helping Relationships Over Time for Participants in the GYP and GYP+TC Groups (with 95% confidence intervals).

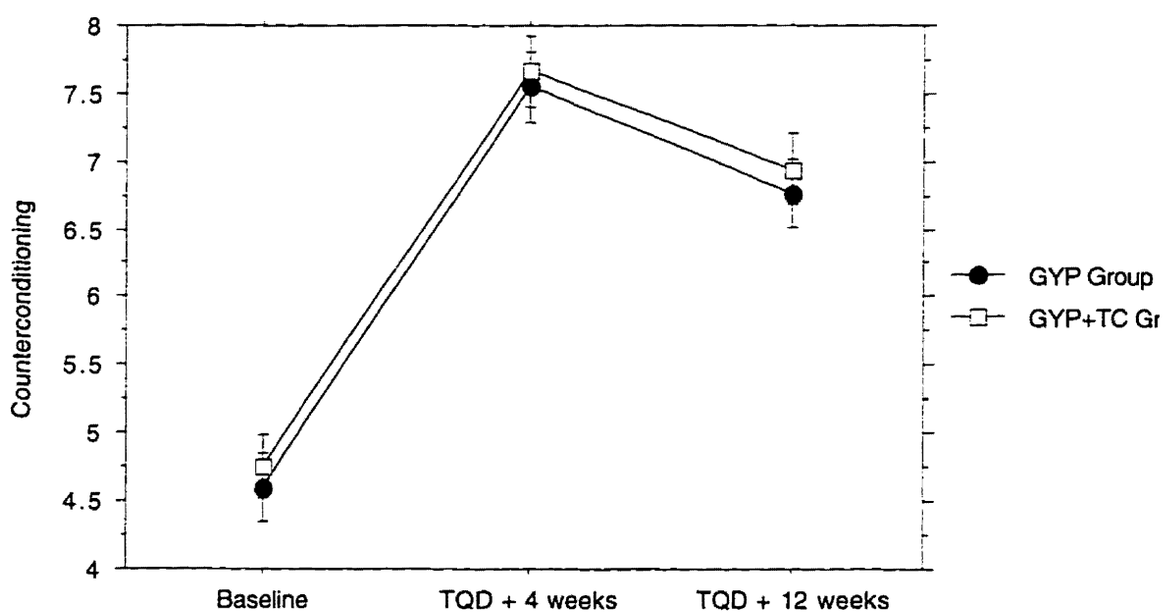

Figure 13: Changes in the Use of Counterconditioning Over Time for Participants in the GYP and GYP+TC Groups (with 95% confidence intervals).

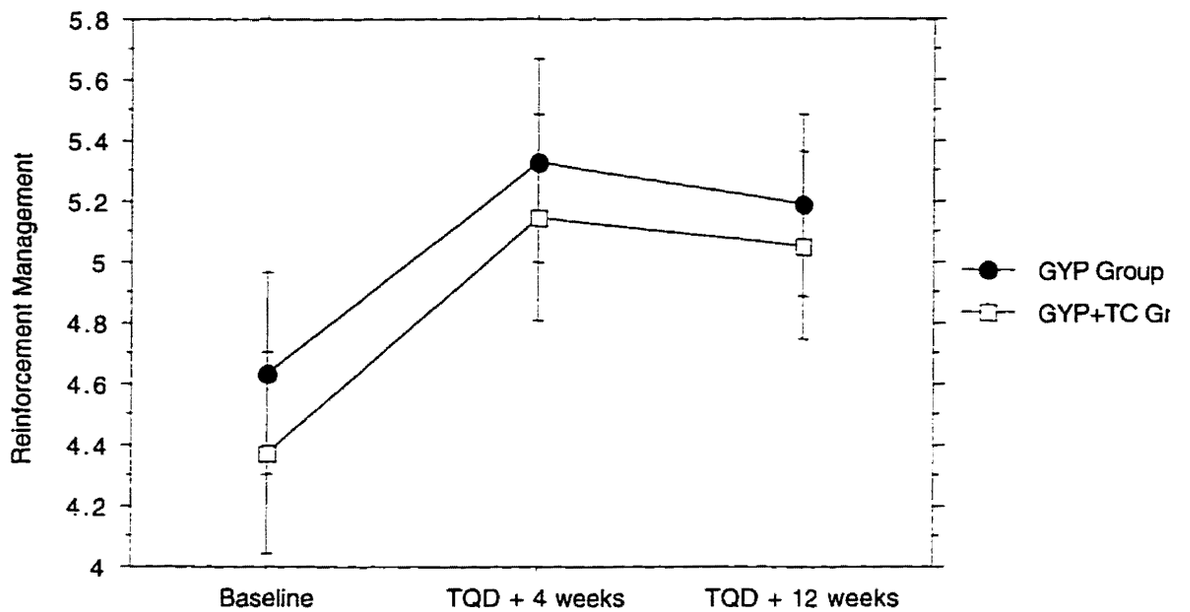

Figure 14: Changes in the Use of Reinforcement Management Over Time for Participants in the GYP and GYP+TC Groups (with 95% confidence intervals).

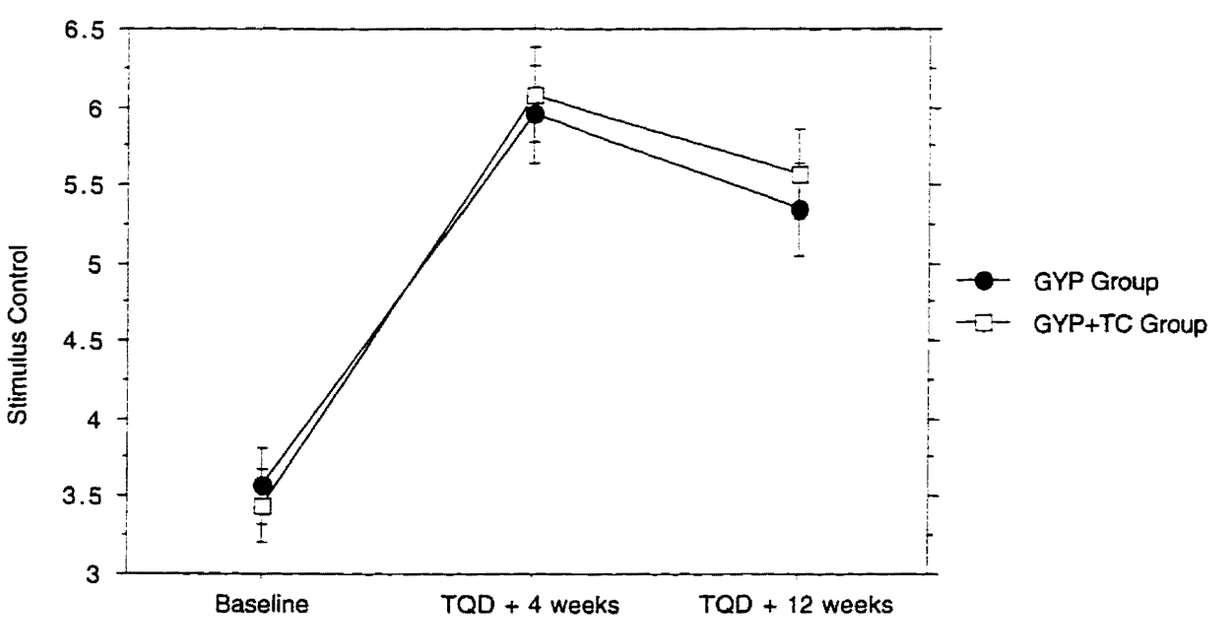

Figure 15: Changes in the Use of Stimulus Control Over Time for Participants in the GYP and GYP+TC Groups (with 95% confidence intervals).

As predicted by the transtheoretical model, participants in both treatment groups made less use of the cognitive/experiential processes of change during the treatment period. Only consciousness raising (Figure 8) showed a tendency to increase over the course of treatment. Consciousness raising increased significantly between the baseline (Treatment Visit #1) and the second treatment visit, four weeks after the target quit date. Between the second and the third treatment visit (at 12 weeks), consciousness raising decreased toward baseline levels. There was no significant difference between baseline and end-of-treatment use of consciousness raising.

The two other cognitive/experiential processes of change which changed significantly over time showed a tendency to decrease over the course of treatment. There was a significant decrease in the use of self-reevaluation (Figure 9) between baseline and the second treatment visit and it remained low throughout the remainder of treatment. The use of social liberation (Figure 10) also decreased and remained lower than baseline throughout the treatment period.

The use of all behavioural processes of change increased over the course of treatment.

Self-liberation increased between the first and second treatment visits, and at the four-week treatment visit the use of self-liberation (Figure 11) was higher than for any other process of change. There was some movement back toward baseline levels between the second and the third visit, however, at the end of treatment the self-liberation remained higher than at study entry. Ahijevych and Wewers (1992) previously described recent quitters very high use of self-liberation to be a key to their cessation success.

The use of helping relationships (Figure 12) increased during the early treatment and then returned toward baseline levels as treatment progressed. At the end of treatment, the use of helping relationships remained higher than at baseline.

Increases were observed in the use of counterconditioning (Figure 13) and stimulus control (Figure 15) during the treatment period. The pattern of use of counterconditioning indicates that participants made good use of alternatives to smoking during treatment. The use of stimulus control increased between baseline and the second treatment visits and remained higher than baseline through the end of the treatment period.

The use of reinforcement management (Figure 14) increased between baseline and the second treatment visits and remained higher than baseline through the end of the treatment period.

The sustained high use of the behavioural processes of change suggests that sustaining abstinence is an active process, and supports the notion that smokers in this study used a variety of behavioural strategies to help address the physical, psychological and social causes of smoking addiction.

4.5.3 Processes of Change X Smoking Status

From a practical standpoint, it would be helpful to know which processes of change are most effective in helping smokers to quit. Secondary analyses were performed to compare the use of the various processes of change between successful quitters and those who had relapsed at the 26-week follow-up.

4.5.3.1 Process of Change Use at Baseline X Smoking Status

Pre-treatment scores for each of the processes of change were compared between participants who were abstinent and those who relapsed at follow-up (Table 13). There were no differences between the two groups on any of these variables at the outset.

	Relapsers (n = 284)		Successful Quitters (n = 112)		
Baseline Variable	Mean	SD	Mean	SD	P-Value
Consciousness Raising	6.4	1.9	6.4	1.8	.78
Social Liberation	8.2	1.7	8.2	1.7	.94
Self-Reevaluation	7.2	2.0	7.2	1.9	.82
Environmental Reevaluation	5.2	2.4	5.3	2.4	.84
Dramatic Relief	5.7	2.3	5.7	2.3	.80
Self-Liberation	7.2	1.9	7.3	2.1	.62
Counterconditioning	4.7	1.7	4.7	1.7	.92
Stimulus Control	3.4	1.7	3.7	1.9	.25
Reinforcement Management	4.6	2.4	4.3	2.2	.19
Helping Relationships	5.9	2.4	5.9	2.5	.82

Table 13: Comparisons of Baseline Process of Change Scores for Relapsers and Successful Quitters (at 26-week follow-up).

4.5.3.2 Process of Change Use During Treatment X Smoking Status

The effect of smoking status on the use of processes of change during treatment was examined using repeated measures ANOVA where the between factor was the smoking status at follow-up, either abstinent or relapsed, and the within factor was the process of change score measured at baseline and four and 12 weeks after the target quit date (Table 14).

Process of Change	Quit Status Effect F-Value	P-Value	Time Effect F-Value	P-Value	Quit Status X Time F-Value	Quit Status X Time P-Value
Consciousness Raising	3.1	.08	6.9	<.01	3.7	.03
Social Liberation	0.2	.63	15.8	<.01	0.1	.88
Self-Reevaluation	34.3	<.01	7.2	<.01	25.3	<.01
Environmental Reevaluation	0.1	.77	1.6	.21	0.2	.79
Dramatic Relief	1.1	.30	0.6	.52	3.1	.04
Self-Liberation	1.1	.30	68.2	<.01	0.1	.89
Counterconditioning	11.2	<.01	404.7	<.01	10.5	<.01
Stimulus Control	0.3	.57	258.1	<.01	0.4	.67
Reinforcement Management	0.2	.63	27.0	<.01	1.6	.21
Helping Relationships	4.8	.03	36.6	<.01	5.4	<.01

Table 14: Summary Data from Repeated Measures ANOVA Examining the Effect of Smoking Status at 26-Week Follow-up and Time for Each of the Processes of Change.

Significant interactions between quit status and time were noted for the use of consciousness raising, self-reevaluation, counterconditioning and helping relationships. Main effects for quit status and time could not be determined for these processes of change. Successful quitters endorsed significantly less use of self-reevaluation processes (Figure 16) and greater use of counterconditioning (Figure 17) and helping relationships (Figure 18) during the treatment period.

In longitudinal research involving recent self-changers, Prochaska. et al. (1985) found that participants who became relapsers had higher self-reevaluation and helping relationship scores than those participants who became long-term quitters. For participants who have recently quit smoking, persistent reevaluation appears to be associated with relapse and may reflect uncertainty about one's commitment to stop smoking. In this study, participants who were more successful

spent less time reevaluating themselves, perhaps in part because they were confident about themselves.

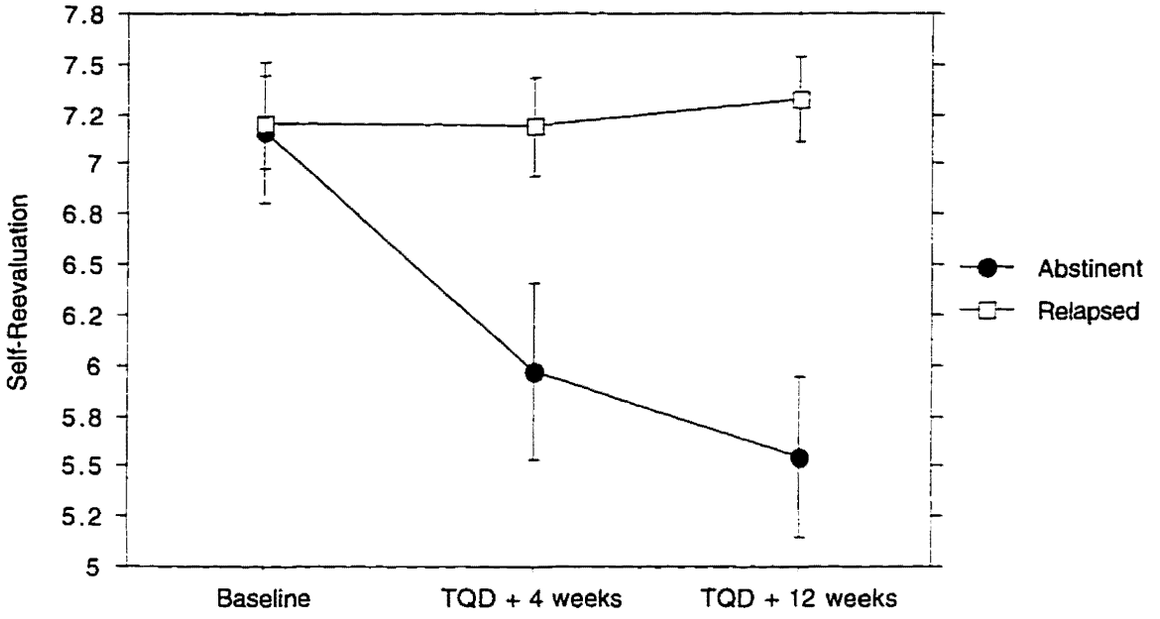

Figure 16: Comparison of the Use of Self-Reevaluation Between Abstinent and Relapsed Participants (with 95% confidence intervals).

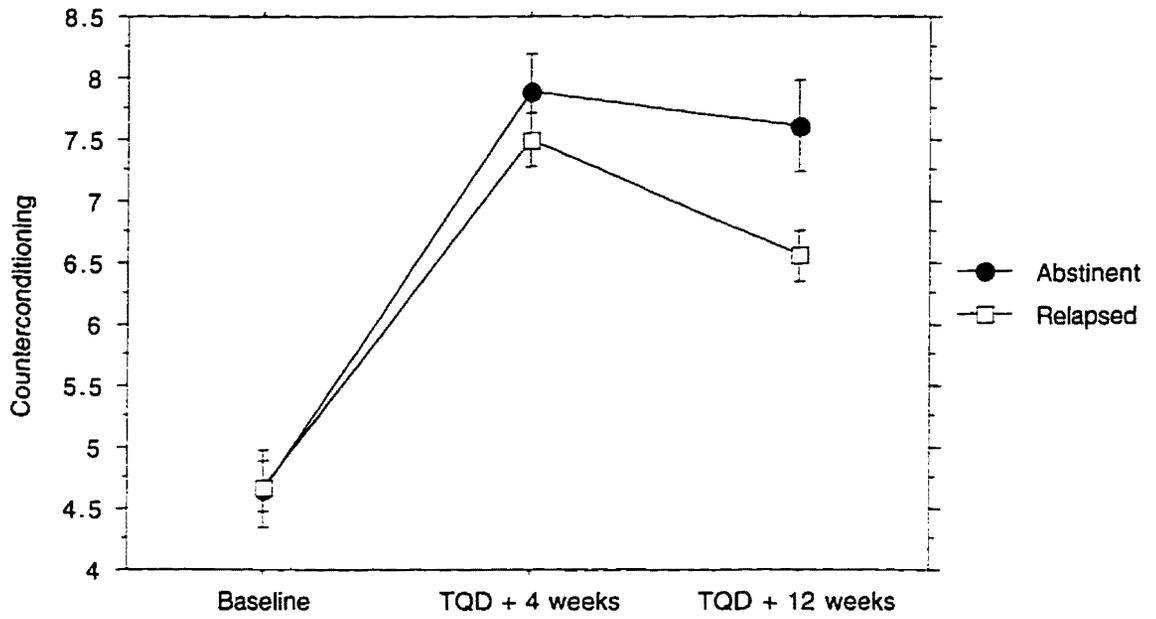

Figure 17: Comparison of the Use of Counterconditioning Between Abstinent and Relapsed Participants (with 95% confidence intervals).

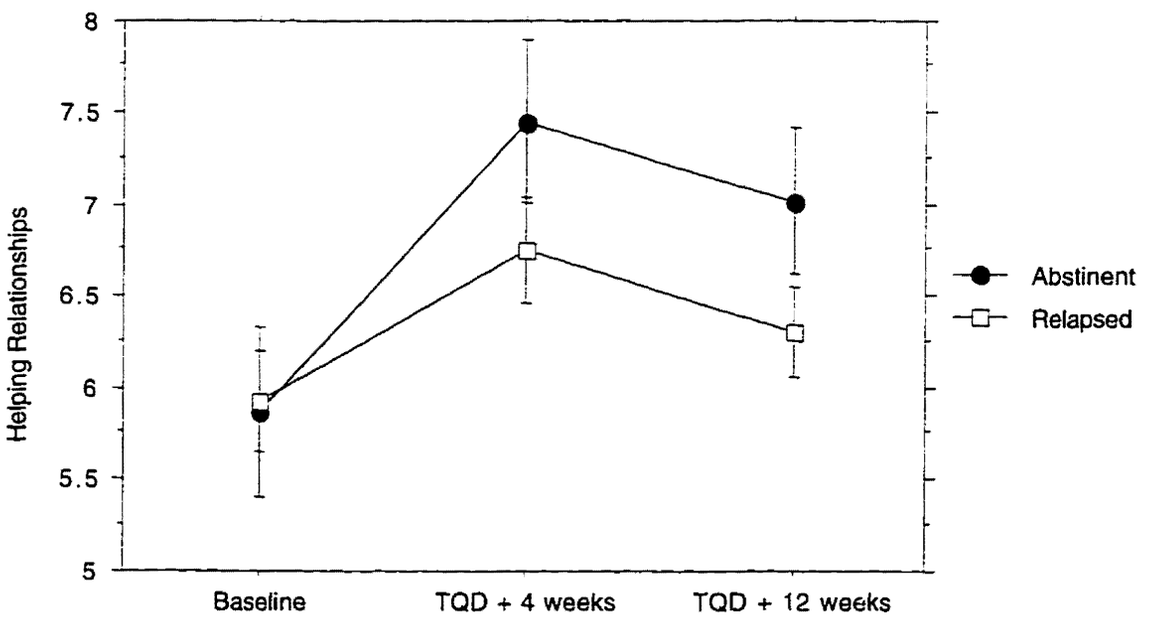

Figure 18: Comparison of the Use of Helping Relationships Between Abstinent and Relapsed Participants (with 95% confidence intervals).

4.6 SELF-EFFICACY

The third objective of this study was to examine the effect of telephone counselling on the development of self-efficacy during smoking cessation. Self-efficacy was measured at baseline, four weeks, and 12 weeks after target quit date using a 20-item questionnaire (Velicer, et al., 1993). For each item, participants were asked to rate their degree of certainty that they could avoid smoking in that situation. Each rating was done on a five-point Likert scale (1 = not at all confident to 5 = extremely confident). Participants' confidence for 18 of the 20 situations were summed to yield a total confidence score. The range of possible scores for total confidence was from 18 to 90 with higher scores indicating increased confidence in not smoking. The total confidence score was also subdivided into three subscale scores reflecting confidence in social situations, negative affect situations, and habitual situations. The range of possible scores for each subscale was from 6 to 30.

4.6.1 Confidence at Baseline

Pre-treatment scores for total confidence and for each of the subscales were compared using two-tailed independent-group *'t'* tests (Table 15). There were no differences between the treatment groups in confidence in social or negative affect situations. There was a significant difference between the two treatment groups with respect to confidence in habitual situations and in total confidence at baseline with the GYP group having higher levels of confidence than the GYP+TC group.

	GYP Group n = 199		GYP+TC Group n = 197		
Baseline Score	Mean	SD	Mean	SD	P-Value
Confidence in Social Situations	17.9	5.6	16.8	5.9	.06
Confidence in Negative Affect Situations	12.9	4.6	12.3	5.3	.19
Confidence in Habitual Situations	16.4	4.7	15.4	5.1	.04
Total Confidence	47.2	13.5	44.5	14.7	.05

Table 15: Comparisons of Subscale and Total Confidence Scores at Baseline for Participants in the GYP vs. GYP+TC Groups.

4.6.2 Self-Efficacy X Treatment Group

A priori, it was hypothesized that telephone counselling could lead to better quitting outcomes if it resulted in greater levels of self-efficacy during treatment. To test this hypothesis, scores for confidence in social situations, negative affect situations, habitual situations, and total confidence were analysed using ANOVA with repeated measures. In these analyses, the within factor was the total confidence or confidence subscale score as measured at baseline, four weeks (mid-treatment), and 12 weeks (end-of-treatment) after the target quit date. The between factor was the treatment assignment, either GYP or GYP+TC. As described in Section 3.5, missing values were replaced using linear interpolation. The last valid value before the missing value and the first valid value after the missing value were used for interpolation. Complete self-efficacy data was available for 100%, 91% and 86% of participants at baseline, four weeks and twelve weeks after the target quit date, respectively.

As in the analysis of processes of change data, the initial interest was in the treatment by time interaction. If the presence of a significant interaction was established, no further hypothesis testing (for main effects of treatment or time) was conducted since the two variables jointly affect the dependent variable. If there was no significant interaction, the main effects variables (i.e., treatment condition and time) were tested individually.

4.6.2.1 Confidence in Social Situations X Treatment Group

There was no significant effect of the treatment condition on confidence in social situations (see Table 16 and Figure 19). The analysis demonstrated that there was a significant increase in confidence in social situations over time (Time effect F-Value = 70.6; p =<.01). Confidence in social situations increased between the first and the second treatment visits, decreased somewhat between the second and the third treatment visits, but remained higher than baseline at the end of treatment.

	DF	Sum of Squares	Mean Square	F-Value	P-Value
Treatment Condition	1	17.8	17.8	0.3	.59
Subject (Group)	394	23812.6	60.4		
Time	2	3271.4	1635.7	70.6	<.01
Time*Treatment	2	107.5	53.7	2.3	.10

Table 16: ANOVA Table for Confidence in Social Situations.

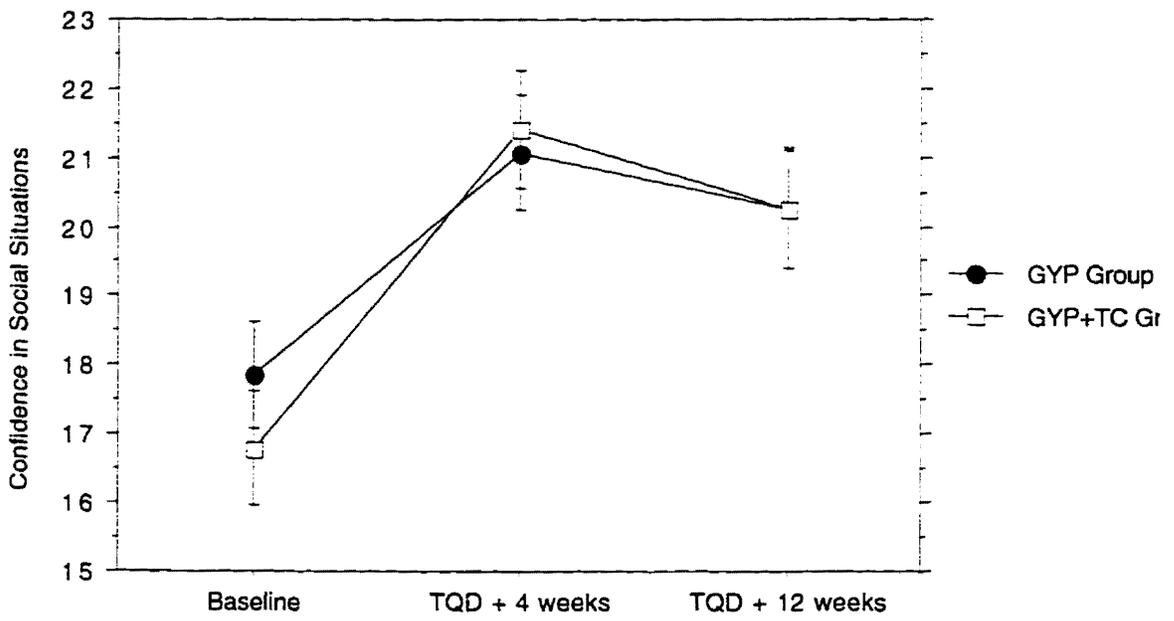

Figure 19: Comparison of Confidence in Social Situations in the GYP vs. GYP+TC Groups (with 95% confidence intervals).

4.6.2.2 Confidence in Negative Affect Situations X Treatment Group

There was no significant effect of the treatment condition on confidence in negative affect situations (see Table 17 and Figure 20). There was a significant increase in confidence in negative affect situations over time (Time effect F-Value = 36.1; p =<.01). Confidence in negative affect situations increased between the first and the second treatment visits, and remained higher through the end of treatment.

	DF	Sum of Squares	Mean Square	F-Value	P-Value
Treatment Condition	1	41.4	41.4	0.8	.37
Subject (Group)	394	20295.3	51.5		
Time	2	1428.2	714.1	36.1	<.01
Time*Treatment	2	14.0	7.0	0.4	.70

Table 17: ANOVA Table for Confidence in Negative Affect Situations.

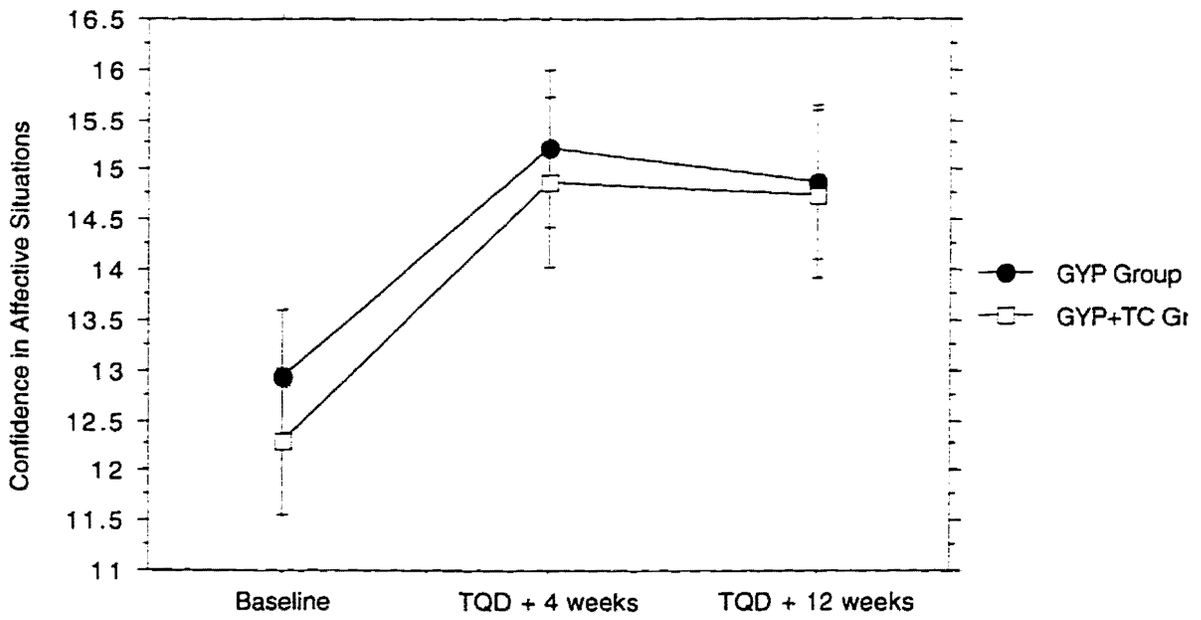

Figure 20: Comparison of Confidence in Negative Affect Situations in the GYP vs. GYP+TC Groups (with 95% confidence intervals).

4.6.2.3 Confidence in Habitual Situations X Treatment Group

There was no significant effect of the treatment condition on confidence in habitual situations (Table 18 and Figure 21). There was a significant increase in confidence in habitual situations over time (Time effect F-Value = 56.4; p =<.01). Confidence in habitual situations increased between the first and the second treatment visits, and remained higher through the end of treatment.

	DF	Sum of Squares	Mean Square	F-Value	P-Value
Treatment Condition	1	66.9	66.9	1.6	.21
Subject (Group)	394	16674.7	42.3		
Time	2	1812.2	906.1	56.4	<.01
Time*Treatment	2	54.2	27.1	1.7	.19

Table 18: ANOVA Table for Confidence in Habitual Situations.

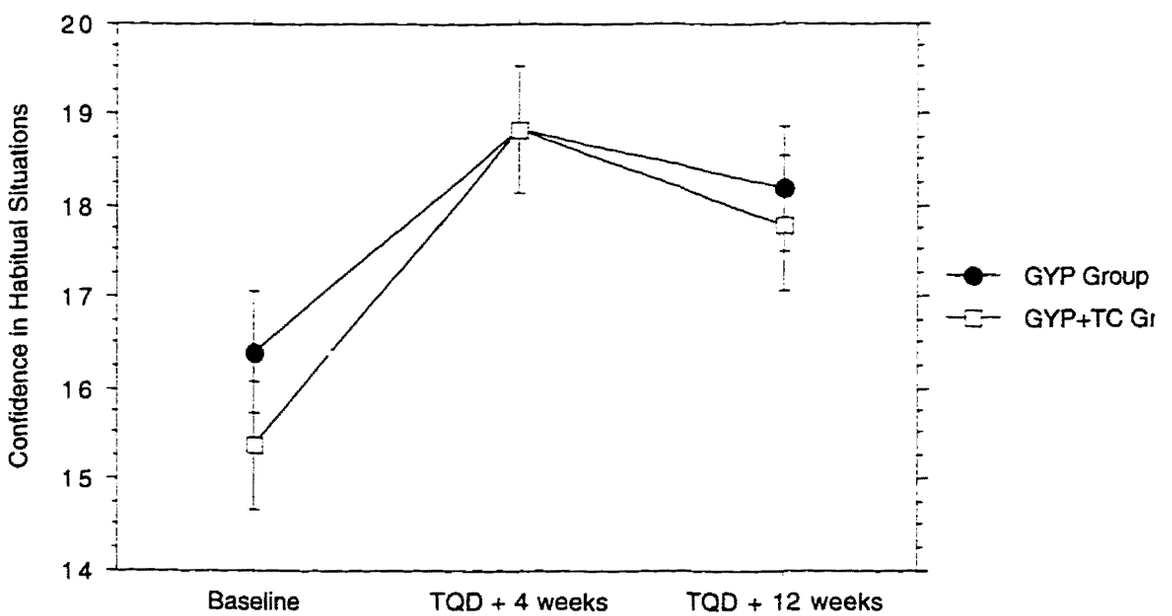

Figure 21: Comparison of Confidence in Habitual Situations in the GYP vs. GYP+TC Groups (with 95% confidence intervals)

4.6.2.4 Total Confidence X Treatment Group

There was no significant effect of the treatment condition on total confidence (Table 19 and Figure 22). There was a significant increase in total confidence over time (Time effect F-Value = 64.8; p =<.01). The initiation of treatment coincided with an increase in confidence for participants, regardless of their treatment group allocation. Total confidence increased between the first and the second treatment visits, and remained higher through the end of treatment.

	DF	Sum of Squares	Mean Square	F-Value	P-Value
Treatment Condition	1	358.2	358.2	0.9	.33
Subject (Group)	394	1449903.5	380.5		
Time	2	18698.3	9349.2	64.8	<.01
Time*Treatment	2	425.0	212.5	1.5	.23

Table 19: ANOVA Table for Total Confidence.

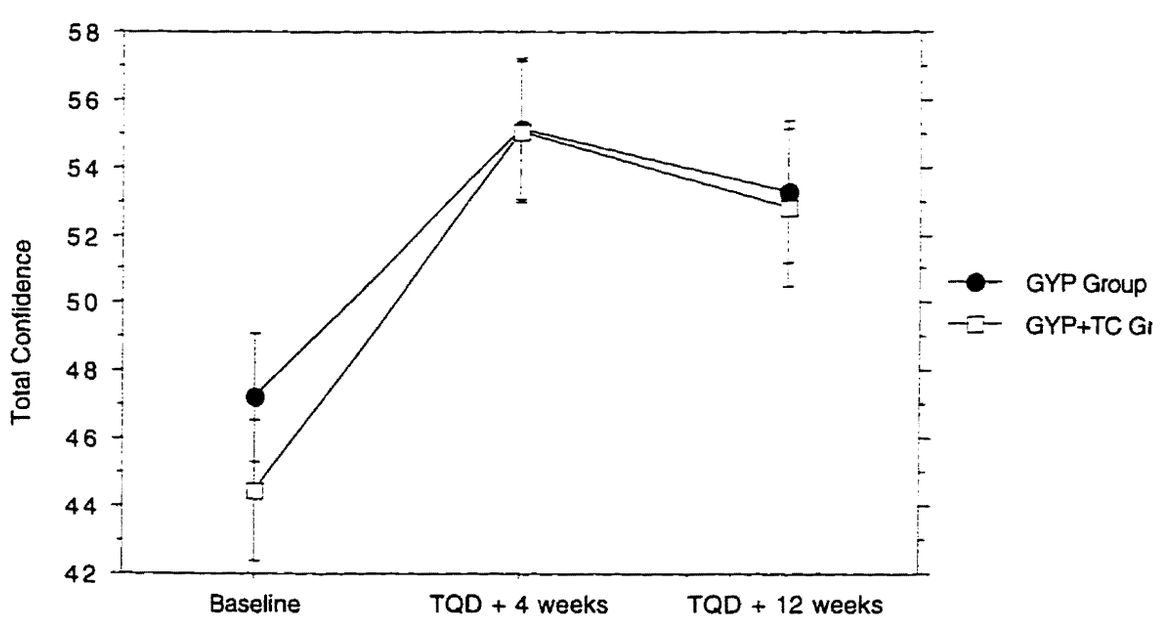

Figure 22: Comparison of Total Confidence in the GYP vs. GYP+TC Groups.

4.6.3 Comparison of Self-Efficacy Between Successful Quitters and Relapsers

4.6.3.1 Confidence in Social Situations X Smoking Status

Table 20 and Figure 23 demonstrate the effect of smoking status on confidence in social situations. There was no difference in the confidence in social situations of successful quitters and relapsers at baseline. However, successful quitters had higher levels of confidence in social situations, four weeks and 12 weeks after their target quit date. For abstinent participants, confidence in social situations continued to rise over the treatment period. For relapsers, confidence in social situations increased initially, but returned toward baseline levels by the end of treatment.

	DF	Sum of Squares	Mean Square	F-Value	P-Value
Smoking Status	1	1906.8	1906.8	34.3	<.01
Subject (Group)	394	21923.6	55.6		
Time	2	3271.4	1635.7	77.0	<.01
Time*Smoking Status	2	1619.6	809.8	38.1	<.01

Table 20: ANOVA Table for Confidence in Social Situations X Smoking Status.

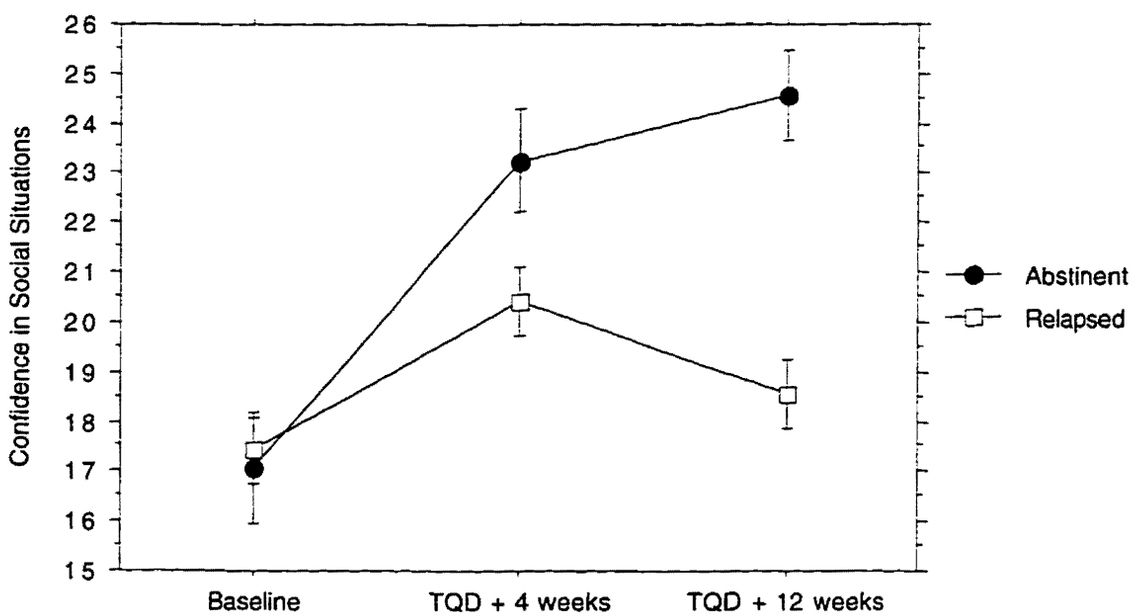

Figure 23: Changes in Confidence in Social Situations for Abstinent and Relapsed Participants (with 95% confidence intervals).

4.6.3.2 Confidence in Negative Affect Situations X Smoking Status

Table 21 and Figure 24 demonstrate the effect of smoking status on reported confidence in negative affect situations. There was no difference in the confidence in negative affect situations of successful quitters and relapsers at baseline. However, successful quitters had higher levels of confidence in negative affect situations, four weeks and 12 weeks after their target quit date. For abstinent participants, confidence in negative affect situations continued to rise over the treatment period. For relapsers, confidence in negative affect situations increased initially, but returned toward baseline levels by the end of treatment.

	DF	Sum of Squares	Mean Square	F-Value	P-Value
Smoking Status	1	2563.6	2563.6	56.8	<.01
Subject (Group)	394	17773.1	45.1		
Time	2	1428.2	714.1	40.1	<.01
Time*Smoking Status	2	1529.4	764.7	42.9	<.01

Table 21: ANOVA Table for Confidence in Negative Affect Situations X Smoking Status.

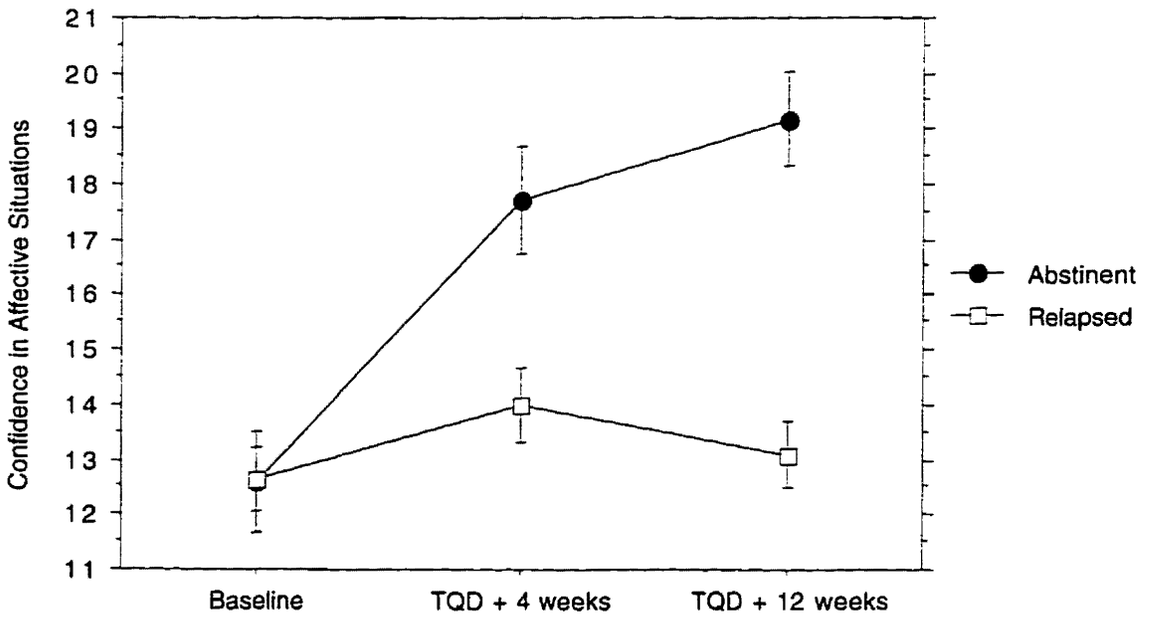

Figure 24: Changes in Confidence in Negative Affect Situations for Abstinent and Relapsed Participants (with 95% confidence intervals).

4.6.3.3 Confidence in Habitual Situations X Smoking Status

Table 22 and Figure 25 demonstrate the effect of smoking status on reported confidence in habitual situations. There was no difference in the confidence in habitual situations of successful quitters and relapsers at baseline. However, successful quitters had higher levels of confidence in habitual situations, four weeks and 12 weeks after their target quit date. For abstinent participants, confidence in habitual situations continued to rise over the treatment period. For relapsers, confidence in habitual situations increased initially, but returned toward baseline levels by the end of treatment.

	DF	Sum of Squares	Mean Square	F-Value	P-Value
Smoking Status	1	1094.5	1094.5	27.6	<.01
Subject (Group)	394	15647.0	39.7		
Time	2	1812.2	906.1	61.3	<.01
Time*Smoking Status	2	1069.1	534.5	36.2	<.01

Table 22: ANOVA Table for Confidence in Habitual Situations X Smoking Status.

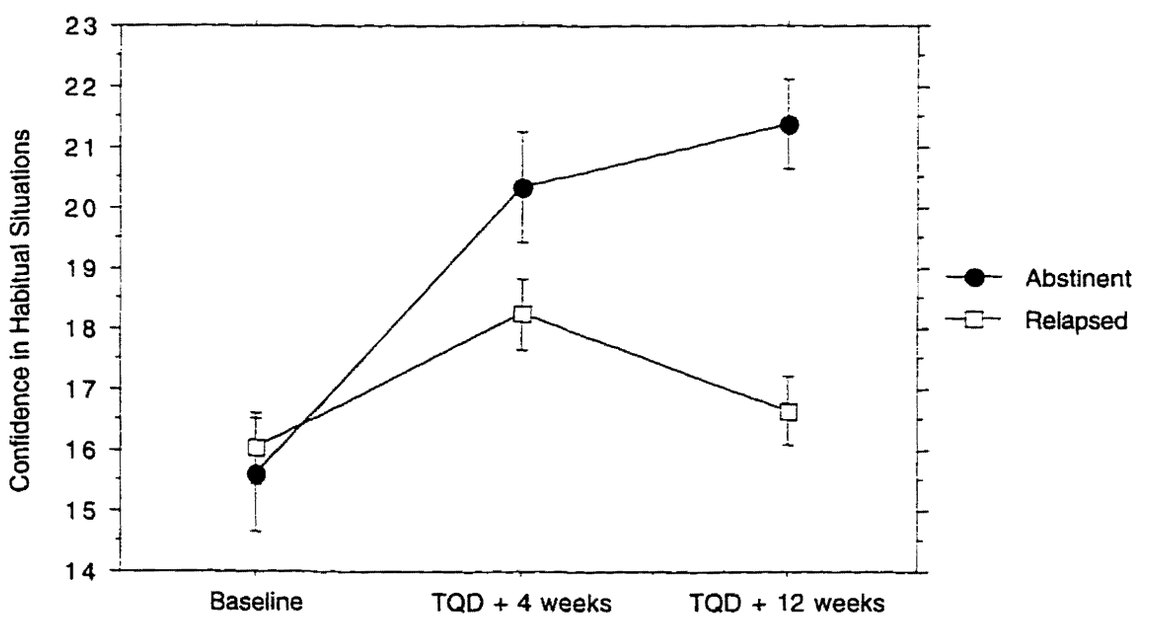

Figure 25: Changes in Confidence in Habitual Situations for Abstinent and Relapsed Participants (with 95% confidence intervals).

4.6.3.4 Total Confidence X Smoking Status

Table 23 and Figure 26 demonstrate the effect of smoking status on total confidence. There was no difference in the total confidence scores of successful quitters and relapsers at baseline. However, successful quitters had higher levels of total confidence, four weeks and 12 weeks after their target quit date. For abstinent participants, total confidence continued to rise over the treatment period. For relapsers, total confidence increased initially, but returned toward baseline levels by the end of treatment.

	DF	Sum of Squares	Mean Square	F-Value	P-Value
Smoking Status	1	2563.6	2563.6	56.8	<.01
Subject (Group)	394	17773.1	45.1		
Time	2	1428.2	714.1	40.1	<.01
Time*Smoking Status	2	1529.4	764.7	42.9	<.01

Table 23: ANOVA Table for Total Confidence X Smoking Status.

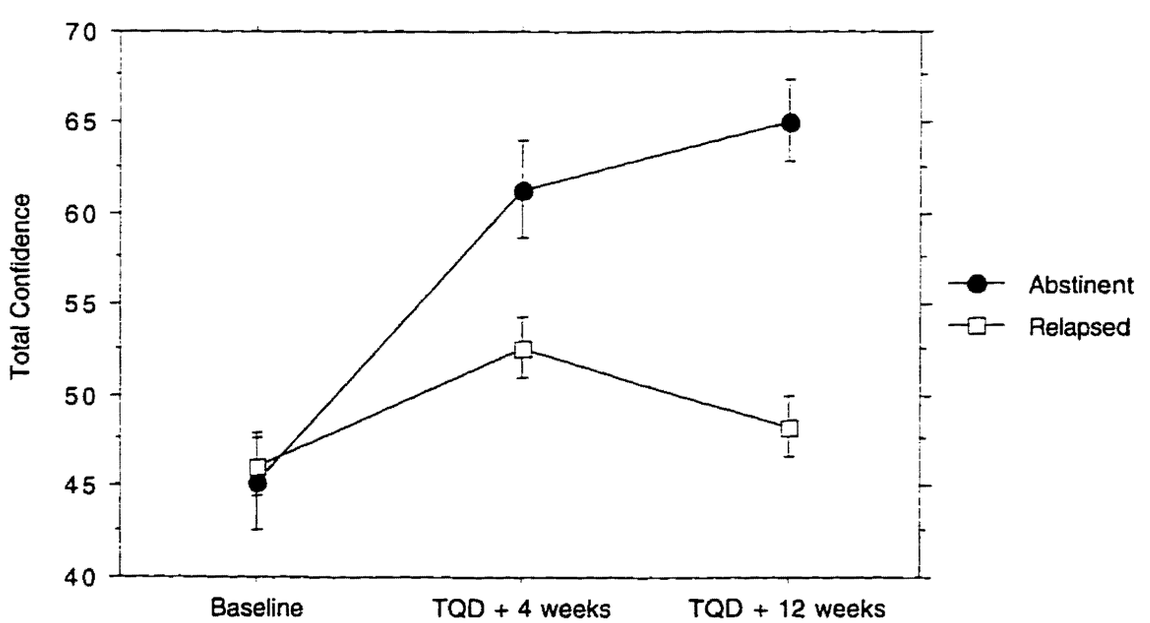

Figure 26: Changes in Total Confidence for Abstinent and Relapsed Participants (with 95% confidence intervals).

4.7 PERCEIVED STRESS

4.7.1 Perceived Stress X Treatment Group

Table 24 and Figure 27 demonstrate the effect of treatment condition on perceived stress over the treatment period. There was a tendency for levels of perceived stress to increase over the treatment period, however these changes failed to reach statistical significance. There were no differences in the perceived stress scores between the treatment groups at baseline, four weeks or 12 weeks after the target quit date.

	DF	Sum of Squares	Mean Square	F-Value	P-Value
Treatment Condition	1	13.8	13.8	0.9	.35
Subject (Group)	394	6238.8	15.8		
Time	2	157.4	78.7	14.8	<.01
Time*Treatment	2	7.2	3.6	0.7	.51

Table 24: ANOVA Table for Changes in Perceived Stress X Treatment Group.

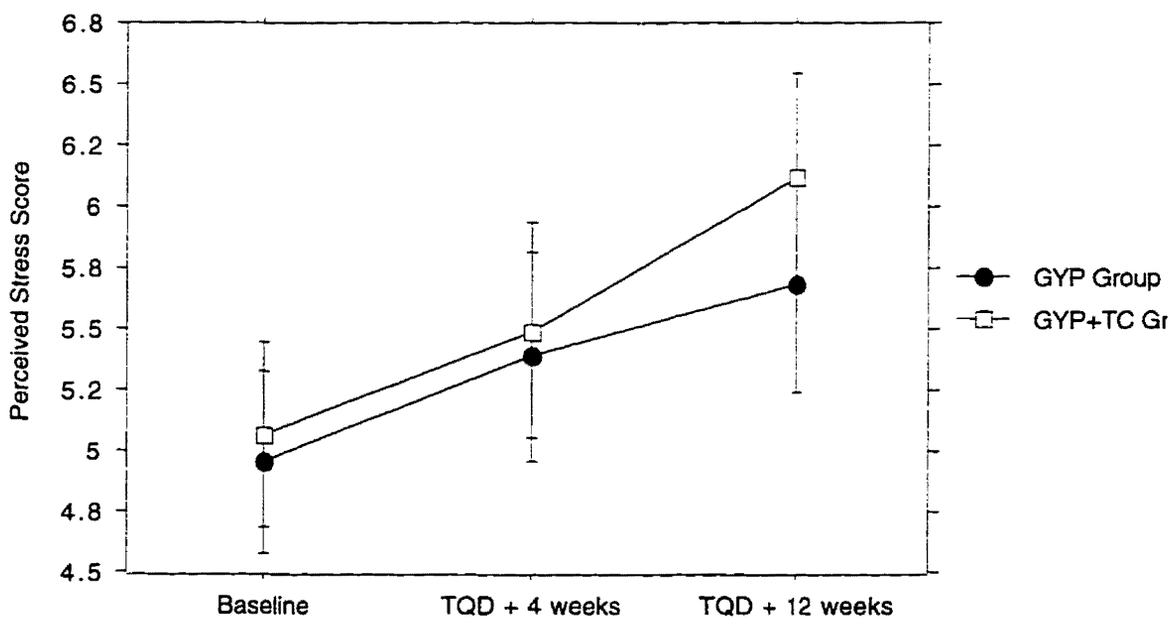

Figure 27: Changes in Perceived Stress in the Two Treatment Groups (with 95% confidence intervals).

4.7.2 Perceived Stress X Smoking Status

Table 25 and Figure 28 demonstrate the effect of smoking status and time on perceived stress over the treatment period. There was a significant interaction between smoking status and time so main effects for these two factors could not be determined. Successful quitters had significantly lower levels of perceived stress at each of the measurement points, including baseline. Perceived stress scores for relapsers rose continuously over each subsequent treatment visit and were higher than baseline levels 12 weeks after the target quit date. For successful quitters, perceived stress scores remained relatively stable over the treatment period.

	DF	Sum of Squares	Mean Square	F-Value	P-Value
Smoking Status	1	2563.6	2563.6	56.8	<.01
Subject (Group)	394	17773.1	45.1		
Time	2	1428.2	714.1	40.1	<.01
Time*Smoking Status	2	1529.4	764.7	42.9	<.01

Table 25: ANOVA Table for Perceived Stress X Smoking Status.

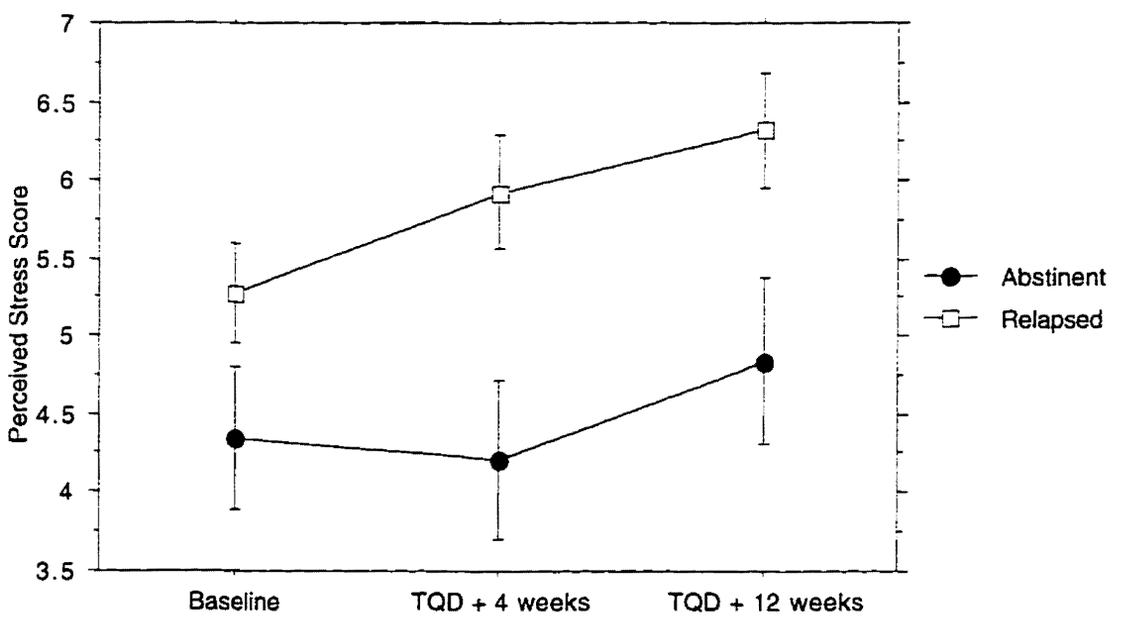

Figure 28: Changes in Perceived Stress in Abstinent and Relapsed Smokers (with 95% confidence intervals).

4.8 EVALUATION OF CARE AGENTS

To evaluate possible differences in the effectiveness of the two telephone counsellors and three study physicians who provided interventions in the study, the extent to which smokers assigned to each of the care agents adhered to the treatment and were successful in quitting smoking were compared using chi-square tests. The results for telephone counsellors are presented in Table 26. The results for physicians are presented in Table 27.

4.8.1 Telephone Counsellors

High adherence to the telephone counselling was defined as completing either two or three of the intended calls. The quit rate was defined as the PPA rate observed at the 26-week follow-up point. There were no apparent differences in the adherence rate or the quit rate observed between telephone counsellors.

	Counsellor A	Counsellor B	P-Value
High Adherence (%)	87.1	92.9	.18
Quit Rate (%)	31.2	22.1	.15

Table 26: Comparison of Adherence and Quit Rates Between the Two Telephone Counsellors.

4.8.2 Study Physicians

High adherence to the MD treatment was defined as attending two or more of the three scheduled physician counselling sessions. The quit rate was defined as the PPA rate observed at the 26-week follow-up point. There were no apparent differences in the adherence rate or the quit rate observed between study physicians.

	Physician #1	Physician #2	Physician #3	P-Value
High Adherence (%)	86.7	83.3	87.9	.60
Quit Rate (%)	29.7	33.3	25.9	.54

Table 27: Comparison of Adherence and Quit Rates Between the Three Study Physicians.

4.8.3 Effect of Counsellor Allocation on Time to Relapse in Low Nicotine-Dependent Males

As described in section 4.4.3, survival analysis indicated a negative effect of telephone counselling on time to relapse in low nicotine dependent males. To ensure that this result was not related to confounding by the nurse-counsellor providing the telephone counselling, survival curves were compared between the counsellors in this strata (Table 28). There was no significant difference between Counsellor A and Counsellor B for the survival curves for low nicotine-dependent males. The results of this analysis demonstrate that poorer outcomes for low nicotine dependent males in the GYP+TC group were not related simply to the counsellor providing the telephone counselling.

	Counsellor A	Counsellor B	P-Value
Median Time to Relapse	97.0	121.0	.89
(in Days)	(72.8, 121.2)	(31.3, 210.7)	

Table 28: Median Time to Relapse and Results of Significance Testing Comparing the Survival Curves Between Counsellors in Low Nicotine-Dependent Males .

4.9 PREDICTORS OF CESSATION

A secondary analysis was performed to identify the characteristics of smokers that were associated with cessation. Univariate logistic regression analyses were used to estimate the effects of individual baseline predictors on the odds of being abstinent from smoking at 26-week follow-up. A total of 25 baseline variables were examined as possible univariate predictors of cessation, including: Treatment Group Assignment, Age, Gender, Education Level, Cigarettes/Day, Smoking Within 30 Minutes of Arising, Fagerstrom Category, Living With Other Smokers, Pros-Cons of Smoking, Previous Quit Attempts in Past Year, Consciousness Raising, Self-Reevaluation, Environmental Reevaluation, Social Liberation, Dramatic Relief, Self-Liberation, Counter-Conditioning, Helping Relationships, Reinforcement Management, Stimulus Control, Total Use of Cognitive Processes, Total Use of Behavioural Processes, Total Confidence, and Perceived Stress. Three of these variables were found to be significant predictors of abstinence at 26-week follow-up: Education Level, Fagerstrom Category, and Perceived Stress. Odds ratios and confidence intervals for each of the variables are shown in Table 29.

Variable	Odds Ratio	95% CI
Education Level		
High School or Less	1.00	
More Than High School	2.30	1.44, 3.68
Fagerstrom Category		
Low Dependent (FTQ < 7)	1.00	
High Dependent (FTQ ≥ 7)	0.63	0.40, 0.99
Perceived Stress Level		
Low Stress (Perceived Stress Score < 8)	1.00	
High Stress (Perceived Stress Score ≥ 8)	0.39	0.22, 0.69

Table 29: Univariate Predictors of Abstinence at 26 Weeks.

A higher level of education was associated with a greater likelihood of being abstinent at follow-up. For baseline smoking characteristics, being in the low Fagerstrom Category (FTQ < 7) increased the probability of being abstinent. Participants reporting a lower stress level at baseline (Perceived Stress Scale Score < 8) were more likely to be abstinent at follow-up.

4.10 PREFERENCES OF PARTICIPANTS

At the baseline assessment, participants were asked about the kinds of assistance that they would most prefer if they were quitting under normal circumstances (i.e., not part of a clinical study of smoking cessation methods). A summary of these responses and the quit rates observed for people identifying the different types of preferred assistance are provided in Table 30.

Type of Preferred Assistance	Number (Percent)	Quit Rate (%)
No Preference	19 (4.8)	26.3
No Assistance Preferred	27 (6.8)	22.2
Self-Help Materials Preferred	68 (17.1)	32.4
Individual Counselling Preferred	143 (36.1)	27.3
Group Counselling Preferred	72 (18.2)	26.1
Telephone Counselling Preferred	47 (11.8)	34.0

Table 30: Type of Preferred Assistance Identified at Baseline and Observed Quit Rates.

At baseline, the most preferred form of assistance identified by participants in the study was individual counselling, followed by group counselling, self-help materials, telephone counselling, no assistance, and no preferred form of assistance, in descending order of preference. At 26-week follow-up, quit rates ranged from a high of 34% for participants who identified a preference for telephone counselling at baseline, to a low of 22% for participants who preferred no assistance. Differences in quit rates according to baseline preferences for assistance were not statistically significant ($X^2 = 2.1$, 5 df; P = .83).

5.0 DISCUSSION

This trial showed that brief physician assistance (incorporating nicotine replacement therapy), applied as suggested in the *Guide Your Patients* program, could assist well-motivated volunteer smokers who would like to quit. The addition of telephone counselling on three occasions did not improve the quit rate or delay time before relapse. Telephone counselling appeared to interfere with quitting in low nicotine-dependent male smokers.

A priori, it was estimated that the cessation rate observed in the telephone counselling group would be 35%, 15% greater than in the control condition (GYP). The sample size of 396 was sufficient to detect a 15% difference in quit rates between the two intervention groups (alpha level = 0.05; beta level = 0.20).

The 26-week PPA and CA rates of 28.3% and 25.5%, respectively, are similar to that achieved in previous studies of NRT in combination with various behavioural treatments (see Table 2). Two previous studies have used the same 16-hour delivery nicotine patch as the current study, with two different levels of behavioural support (Sachs, et al., 1993; Tonnesen, et al., 1991). Tonnesen, Norregaard and Simonsen (1991) obtained a PPA rate of 28% at 6-month follow-up in a sample of 289 volunteers in a placebo-controlled trial of NRT combined with minimal behavioural support. Sachs, Sawe and Leischew (1993) achieved a CA rate of 34% at 6-month follow-up in a sample of 220 volunteer smokers participating in a placebo-controlled trial of NRT used in conjunction with a medical office setting but without the use of group counselling, psychological counselling, or behaviour modification.

The current results are also similar to those reported by Westman, Levin and Rose (1993). They conducted a study to determine the efficacy of the nicotine patch when combined with self-help materials, three brief visits, and telephone counselling. (The specific effect of telephone counselling was not isolated). One hundred and fifty-nine healthy volunteers who smoked at least one pack of cigarettes per day and desired to quit smoking were enrolled in a double-blind trial with 6-week treatment and 6-month follow-up periods. Subjects were randomly assigned to regimens of nicotine or placebo patches. Telephone counselling was given during weeks one, two, three, and five. Validated abstinence rates at six weeks, three months, and six months were 29.5%, 21.8%, and 20.5% in the active group, and 8.8%, 3.8%, and 2.5% in the placebo group ($P \leq .01$ for each comparison), respectively.

The current study was not specifically designed to evaluate the efficacy of the Guide Your Patients program (since it lacked an untreated control group). However, the results achieved by participants in the GYP only group provide some tentative evidence regarding the potential impact of the GYP program. The ability to generalize these results may be limited since the protocol implemented in the study (from recruitment through follow-up) may not be feasible in a normal office practice.

Although the current study did not have sufficient power to examine differences in quit rates in each of the strata created prior to treatment allocation, there was a tendency for quit rates to vary by gender and level of nicotine dependence. In descending order, overall PPA rates (when treatment groups were combined) were: 38.0% for low nicotine-dependent males, 28.3% for low nicotine-dependent females, 27.9% for high nicotine-dependent males, and 23.0% for high nicotine-dependent females.

No significant effects of treatment were found in the main survival analysis with all participants considered. When data were analysed in strata, low-nicotine dependent males receiving telephone counselling had a reduced time to relapse. The stratified survival analysis demonstrated that time-to-relapse varied by participant gender and level of nicotine dependence. Time to relapse was longest in low nicotine-dependent men, followed by low nicotine-dependent women, high nicotine-dependent women, and high nicotine-dependent men, in descending order of survival.

The results of the current study are strikingly different from results obtained during a pilot study. The pilot study showed an absolute increase of 10% in PPA at 26-week follow-up in favour of GYP+TC over GYP (28% vs. 18%; $p = .20$) in a sample of 119 smokers (Reid, et al., 1996). There were no differences in the selection procedures or changes in the personnel used between the pilot study and the current study. There was one change in the methods that may have accounted for some of the discrepancy in outcome. In the pilot study, participants in both treatment groups received only two physician counselling sessions. The first and second physician counselling sessions occurred as in the current study, two weeks before and four weeks after the target quit date, respectively. The third visit at 12 weeks in the pilot study was completed with a study coordinator, whereas a third visit with a study physician was added in the main study. The main difference in quit rates between the two studies occurred in the GYP group. In the pilot study, the GYP group achieved a quit rate of 18% at 26-week follow-up. In the current study, the GYP group achieved a quit rate of 29.6% at 26-week follow-up. The quit rate in the GYP+TC group was relatively stable between the two studies (28% in the pilot study, and 26.9% in the current study).

The lack of significant intervention effects at 26-week follow-up need to be interpreted in the context of the rather impressive abstinence rate in the GYP group. The GYP condition used in this study represented optimal medical treatment of the smoking patient, according to established guidelines. This put considerable pressure on the GYP+TC intervention to demonstrate a significant treatment effect under controlled circumstances. It is possible that telephone counselling could benefit smokers receiving less than optimal care or no care from their personal physician. To the extent that adjunctive treatment is necessary to maximize the impact of NRT, telephone counselling may be useful as an adjunct to self-administered NRT.

The method of recruitment to the study may have had an effect on the outcome. Clinical research samples assembled from reactive recruitment typically consist disproportionately of smokers who are in high motivation. There is some evidence that people who were recruited to the study in the first wave of recruitment (September 1995) were more likely to quit than people recruited during the second wave (January 1996). Quit rates for the two waves were 30.9% and 25.4%, respectively (p-value = 0.22). Within each recruitment wave, there was no evidence that participants in the cohort that started treatment within two weeks were more successful than participants in the cohort starting after six weeks.

One possible reason for the lack of effect for telephone counselling may lie in the high level of preparedness to quit smoking of participants in this study. Previous studies of telephone counselling have used volunteer and non-volunteer participants at a variety of stages of preparedness to quit, including precontemplation, contemplation and preparation. Curry et al (1995) found that outreach telephone counselling had its biggest and most consistent impact over the long term in smokers who were precontemplative at baseline. They found no significant effect of telephone counselling on participants who were in the preparation stage at baseline. In the current study, more than 80% of participants were in the preparation stage at baseline.

The counter-productive effect of telephone counselling on the time to relapse in low nicotine-dependent male smokers was surprising. Results for this subgroup are similar to the results observed by Prochaska, DiClemente, Velicer, and Rossi (1993) who found that telephone counselling detracted from the effectiveness of personalized messages provided by an expert (computerized) system. In their study, Prochaska and his colleagues speculated that the telephone counsellors may have pressured participants to take action when they were not ready. Men generally appear to prefer to use fewer processes of change while quitting than women. In the current study, men consistently used fewer cognitive and behavioural processes of change at each

of the measurement points before and during treatment (baseline, 4 weeks and 12 weeks post-quit date). It is also possible that telephone counselling in the current study reminded low nicotine-dependent men about smoking in a way that was not constructive or that tempted them to smoke. At baseline, low nicotine-dependent men reported the lowest number of temptations (data not shown) of any of the subgroups. From a treatment matching perspective, this suggests that low nicotine-dependent male smokers should not be offered telephone counselling if they are receiving care equivalent to the *Guide Your Patients* program.

Possible confounders were the interaction between the physician or telephone counsellor providing the care and the treatment condition. Stratified analyses showed that the study physicians and telephone counsellors each achieved similar rates of compliance and cessation among patients randomly assigned to their care.

Previous research has also established that participants in the later stages of change at baseline have an increased likelihood of being abstinent at follow-up (Prochaska and DiClemente, 1992; Prochaska, et al., 1992). The results were not confounded by this factor since the two treatment groups were comparable with respect to the proportion of participants in the contemplation and preparation stages at baseline.

Despite the random assignment of participants to the treatment conditions, there were baseline differences between the treatment groups with respect to confidence in habitual situations and total confidence. However, efficacy assessed prior to treatment has not been associated with treatment success (Candiotte and Lichtenstein, 1981; McIntyre, et al., 1983). There is evidence that post-treatment self-efficacy is the most predictive of smoking status at later follow-up (Baer, Holt, and Lichtenstein, 1986). Baseline differences in confidence were controlled for by the repeated measures ANOVA used in the analysis of the self-efficacy data.

The telephone counselling protocol used here had no additive effect over "best practices" for smoking cessation applied in a medical setting. It is possible that another schedule of telephone counselling may have helped. DeBusk and his colleagues (1994) evaluated a multicomponent home-based smoking cessation program for patients after acute myocardial infarction which included individual counselling, audiovisual materials, a workbook, NRT, and RN-initiated telephone follow-up at 2, 7, 21, and 90 days post-discharge. The intervention produced one-year, biochemically corroborated quit rates of 70% versus 53% for usual care. Zhu et al (1996) used a relapse-sensitive schedule which provided five counselling sessions over a 30 day period - three in the first two weeks and two over the next two weeks in their study of telephone support with a

self-help intervention. These authors suggest that the critical period for delivering counselling services is over the first one to two weeks.

Personal preference may play a role in the effectiveness of telephone counselling, although the current study was not designed to answer this specific question. People who indicated a preference for telephone counselling at baseline had the highest quit rate (34%) at 26-week follow-up, whereas people who identified no assistance as their preference had the worst quit rate (22%). Perhaps telephone counselling is best offered on an optional basis to people who think that this type of assistance may help them.

This is the first time that telephone counselling has been paired with other powerful interventions such as the structured physician advice and NRT that comprise the *Guide Your Patients* program. Previous studies have used telephone counselling only in combination with self-help materials, personalized feedback and social support training. It appears that telephone counselling may be more valuable if it is used in motivated volunteers with less powerful interventions (such as self-help). There is no incremental benefit when it is combined with already powerful interventions such as the *Guide Your Patients* program.

A secondary objective of this study was to explore the impact of proactive telephone counselling on the use of processes of change during smoking cessation. Analyses of the various processes of change indicated that eight of 10 processes of change changed significantly during the treatment period, but there were no differences in the use of the processes of change between the two treatment groups. As suggested by the transtheoretical model (Prochaska and DiClemente, 1992), the onset of treatment coincided with a decline in the use of cognitive/experiential processes of change, and the increased use of all behavioural processes of change, in particular, counterconditioning, stimulus control and self-liberation. While there is evidence that there were positive changes in the processes of change during the treatment period, these changes are not necessarily attributable to treatment. It is conceivable that limitations in the reliability of the measures and demand characteristics could account for some or all of the observed change: there was no untreated control group to assess these issues.

During the treatment period, it was observed that successful quitters endorsed significantly less use of self-reevaluation processes and more use of counterconditioning and helping relationships than people who had relapsed by the 26-week follow-up point. Partially consistent with the findings in the current study, the cross-sectional study of Ahijevch and Wewers (1992) reported that long-term quitters made frequent use of environmental reevaluation and counterconditioining. More

generally. Prochaska and DiClemente (1992) found successful quitters used more behavioural processes (such as counterconditioning and helping relationships) in the action stage of quitting.

The third objective of this study was to explore the impact of telephone counselling on the development of self-efficacy during smoking cessation. It had been hypothesized that telephone counselling would enhance the development of self-efficacy. There was no effect of treatment on the development of self-efficacy in social, negative affect, or habitual situations or on total self-efficacy. Both treatments resulted in significant enhancements in self-efficacy during the treatment period. Confidence in social, negative affect and habitual situations increased significantly between the baseline and mid-treatment assessment points and remained high or decreased slightly through the end of treatment. As with the evaluation of changes in the use of processes of change during treatment, changes in self-efficacy may not necessarily be attributable to treatment. There was no untreated control group to assess these changes.

The results of the current study are consistent with previous studies that have demonstrated that perceived self-efficacy increases during successful treatment (Candiotte and Lichtenstein. 1981; Coelho, 1984; de Vries and Backbier. 1994; DiClemente, 1986; DiClemente, et al., 1985; O'Leary, 1985). At the end of treatment, participants who were able to stop smoking had significantly greater self-efficacy expectations than those who had not. Post-treatment self-efficacy evaluations are significant predictors of maintenance of smoking cessation, at least in the short-term of three to six months after treatment (Coelho, 1984; McIntyre, et al., 1983). There is potential for circular explanations in the discussion of the relationship between self-efficacy and abstinence, i.e., are people abstinent because their self-efficacy is high or is their self-efficacy high because they are abstinent? (Baer, et al., 1986).

Similarities between the groups with respect to cessation outcomes are consistent with the similarities between the groups for processes of change and self-efficacy, key psychological and behavioural factors that underlie the quitting process.

In examining the characteristics of individuals who were successful, regression analysis identified perceived stress at baseline, level of nicotine dependence, and educational attainment as factors which were predictive of abstinence at 26-week follow-up. Participants with a low level of stress (PSS < 8), post-secondary education, and/or a low FTQ score (< 7) at baseline were more likely to be abstinent at follow-up.

A number of other studies have examined predictors of smoking cessation. Norregaard, Tonnesen and Petersen (1993) identified predictors and reasons for relapse with nicotine and placebo patches in a study of 289 volunteer subjects participating in a smoking cessation trial. Stepwise multiple logistic regression analysis showed nicotine treatment (as opposed to placebo treatment) to be the most important predictor of outcome after six weeks. For nicotine treated subjects, subjects who had tried to quit before had higher abstinence rates (odds ratio = 6.7, CI: 1.8-24.7). Saliva cotinine concentration at baseline (indicative of baseline nicotine intake) was the most important smoking-related parameter (> 425 ng/ml odds ratio = 0.4, CI: 0.3-0.8). Other predictors (years smoking, Horn-Russell Scale score, BMI, cigarette consumption, age, sex, and FTQ score) failed to reach statistical significance. None of the predictor variables reached significance using abstinence at 1-year as the dependent variable.

Nides, Rakos, Gonzales, Murray, Tashkin and Bjornson-Benson (1995) analysed predictors of end-of-treatment (four months) smoking cessation and subsequent relapse at 12 and 24 months among 3,923 participants enrolled in the Lung Health Study's cognitive-behavioural group smoking cessation program. Nicotine gum (2 mg) was available to all participants. Baseline variables associated with initial quitting in both genders included greater education, being married, lower nicotine dependence, and fewer respiratory symptoms. Social support for quitting also contributed to the prediction of initial quitting. Both men and women were more likely to quit if there were no other smokers in the house, and men were more likely to quit if a support person attended the smoking cessation orientation meeting.

6.0 CONCLUSIONS

Physician assistance, as described in the *Guide Your Patients to a Smoke-Free Future* program, and incorporating nicotine replacement therapy, can help some well-motivated volunteer smokers to quit smoking. Quit rates are not improved by the addition of nurse-mediated telephone counselling. Additional research may determine if telephone counselling benefits smokers receiving less than optimal assistance from their physician, or smokers who self-select this form of assistance. Further studies may also determine if a different telephone intervention or altered timing of the calls could yield different results.

The current study was not specifically designed to evaluate the efficacy of the Guide Your Patients program. However, these findings generally support the notion that a well-conducted brief intervention by physicians, supported with NRT and self-help materials, can have a significant effect on the smoking behaviour of relatively heavy smokers. The results achieved by participants in the control (GYP) group provide some tentative evidence regarding the potential impact of the Guide Your Patients program. The ability to generalize these results to a normal office practice may be limited by the method of recruitment and follow-up procedures used in this study.

Since overall cessation rates are highest in low nicotine-dependent smokers, NRT use should be more frequently extended to low dependent smokers, rather than being reserved for high nicotine dependent smokers.

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APPENDIX A: *RADIO SPOTS - Study Recruitment*

Advertisement #1 - Opening speaker is a male, about age 40.

Male Ex-Smoker:

I must have tried a hundred times to quit smoking. But nothing ever made me stop for good. Having to smoke outside in the rain and cold didn't do it. My kids nagging me all the time didn't do it. Even watching what smoking did to my *own* dad's health wasn't enough to make me quit. I felt like there was no point in even trying anymore. So when my doctor asked, I said that I would never be able to quit -- case closed, you know? But he said there was something that might help me .....

Announcer:

The University of Ottawa Heart Institute is recruiting smokers for a stop-smoking study. If you're nineteen or older, smoke at least 15 cigarettes a day - and really want to quit - you may be eligible. To find out more, call 761-4753. That's 761-4753, to see if you qualify for this 13-week study. This study uses a product that helps relieve your physical craving for cigarettes. Even if you've tried before and failed, you may still be eligible. Call 761-4753.

Advertisement #2 - Opening speaker is an ex-smoker, a woman about 45 years old.

Female ex-smoker:

People who don't smoke don't understand what it's like to quit --- it's hard ..... Really hard. I never made it through more than a week without starting up again. And the terrible thing was, each time I caved in, I would be thinking ---- as I lit up that cigarette ---- "oh, I really wanted to quit this time." When my doctor suggested I quit smoking, I told her that I had tried many times .... And just couldn't pull it off. And she said that most people who want to quit try several times -- and that some people just need a little extra help ....

Announcer:

Same as in Advertisement #1.

APPENDIX B: *Operational Definitions For Exclusion Factors*

Exclusion Factor	Operational Definition
1. Participation in another program for smoking cessation.	Participant is participating in another program of smoking cessation.
2. Pregnancy or lactation.	Participant is a woman who is pregnant, or nursing or is planning to become pregnant in the near future.
3. Unreliable birth control.	Participant is a woman who is of child-bearing potential and is not using a reliable method of birth control.
4. Recent heart disease.	Participant has had a heart attack within the past 6 months.
5. Severe heart disease.	Participant has severe heart disease (NYHA Class III or greater).
6. Active or untreated arrhythmias.	Participant has clinical evidence of major rhythm or conduction disturbance requiring treatment with anti-arrhythmic medication.
7. Cerebral vascular disease.	Participant has a clinical history of severe atherosclerotic cerebral vascular disease.
8. Liver or kidney disease.	Participant has severe liver disease (liver enzymes twice the upper limit of "normal", other gastrointestinal tract or renal disease (creatinine > 2.0 mg/dL), which could alter the absorption, metabolism or excretion of the study drug.
9. Other systemic diseases.	Participant is suffering from neutropenia (WBC < 2.5 X 10^9/L), failure of a major organ system, severe infection, or malignancy.
10. Dermatological disorders.	Participant has contraindications to, or known hypersensitivity to, transdermal nicotine replacement therapy.
11. Alcoholism or drug abuse.	Participant has current or past diagnosis for alcohol or drug abuse; current recreational drug use.
12. Psychiatric illness.	Participant is currently using psychotropic medications; and/or has had psychiatric episodes within the past 12 months.
13. Diabetes.	Participant has diabetes requiring insulin.

APPENDIX C:

STUDY TITLE: TELEPHONE COUNSELLING AS AN ADJUNCT TO NICOTINE REPLACEMENT THERAPY IN SMOKING CESSATION

PARTICIPANT INFORMED CONSENT

INTRODUCTION

I understand that I am being asked to take part in a research study being conducted by the Smoking Cessation Clinic at the University of Ottawa Heart Institute Prevention and Rehabilitation Centre. The Principal Investigator for this project is Dr. Andrew Pipe. The Co-Investigator is Mr. Bob Reid. The purpose of this study is to evaluate different forms of educational advice designed to assist smokers attempting to quit smoking using nicotine replacement therapy (the "nicotine patch"). In addition, the data from this study will be used by Mr. Reid in the preparation of a doctoral thesis for the Department of Health Studies at the University of Waterloo. This thesis research is being supervised by Dr. Roy Cameron at the University of Waterloo. This study will involve my quitting smoking and using a nicotine patch called NICOTROL with one of two levels of educational support. NICOTROL is a form of nicotine replacement therapy (patch) and has been approved in Canada by the Health Protection Branch for use as an aid to individuals who are quitting smoking.

PROCEDURES

In order to determine my eligibility for participation in this study, I will be asked to complete a number of paper and pencil surveys which ask about my experience with and attitude toward cigarette smoking/use of tobacco. If I am eligible to participate in this study, I will have a physical exam completed by a study physician and blood work (a single sample of approximately 2 tablespoons) completed. If I am enrolled in the study, I understand that I will then be randomized (like the toss of a coin) to receive a treatment program for smoking cessation that does or does not include a telephone counselling component. The doctor will not know which program I am receiving.

The study will require me to visit the Heart Institute 6 times over the next year. Together with a study physician, I will establish a date to quit smoking. Treatment during smoking cessation will consist of two clinic visits 4 and 12 weeks after my quit date, and the use of the nicotine patch over a period of 12 weeks from my target quit date. Each clinic visit will last approximately 15-20 minutes. At each clinic visit, I will also be asked to complete a number of questionnaires. These questionnaires will take approximately 15 minutes to complete. There are 3 dosage strengths of the NICOTROL patches. I understand that I will use the NICOTROL patch for a total of 12 weeks. I will begin my treatment with the starting dose of NICOTROL. After 8 weeks, I will be given smaller patches containing less nicotine. These patches will be used for 2 weeks. For the final 2 weeks of my treatment I will use the smallest patch. If I am randomized to the group that is to receive telephone counselling, I must also be willing to receive telephone calls from a study counsellor on a three occasions during the treatment period. Each telephone call will take approximately 20 minutes. I will provide to the study coordinator a time to receive these calls that is convenient to me.

Follow-up by mail, telephone and in person will occur 6 and 12 months after the beginning of the study. At each visit, my progress will be followed through the use of questionnaires. I will also be asked to provide a breath sample or a saliva sample (1 table spoon) to assess my smoking status. No hospitalization is required for this study.

RISKS

I understand that there are some risks involved. As with any blood sampling procedure, drawing blood may result in pain or bruising at the needle site. I may also be inconvenienced by receiving telephone counselling at home or work and by returning to the Heart Institute for treatment and follow-up tracking visits.

I understand that I must not smoke while using a NICOTROL patch because the risk of side effects will increase. Possible side effects of using the NICOTROL patch include headache, dizziness, upset stomach, and skin irritation. Should any of these side effects occur, I should contact the study coordinator at 761-4753. The study doctor will stop the medication. If any new problems and side effects occur which are not listed and are not expected, I will be informed of any changes in the way the study will be done and any new risks to which I may be exposed.

If I am a women, I should not become pregnant (that is, I should use a reliable method of birth control) while I am using the NICOTROL patches during the first 12 weeks of the study.

I also understand that I should not participate in this study if:

- I am a woman, and am pregnant or breast-feeding;
- I have recently (within the past 6 months) suffered a heart attack;
- I have severe heart disease;
- I have kidney or liver disease;
- I have diabetes requiring insulin;
- I am being treated for a psychiatric illness;
- I have alcohol or other chemical dependencies.

NICOTROL can be poisonous to children or pets if applied to the skin or swallowed. I understand that I must keep new or used NICOTROL patches out of the reach of children and pets.

BENEFITS

The potential benefits of participating in the study, above and beyond normal treatment, include: an improved chance of successful smoking cessation; and structured support and care during smoking cessation.

REMUNERATION

I will not receive money for participation in this study. I understand that if I agree to voluntarily participate in the study, NICOTROL patches will be provided at no cost to me (approximate value = $350). I will be reimbursed for parking for the follow-up tracking visits at 26 and 52 weeks.

CONFIDENTIALITY

I understand that no information bearing my name will leave the University of Ottawa Heart Institute and I will be identified by study number only. The data collected may be examined by the study sponsors, McNeil Consumer Products and the National Cancer Institute of Canada. Results from this study may be published in the final research report, but under no circumstances would any names or identifying characteristics be used. I will receive a copy of this consent and an executive summary of the study once it has been completed.

PARTICIPATION

Participation in this study is entirely voluntary. I may refuse to answer any questions or refuse any component of the evaluation at any time. I may discontinue my participation in this study at any time without giving any reasons for discontinuation. Discontinuation of participation would in no way reflect on further care which is received either from my own physician or from the University of Ottawa Heart Institute.

I have been invited to discuss any further questions about this study with the investigator, Dr. Andrew Pipe at 761-4682 or the co-investigator, Bob Reid at 761-5058.

I agree to participate in this study.

_____
Name (please print)

_____ _____
Participant Signature Witness

_____
Date

_____
Investigator's Signature

APPENDIX D: HEART INSTITUTE SMOKING STUDY PARTICIPANT INTAKE QUESTIONNAIRE

Name: _____ **Today's Date:** _____
Tel# H: _____ **W:** _____
Mailing Address:
_____
City: _____ **Province:** _____ **Postal Code:** _____
Family or Referring Physician: _____
Participant Number:

A. DEMOGRAPHICS

1. Gender
Male____ Female_____

2. Age
Date of Birth _____/_____/_____ Age_____ yrs
Y M D

3. Education

Check off the highest level of education completed:
i) Primary school _____
ii) High school _____
iii) College _____
iv) University _____

4. Height: ____ in/cm. Weight: _____lbs/kg.

5. What language do you speak at home? English French Other

B. MEDICAL HISTORY

1. Has a physician told you that you suffer from any of the following conditions or illnesses? (Check all that apply).

Heart attack _____
Coronary heart disease _____
Angina _____
Stroke _____
Blood vessel disease _____
Diabetes _____
High blood pressure _____
Kidney disease _____
Liver disease _____
Lung disease _____
Cancer _____

2. Have you ever been treated for alcoholism or other drug dependency?
yes..... 1
no..... 2

3. Have you ever had any known indication of or been treated for a mental disorder or psychosis?
yes..... 1
no..... 2

(Questions B4 - 6 apply to women only).

4. Are you currently pregnant?
yes..... 1
no..... 2

5. Are you currently lactating or breast feeding?
yes..... 1
no..... 2

6. If you are in your child bearing years, are you currently using a reliable form of birth control?
yes..... 1
no..... 2

C. SMOKING STATUS AND HISTORY

1. Do you currently smoke cigarettes?
yes..... 1
no..... 2

2. Have you smoked any cigarettes during the past 6 months?
yes..... 1
no..... 2

3. Are you seriously considering quitting within the next 6 months?
yes..... 1
no..... 2

4. Are you planning to quit in the next 30 days?
yes..... 1
no..... 2

5. In the last year, how many times have you quit for a least 24 hours?
0____1____ 2____3____4____5____6____7____8____9____>9____

6. On average how many cigarettes per day do you smoke? _____ cigs/day.

7. What is the name of your usual brand? _____

8. At what age did you begin smoking on a daily basis? ____yrs.

D. USE OF OTHER SMOKING CESSATION MATERIALS

1. Do you currently use any of the following products? (check all that apply)

   ___ Nicotine gum (e.g. Nicorette)
   ___ Nicotine patch (e.g., Nicoderm, Habitrol, Pro-step, Nicotrol)
   ___ Lifesign Computer
   ___ Other smoking cessation devices? _____

2. Are you currently participating in a stop-smoking program?
   yes..... 1
   no..... 2

E. NICOTINE DEPENDENCE

1. How soon after you wake up do you smoke your first cigarette.
   within 30 min..... 1
   after 30 min..... 0

2. Do you find it difficult to refrain from smoking in places where it is forbidden?
   yes..... 1
   no..... 0

3. Which cigarette would you hate most to give up?
   the first one in the morning..... 1
   any other..... 0

4. How many cigarettes/day do you smoke?
   15 or less..... 0
   16-25..... 1
   26 or more..... 2

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?
   yes..... 1
   no..... 0

6. Do you smoke if you are so ill that you are in bed most of the day?
   yes..... 1
   no..... 0

7. What is the nicotine level of your usual brand of cigarette?
   0.9 mg or less..... 0
   1.0-1.2 mg..... 1
   1.3 mg or more..... 2

8. Do you inhale?
   never... 0
   sometimes... 1
   always..... 2

F. SMOKERS IN YOUR ENVIRONMENT

1. What percentage of your friends smoke?

0% 10 20 30 40 50 60 70 80 90 100%

2. What percentage of your co-workers smoke?

0% 10 20 30 40 50 60 70 80 90 100%

3. What percentage of time do you spend with others who smoke?

0% 10 20 30 40 50 60 70 80 90 100%

4. How many smokers currently live in your household?

Please fill in the number _____

5. Are you exposed to other people's tobacco smoke at work?
yes..... 1
no..... 2

6. If you have a spouse or partner, does this person smoke?
yes..... 1
no..... 2

Does this person live in the same household as you?
yes..... 1
no..... 2

Please estimate how much this person smokes: _____ cigarettes per day

7. Please think about your social activities in the average week. At what percentage of these activities is there someone (or a group of people) smoking? Please circle one number.

0% 10 20 30 40 50 60 70 80 90 100%

G. PROS AND CONS OF SMOKING

The following statements represent different opinions about smoking. Please rate HOW IMPORTANT each statement is to your decision to smoke according to the following 5 point scale with 5 = Extremely Important and 1 = Not Important.

	Not Important				Extremely Important
1. Smoking cigarettes relieves tension.	1	2	3	4	5
2. I'm embarrassed to have to smoke.	1	2	3	4	5
3. Smoking helps me concentrate and do better work.	1	2	3	4	5
4. My cigarette smoking bothers others.	1	2	3	4	5
5. I am relaxed and therefore more pleasant when smoking.	1	2	3	4	5
6. People think I'm foolish for ignoring the warnings about cigarette smoking.	1	2	3	4	5

H. IMPACTS ON SMOKING

The following experiences can affect the smoking pattern of some people. Think of any similar experiences you may be currently having or have had in the last month. Then rate the FREQUENCY of each event on a 5 point scale with 5 = Repeatedly and 1 =Never.

	Never		Occasionally		Repeatedly
1. When I am tempted to smoke, I think about something else.	1	2	3	4	5
2. I tell myself I can quit smoking if I want to.	1	2	3	4	5
3. I notice that nonsmokers are asserting their rights.	1	2	3	4	5
4. I recall information people have given me on the benefits of quitting smoking.	1	2	3	4	5
5. I can expect to be rewarded by others if I don't smoke.	1	2	3	4	5
6. I stop to think that smoking is polluting the environment.	1	2	3	4	5
7. Warnings about the health hazards of smoking move me emotionally.	1	2	3	4	5
8. I get upset when I think about my smoking.	1	2	3	4	5
9. I remove things from my home or place of work that remind me of smoking.	1	2	3	4	5
10. I have someone who listens when I need to talk about my smoking.	1	2	3	4	5
11. I think about information from articles and ads on how to stop smoking.	1	2	3	4	5
12. I consider the view that smoking can be harmful to the environment.	1	2	3	4	5
13. I tell myself that if I try hard enough I can keep from smoking.	1	2	3	4	5
14. I find society changing in ways that make it easier for nonsmokers.	1	2	3	4	5
15. My need for cigarettes makes me feel disappointed in myself.	1	2	3	4	5
16. I have someone I can count on when I'm having problems with smoking.	1	2	3	4	5
17. I do something else instead of smoking when I need to relax.	1	2	3	4	5
18. I react emotionally to warnings about smoking cigarettes.	1	2	3	4	5
19. I keep things around my home or place of work that remind me not to smoke.	1	2	3	4	5
20. I am rewarded by others if I don't smoke.	1	2	3	4	5

I. TEMPTATIONS TO SMOKE

The following is a list of situations that lead some people to smoke. Please indicate how **tempted** you would feel to smoke in each of these situations by circling the appropriate number.

	Not at all tempted	Slightly tempted	Moderately tempted	Very tempted	Extremely tempted
1. At a bar or cocktail lounge having a drink.	1	2	3	4	5
2. When I am desiring a cigarette.	1	2	3	4	5
3. When things are just not going the way I want and I am frustrated.	1	2	3	4	5
4. With my spouse or close friend who is smoking.	1	2	3	4	5
5. When there are arguments and conflicts with my family.	1	2	3	4	5
6. When I am happy and celebrating.	1	2	3	4	5
7. When I am very angry about something or someone.	1	2	3	4	5
8. When I would experience an emotional crisis, such as an accident or death in the family.	1	2	3	4	5
9. When I see someone smoking and enjoying it.	1	2	3	4	5
10. Over coffee while talking and relaxing.	1	2	3	4	5
11. When I realize that quitting smoking is an extremely difficult task for me.	1	2	3	4	5
12. When I am craving a cigarette.	1	2	3	4	5
13. When I first get up in the morning.	1	2	3	4	5
14. When I feel I need a lift.	1	2	3	4	5
15. When I begin to let down on my concern about my health and am less physically active.	1	2	3	4	5
16. With friends at a party.	1	2	3	4	5
17. When I wake up in the morning and face a tough day.	1	2	3	4	5
18. When I am extremely depressed.	1	2	3	4	5
19. When I am extremely anxious and stressed.	1	2	3	4	5
20. When I realize I haven't smoked for awhile.	1	2	3	4	5

J. CONFIDENCE IN NOT SMOKING

Here is the same list of situations from the previous page. This time, please indicate how **confident** you are that you would not smoke in each of these situations by circling the appropriate number.

	Not at all Confident	Slightly Confident	Moderately Confident	Very Confident	Extremely Confident
1. At a bar or cocktail lounge having a drink.	1	2	3	4	5
2. When I am desiring a cigarette.	1	2	3	4	5
3. When things are just not going the way I want and I am frustrated.	1	2	3	4	5
4. With my spouse or close friend who is smoking.	1	2	3	4	5
5. When there are arguments and conflicts with my family.	1	2	3	4	5
6. When I am happy and celebrating.	1	2	3	4	5
7. When I am very angry about something or someone.	1	2	3	4	5
8. When I would experience an emotional crisis, such as an accident or death in the family.	1	2	3	4	5
9. When I see someone smoking and enjoying it.	1	2	3	4	5
10. Over coffee while talking and relaxing.	1	2	3	4	5
11. When I realize that quitting smoking is an extremely difficult task for me.	1	2	3	4	5
12. When I am craving a cigarette.	1	2	3	4	5
13. When I first get up in the morning.	1	2	3	4	5
14. When I feel I need a lift.	1	2	3	4	5
15. When I begin to let down on my concern about my health and am less physically active.	1	2	3	4	5
16. With friends at a party.	1	2	3	4	5
17. When I wake up in the morning and face a tough day.	1	2	3	4	5
18. When I am extremely depressed.	1	2	3	4	5
19. When I am extremely anxious and stressed.	1	2	3	4	5
20. When I realize I haven't smoked for awhile.	1	2	3	4	5

K. PERCEIVED STRESS

1. In the last month, how often have you felt that you were unable to control the important things in your life?

never	0
almost never	1
sometimes	2
fairly often	3
very often	4

2. In the last month, how often have you felt confident about your ability to handle your personal problems?

never	0
almost never	1
sometimes	2
fairly often	3
very often	4

3. In the last month, how often have you felt that things were going your way?

never	0
almost never	1
sometimes	2
fairly often	3
very often	4

4. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

never	0
almost never	1
sometimes	2
fairly often	3
very often	4

L. PREFERENCES

1. Under normal circumstances, that is, if you were not involved in this research study, what kinds of counselling assistance would you <u>most</u> prefer to help you quit smoking? (Circle only one).

No assistance preferred	1
Self-help materials	2
Individual counselling	3
Group counselling	4
Telephone counselling	5

APPENDIX E: HEART INSTITUTE SMOKING STUDY
Physician and Clinical Data Form

Participant No. _____ **Initials** _____
Visit Date: _____ **Physician:** _____
day month year

A. INCLUSION CRITERIA

		No	Yes
1.	Participant is at least 19 years of age.	___	___
2.	Participant smokes at least 15 cigarettes per day.	___	___
3.	Participant is seriously interested in quitting smoking.	___	___
4.	Participant has provided informed consent before any study procedure or change in treatment has occurred.	___	___

If the answer to any of the above questions is NO, the participant is not eligible for inclusion into the study.

B. EXCLUSION CRITERIA

1.	Participant is participating in another program of smoking cessation.	___	___
2.	Participant is a woman who is pregnant, or nursing or is planning to become pregnant in the near future.	___	___
3.	Participant is a woman who is of child bearing potential and who is not using a reliable method of birth control.	___	___
4.	Participant has had a heart attack within the past 6 months.	___	___
5.	Participant has severe heart disease (NYHA Class III or greater).	___	___
6.	Participant has clinical evidence of major arrhythmia or conduction disturbance requiring treatment with antiarrhythmic medication.	___	___
7.	Participant has severe atherosclerotic cerebral vascular disease.	___	___
8.	Participant has severe liver disease (liver enzymes twice the upper limit of "normal"), other gastrointestinal tract or renal disease (creatinine > 2.0mg/dL), which could alter the absorption, metabolism, or excretion of the study drugs.	___	___
9.	Participant is suffering from neutropenia (WBC < 2.5 x 10^9/L), failure of a major organ system,	___	___

severe infection, or malignancy.

10. Participant has contraindications to, or known hypersensitivity to transdermal nicotine replacement therapy. ____ ____

11. Participant has a history of alcoholism or other drug abuse (past diagnosis or treatment for alcohol or drug abuse; current recreational drug use). ____ ____

12. Participant is suffering from a psychiatric illness. (Current use of psychotropic medications; psychiatric episodes within the past 12 months) ____ ____

13. Participant has diabetes requiring insulin. ____ ____

If the answer to any of the above questions is YES, the participant is not eligible for inclusion in the study.

C. OTHER MEDICATIONS:

List any other medications the participant is taking.

Type	Name	Dose	Comments
Blood Pressure			
Cholesterol Reduction			
Heart			
Birth Control			
Hormones			
Other			

Allergies:

_____

_____

_____

D. CLINICAL TEST DATA

Visit: **Date:**	**Pre** ----------	**TR1** ----------	**TR2** ----------	**FU1** ----------	**FU2** ----------
Blood Pressure (mm Hg)					
Weight (kg)					
CO (ppm)					
Has the patient smoked (even a puff) in the past 7 days?					
Has the patient smoked (even a puff) since the last appointment?					

APPENDIX F: HEART INSTITUTE SMOKING STUDY

Physician Contact Sheet
Treatment Visit # 1

Participant No. _____ **Initials** _____
Visit Date: _____ **Physician:** _____
day month year

A. ASK

8 Smoking status — number of years smoked _____ years
number of cigarettes per day 8 < 20 8 > 20
first cigarette 8 > 30 min. 8 < 30 min.

8 Reasons to stop _____

8 Concerns about stopping/reasons not to stop
8 withdrawal 8 weight gain 8 other smokers 8 other _____

B ADVISE

"You've made an excellent decision to quit smoking. I can support you and help you stop smoking. Let's talk about some things that might help you to quit."

C. ASSIST

8 Have patient use Stop Smoking Now! video and booklet <u>before</u> quit date to develop plan

8 Past attempts discussed 8 Why Test discussed

8 Symptoms of withdrawal are normal

8 Negotiate Target Quit Date (the patient must select a day within the next week)

_____
day month year

8 Address Personal Concerns

8 withdrawal - lasts 3-5 days, then decreases

- urges last 3-5 minutes and decrease over 2-3 weeks

8 weight gain - exercise, eat right, stress control

8 other smokers - avoid triggers, contract them to help you

8 other _____

8 Describe use of Nicotrol patch

8 apply first thing in the AM

8 apply to smooth, clean part of the skin - use different site each day

8 remove the patch before retiring at night

8 Behavioural Strategies
8 Triggers - meals, coffee, alcohol, stress, weight gain
- avoidance, change routine, plan response
8 Attitude - you are in control
- rewards
8 Stress - one day at a time, relaxation, activity, caffeine, limit worrying

8 Discuss Relapse Prevention

APPENDIX G: HEART INSTITUTE SMOKING STUDY
Physician Contact Sheet
Treatment Visit # 2 and 3

Participant No. _____ **Initials** _____
Visit Date: _____ **Physician:** _____
day month year

A. ASK

8 Smoking status

Smoked (even a puff) in the past 7 days? 8 Yes 8 No
Smoked (even a puff) since the last appointment? 8 Yes 8 No
Date of relapse _____

If no, congratulate on success to date

B. ASSIST

8 Assess quit attempt/discuss relapse as a predictor of success

8 Address concerns (CHECK)

8 withdrawal reactions/cravings	8 cut down so don't need to quit
8 weight gain/increased appetite	8 need to cut down more
8 handling negative emotions/stress	8 lack willpower
8 loss of pleasure/companion	8 low confidence/fear failure
8 slips/temptations	8 too much pressure to quit
8 travel	8 not enough support
8 ambivalence	8 need extra help/clinic
8 poor timing	8 other

IF SMOKING

8 Re-negotiate Target Quit Date (the patient must select a day within the next week)

_____
day month year

8 Direct patient to review information in self-help material

8 If discontinued patch because of side effects, restart on smaller dose on new quit date

IF NOT SMOKING

8 Discuss relapse prevention plan

8 Review common situations associated with relapse

8 environmental cues, especially alcohol

8 emotional stress

8 when around others who continue to smoke

8 when undesired weight gain occurs

8 Review delay, avoidance and substitution strategies to cope with these situations

APPENDIX H: *Participant Treatment Questionnaire*

Today's Date:_____ TR1___ TR2___
Participant Number:_____

A. SMOKING STATUS

1. Have you smoked a cigarette, even a puff, in the last 7 days? Yes____No_____
2. Have you smoked a cigarette, even a puff, since we last contacted you?Yes____No____
3. Date of relapse_____

B. IMPACTS ON SMOKING

The following experiences can affect the smoking pattern of some people. Think of any similar experiences you may be currently having or have had in the last month. Then rate the FREQUENCY of each event on a 5 point scale with 5 = Repeatedly and 1 = Never.

	Never		Occasionally		Repeatedly
1. When I am tempted to smoke, I think about something else.	1	2	3	4	5
2. I tell myself I can quit smoking if I want to.	1	2	3	4	5
3. I notice that nonsmokers are asserting their rights.	1	2	3	4	5
4. I recall information people have given me on the benefits of quitting smoking.	1	2	3	4	5
5. I can expect to be rewarded by others if I don't smoke.	1	2	3	4	5
6. I stop to think that smoking is polluting the environment.	1	2	3	4	5
7. Warnings about the health hazards of smoking move me emotionally.	1	2	3	4	5
8. I get upset when I think about my smoking.	1	2	3	4	5
9. I remove things from my home or place of work that remind me of smoking.	1	2	3	4	5
10. I have someone who listens when I need to talk about my smoking.	1	2	3	4	5
11. I think about information from articles and ads on how to stop smoking.	1	2	3	4	5
12. I consider the view that smoking can be harmful to the environment.	1	2	3	4	5
13. I tell myself that if I try hard enough I can keep from smoking.	1	2	3	4	5
14. I find society changing in ways that make it easier for nonsmokers.	1	2	3	4	5
15. My need for cigarettes makes me feel disappointed in myself.	1	2	3	4	5
16. I have someone I can count on when I'm having problems with smoking.	1	2	3	4	5
17. I do something else instead of smoking when I need to relax.	1	2	3	4	5
18. I react emotionally to warnings about smoking cigarettes.	1	2	3	4	5
19. I keep things around my home or place of work that remind me not to smoke.	1	2	3	4	5
20. I am rewarded by others if I don't smoke.	1	2	3	4	5

C TEMPTATIONS TO SMOKE

The following is a list of situations that lead some people to smoke. Please indicate how **tempted** you would feel to smoke in each of these situations by circling the appropriate number.

	Not at all tempted	Slightly tempted	Moderately tempted	Very tempted	Extremely tempted
1. At a bar or cocktail lounge having a drink.	1	2	3	4	5
2. When I am desiring a cigarette.	1	2	3	4	5
3. When things are just not going the way I want and I am frustrated.	1	2	3	4	5
4. With my spouse or close friend who is smoking.	1	2	3	4	5
5. When there are arguments and conflicts with my family.	1	2	3	4	5
6. When I am happy and celebrating.	1	2	3	4	5
7. When I am very angry about something or someone.	1	2	3	4	5
8. When I would experience an emotional crisis, such as an accident or death in the family.	1	2	3	4	5
9. When I see someone smoking and enjoying it.	1	2	3	4	5
10. Over coffee while talking and relaxing.	1	2	3	4	5
11. When I realize that quitting smoking is an extremely difficult task for me.	1	2	3	4	5
12. When I am craving a cigarette.	1	2	3	4	5
13. When I first get up in the morning.	1	2	3	4	5
14. When I feel I need a lift.	1	2	3	4	5
15. When I begin to let down on my concern about my health and am less physically active.	1	2	3	4	5
16. With friends at a party.	1	2	3	4	5
17. When I wake up in the morning and face a tough day.	1	2	3	4	5
18. When I am extremely depressed.	1	2	3	4	5
19. When I am extremely anxious and stressed.	1	2	3	4	5
20. When I realize I haven't smoked for awhile.	1	2	3	4	5

D. CONFIDENCE IN NOT SMOKING

Here is the same list of situations from the previous section. This time, please indicate how **confident** you are that you would not smoke in each of these situations by circling the appropriate number.

	Not at all Confident	Slightly Confident	Moderately Confident	Very Confident	Extremely Confident
1. At a bar or cocktail lounge having a drink.	1	2	3	4	5
2. When I am desiring a cigarette.	1	2	3	4	5
3. When things are just not going the way I want and I am frustrated.	1	2	3	4	5
4. With my spouse or close friend who is smoking.	1	2	3	4	5
5. When there are arguments and conflicts with my family.	1	2	3	4	5
6. When I am happy and celebrating.	1	2	3	4	5
7. When I am very angry about something or someone.	1	2	3	4	5
8. When I would experience an emotional crisis, such as an accident or death in the family.	1	2	3	4	5
9. When I see someone smoking and enjoying it.	1	2	3	4	5
10. Over coffee while talking and relaxing.	1	2	3	4	5
11. When I realize that quitting smoking is an extremely difficult task for me.	1	2	3	4	5
12. When I am craving a cigarette.	1	2	3	4	5
13. When I first get up in the morning.	1	2	3	4	5
14. When I feel I need a lift.	1	2	3	4	5
15. When I begin to let down on my concern about my health and am less physically active.	1	2	3	4	5
16. With friends at a party.	1	2	3	4	5
17. When I wake up in the morning and face a tough day.	1	2	3	4	5
18. When I am extremely depressed.	1	2	3	4	5
19. When I am extremely anxious and stressed.	1	2	3	4	5
20. When I realize I haven't smoked for awhile.	1	2	3	4	5

E. PERCEIVED STRESS

1. In the last month, how often have you felt that you were unable to control the important things in your life?

never	0
almost never	1
sometimes	2
fairly often	3
very often	4

2. In the last month, how often have felt confident about your ability to handle your personal problems?

never	0
almost never	1
sometimes	2
fairly often	3
very often	4

3. In the last month, how often have you felt that things were going your way?

never	0
almost never	1
sometimes	2
fairly often	3
very often	4

4. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

never	0
almost never	1
sometimes	2
fairly often	3
very often	4

SCORE:

F. NICOTINE REPLACEMENT THERAPY

THE FOLLOWING INFORMATION IS TO BE FILLED IN BY STUDY PERSONNEL ONLY.

1. Using prescription: yes____ no____ dose___

2. Side effects/overdose effects:

1.	skin irritation	2.	itchiness or redness
3.	sleep disturbances	4.	headaches
5.	dizziness	6.	anxiety
7.	irritability	8.	stomach upset
9.	drooling	10.	vomiting/diarrhea
11.	cold sweat	12.	blurred vision
13.	difficulty hearing	14.	fainting/confusion

G. CO_____ WEIGHT_____

H. REASONS FOR RELAPSE OR CONCERNS

1. withdrawal reactions/cravings
2. weight gain/increased appetite
3. handling negative emotions/stress
4. loss of pleasure/companion
5. slips/temptations
6. travel
7. ambivalence
8. poor timing/too busy/too much stress
9. cut down so don't need to quit
10. need to cut down more
11. lack willpower
12. low confidence/fear failure
13. too much pressure to quit
14. not enough support
15. need extra help/clinic
16. other

APPENDIX I: Telephone Counselling Scripts

FOX CHASE
CANCER CENTER

Patricia Harsche
Vice President
Business Development and Regulatory Affairs

7701 Burholme Avenue
Philadelphia, Pennsylvania 19111
215 728 2468
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July 19, 1994

W.A. Dafoe, M.D.
Director
Prevention and Rehabilitation Centre
University of Ottawa Heart Institute
1053 Carling Avenue
Ottawa, Ontario, Canada K1Y 4E9

Dear Dr. Dafoe:

This is in response to various conversations and correspondence with Bob Reid related to the use of telephone scripts developed by Fox Chase Cancer Center (hereinafter "Fox Chase"), as part of its Clear Horizons program, in the University of Ottawa Heart Institute's (hereinafter "Heart Institute") smoking cessation program known as "Stop Smoking Now". Fox Chase would be pleased to license the use of these scripts under the following terms and conditions:

1. The Heart Institute acknowledges that Fox Chase owns the copyright in and all rights, title and interest in those portions of the smoking cessation telephone scripts developed by Fox Chase and used by the Heart Institute ("Fox Chase Material").

2. Fox Chase grants to the University of Ottawa Heart Institute a non-exclusive, non-transferable, non-assignable royalty free license to use, produce, copy, modify, display, translate & perform in any material form, the Fox Chase Material for non-profit use including, but not limited to:

   a. telephone counseling in your smoking cessation clinic;
   b. telephone counseling in smoking cessation research;
   c. the preparation of Mr. Reid's Ph.D. thesis.

3. In addition, Fox Chase grants to the Heart Institute a non-exclusive right to sub-license the right to use, produce, copy, modify, display, translate & perform in any material form the Fox Chase Material as part of a commercial agreement between the Heart Institute and McNeil Consumer Products for a telephone counselling program.

4. As consideration for the right to sublicense to McNeil, the Heart Institute agrees to pay Fox Chase Cancer Center $1.00 (U.S.) for each person enrolled in the Heart Institute telephone counselling program during each year of the agreement between the Heart Institute and McNeil Consumer Products. Payments will be made within 30 days of the end of each quarter ending September 30th.

December 30th, March 31st and June 30th until such time as the agreement between the Heart Institute and McNeil terminates. Payments will be made in the form of a check made payable to the Treasurer, Fox Chase Cancer Center and will be accompanied by a report providing details of the number of persons enrolled in the previous quarter as well as the total to date.

The Heart Institute shall keep accurate records and books of account of all persons enrolled in the program and shall take reasonable steps to ensure that its sublicensee maintains such books and records. The Heart Institute shall permit Fox Chase to conduct an audit upon 10 days prior written notice and during normal business hours of such books and records to verify the correctness of the reports given to Fox Chase with respect to the payments due to Fox Chase under this agreement. Such audits shall take place no more frequently than annually.

5. The Heart Institute agrees to acknowledge the contribution of the Fox Chase Cancer Center in all written materials, brochures, reports and publicity materials whether developed for its own use or as part of the commercial agreement with McNeil where same includes the Fox Chase Material.

6. The Heart Institute and Fox Chase represent that each has the full power and authority to enter into and perform its obligations under this agreement and to grant the rights granted to the other.

7. This license from Fox Chase to the Heart Institute shall continue in effect, unless earlier terminated, for the duration of Fox Chase's copyright term to the Fox Chase Material. Fox Chase may terminate this license at any time, by 10 days written notice to the Heart Institute, in the event that the Heart Institute violates any of the provisions of this agreement and fails to cure or to be attempting to cure same within said 10 day period.

8. Fox Chase makes no warranties whatsoever and hereby disclaims all warranties either expressed or implied, including, without limitation, any implied warranties of marketability, fitness for a particular purpose, or any implied warranties arising from the course of dealing, usage or trade practice. The Heart Institute hereby agrees to hold Fox Chase harmless from any and all claims or damages, expenses, costs and/or liabilities, including any costs or fees for litigation or threatened litigation, arising from the Heart Institute's printing, publication, reproduction and/or use of the Fox Chase Material, save & except written said claims/damages, etc. arise from Fox Chase's infringement of third party intellectual property rights by the Fox Chase Material or by the negligence or wilful acts of Fox Chase, ~~will identify~~ the Heart Institute concerning claims/damages etc. arising from Fox Chase's infringement of third party intellectual property rights up to but not exceeding the value of the royalties received by Fox Chase hereunder.
Fox Chase will indemnify . . . .

9. This license shall be effective upon the date of execution by Fox Chase and the Heart Institute noted below.

10. This agreement contains the complete and exclusive agreement between the parties, supersedes any and all prior oral and written communications, proposals and agreements, and may not be waived and modified except by written agreement of the parties.

11. Fox Chase releases the Heart Institute from any claims whatsoever regarding infringement of copyright in the Fox Chase Material prior to this agreement.

If you agree to these terms, please acknowledge that agreement by signing one of the originals and returning it to me. Thank you.

Sincerely,

Patricia Harsche

Patricia Harsche

Acknowledged and agreed to by the
University of Ottawa Heart Institute

Name: DR. W. KEON
Title: DIRECTOR GENERAL
Date: 94.08.15

cc: C. Tracy Orleans, Ph.D.
Bob Reid

Call No. 1

INTRODUCTION

A. **"Hello Mr./Ms./Mrs. This is_ _____ I'm calling on behalf of the Heart Institute Smoking Cessation Study to welcome you on board and see if you have any questions. Do you have a few minutes right now?"**

If yes, go to B.
If no, **"When could I call you back in the next day or so?"**
Date: ___/___/___ Time: _ _ 00 Hrs.

B. **"What are some of your reasons for wanting to quit smoking?"**

1. Personal health
2. Family health
3. Economic
4. Social
5. Control of Behaviour
6. Physicians suggestion
7. Other

"Those are (all) important/good reasons. I hope you'll find the program and materials we have provided for you helpful."

C1.	**"Have you quit smoking?"**	**Yes**	**No**
C2.	If yes, **"for how long?"**	_____	**Days**
D	**"Are you smoking now?**	**Yes**	**No**

E. **What dose of Nicotrol has your doctor prescribed for you?**
____mg

F.	**"It would be helpful if you could get your kit out now. Is it close by?**	**Yes**	**No**
G.	**"Have you had a chance to review the contents of the kit?**	**Yes**	**No**
	"Get started with your quitting plans?"	**Yes**	**No**

Prompt with description, if necessary
(Box set containing video, booklet, and coping card)

H. BEHAVIORAL CRITERIA	STAGE	GO TO PAGE
Not looked at kit contents or Not made any quitting plans, or Not made a serious quit attempt	PREPARATION	BUFF
Looked over kit or Made some quitting plans, or Taken pre-quitting actions or Quit less than 48 hours but **now** smoking - **Go to I Below**	ACTION	GOLD
Has quit and been smoke-free for 24 hours or more (with or without slips) and is **not** smoking right now.	MAINTENANCE	GREEN
Quit for 48 hours or more, but is now smoking daily - **Go to I Below**	RELAPSE	BLUE

I. For anyone who has quit since receiving materials but has gone back to smoking and is smoking now.

CONGRATULATE: "Congratulations! Quitting for even a short time puts you a step ahead."

REASSURE: "Most people try more than once before they quit for good. IN FACT, success rates are twice as high for people who recently stopped for even just 24 hours. I'd like to hear more about how things have gone for you."

PREPARATION

A. Review workbook and video and emphasize choice

("Please open workbook to Table of Contents")
"Let me go over what's in the Stop Smoking Now! Workbook and video so that you can use it to your best advantage. The workbook and video are organized into 3 parts, for the different stages of quitting, starting with Preparing to take Action."

B. **"It all starts with understanding why you smoke and picking a quitting plan and date. The second section suggests ways to cope with urges and triggers to smoke. It also outlines ways to deal with stress, tension and weight gain without smoking. Are any of these concerns for you?**

1. Urges to Smoke — Yes No
   If Yes, see page 19
2. Stress and tension — Yes No
   If Yes, see page 23
3. Weight Gain — Yes No
   If Yes, see page 25

C. Smoking Habit

"I'd like to ask you a few questions about your smoking."

D1. "On average how many cigarettes per day?" ___/day

2. "Do you usually smoke within 30 minutes of waking?"
. Elicit commitment to start quitting plan.

"When would you want to get started with your quitting plan (reviewing the booklet and video tape, getting Nicotrol prescription filled, revisiting doctor)"

E. Elicit commitment to quit date.

(consult calendar)
"What makes sense as a quit date for you?" ___/___/___

F. Assist to pick a date - see **CHOOSE A QUIT DATE - pg 10**

"Write this date on your calendar and on your personal action plan.

G. **"Stop Smoking Now! also suggests other things that will help you quit smoking. In general we've found that the more suggestions you try, the easier quitting will be, and the more successful you'll be."**

"For instance, the workbook and video recommend understanding why you smoke and locating alternatives to smoking that can help you when you quit. It can be helpful to complete the Why I Smoke Test and Automatic Response Test on pages 6 and 8.

"Pages ** will help you get ready to quit, and page ** will help you from your quit date on, with lots of tips for getting through urges and handling temptations after you quit."

H. Social Support - Other Smokers

"What about support from your family and friends? Do you live with other people who smoke?" Yes No

"Stop Smoking Now! may also give you some new ideas about how friends and family can help, even if they smoke. For instance, the workbook and video suggests asking friends and family to help support you through your quit effort."

"OK. You're on your way. If there's time: **Do you have any questions at this point?"...**(ALWAYS REFER TO THE WORKBOOK AND VIDEO - CHECK TABLE OF CONTENTS)

GO TO CLOSING

ACTION

A. **Praise any actions taken**, even if just looking over the workbook and video.

B. Review workbook and video and emphasize choice.
("Please open to Table of Contents") " The workbook and video is organized into 3 parts, for the different stages of quitting".

C. **"It all starts with understanding why you smoke and picking a quitting plan and date. The second section suggests ways to cope with urges and triggers to smoke. It also outlines ways to deal with stress, tension and weight gain without smoking. Are any of these concerns for you?"**

1. Urges to Smoke	Yes	No
	If Yes, see page 19	
2. Stress and tension	Yes	No
	If Yes, see page 23	
3. Weight Gain	Yes	No
	If Yes, see page 25	

E.1 **Have you picked/started with your Preparing to Quit methods? What things have you done?**

		Yes	No
E2.	1. Identify Reasons for Stopping		
	2. Why I Smoke		
	3. Locate Alternatives to Smoking		
	4. Select a Quit Date		
	5. Have Prescription Filled		
	6. Enlist Social Support		
	7. Complete Personal Action Plan		
	8. Complete 48 Hour Checklist		
	9. Complete 24 Hour Checklist		

If none of the above have been done return to Section D in **preparation.**

IF YES: **"GREAT! How's it going?" or "Do you have any questions?"**

F1. If yes to prescription filled.
1. "Did you use OR Are you planning on using the patch during your quit attempt?"
If using the patch now.

F2. **"Any side effects?" (do not prompt) Yes No**

F4.
1. Sleep disturbance
2. Skin Irritation
3. Headaches
4. Dizziness
5. Anxiety
6. Irritability
7. Fatigue
8. Constipation
9. Stomach Upset

At this time I would like to talk to you about the NICOTROL patch. On page * you will find a detailed description on how to use the patch. Please remember that you should not smoke while using the NICOTROL patch.**

G. Smoking Habit

"I'd like to ask you a few questions about your smoking."

1. "On average, how many cigarettes/day?" ____cigs/day

2. "Do you usually smoke within 30 minutes of waking?" Yes No

H. **IF QUIT FOR LESS THAN 48 HOURS** (but smoking now),
Urge to try again.
If quit with a plan, go to J.
If quit without a plan, urge to try again with a new plan.

I. Elicit commitment to start quitting plan.
"When would you want to get started with your quitting plan (reviewing the booklet and video tape, getting Nicotrol prescription filled, revisiting doctor, completing the checklists)"

J. Elicit commitment to quit date.

(consult calendar)
"What makes sense as a quit date for you?"
"Write this date on your calendar and on your personal action plan." ___/___/___

K. **"Stop Smoking Now! also suggests other things that will help you quit smoking. In general we've found that the more of these you try, the easier quitting will be."**

"For instance, the workbook and video recommend understanding why you smoke and locating alternatives to smoking that can help you when you quit. It might be helpful to complete the Why I Smoke Test and the Automatic Response Test on pages 6 and 8."

"Pages 3-14 will help you get ready to quit, and page 15 will help you from your quit date on, with lots of tips for getting through urges and handling temptations after you quit."

L. Social Support - Other Smokers

1. "Do you live with other people who smoke?" Yes No

"Stop Smoking Now! may also give you some new ideas about how friends and family can help, even if they smoke. For instance, the workbook and video suggests asking friends and family to help support you through your quit effort."

M. GO TO CLOSING

MAINTENANCE

A. **"Congratulations! How long ago did you quit?"** ____ Days

B1. **"Did you use any of the Preparation to Quit Methods suggested to help you quit?"**
Yes No

B2.
1. Reasons for Stopping
2. Why I Smoke
3. Alternatives to Smoking
4. Select a Quit Date
5. Prescription Filled
6. Social Support
7. Personal Action Plan
8. 48 Hour Checklist
9. 24 Hour Checklist

C1. If **yes** to prescription filled
"Are you using the Nicotrol patch now?" Yes No

C2. If yes. **"what strength?"** ____**mg**

C3. **"Are you experiencing any side effects?"**
(do not prompt)

1. Sleep disturbance
2. Skin irritation
3. Headaches
4. Dizziness
5. Irritability
6. Fatigue
7. Constipation
8. Stomach Upset
9. Anxiety

D. **"What alternatives to smoking did you find the most helpful?"**

1. Increased physical activity
2. Increased sleep
3. Using gum/mints/sticks/toothpicks
4. Find alternate pleasures (e.g.. music/reading/crosswords)
5. Relaxation/breathing techniques
6. Removing smoking materials from environment (e.g.. ashtrays)
7. Delay tactics
8. Positive self-talk
9. Assertive statements
10. Social support
11. Professional support
12. Change in routine

Praise all coping tactics mentioned - urge to keep using what works.
If none are mentioned, encourage to review WHY I SMOKE ALTERNATIVES CHART.
"These activities continue to help during your first few months off cigarettes."

E. **"What about support from family and friends?"**
1. "Do you live with other people who smoke?" **Yes** **No**

Praise actions to get support. Troubleshoot if there are problems. Refer to workbook and video for tactful ways to deal with pressure.

F. **"Have you had any particular (or other) concerns or problems?" or "Is anything coming up that you are concerned about?"** Circle as many as apply.

1) withdrawal reactions/cravings	10) cut down so don't need to quit
2) weight gain/increased appetite	11) need to cut down more
3) handling negative emotions/stress	12) lack willpower
4) loss of pleasure/companion	13) low confidence/fear failure
5) slips/temptations	14) too much pressure to quit
6) travel	15) not enough support
7) ambivalence	16) need extra help/clinic
8) poor timing/too busy/too much stress	00)other:_____
9) don't like Stop Smoking Now! methods	specify

(refer to corresponding page for identified problem)

G1. **"Have you been tempted to smoke or smoked at all since quitting?"**
SLIPS? Yes No

At this time I would like to talk to you about the NICOTROL patch. On page * you will find a detailed description on how to use the patch . Please remember that you should not smoke while using the NICOTROL patch.**

If many slips,
G2 **"Are you now having slips on a daily basis?"** **Yes No**

"Temptations are inevitable. The key is being prepared, anticipating events that are likely to catch you off guard. The last section of the workbook and video explains how you can handle temptations to prevent slips. It also explains how to handle a slip, if you should ever slip and smoke even one cigarette. It's best never to slip. But, if you <u>should</u>, remember: a slip is NOT a failure. Don't let guilt or disappointment lead you back to smoking. Instead, <u>learn</u> from the slip. It can be helpful to follow the directions in the workbook and video for getting back on track. Your Coping Card can be carried with you to serve as a reminder."

If smoking on a daily basis, find out where slips are occurring and suggest alternative activities. Recommend establishing a new quit date in 1-2 weeks.

H. **REINFORCE STAYING SMOKE FREE. "Use whatever is working for you now. Add some new ideas from sections 2 and 3 of the workbook and video - the more you try, the easier quitting will be."**

"Getting more exercise can be very helpful (p 26), so can finding new hobbies/pastimes to take the place of smoking."

I. GO TO CLOSING

RELAPSE/RE-CYCLING

A. CONGRATULATE AND REASSURE
(SEE COVER PAGE - **"Congratulations! Quitting for even a short time..."**)

B. 1. **"How long did you stay off cigarettes?** ____Days

C1. **"Did you use any of the Preparation to Quit methods suggested?**
Yes **No**

C2. **What things did you do?"**

1. Reasons for Stopping
2. Why I Smoke
3. Alternatives to Smoking
4. Select a Quit Date
5. Prescription Filled
6. Social Support
7. Personal Action Plan
8. 48 Hour Checklist
9. 24 Hour Checklist

. If yes to prescription filled
D1. **"Did you use the patch during your quit attempt?"** Yes No
If yes,
D2. **"What strength did you use?"** _____**mg**
D3. **"Are you using the Nicotrol patch now?"** Yes No
D4. **"Any side effects?" (do not prompt)**
1. Sleep disturbance
2. Skin irritation
3. Headaches
4. Dizziness
5. Anxiety
6. Irritability
7. Fatigue
8. Constipation
9. Stomach Upset

At this time I would like to talk to you about the NICOTROL patch. On page * you will find a detailed description on how to use the patch . Please remember that you should not smoke while using the NICOTROL patch.**

E. **"What were the circumstances that caused you to start smoking again?"** (CIRCLE ANY THAT COME UP)

1) withdrawal reactions/cravings
2) weight gain/increased appetite
3) handling negative emotions/stress
4) loss of pleasure/companion
5) slips/temptations
6) travel
7) ambivalence
8) poor timing/too busy/too much stress
9) don't like Stop Smoking Now! methods
(refer to corresponding page for identified problem)
10) cut down so don't need to quit
11) need to cut down more
12) lack willpower
13) low confidence/fear failure
14) too much pressure to quit
15) not enough support
16) need extra help/clinic
00)other:_____
specify

F. **FIRST ASK: "What do you think might have helped?"**

THEN "Sounds like you ran into unexpected problems with

_____
(Circumstance)

"Many people find this (...) difficult. The Stop Smoking Now! workbook and video suggests several ways to deal with it... But, generally it is best to think about delay - avoidance and substitution."

G. 1. **"Have you thought about giving it another try?"** **Yes** **No**
Encourage to set up a new quitting plan and date...

Revised Quit Date: ___/___/___

H. **"I'd like to ask you some questions about your smoking."**

1. **"On average, how many cigarettes/day?"** ____cigs

2. **"Usually smoke within 30 minutes of waking?"** Yes No

I. **IDEAS FOR GETTING BACK ON TRACK**

____ Read over page 30, with ideas for getting back on track

____ Review first section again, renew your reasons for quitting

____ Talk with you Dr. re: the Nicotrol patch and re-read the sections about how to use the patch (p. 15-18) (especially if used too little, had withdrawal problems, seems to be highly addicted smoker).

____ Read about ways family and friends can help.

J. 1. **"What about support from family and friends? Do you live with other people who smoke?"** Yes No

Praise actions to get support. Troubleshoot if there are problems. Refer to workbook and video for tactful ways to deal with pressure.

K. Go to Closing

CLOSING

One last question before you go, I'd like to find out how you learned about the Nicotrol Stop Smoking Now!?"

1. Doctor's recommendation
2. Friend's suggestion
3. Word-of-mouth (other)
4. Magazine Advertisement
5. TV ad
6. Other _____

"Before I say good-bye, I want to let you know that I will be calling you again in 4 weeks to see how you are doing, or see if you need any help.
Let me confirm your address."

"Will this be a good time to reach you?"
Best day:_____ Best time:_____
At this number? Yes No

"Alright then I've really enjoyed talking with you today and am looking forward to talking with you again."

Call # 2

INTRODUCTION

A. **"Hello Mr./Ms./Mrs. This is _____ from the Heart Institute quit smoking study. I called about 4 weeks ago to introduce the Stop Smoking Now! workbook and video. I'm calling back this time, as I said I would, to find out how things have gone for you and to see if I can be of any help. Do you have a few minutes now? If no, "When could I call you back in the next day or so?"**

DATE: ___/___/___ TIME: ___:00

If client refuses, code on cover page and go to closing.
If client can talk now, go to B

B. **"When we last talked, you had...[describe any action taken] and were planning to [describe any quitting plans and mention quit date]. How have things gone for you ?"**

If appropriate:
B1. **"Have you quit at all since getting the workbook and video?"**

If Yes,
B2. **"...for how long?"**____Days/Wks

C1. **"Do you still have your workbook and video?"** Yes No
If yes:
C2. **"Is it close by? It would be helpful if you could get it out now."**
RECORD IF CLIENT HAS WORKBOOK AND VIDEO IN HAND Yes No

D. FOR ANYONE WHO HAS QUIT SINCE RECEIVING MATERIALS
BUT HAS GONE BACK TO SMOKING AND IS SMOKING NOW. check here__

E. BEHAVIORAL CRITERIA	STAGE		GO TO PAGE
Not looked over workbook and video or Not made any quitting plans or Not taken any pre-quitting actions or Not made a serious quite attempt	preparation	buff	
Taken some pre-quitting actions or Make some quitting plans, or Quit less than 48 hours but now smoking --GO TO F BELOW	action	gold	
Has quit and been smoke-free for 24 hours or more (with or without slips) and is not smoking now.	maintenance (new) maintenance quit at call 1	green yellow	
Quit for 48 hours or more, but is now smoking daily--GO TO F BELOW	relapse relapse call 1	blue orange	

F. CONGRATULATE: "Congratulations! Quitting for even a short time means you're a step ahead".
REASSURE: "most people try more than once before they quit for good, IN FACT, success rates are twice as high for people who have recently stopped for even just 24 hours. I'd like to hear more about how things have gone for you."

PREPARATION

A. **"Sometimes it takes awhile after you decide to quit to get started. The nice thing about the Heart Institute Smoking Cessation Study is that you can start at the time that is best for you. Would you still like to try to quit smoking in the next few weeks?"**
(Even if answer is "no", continue to probe to help clear the way to quitting when the time does come.)

"Has there been (or do you foresee) anything in particular in the way of you getting started?" (CIRCLE ANY THAT COME).

1) withdrawal reactions/cravings	10) cut down so don't need to quit
2) weight gain/increased appetite	11) need to cut down more
3) handling negative emotions/stress	12) lack willpower
4) loss of pleasure/companion	13) low confidence/fear failure
5) slips/temptations	14) too much pressure to quit
6) travel	15) not enough support
7) ambivalence	16) need extra help/clinic
8) poor timing/too busy/too much stress	00)other:_____
9) don't like Stop Smoking Now! methods	specify

(refer to corresponding page for identified problem)

B. **"It all starts with understanding why you smoke and picking a quitting plan and date. The second section of the workbook and video suggests ways to cope with urges and triggers to smoke. They also outline ways to deal with stress, tension and weight gain without smoking. Are any of these concerns for you?"**

1. Urges to Smoke see page 19

2. Stress and tension see page 23

3. Weight Gain see page 25

C. **"I'd like to ask you a few questions about your smoking."**

1. "How many cigarettes are you smoking each day, now?" ____cigs/day

D. Elicit commitment to start quitting plan.
"When would you want to get started with your quitting plan?" (reviewing the booklet and video tape, getting Nicotrol prescription filled, revisiting their doctor)

E. Elicit commitment to quit date.

HELP TO PICK QUIT DATE IF NECESSARY
1. "What makes sense as a quit date for you?" ___/___/___

Assist to pick a date - see **CHOOSE A QUIT DATE - pg 10**

"Write this date on your calendar and on your personal action plan."

G. **"Stop Smoking Now! also suggests other things that will help you quit smoking. In general we've found that the more of these you try, the easier quitting will be, the more successful you'll be."**

"For instance, the workbook and video recommend understanding why you smoke and locating alternatives to smoking that can help you when you quit. It can be helpful to complete the Why I Smoke Test and the Automatic Response Test. They are on pages 6 and 8 of the workbook."

Pages ** will help you get ready to quit, and page ** will help you from your quit date on, with lots of tips for getting through urges and handling temptations after you quit

H. **"Do you have friends and family that can help you?" Yes No**

Stop Smoking Now! may also give you some new ideas about how friends and family can help, even if they smoke. For instance, the workbook and video suggest asking friends and family to help support you through your quit effort."

"**OK. You're on your way.** If there's time: **Do you have any questions at this point?"**...(ALWAYS REFER TO THE WORKBOOK AND VIDEO - CHECK TABLE OF CONTENTS - and <u>GO TO CLOSING</u>)

I. GO TO CLOSING

ACTION

A. PRAISE ANY ACTIONS TAKEN. whether part of Heart Institute Smoking Cessation Study or not.
"Great. Sometimes the hardest part is getting started. The nice thing about this program is that you can pick the timing that works best for you."

B. 1. **"Have you used the workbook and video at all to help you quit?"**
Yes No

C. CLARIFY PRE-QUITTING ACTIVITIES
"What things did you try to help get you ready to quit?"

1. Reasons for Stopping
2. Why I Smoke
3. Alternatives to Smoking
4. Select a Quit Date
5. Prescription Filled
6. Social Support
7. Personal Action Plan
8. 48 Hour Checklist
9. 24 Hour Checklist

D. **"Where are you now in your quitting plans?"** or **"Would you still like to try to quit in the next few weeks?"** (If quit for less than 48 hrs and relapsed: **"Have you thought about giving it another try?"**) **Y__ N__**

E. **"Can you think of anything that might get in your way of taking the next step?"**(CIRCLE ANY THAT COME UP)

1) withdrawal reactions/cravings	10) cut down so don't need to quit
2) weight gain/increased appetite	11) need to cut down more
3) handling negative emotions/stress	12) lack willpower
4) loss of pleasure/companion	13) low confidence/fear failure
5) slips/temptations	14) too much pressure to quit
6) travel	15) not enough support
7) ambivalence	16) need extra help/clinic
8) poor timing/too busy/too much stress	00)other:_____
9) don't like Stop Smoking Now! methods	specify

(refer to corresponding page for identified problem)

F. **"As we discussed last time. The first step in getting started again is picking a quit plan and date. It's easy to pick up right where you left off. What seems like a good date to try again?"**

Revised Quit Date: ___/___/___

"Write this date on you calendar and on your Personal Action Plan."

G. 1. **"How many cigarettes are you smoking each day, now?** ___cig/day

I. **"Stop Smoking Now! also suggests other things that will help you quit smoking. In general we've found that the more you try, the easier quitting will be, the more successful you'll be."**

"For instance, the workbook and video recommend understanding why you smoke and locating alternatives to smoking that can help you when you quit. Completing the Why I Smoke Test and Automatic Response Test on pages 6 and 8 can be helpful."

"Pages 3-8 will help you get ready to quit, and page 15 on will help you from your quit date on, with lots of tips for getting through smoking urges and handling temptations after you quit."

J. GO TO CLOSING

MAINTENANCE (NEW QUITTER)

A. **"Congratulations!**
1. **How long ago did you quit?"** ____ Days

B. 2. **"Did you use the workbook and video at all to help you quit?"**
Yes No

C1. **"Did you use any of the Preparation to Quit methods suggested? What things have you done?"** **Yes** **No**

C2.
1. Reasons for Stopping
2. Why I Smoke
3. Alternatives to Smoking
4. Select a Quit Date
5. Prescription Filled
6. Social Support
7. Personal Action Plan
8. 48 Hour Checklist
9. 24 Hour Checklist

D. If yes to prescription filled
D1. **"Are you using the Nicotrol patch now?"** Yes No
D2. If yes, what dose? ____ mg
D3. Any side effects? (do not prompt)
1. Sleep disturbance
2. Skin irritation
3. Headaches
4. Dizziness
5. Anxiety
6. Irritability
7. Fatigue
8. Constipation
9. Stomach Upset

E. **"What alternatives to smoking did you find the most helpful?"**
1. Increased physical activity
2. Increased sleep
3. Using gum/mints/sticks/toothpicks
4. Find alternate pleasures (eg. music/reading/crosswords)
5. Relaxation/breathing techniques
6. Removing smoking materials from environment (eg. ashtrays)
7. Delay tactics
8. Positive self-talk
9. Assertive statements
10. Social support
11. Professional support
12. Change in routine

Praise all coping tactics mentioned - urge to keep using what works.
If none are mentioned, encourage to review WHY I SMOKE ALTERNATIVES CHART.

"These activities continue to help during your first few months off cigarettes."

F. **"Have you had any particular (or other) concerns or problems?" or "Is anything coming up that you are concerned about?"** Circle as many as apply.

1) withdrawal reactions/cravings	10) cut down so don't need to quit
2) weight gain/increased appetite	11) need to cut down more
3) handling negative emotions/stress	12) lack willpower
4) loss of pleasure/companion	13) low confidence/fear failure
5) slips/temptations	14) too much pressure to quit
6) travel	15) not enough support
7) ambivalence	16) need extra help/clinic
8) poor timing/too busy/too much stress	00)other:_____
9) don't like Stop Smoking Now! methods	specify

(refer to corresponding page for identified problem)

G. **1. "Have you been tempted or smoked at all since quitting?"**
Yes No

At this time I would like to talk to you about the NICOTROL patch. On page * you will find a detailed description on how to use the patch . Please remember that you should not smoke while using the NICOTROL patch.**

3. **"Smoking on a daily basis?"** Yes No

"Temptations are inevitable. The key is being prepared, anticipating events that are likely to catch you off guard. The last sections of the workbook and video explain how you can handle temptations to prevent slips. They also explain how to handle a slip, if you should ever slip and smoke even one cigarette. It's best never to slip. But, if you <u>should</u>, remember: a slip is NOT a failure. Don't let guilt or disappointment lead you back to smoking. Instead, <u>learn</u> from the slip. Try following the directions in the workbook and on the video for getting back on track. Your Coping Card can be carried with you to serve as a reminder."

IF SMOKING ON A DAILY BASIS, FIND OUT WHERE SLIPS ARE OCCURRING AND SUGGEST ALTERNATIVE ACTIVITIES. RECOMMEND NEW QUIT DATE IN 1-2 WEEKS.

H. **REINFORCE STAYING SMOKE FREE, "Use whatever's working for you now. Add some new ideas from sections 2 and 3 of the workbook and video. The more you try - the easier quitting will be."**

"Getting more exercise can be very helpful (p 26), so can finding new hobbies/pastimes to take the place of smoking.

I. GO TO CLOSING

MAINTENANCE (HAD QUIT BY CALL 1)

A. **"Congratulations! How long has it been now?"** ____ Days/Weeks
"How are things going?"
A1. **"Have you noticed any positive changes ?"**
Yes No

A2.
1. breathe easier
2. cough less
3. less shortness of breath
4. food taste better
5. other:_____

B. **"Have you used the video and workbook to help you stay quit?"**
Yes No

C. **"Did you use any of the Staying Smoke-Free methods suggested?**

Yes **No**

1. Review of High Risk Situations
2. Delay-Avoid-Substitute
3. Increased Physical Activity
4. Breathing Exercises
5. Muscle Tension Reduction.

D1. **"Are you using the Nicotrol patch now?"** Yes No If yes,
D2. what dose? ____ mg
Any side effects? (do not prompt)
D3.
1. Sleep disturbance
2. Skin irritation
3. Headaches
4. Dizziness
5. Anxiety
6. Irritability
7. Fatigue
8. Constipation
9. Stomach Upset

E. **"What alternative to smoking have you found to be the most helpful in keeping you from smoking?"**

1. Increased physical activity
2. Increased sleep
3. Using gum/mints/sticks/toothpicks
4. Find alternate pleasures (eg. music/reading/crosswords)
5. Relaxation/breathing techniques
6. Removing smoking materials from environment (eg. ashtrays)
7. Delay tactics
8. Positive self-talk
9. Assertive statements
10. Social support
11. Professional support
12. Change in routine

Praise all coping tactics mentioned - urge to keep using what works.
"These strategies will continue to help you your first few months off cigarettes."

F. **"What about support from family and friends?"**
Praise actions to get support. Troubleshoot if there are problems.

G. **"You mentioned concerns about ..... last time we talked. Any concerns about that now? Have you had any other problems or concerns?" Or "Is there anything coming up that you are concerned about?"**
(CIRCLE ANY THAT COME UP)

1) withdrawal reactions/cravings	10) cut down so don't need to quit
2) weight gain/increased appetite	11) need to cut down more
3) handling negative emotions/stress	12) lack willpower
4) loss of pleasure/companion	13) low confidence/fear failure
5) slips/temptations	14) too much pressure to quit
6) travel	15) not enough support
7) ambivalence	16) need extra help/clinic
8) poor timing/too busy/too much stress	00)other:_____
9) don't like Stop Smoking Now! methods	specify

(refer to corresponding page for identified problem)

H1. **"Have you been tempted to smoke or smoked at all since you quit?**
Yes No
H2. **"Smoking now on a daily basis?"** Yes No
If yes to slips, **"At this point I would like to take the time to emphasize the risks involved with smoking when using the Nicotrol patch as it can be hazardous to your health.**
COUNSEL ABOUT SLIPS: **"Being prepared is the best way to prevent slips. It's better never to slip, but if you do you should get back on track. Figure out what went wrong, plan how to prevent a slip next time."**

IF SMOKING ON DAILY BASIS, find out where slips are occurring and suggest alternative activities. Recommend new quit date in 1-2 weeks.

I. REINFORCE STAYING SMOKE-FREE, USING WHATEVER'S WORKING FOR YOU NOW. ADD SOME NEW IDEAS FROM SECTIONS 2 AND 3 OF THE WORKBOOK AND VIDEO - THE MORE OF THESE YOU TRY, THE EASIER QUITTING WILL BE".
"Keep using whatever coping methods are working for you now - add some if needed like..."

"Getting more exercise can be very helpful (p 26), so can finding new hobbies/pastimes to take the place of smoking.
Keep the workbook and video handy, view it often (useful as a reference long after you quit)."

J. GO TO CLOSING

RELAPSE/RE-CYCLING (NEW RELAPSER)

A. 1. **"How long ago did you quit?"** ____ days/weeks

2. **"How long did you stay off cigarettes?"** ____ days/weeks

B. **"What alternatives to smoking did you find to be the most helpful during the time you were not smoking?"**

1. Increased physical activity
2. Increased sleep
3. Using gum/mints/sticks/toothpicks
4. Find alternate pleasures (eg. music/reading/crosswords)
5. Relaxation/breathing techniques
6. Removing smoking materials from environment (eg. ashtrays)
7. Delay tactics
8. Positive self-talk
9. Assertive statements
10. Social support
11. Professional support
12. Change in routine

C. 1. **"Did you use the workbook and video to help you stay quit?"**
Yes No If no, Go To E

D. **"Did you use any of the Preparation to Quit methods suggested? Which things did you do?"**

Yes **No**

1. Reasons for Stopping
2. Why I Smoke
3. Alternatives to Smoking
4. Select a Quit Date
5. Prescription Filled
6. Social Support
7. Personal Action Plan
8. 48 Hour Checklist
9. 24 Hour Checklist

E. If **yes** to prescription filled

E1. **"Are you using the Nicotrol patch now?"** Yes No

E2. **"Were you using the patch during your period of non-smoking?"**
Yes **No**

E3. If yes, **what dose?** _____ mg **For how long?**_____days/wks

E4. **"Any side effects?"** (do not prompt)

1. Sleep disturbance
2. Skin irritation
3. Headaches
4. Dizziness
5. Anxiety
6. Irritability
7. Fatigue
8. Constipation
9. Stomach Upset

F. **"What were the circumstances that caused you to start smoking again?"** (CIRCLE ANY THAT COME UP)

1) withdrawal reactions/cravings
2) weight gain/increased appetite
3) handling negative emotions/stress
4) loss of pleasure/companion
5) slips/temptations
6) travel
7) ambivalence
8) poor timing/too busy/too much stress
9) don't like Stop Smoking Now! methods
(refer to corresponding page for identified problem)

10) cut down so don't need to quit
11) need to cut down more
12) lack willpower
13) low confidence/fear failure
14) too much pressure to quit
15) not enough support
16) need extra help/clinic
00)other:_____
specify

G. FIRST ASK: **"What do you think might have helped?"**

THEN "Sounds like you ran into unexpected problems with _____"
(Circumstance)

"Many people find this (...) difficult. The Stop Smoking Now! workbook and video suggests several ways to deal with it... But, generally it is best to think about delay - avoidance and substitution."

H. 1. **"Have you thought about giving it another try?"**
Encourage to set up a new quitting plan and date...

Revised Quit Date: ___/___/___

I. **"I'd like to ask you some questions about your smoking."**

1. **"On average, how many cigarettes/day now?"** ____ cigs

J. **IDEAS FOR GETTING BACK ON TRACK**

____ Read over page 30, with ideas for getting back on track

____ Review first section again, renew your reasons for quitting

____ Talk with you Dr. re: the Nicotrol patch and re-read the sections about how to use the patch (p. 15-18) (especially if used too little, had withdrawal problems, seems to be highly addicted smoker).

____ Read about ways family and friends can help.

K. GO TO CLOSING

RELAPSE/RE-CYCLING (HAD RELAPSED AT CALL 1)

A. **"When we last talked, you had quit for ____ (duration) then gone back to smoking. You were thinking of quitting again using ____ (methods). What happened then?"**

IF THERE WAS A NEW QUIT ATTEMPT AND RELAPSE, ASK:
1. **"How long did you stay off cigarettes this last time?"** ____ days

B. **"What alternatives to smoking did you find the most helpful to quit and keep you from smoking?"**
1. Increased physical activity
2. Increased sleep
3. Using gum/mints/sticks/toothpicks
4. Find alternate pleasures (eg. music/reading/crosswords)
5. Relaxation/breathing techniques
6. Removing smoking materials from environment (eg. ashtrays)
7. Delay tactics
8. Positive self-talk
9. Assertive statements
10. Social support
11. Professional support
12. Change in routine

C1. **"Did you use any of the Preparation to Quit methods suggested? What things have you done?"** **Yes** **No**

C2.
1. Reasons for Stopping
2. Why I Smoke
3. Alternatives to Smoking
4. Select a Quit Date
5. Prescription Filled
6. Social Support
7. Personal Action Plan
8. 48 Hour Checklist
9. 24 Hour Checklist

D. If **yes** to prescription filled

D. **"Are you using the Nicotrol patch now?"** **Yes** **No**

D2. **"Were you using the patch during your period of non-smoking?"**
Yes **No**

D3. If yes, **what dose?** _____ mg **For how long?**_____days/wks

D4. **"Any side effects?"** (do not prompt)
1. Sleep disturbance
2. Skin irritation
3. Headaches
4. Dizziness
5. Anxiety
6. Irritability
7. Fatigue
8. Constipation
9. Stomach Upset

E. **"What were the circumstances that caused you to start smoking again?"** (CIRCLE ANY THAT COME UP)

1) withdrawal reactions/cravings
2) weight gain/increased appetite
3) handling negative emotions/stress
4) loss of pleasure/companion
5) slips/temptations
10) cut down so don't need to quit
11) need to cut down more
12) lack willpower
13) low confidence/fear failure
14) too much pressure to quit

6) travel
7) ambivalence
8) poor timing/too busy/too much stress
9) don't like Stop Smoking Now! methods
(refer to corresponding page for identified problem)

15) not enough support
16) need extra help/clinic
00)other:_____
specify

F. FIRST ASK: **"What do you think might have helped?"**

THEN: "Sounds like you ran into unexpected problems with _____"
(Circumstance)

"Many people find this (...) difficult. The Stop Smoking Now! workbook and video suggests several ways to deal with it... But, generally it is best to think about delay - avoidance and substitution."

G. 1. **"Have you thought about giving it another try?"**
Encourage to set up a new quitting plan and date...

Revised Quit Date: __/__/__

H. **"I'd like to ask you a few questions about your smoking."**

1. "How many cigarettes are you smoking each day, now?" ____cig/day

I. **IDEAS FOR GETTING BACK ON TRACK**

____ Read over page 30 with ideas for getting back on track

____ Review first section again, renew your reasons for quitting

____ Talk with Dr. re: the Nicotrol patch and re-read the sections about how to use the patch (p. 15-18) (especially if used too little, had withdrawal problems, seems to be highly addicted smoker).

____ Read about ways family and friends can help.

J. GO TO CLOSING

CLOSING

"Before I say good-bye, I want to let you know that I will be calling you again in 7 weeks to see how you are doing, or if you need any help."

"Will this still be a good time to reach you?"
Best day:_____ Best time:_____
At this number?

"Alright then I've really enjoyed talking with you once again and am looking forward to talking with you in 7 weeks."

CALL # 3

A. **"Hello Mr/Mrs/Ms_____ This is _____from the Heart Institute Smoking Cessation Study. I'm calling back as I said I would, to find out how things are going for you and to see if I can be of any help to you. Is this a good time?"** If no. **"when could I call you back in the next day or so?"**
Date: ___/___/___ Time: ___:00

B1. **"In the past 7 days, have you smoked?"**
If yes, go to relapse/recycle

If no
B2. **"How long have you quit for?"** ____ days/wks
Congratulate and go to C.

"Congratulations! You've reached another milestone. You've been smoke-free for almost __ months. Each day you've become stronger and have grown closer to total independence from tobacco."

C.1. **"Have you completed your Nicotrol prescription?" Yes No**
C2. If yes, **what dose(s) _____ mg**
C3. **"When did you complete your prescription?"**
_____ Days/Weeks ago.
C4. **"Have you experienced any symptoms of withdrawal since completing your prescription?" (do not prompt)**
1. cravings?
2. unable to concentrate?
3. sleep disturbances?
4. change in appetite?
5. fatigue?
6. irritability?
7. restlessness?
8. anxiety?
9. anger?
10. frustration?

(Counsel according to symptom)

D. **"The last time we talked, you mentioned that you were concerned about _____? Do you have any concerns about these (this) now?"**
"Have you any new problems or concerns?"
(CIRCLE ANY THAT COME UP)

1) withdrawal reactions/cravings
2) weight gain/increased appetite
3) handling negative emotions/stress
4) loss of pleasure/companion
5) slips/temptations
6) travel
7) ambivalence
8) poor timing/too busy/too much stress
9) don't like Stop Smoking Now! methods
10) cut down so don't need to quit
11) need to cut down more
12) lack willpower
13) low confidence/fear failure
14) too much pressure to quit
15) not enough support
16) need extra help/clinic
00)other:_____
specify

(refer to corresponding page for identified problem)

F. 1. **"Have you been tempted or smoked at all since quitting?"**
If yes,
2. "Smoking now on a daily basis?" Yes No

If yes to slips, **"At this point I would like to take the time to emphasize the risks involved with smoking when using the Nicotrol patch as it can be hazardous to your health.**

COUNSEL ABOUT SLIPS: **"Being prepared is the best way to prevent slips. It's better never to slip, but if you do you should get back on track. Figure out what went wrong, plan how to prevent a slip next time."**

G. REINFORCE STAYING SMOKE-FREE, USING WHATEVER'S WORKING FOR YOU NOW. ADD SOME NEW IDEAS FROM SECTIONS 2 AND 3 OF THE WORKBOOK AND VIDEO - THE MORE YOU TRY, THE EASIER QUITTING WILL BE, THE MORE SUCCESSFUL YOU'LL BE.
"Keep using whatever coping methods are working for you now - add some if needed like..."

"Getting more exercise can be very helpful (p 26), so can finding new hobbies/pastimes to take the place of smoking.
Keep the workbook and video handy, view it often (useful as a reference long after you quit)."

H. GO TO CLOSING

RELAPSE/RE-CYCLING (NEW RELAPSER)

A. 1. **"How long did you stay off cigarettes in total?"** ____ **Days/Wks**
2. **"How long have you been back to smoking"** ____ **Days/Wks**

B. **"What alternatives to smoking did you find to be the most helpful to quit and to remain a non-smoker?"**

1. Increased physical activity
2. Increased sleep
3. Find alternate pleasures (eg. music/reading/crosswords)
4. Relaxation/breathing techniques
5. Removing smoking materials from environment (eg. ashtrays)
6. Delay tactics
7. Positive self-talk
8. Assertive statements
9. Social support
10. Professional support
11. Change in routine

C1. **"Are you using the Nicotrol patch now?"** Yes No

If yes,

C2. **what dose?** _____

Any side effects? (do not prompt)

C3.

1. Sleep disturbance
2 Skin irritation
3. Headaches
4. Dizziness
5. Anxiety
6. Irritability
7. Fatigue
8. Constipation
9. Stomach Upset

D. **What were the circumstances that caused you to start smoking again?"** (ASK ABOUT THE CIRCUMSTANCES)

1) withdrawal reactions/cravings
2) weight gain/increased appetite
3) handling negative emotions/stress
4) loss of pleasure/companion
5) slips/temptations
6) travel
7) ambivalence
8) poor timing/too busy/too much stress
9) don't like Stop Smoking Now! methods
10) cut down so don't need to quit
11) need to cut down more
12) lack willpower
13) low confidence/fear failure
14) too much pressure to quit
15) not enough support
16) need extra help/clinic
00)other:_____
specify

(refer to corresponding page for identified problem)

F. FIRST ASK: **"What do you think might have helped?"**

THEN: "Sounds like you ran into unexpected problems with _____**"**

(Circumstance)

"Many people find this (...) difficult. The Stop Smoking Now! workbook and video suggests several ways to deal with it... But, generally it is best to think about delay - avoidance and substitution."

G. I. **"Have you thought about giving it another try?"**
Encourage to set up a new quitting plan and date...

Revised Quit Date: ___/___/___

H. **"I'd like to ask you some questions about your smoking."**

1. **"On average, how many cigarettes/day?"** ____ cigs/day

I. **IDEAS FOR GETTING BACK ON TRACK**

____ Read over page 30, with ideas for getting back on track

____ Review first section again, renew your reasons for quitting

____ Talk with Dr.re: the Nicotrol patch and re-read the sections about how to use the patch (p. 15-18) (especially if used too little, had withdrawal problems, seems to be highly addicted smoker).

____ Read about ways family and friends can help.

J. GO TO CLOSING

RELAPSE/RE-CYCLING (HAD RELAPSED AT CALL 2)

A. **"When we last talked, you had quit for ____ (duration) then gone back to smoking. You were thinking of quitting again using ____ (methods). What happened then?"**

IF THERE WAS A NEW QUIT ATTEMPT AND RELAPSE, ASK:

1. **"How long did you stay off cigarettes this last time?"** ____ days

B. **"What alternatives to smoking did you find the most helpful to quit and keep you from smoking?"**

1. Increased physical activity
2. Increased sleep
3. Using gum/mints/sticks/toothpicks
4. Find alternate pleasures (eg. music/reading/crosswords)
5. Relaxation/breathing techniques
6. Removing smoking materials from environment (eg. ashtrays)
7. Delay tactics
8. Positive self-talk
9. Assertive statements
10. Social support
11. Professional support
12. Change in routine

C1. **"Did you use any of the Preparation to Quit methods suggested?**
Yes **No**

C2. **What things have you done?"**

1. Reasons for Stopping
2. Why I Smoke
3. Alternatives to Smoking
4. Select a Quit Date
5. Prescription Filled
6. Social Support
7. Personal Action Plan
8. 48 Hour Checklist
9. 24 Hour Checklist

D. If yes to prescription filled

D1. "Are you using the Nicotrol patch now?" Yes No

If yes,

D2. what dose? ____ mg

D3. Any side effects? (do not prompt)

1. Sleep disturbance
2. Skin irritation
3. Headaches
4. Dizziness
5. Anxiety
6. Irritability
7. Fatigue
8. Constipation
9. Stomach Upset

E. **"What were the circumstances that caused you to start smoking again?** (CIRCLE ANY THAT COME UP)

1) withdrawal reactions/cravings
2) weight gain/increased appetite
3) handling negative emotions/stress
4) loss of pleasure/companion
5) slips/temptations
6) travel
7) ambivalence
8) poor timing/too busy/too much stress
9) don't like Stop Smoking Now! methods
(refer to corresponding page for identified problem)
10) cut down so don't need to quit
11) need to cut down more
12) lack willpower
13) low confidence/fear failure
14) too much pressure to quit
15) not enough support
16) need extra help/clinic
00)other:_____
specify

F. FIRST ASK: **"What do you think might have helped?"**

THEN: "Sounds like you ran into unexpected problems with

_____
(Circumstance)

"Many people find this (...) difficult. The Stop Smoking Now! workbook and video suggests several ways to deal with it... But, generally it is best to think about delay - avoidance and substitution."

G. 1. **"Have you thought about giving it another try?"**
Encourage to set up a new quitting plan and date...

Revised Quit Date: ___/___/___

H. **"I'd like to ask you a few questions about your smoking."**

1. **"How many cigarettes are you smoking each day, now?"** ____cig/day

I. **IDEAS FOR GETTING BACK ON TRACK**

____ Read over page 30, with ideas for getting back on track

____ Review first section again, renew your reasons for quitting

____ Talk with you Dr. re: the Nicotrol patch and re-read the sections about how to use the patch (p. 15-18) (especially if used too little, had withdrawal problems, seems to be highly addicted smoker).

____ Read about ways family and friends can help.

J. GO TO CLOSING

CLOSING

"I've really enjoyed talking to you today. This is the last time I'll be calling you. I'd like to take this opportunity to wish you all the best and to thank you again for participating in the Heart Institute Smoking Cessation Study. Good-bye."

APPENDIX J: Participant Follow-up Questionnaire

Today's Date:___/___/____ F/U 1_____ F/U 2_____
PT NUMBER:_____

A. SMOKING STATUS

1. Have you smoked a cigarette, even a puff, in the last 7 days?
   yes..... 1 Date of Relapse for 7 consecutive days_____/____/____
   no..... 2
2. Have you smoked a cigarette, even a puff, since we last contacted you?
   yes..... 1
   no..... 2
3. If you are currently smoking, on average how many cigarettes per day do you smoke? ____ cigs/day
4. If you are currently smoking, are you seriously considering quitting within the next 6 months?
   yes..... 1
   no..... 2
5. If you are currently smoking, are you planning to quit in the next 30 days?
   yes..... 1
   no..... 2
6. Since the last time we contacted you, how many times have you quit for at least 24 hours?
   0____1____ 2____3____4____5____6____7____8____9____>9____

B. IMPACTS ON SMOKING

The following experiences can affect the smoking pattern of some people. Think of any similar experiences you may be currently having or have had in the last month. Then rate the FREQUENCY of each event on a 5 point scale with 5 = Repeatedly and 1 =Never.

	Never		Occasionally		Repeatedly
1. When I am tempted to smoke, I think about something else.	1	2	3	4	5
2. I tell myself I can quit smoking if I want to.	1	2	3	4	5
3. I notice that nonsmokers are asserting their rights.	1	2	3	4	5
4. I recall information people have given me on the benefits of quitting smoking.	1	2	3	4	5
5. I can expect to be rewarded by others if I don't smoke.	1	2	3	4	5
6. I stop to think that smoking is polluting the environment.	1	2	3	4	5
7. Warnings about the health hazards of smoking move me emotionally.	1	2	3	4	5
8. I get upset when I think about my smoking.	1	2	3	4	5
9. I remove things from my home or place of work that remind me of smoking.	1	2	3	4	5
10. I have someone who listens when I need to talk about my smoking.	1	2	3	4	5
11. I think about information from articles and ads on how to stop smoking.	1	2	3	4	5
12. I consider the view that smoking can be harmful to the environment.	1	2	3	4	5
13. I tell myself that if I try hard enough I can keep from smoking.	1	2	3	4	5
14. I find society changing in ways that make it easier for nonsmokers.	1	2	3	4	5
15. My need for cigarettes makes me feel disappointed in myself.	1	2	3	4	5
16. I have someone I can count on when I'm having problems with smoking.	1	2	3	4	5
17. I do something else instead of smoking when I need to relax.	1	2	3	4	5
18. I react emotionally to warnings about smoking cigarettes.	1	2	3	4	5
19. I keep things around my home or place of work that remind me not to smoke.	1	2	3	4	5
20. I am rewarded by others if I don't smoke.	1	2	3	4	5

C TEMPTATIONS TO SMOKE

The following is a list of situations that lead some people to smoke. Please indicate how **tempted** you would feel to smoke in each of these situations by circling the appropriate number.

	Not at all tempted	Slightly tempted	Moderately tempted	Very tempted	Extremely tempted
1. At a bar or cocktail lounge having a drink.	1	2	3	4	5
2. When I am desiring a cigarette.	1	2	3	4	5
3. When things are just not going the way I want and I am frustrated.	1	2	3	4	5
4. With my spouse or close friend who is smoking.	1	2	3	4	5
5. When there are arguments and conflicts with my family.	1	2	3	4	5
6. When I am happy and celebrating.	1	2	3	4	5
7. When I am very angry about something or someone.	1	2	3	4	5
8. When I would experience an emotional crisis, such as an accident or death in the family.	1	2	3	4	5
9. When I see someone smoking and enjoying it.	1	2	3	4	5
10. Over coffee while talking and relaxing.	1	2	3	4	5
11. When I realize that quitting smoking is an extremely difficult task for me.	1	2	3	4	5
12. When I am craving a cigarette.	1	2	3	4	5
13. When I first get up in the morning.	1	2	3	4	5
14. When I feel I need a lift.	1	2	3	4	5
15. When I begin to let down on my concern about my health and am less physically active.	1	2	3	4	5
16. With friends at a party.	1	2	3	4	5
17. When I wake up in the morning and face a tough day.	1	2	3	4	5
18. When I am extremely depressed.	1	2	3	4	5
19. When I am extremely anxious and stressed.	1	2	3	4	5
20. When I realize I haven't smoked for awhile.	1	2	3	4	5

D. CONFIDENCE IN NOT SMOKING

Here is the same list of situations from the previous section. This time, please indicate how **confident** you are that you would not smoke in each of these situations by circling the appropriate number.

	Not at all Confident	Slightly Confident	Moderately Confident	Very Confident	Extremely Confident
1. At a bar or cocktail lounge having a drink.	1	2	3	4	5
2. When I am desiring a cigarette.	1	2	3	4	5
3. When things are just not going the way I want and I am frustrated.	1	2	3	4	5
4. With my spouse or close friend who is smoking.	1	2	3	4	5
5. When there are arguments and conflicts with my family.	1	2	3	4	5
6. When I am happy and celebrating.	1	2	3	4	5
7. When I am very angry about something or someone.	1	2	3	4	5
8. When I would experience an emotional crisis, such as an accident or death in the family.	1	2	3	4	5
9. When I see someone smoking and enjoying it.	1	2	3	4	5
10. Over coffee while talking and relaxing.	1	2	3	4	5
11. When I realize that quitting smoking is an extremely difficult task for me.	1	2	3	4	5
12. When I am craving a cigarette.	1	2	3	4	5
13. When I first get up in the morning.	1	2	3	4	5
14. When I feel I need a lift.	1	2	3	4	5
15. When I begin to let down on my concern about my health and am less physically active.	1	2	3	4	5
16. With friends at a party.	1	2	3	4	5
17. When I wake up in the morning and face a tough day.	1	2	3	4	5
18. When I am extremely depressed.	1	2	3	4	5
19. When I am extremely anxious and stressed.	1	2	3	4	5
20. When I realize I haven't smoked for awhile.	1	2	3	4	5

E. PERCEIVED STRESS

1. In the last month, how often have you felt that you were unable to control the important things in your life?

never	0
almost never	1
sometimes	2
fairly often	3
very often	4

2. In the last month, how often have felt confident about your ability to handle your personal problems?

never	0
almost never	1
sometimes	2
fairly often	3
very often	4

3. In the last month, how often have you felt that things were going your way?

never	0
almost never	1
sometimes	2
fairly often	3
very often	4

4. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

never	0
almost never	1
sometimes	2
fairly often	3
very often	4

SCORE:

F. NICOTINE REPLACEMENT THERAPY

THE FOLLOWING INFORMATION IS TO BE FILLED IN BY STUDY PERSONNEL ONLY.

1. Using prescription: yes____ no____ dose___
2. Side effects/overdose effects:

1.	skin irritation	2.	itchiness or redness
3.	sleep disturbances	4.	headaches
5.	dizziness	6.	anxiety
7.	irritability	8.	stomach upset
9.	drooling	10.	vomiting/diarrhea
11.	cold sweat	12.	blurred vision
13.	difficulty hearing	14.	fainting/confusion

G. CO_____ WEIGHT_____

H. REASONS FOR RELAPSE OR CONCERNS

1. withdrawal reactions/cravings
2. weight gain/increased appetite
3. handling negative emotions/stress
4. loss of pleasure/companion
5. slips/temptations
6. travel
7. ambivalence
8. poor timing/too busy/too much stress
9. cut down so don't need to quit
10. need to cut down more
11. lack willpower
12. low confidence/fear failure
13. too much pressure to quit
14. not enough support
15. need extra help/clinic
16. other