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Predictors of Attendance and Dropout at the Lung Health Study 11-Year Follow-Up

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Abstract

Participant attrition and attendance at follow-up were examined in a multicenter, randomized, clinical trial. The Lung Health Study (LHS) enrolled a total of 5, 887 adults to examine the impact of smoking cessation coupled with the use of an inhaled bronchodilator on chronic obstructive pulmonary disease (COPD). Of the initial LHS 1 volunteers still living at the time of enrolment in LHS 3 (5,332), 4,457 (84%) attended the LHS 3 clinic visit, a follow-up session to determine current smoking status and lung function. The average period between the beginning of LHS 1 and baseline interview for LHS 3 was 11 years. In univariate analyses, attenders were older, more likely female, more likely to be married, smoked fewer cigarettes per day, and were more likely to have children who smoked at the start of LHS 1 than non-attenders. Attenders were also less likely to experience respiratory symptoms, such as cough, but had decreased baseline lung function compared with non-attenders. Volunteers recruited via mass mailing were more likely to attend the long-term follow-up visit. Those recruited by public site, worksite, or referral methods were less likely to attend. In multivariate models, age, gender, cigarettes smoked per day, married status, and whether participants' children smoked were identified as significant predictors of attendance versus non-attendance at LHS 3 using stepwise logistic regression. Treatment condition (smoking intervention or usual care) was not a significant predictor of attendance at LHS 3. Older females who smoked less heavily were most likely to participate. These findings may be applied to improve participant recruitment and retention in future clinical trials.

Keywords

subject attrition; participation; predictors; clinical trial; smoking cessation; Lung Health Study

Introduction

The subject of attendance and retention in clinical trials has received little research attention, despite its importance to the validity of research findings. Examining variables associated with

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participant retention during follow-up is required to determine if particular subgroups of the population are more likely to drop out, which could result in an inadvertently biased sample, despite even the most stringent recruitment and randomization methods. Moreover, elucidating what factors contribute to decreased attrition in programs could help with targeting limited resources by tailoring retention strategies.

The issue of study compliance and attendance has been difficult due to the lack of consensus on the criterion used to measure dropout across studies. Research on study compliance, a broadly defined term, has tended to focus on issues related to treatment participation and adherence rather than attendance at follow-up. Moreover, attendance and attrition rates vary significantly from study to study as a function of the study design, as dropout rates in randomized clinical trials tend to be lower than in non-controlled studies [1]. Characteristics of the target population also affect attrition rates and account for some of the variability in retention rates across studies. Some predictors of attendance at follow-up evaluations have emerged in the literature, but again, there is a lack of consistency, in part, due to the extreme heterogeneity of participants across studies. Predictors of increased attrition include previous treatment for psychiatric or emotional problems, slower initiation of participant into a treatment program after randomization [2], depressed mood [3,4], and failure to complete at least one treatment session [5]. Attrition appears lowest when the research area is of personal interest to participants [6]. Rates of dropout among participants in addiction-based treatments, including alcohol addiction, are generally deemed low, and this is commonly accepted as the norm [2]. Baekeland and Lundwall [7] reported dropout rates ranging from 14 to 39%. A more recent randomized multicenter trial that matched treatment protocol with particular patient types found much lower attrition rates, with 87% of participants attending a three-year follow-up evaluation [2]. Regarding smoking cessation, older, heavier smokers were more likely to participate but less likely to abstain [3].

In longitudinal non-addiction studies related to disease, attempts to retain subjects throughout the study do not seem to fare much better, and attrition rates again vary widely. A clinical trial of weight loss management for adults with type II diabetes reported attrition rates of 18% [8], whereas a 60% dropout rate was noted in an infant cardiopulmonary study [9].

The literature on predictors of attrition in clinical trials is scarce, and what has been disseminated is inconclusive, providing few concrete findings. We chose to examine characteristics of participants and attrition using LHS data, as few other studies examine data from such a large-scale, multicenter, clinical trial. Identifying predictors could increase retention rates of participants in long-term clinical trials by identifying subgroups of the study population who may be at risk of attrition and tailoring retention strategies in efforts to maintain their involvement throughout the study period.

Methods

Sample

The LHS was a randomized controlled trial designed to test the effectiveness of a smoking cessation program, with and without the use of an inhaled bronchodilator for the prevention and treatment of symptomatic chronic obstructive pulmonary disease (COPD). Smokers, 35 to 60 years of age, were recruited in 10 clinics throughout the U.S. and Canada, and inclusion in the study was contingent on mild lung function impairment (N=5,887). Specifically, their ratio of forced expiratory volume (FEV_1) to forced vital capacity (FVC) had to be below 70%, and FEV_1 had to fall in the range of 55 to 90% of predicted normal based on age, height, race, and gender [10]. Participants were excluded if they had serious medical conditions that could affect measures of lung function, or if they used prescription drugs that may have modified lung function. Participants were recruited through various means, including worksite, public

site, mass mailing, telephone, media, and referral methods. Each of the 10 clinics devised its own specific recruitment plan, using a combination of the aforementioned methods to varying degrees. As the study involved randomization to intervention or control groups, volunteers had to be willing to engage in a smoking cessation program for inclusion in the study.

After recruitment, participants were randomly assigned to one of three groups: 1) smoking intervention (SI) with ipratropium bromide inhaler, 2) SI with placebo inhaler, or 3) usual care (UC). For the present study, the two intervention groups were combined and referred to as the SI group, as use of the ipratropium bromide inhaler was not associated with any changes in cessation rates or measures of long-term change in lung function. The smoking intervention program is described in detail elsewhere [11].

Participants were followed for five years after baseline, with 94% of surviving participants attending clinic visits for a fifth-year interview and spirometry. After this follow-up period, the Lung Cancer Substudy (LCS) recruited 5,003 of the original 5,887 LHS participants to investigate rates of lung cancer among LHS participants. Members were contacted by telephone and interviewed every six months to determine smoking status and morbidity. This follow-up continued until recruitment began for LHS 3, a long-term follow-up of clinical trial participants. The purposed of LHS 3 was to investigate whether smoking cessation intervention through random assignment to treatment status influenced lung function and smoking status over the long term. The sample of possible attendees in the present analyses (N=5,332) consisted of those who were still living prior to LHS 3 enrolment or those who died after March 20, 2000, the end of the enrolment period for LHS 3. Of the initial 5,887 members in LHS 1, 84% (4,457) of surviving members volunteered for LHS 3, and all gave informed consent for continued participation. Non-attenders included those who could not be contacted (N=853) as well as those who explicitly refused to participate (N=22), for a total of 875 non-attenders at the long-term follow-up. The average period between the beginning of LHS 1 and baseline interview for LHS 3 was 11.0 years (*SD* = 0.63).

Measures

A total of 30 variables ascertained at baseline interviews of LHS 1 were tested to determine predictability of attendance for all eligible 5,332 participants at LHS 3. As preliminary analyses revealed that treatment assignment was not a significant predictor of attendance at LHS 3, the analyses presented in this report are for both SI groups and the UC group combined. The variables tested as predictors consisted of demographic variables, alcohol intake, body mass index (BMI), smoking-related variables, past and present illness, lung function, and social support variables (see Table 1).

Demographic variables included age, gender, race, marital status, education level, employment status (full or part-time). Usual alcohol intake was measured using a quantity by frequency approach.

Smoking-related variables included number of cigarettes smoked per day at baseline, and number of other smokers in the household (spouse, children, other and total number of smokers in the household). Various measures of social support have been identified as important contributors to both initial smoking cessation and maintenance of cessation up to one year post intervention [12,13] and were included in the present analyses. Specifically, the desire of a spouse or close friend for the participant to quit was examined. Participants were asked about general health and the presence of symptoms including the prevalence of cough, phlegm, wheezing, chest colds, and bronchitis.

Lung function was measured during the LHS by spirometry. FEV_1 and FVC were obtained for participants at baseline and annual clinic visits from year one to year five, and again at LHS

3. Participants were given spirometry followed by a bronchodilator. Spirometry measures were then repeated. The post-bronchodilator tests (Post BD FEV_1 and Post BD FVC) were considered to be more reliable measures of lung function and are reported for the present analyses.

Participants in LHS 1 were considered sustained quitters if non-smoking status was confirmed at each of the five annual clinic visits. Those who were absent at any of the annual visits were treated as smokers. Sustained abstainers in LHS 3 were those who achieved sustained quitting status in LHS 1 and maintained cessation throughout their involvement in LCS and at the point of LHS 3 enrollment, where smoking status was confirmed by expired carbon monoxide. In the LCS, a participant absent from an annual visit was treated as missing without any modification to smoking status, nor did the lack of verification of smoking status with carbon monoxide measures affect the recorded status. The outcome of interest was attendance or not at LHS 3.

Statistical Methods

All quantitative variables are represented by means ± standard deviations, whereas dichotomous variables are shown as percentages. Between-group differences were tested using t-tests for quantitative variables and chi-squared tests for dichotomous variables. Models were created using ordinary and stepwise logistic regression to assess predictors of attendance at LHS 3. Preliminary analysis showed an effect for clinic, and clinic was included as an adjustment in the final analyses. All statistical analyses were performed using SAS, version 8.

Results

Of the initial LHS 1 volunteers still living at the time of enrolment in LHS 3 (5,332), 4,457 (84%) attended the LHS 3 visit, and 875 did not. Data were missing from 555 members who were known or assumed to be deceased. Table 1 presents the baseline characteristics of attenders versus non-attenders at LHS 3. The results of univariate logistic regression analyses are reported in Table 2. Attenders at LHS 3 were slightly older, smoked fewer cigarettes per day at baseline, more likely to have children who smoked at the start of LHS 1, and more likely to have been recruited via mass mailing than non-attenders. Participants recruited at a public site, or through worksite and referral methods were less likely to attend. Attenders were less likely to experience respiratory symptoms but more likely to exhibit decreased lung function, as measured by decreased Post BD FEV_1 and FVC scores. Attenders at LHS3 were more likely female and more likely to be married than non-attenders. No significant differences were found for non-attenders versus attenders on race, education, employment status, BMI, and alcohol intake.

Stepwise logistic regression was performed using the variables in Table 1, and Table 3 reports the odds ratios for significant predictors of attendance at LHS 3. In the final model, age, gender, cigarettes smoked per day, married status and whether participants' children smoked were all significant predictors of attendance versus non-attendance at LHS 3. Although significant in univariate analyses, mass mailing and other recruitment methods, pulmonary function measures of FEV_1 and FVC, and respiratory symptoms failed to predict attendance in multivariate models. The final multivariate model accounted for a small portion of the variability between attendance and non-attendance at LHS 3 (pseudo-R^2 = 0.028).

Discussion

The present study attempted to identify predictors of continued participation versus non-attendance at long-term follow-up in a randomized clinical trial. Attenders of LHS 3 were

older, smoked fewer cigarettes at baseline, were more likely to be married, and were more likely to have children who smoked than non-attenders.

Of those who attended LHS 3, 22% of SI participants maintained cessation after 11 years as compared to 6% of UC participants [14]. It may be reasoned that participants who were not successful abstainers after 11 years may have felt their lack of ability to quit was not socially acceptable after being involved in a cessation intervention. If this were true, we would have expected fewer members of the UC group to attend, as there were fewer sustained quitters in this group compared to the SI group. Treatment assignment, however, was not a significant predictor of attendance at LHS 3. Of those in the UC group who did not participate in LHS 3, 82% were still smoking after 5 years of follow-up at the end of LHS 1 compared with 68% of attenders at LHS 3 from this group [14]. As such, those in the UC who were still smoking after 5 years of follow-up were less likely to participate in LHS 3, which is consistent with this hypothesis. As we have no available means to ascertain smoking status after 11 years for non-attenders, however, we cannot empirically test whether smoking status after 11 years predicts attendance.

Having children who smoked at baseline was a significant predictor of attendance at LHS 3. This is the first paper of LHS participants to include this variable in the analyses. Factors affecting long-term attendance at clinic follow-up are likely complex, making it difficult to speculate why and how having children who smoked at baseline influenced attendance years later. This finding does, however, identify potential groups of participants of clinical trials, in particular, those involved in smoking cessation programs, who appear to be more likely to maintain their involvement in the trial.

An additional interesting characteristic of attenders at follow-up 11 years after baseline in the LHS was the method used to initially recruit participants, a modifiable factor. Although not significant in the multivariate models, univariate analyses revealed that those contacted via mass mailing were more likely to attend LHS 3 than those contacted by other methods. Overall, mass mailing was the most productive and efficient method of recruitment in the LHS [15], and has a stronger volunteer component than other recruitment methods. This is consistent with the findings of decreased subject attrition with voluntary recruitment [6]. The fact that an effect still existed for recruitment method with outcomes measured at a considerably later time point was unexpected.

The findings reported in the present study should be interpreted with caution, as these findings relate to those in a clinical trial of smoking cessation and may not apply to clinical trials in general. Moreover, one of the inclusionary criteria for participants in the Lung Health Study was some evidence of lung function impairment, specifically mild COPD. As such, these results should be generalized with caution to smokers within the general population, a group that is likely more heterogeneous than in the LHS. Smokers in the LHS differed from those in the general population of smokers within the U.S. and Canada on a number of variables. LHS participants were predominantly white, smoked more, had higher levels of education, and included a higher proportion of women [16]. In fact, increased representation of more educated participants occurs frequently in clinical trial samples [17]. Although there were no significant differences between the SI and UC groups regarding these variables, our participants were a distinct group of smokers that may not adequately represent the general population of smokers.

Non-attenders were defined to be those who could not be contacted as well as those who refused to participate. Mortality data for all U.S. study participants were obtained via a review of the National Death Index and mortality status was determined for 98% of participants by the end of 2001. During LHS 3 enrolment, we were unable to contact 16% of the original participants who were known not to be deceased. A concern is that some of these participants may have

attended LHS 3 if contacted. Although this may be a caveat in using this sample, there is a paucity of other studies that involve a lengthy follow-up period from which to examine predictors of subject attrition.

One of the advantages of examining predictors of attendance in this sample of participants is the low number of dropouts, which highlights the intensive nature of the program. Participants were followed for five years with annual visits, and phone contacts were made thereafter. Additional intervention strategies were available for those who relapsed after the initial intervention in LHS 1 [18]. As such, the rate of overall dropout was very low (17%). Identifying predictors of dropout in this group can help with targeting strategies for those particularly resistant to current methods and can assist with participant retention in clinical trials in general.

By detecting variables that are modifiable, examining predictors of long-term attendance can help decrease subject attrition and identify relationships that may improve the efficacy of existing programs for targeted individuals, and, in doing so, improve the power of studies to detect differences. For example, the results of the present study indicate that older female participants who smoked less heavily were more likely to attend, whereas younger men who smoked more heavily and suffered from higher rates of respiratory symptoms were more likely to drop out. Efforts could be made in future studies to incorporate more intensive follow-up strategies for this subgroup of the sample population in anticipation of their increased likelihood of attrition. This research highlights the impact of recruitment methods, knowledge that can be applied in recruitment of participants in future studies. Although the use of multiple recruitment strategies is likely to result in the most random study sample, identifying recruitment strategies that are the most effective while still allowing for randomized selection can greatly assist with the time and budgetary constraints faced by researchers conducting such large-scale clinical trials.

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Table 1

LHS1 Baseline Characteristics of Participants of LHS 3 Visit[abc].

Variable	Non-Attenders	Attenders	*p*-value
Treatment Assignment	64.6	67.4	0.11
Age (years)	46.8 (6.8)[b]	48.4 (6.8)	<0.0001[c]*
Female %	33.9	38.3	0.01*
White %	96.1	96.1	0.97
Black %	3.5	3.4	0.87
Oriental %	0.1	0.1	0.87
Married %	68.2	72.2	0.02*
Education (years)	13.7 (2.69)	13.6 (2.84)	0.42
Full-time Job %	81.5	81.3	0.88
Part-time Job %	6.7	7.9	0.20
BMI	25.8 (3.89)	25.5 (3.88)	0.06
Drinks/week	4.3 (5.36)	4.4 (5.52)	0.79
Cigarettes/day	32.7 (13.2)	30.8 (12.7)	<0.0001*
Spouse Smoke %	28.5	28.3	0.91
Children smoke %	7.2	12.2	<0.0001*
Others smoke %	6.1	5.7	0.66
No. Household Smokers[df]	0.5 (0.71)	0.5 (0.71)	0.07
Spouse Like Quit %	90.6	89.6	0.36
Cough %	38.6	35.1	0.05*
Phlegm %	32.6	30.0	0.13
Wheeze %	61.8	58.9	0.10
Chest Cold %	5.6	5.6	0.97
Bronchitis %	7.7	7.0	0.50
Mass Mail Recruitment %	28.1	35.0	<0.0001*
Public Site %	9.3	6.5	0.01*
Phone Survey %	3.2	3.2	0.98
Other Recruitment %[e]	24.6	20.9	0.02*
Post BD FEV_1[g]	2.81 (0.63)	2.75 (0.63)	0.01*
Post BD FVC[g]	4.33 (0.96)	4.24 (0.95)	0.01*

[a] Analyses done on data from 4,457 attenders and 875 non-attenders at LHS 3.

[b] *Note:* Numbers in parentheses represent standard deviations.

[c] *Note*: * Denotes statistical significance at $p<0.05$

[d] Number of household smokers excludes participant.

[e] Other recruitment is a composite of worksite and referral methods.

[f] Number of household smokers had missing data for 1 non-attender.

[g] Post BD FEV_1 and FVC had missing data for 1 attender and 1 non-attender.

Table 2

Univariate Analysis of Predictors of Attendance at LHS 3 Visit Identified by Logistic Regression[ab].

Variable	Odds Ratio (95 % Confidence Interval)	*p*-value	*Pseudo-R*^{2}
Treatment Assignment	1.14 (0.98–1.33)	0.10	0.014
Age	1.03 (1.02–1.04)	0.0000*[c]	0.020
Gender	1.24 (1.06–1.45)	0.01*	0.014
White	0.99 (0.68–1.45)	0.95	0.014
Black	1.02 (0.68–1.52)	0.94	0.014
Oriental	0.96 (0.12–8.07)	0.97	0.014
Married	1.25 (1.06–1.47)	0.01*	0.015
Education	1.00 (0.97–1.03)	0.96	0.014
Full-time Job	0.98 (0.79–1.16)	0.65	0.014
Part-time Job	1.21 (0.90–1.61)	0.21	0.014
BMI	0.99 (0.97–1.01)	0.21	0.014
Drinks/week	1.00 (0.99–1.01)	0.93	0.014
Cigarettes/day	0.99 (0.98–0.995)	0.0001*	0.016
Spouse Smoke	1.00 (0.85–1.17)	0.95	0.014
Children smoke	1.83 (1.39–2.41)	0.0000*	0.018
Others smoke	0.91 (0.67–1.24)	0.55	0.014
No. Household Smokers[d,f]	1.11 (0.99–1.23)	0.07	0.014
Spouse Like Quit	0.87 (0.67–1.11)	0.25	0.014
Cough	0.86 (0.74–0.995	0.04*	0.014
Phlegm	0.89 (0.76–1.04)	0.16	0.014
Wheeze	0.89 (0.76–1.03)	0.12	0.014
Chest Cold	1.01 (0.74–1.39)	0.95	0.014
Bronchitis	0.92 (0.70–1.22)	0.56	0.014
Public Site	0.81 (0.62–1.07)	0.14	0.014
Mass Mail	1.24 (1.04–1.48)	0.02*	0.015
Mass Media	1.07 (0.91–1.26)	0.42	0.014
Phone Survey	0.88 (0.56–1.36)	0.56	0.014
Other Recruitment[e]	0.83 (0.69–0.99)	0.03*	0.014
Post BD FEV_1[g]	0.85 (0.75–0.95)	0.005*	0.015
Post BD FVC[g]	0.90 (0.84–0.97)	0.01*	0.015

[a] *Note:* Models adjusted by LHS clinic.

[b] Analyses done on data from 4,457 attenders and 875 non-attenders at LHS 3.

[c] Note: *Denotes statistical significance at $p<0.05$.

[d] Number of household smokers excludes participant.

[e] Other recruitment is a composite of worksite and referral methods.

[f] Number of household smokers had missing data for 1 non-attender.

[g] Post BD FEV_1 and FVC had missing data for 1 attender and 1 non-attender.

Table 3

Multivariate Analysis of Predictors of Attendance at LHS 3 Visit Identified by Stepwise Logistic Regression[ab].

Variable	Odds Ratio (95 % Confidence Interval)	*p*-value
Age	1.03 (1.02–1.04)	<0.0001
Gender	1.21 (1.03–1.42)	0.02
Married	1.28 (1.08–1.51)	0.004
Cigarettes/day	0.99 (0.99–1.00)	0.001
Children smoke	1.73 (1.31–2.28)	0.0001
Public Site[c]	1.00	

[a] *Note:* Model adjusted by LHS clinic.

[b] Analyses done on data from 4,455 attenders and 874 non-attenders at LHS 3 (3 participants had missing data and as such were not included in the multivariate analyses).

[c] Public site used as the reference group for odds ratios for all recruitment methods.