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Abstract

BACKGROUND: The Internet has introduced an alternative approach to traditional methods for conducting multinational cohort studies. However, the validity of Internet studies is not well-established. The ATTEMPT study was designed to describe the natural history and patterns of smoking cessation as well as the short-term health outcomes associated with smoking cessation.

OBJECTIVES: The objective of this sub-analysis was to evaluate the validity, loss to follow-up, and missing data within a cohort of smokers (ATTEMPT).

METHODS: ATTEMPT participants (n=2,009), were recruited by e-mail from existing Internet panels in four countries—Canada (CA) (n=208), France (FR) (n=201), the United Kingdom (UK) (n=200), and the United States (US) (n=1,400)—in spring 2003. Participants had to be aged 35 years–65 years, smoke at least 5 cigarettes per day, and intend to quit smoking within the next 3 months. Online assessments were conducted at baseline and quarterly thereafter for 1 year during the ATTEMPT pilot phase.

Assessments took approximately 25 minutes to complete and included questions about smoking, health and medical resources, and weight. Study participants were mailed standardized weight scales. Self-reported body weight was validated in a random sample of US participants who agreed to an in-home visit by a health professional. Agreement between self-reported weight and actual weight was tested using the Bradley-Blackwood method.

RESULTS: The overall response rate was 76% at Month 3 and 52% at Month 12 and varied by country (CA-55%; FR-36%; UK-39%; US-56%). Duration of baseline data collection ranged from 3 days (CA) to 16 days (FR), and duration of Month 12 data ranged from 12 days (CA) to 21 days (FR, UK). There was no difference in age, sex, race, or selected health conditions between baseline and Month 12 respondents. Mean number of missing items per respondent was 2.2 items at Month 3 and decreased after minor questionnaire revision at Month 6. Eighty-two percent of participants agreed to an in-home visit. Of 815 randomly sampled participants, 64% completed an in-home assessment, 23% could not be reached, and 13% refused. There was no difference between self-reported and in-home visit weight at Month 3 (-0.24 kg NS). Only a slight difference was seen at Months 6 and 9 (-1.2 kg [p=0.02], and -1.01 kg [p=0.01]), respectively.

CONCLUSIONS: This analysis demonstrated the feasibility of using an Internet panel to enroll a cohort of smokers. There was no indication of bias related to non-response associated with demographic and health characteristics.

Conflict of Interest

Sanofi-Aventis and RTI Health Solutions employees and consultants contributed significantly to the design of and analysis plan for this study. Data collection and analyses were conducted by employees of RTI Health Solutions, a nonprofit research organization. The study was fully funded by Sanofi-Aventis.

Background

ATTEMPT Study

ATTEMPT is an ongoing multinational, longitudinal, observational Internet cohort study of smokers who, at enrollment, intended to quit smoking.

ATTEMPT OBJECTIVES

Primary

To describe the natural course and patterns of consecutive smoking cessation attempts

Secondary

To describe the medical and economic benefits of smoking cessation
To explore the impact of weight and craving on smoking cessation
To identify factors associated with smoking cessation success/failure
To assess the relationship between duration of smoking abstinence and level of health care consumption, productivity, and weight gain.

Because few studies have demonstrated the reliability and validity of Internet studies for health services research, ATTEMPT Year 1 data was evaluated to assess the feasibility and validity of online recruitment and assessment.

Objectives

Feasibility Assessment: The objectives of this sub-analysis of the ATTEMPT cohort were:

- To evaluate the response rates in follow-up assessments
- To compare responders with non-responders in terms of baseline demographic characteristics, comorbidities, and smoking status
- To evaluate item non-response
- To evaluate validity of self-reported weight

Methods [1]

Study Population

- 2,009 adults from Canada, France, the UK, and the US:

- Members of an existing Internet panel (i.e., large number of individuals who had agreed to participate in research studies via the Internet) were the source for subject recruitment
- Demographic data were available to characterize the panel members relative to the general population in each country

Inclusion Criteria

- Aged 35–65 years
- Smoked at least 5 cigarettes per day
- Intended to quit smoking within the next 3 months

Exclusion Criteria

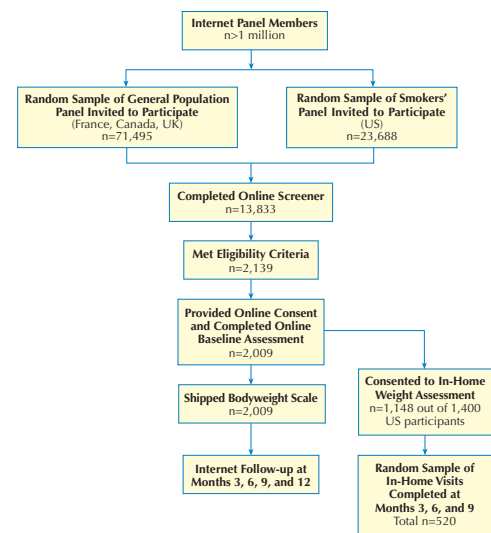
- No access to Internet
- Weight >135 kg (maximum capacity of scale is 150 kg)

Data Collection

- 25-minute online assessments:
 - Were conducted at baseline and quarterly for 1 year
 - Included questions about smoking, health conditions, medical resource use, demographics, quality of life, productivity, and insurance
 - Target response rate was 50% at the end of 1 year
- Baseline respondents were invited to participate at each follow-up, even if they had missed the previous assessment.
- Self-reported weight was provided at each assessment (using standardized weight scales shipped to participants' homes).
- In-home weight assessments of a random sample of participants (US only) at Months 3, 6, and 9 were scheduled within 2 weeks of online assessment in order to assess the validity of self-reported weight.
- Incentives were given via bonus points that could be redeemed for products online (equivalent to approximately \$2 USD per assessment). Incentives in France and the UK were increased to equivalent of \$15 USD per assessment for Month 9 and Month 12 assessments to increase participation. If participants completed three of the four follow-up assessments, their incentives were doubled for each assessment completed.

Methods [2]

Figure 1. Data Collection Flow Chart



Results [1]

Enrollment

Figure 2. Baseline Enrollment

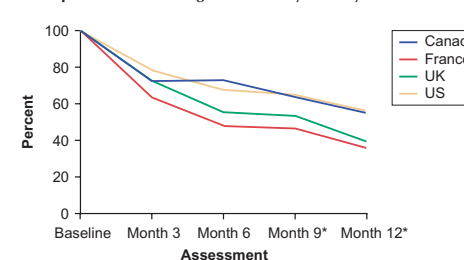
Country	Length of Recruitment	Number Enrolled
Canada	3 days	208
France	16 days	201
UK	15 days	200
US	8 days	1,400

Results [2]

Response Rate

- Overall response rate was 76% at Month 3 and 52% at Month 12
- Response rates were higher in the US and Canada compared to France and the UK
- Largest decrease in response rate was seen between Baseline and Month 3
- 57% of ATTEMPT participants completed the baseline assessment plus three or more follow-up assessments
- 38% completed all five assessments

Figure 3. Response Rate Following Enrollment by Country



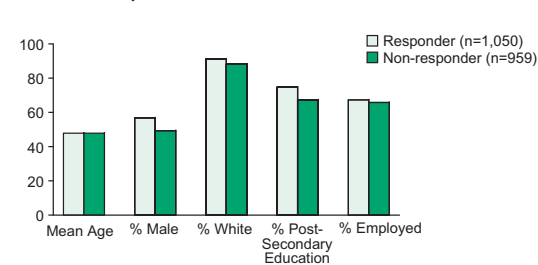
*Incentive increased in France and the UK at Month 9 and Month 12.

Results [3]

Comparison of Responders vs. Non-Responders

- There was little evidence of differential losses to follow-up throughout the 12 months with respect to demographic characteristics.

Figure 4. Baseline Demographic Characteristics for Month 12 Responders and Non-Responders



Results [4]

Comparison of Responders vs. Non-Responders (continued)

- There was little evidence of differential losses to follow-up throughout the 12 months with respect to baseline comorbidities.

Figure 5. Baseline Comorbidities for Month 12 Responders and Non-Responders

Have seen a doctor at least twice in the past year for the condition (Baseline)	Responder (n=1,050)	Non-Responder (n=959)
Angina (chest pain)	3%	6%
Arthritis	14%	16%
Asthma	6%	7%
Cholesterol problems/high cholesterol	23%	19%
Circulation problems (coldness, loss of feeling) in hands or feet	9%	8%
COPD (chronic obstructive pulmonary disease) or emphysema	4%	6%
Depression	16%	21%
Diabetes or high blood sugar	8%	6%
Heart attack or heart disease	7%	6%
Hypertension or high blood pressure	19%	18%
Problems with weight gain or obesity	7%	9%
None	37%	35%

Results [5]

- The non-response rate is similar among previous smokers and abstainers.
- For example, at Month 6, 24% of Month 3 smokers and 24% of Month 3 abstainers did not respond, and at Month 9, 20% of Month 6 smokers and 18% of Month 6 abstainers did not respond.

Figure 6. Non-Response Rate by Smoking Status* in Previous Assessment

	Non-Response Rate		
	Month 6	Month 9	Month 12
Smoker in previous assessment	24%	20%	25%
Abstainer in previous assessment	24%	18%	26%

*30-day point prevalence abstinence at previous assessment.

Results [6]

Item Non-Response

- Minimal item non-response was observed throughout the study.

Figure 7. Item Non-Response

Number of missing items excluding demographics (out of approximately 260 items per assessment)	Average 0.5 items per responder (Month 12) to 2.2 items per responder (Month 3)
Most frequently skipped items	Income (Canada, UK, and US: 10%; France: 13%) Race (Canada: 3%; France: 4%; UK: 6%; US: 2%)

Results [7]

Validity of Self-Reported Weight

- No significant differences were found between the in-home assessed sample and remaining web-assessment responders in terms of age, gender, and race (data not shown).
- Participant self-reporting of body weight was a reasonable proxy for more expensive and intrusive methods of measuring weight.

Figure 8. Validity of Self-Reported Weight (US only)

Consented to in-home visit upon enrollment (%)	82% (1,148/1,400)		
Randomly selected at Months 3, 6, and 9 for in-home weight assessment	815		
Completed in-home weight assessment (%)	64%		
Refused at time of in-home assessment (%)	13%		
Could not be reached (%)	23%		
	Month 3 (n = 196)	Month 6 (n = 175)	Month 9 (n = 149)
Mean difference in weight (self-reported relative to in-home weight)	-0.2 kg	-1.2 kg	-1.0 kg
P-value*	0.11	0.02	0.01
Pearson's correlation coefficient	0.996	0.96	0.98
Mean number of days between in-home and web (self-reported) assessment of weight	12.2	7.6	11.6

*P-values were from Bradley-Blackwood test for the equivalence of the means and variances.

Conclusions

Feasibility

- We were able to enroll a large-scale study cohort meeting study criteria in four countries within a brief time period (less than 20 days per country).
- Retention rate at Month 12 was 52%, but there was no indication of bias related to non-response associated with demographic or health characteristics.
- Item non-response rate was extremely low.
- A large proportion of participants agreed to in-home weight assessment.

Validity

- Self-reported weight was highly correlated with observed weight from in-home assessment.

Overall

- This analysis demonstrates the feasibility and validity of key aspects of a study that used an Internet panel to enroll and follow a cohort of smokers.
- Analyses of the representativeness of the study cohort demonstrated that demographic and smoking characteristics within the ATTEMPT cohort are generally similar to national estimates (see Gilsenan and colleagues' presentation during "Methods Jam" session).

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