

# Monitoring Recruitment Success and Cost in a Randomized Clinical Trial

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**Abstract** - Recruitment of older adults into research studies is challenging and, as a consequence, the recruitment period is often extended and more expensive than planned <sup>1</sup>. This study monitored the effectiveness (number of subjects attracted) and cost of different recruitment strategies when recruiting edentulous elderly adults. Socio-demographic data were gathered and compared to 2001 Canadian census data. Advertisements in major Montreal newspapers attracted the most people (24.3%). However, the most economical recruitment method proved to be placement of ads in senior newspapers (\$73.74 per subject). The information gathered in this study will assist others in planning recruitment strategies for edentulous elderly populations.

KEY WORDS: Recruitment, Clinical trials, Cost effectiveness, Edentulous elderly, Prosthodontics

## INTRODUCTION

Patient recruitment is one of the most challenging aspects of a clinical trial. Careful planning and monitoring of recruitment methods is vital to ensure that the various recruitment strategies implemented are effective in finding the requisite number of eligible participants <sup>2</sup>. It is necessary to recruit an adequate sample size, as insufficient participation may reduce the power of the research study, ultimately leading to inconclusive results. In addition to the many challenges brought by recruitment in general, studies have shown that it is more difficult to recruit older individuals <sup>3</sup>. As a consequence, greater efforts must be made to recruit an older population within the allotted recruitment period. The cost associated with subject recruitment is often underestimated and recruitment problems or delays will have an impact on the cost of the trial <sup>4</sup>. Identification of cost-effective recruitment strategies will aid in making future recruitment decisions.

This study uses subject recruitment information gathered from an on-going randomized clinical trial. The impetus to commence the study arose from the evidence of a pilot study (Morais *et al.*) which suggested that low-cost implant overdenture treatment may improve the nutritional state of edentulous people <sup>5</sup>. As a result, recruitment for a larger study began in January 2003. The purpose of the study is to examine post-treatment differences in nutritional status between patients with mandibular two-implant retained overdentures and those with conventional dentures. Participants include 254 edentulous men and women, aged 65 or older, from the Montréal region.

The purpose of the current study was to monitor the effectiveness of various recruitment strategies, to determine the costs associated with recruiting elderly edentulous people and to perform a socio-demographic analysis of individuals attracted from the different recruitment strategies.

## METHODS AND MATERIALS

### Recruitment Plan

The recruitment strategies implemented for the study included: 1) newspaper advertisements, 2) magazine advertisements, 3) a feature television and radio appearance, 4) community postings and 5) referrals from dentists, friends or other active study subjects. These recruitment methods were selected in order to reach various segments of the population, primarily targeting adults aged 65 and over. In order to ensure a steady screening and recruitment rate, we phased in different recruitment strategies. Interested candidates responded to the various recruitment methods and contacted the study centre. Those who met the initial criteria were given a telephone interview and subsequently invited to attend an information session. Subjects then underwent clinical screening to determine if they met the clinical inclusion criteria (Table 1).

### Monitoring and Evaluation

A data-based system for management of subject recruitment was developed to facilitate evaluation of the recruitment progress. Telephone interviewers maintained detailed log sheets of messages taken and of returned calls. Evaluation of telephone interviewer log sheets during the recruitment period provided information regarding the response rates of people attracted from the different recruitment strategies. Information obtained from screened participants was added to a computerized database from which variables were extracted for evaluation.

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**Table 1.** Inclusion and exclusion criteria for subject participation in the clinical

|                                                                                                                                                                        |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <i>Inclusion Criteria</i>                                                                                                                                              |  |
| 1. Male or female                                                                                                                                                      |  |
| 2. Aged 65 years and older                                                                                                                                             |  |
| 3. Completely edentulous for a minimum of 5 years                                                                                                                      |  |
| 4. Wishing to replace existing conventional dentures                                                                                                                   |  |
| 5. An adequate understanding of written and spoken English or French                                                                                                   |  |
| 6. Able to understand and respond to the questionnaires used in the study                                                                                              |  |
| 7. Willing and able to accept the protocol and to give informed consent                                                                                                |  |
| <i>Exclusion Criteria</i>                                                                                                                                              |  |
| 1. Insufficient bone to place two implants in the anterior mandible                                                                                                    |  |
| 2. Other oral conditions that preclude immediate prosthetic treatment                                                                                                  |  |
| 3. Acute or chronic symptoms of temporomandibular disorders                                                                                                            |  |
| 4. History of radiation therapy to orofacial region                                                                                                                    |  |
| 5. Systemic or neurological disease that contraindicates implant surgery                                                                                               |  |
| 6. Any neoplasia diagnosed less than five years previously                                                                                                             |  |
| 7. A BMI less than 20 or more than 32 kg/m <sup>2</sup>                                                                                                                |  |
| 8. A score of 24 or less on the Mini-Mental State Evaluation (to eliminate subjects with impaired cognitive function)                                                  |  |
| 9. Presently taking any of the following which will affect blood nutrient concentration: dietary supplements, anti-neoplasia medications, phenytoin or corticosteroids |  |
| 10. Other health conditions that jeopardize surgical treatment (alcoholism, etc.)                                                                                      |  |
| 11. Psychological or psychiatric conditions that could influence diet and reaction to treatment                                                                        |  |

**Table 2.** Different recruitment strategies and their cost

| <i>Recruitment Strategy</i> | <i>Strategy Location Of Advertisement<br/>(Number Of Appearances)</i> | <i>Cost (Can \$)*</i> |
|-----------------------------|-----------------------------------------------------------------------|-----------------------|
| Major Montreal newspapers   | La Presse (5)                                                         | 3352.80               |
|                             | Journal de Montreal (7)                                               | 1274.03               |
|                             | The Montreal Gazette (1)                                              | 550.39                |
|                             |                                                                       | 5177.22               |
| Senior newspapers           | Journal Bel Age (3)                                                   | 1297.48               |
|                             | The Senior Times (1)                                                  | 274.91                |
|                             | FADOQ Virage (1)                                                      | 345.08                |
|                             |                                                                       | 1917.47               |
| Community newspapers        | 10 Transcontinental papers (5)                                        | 1581.73               |
|                             | Courrier Laval (7)                                                    | 1253.26               |
|                             | Suburban (4)                                                          | 1394.24               |
|                             | The Chronicle (2)                                                     | 1703.60               |
|                             |                                                                       | 5932.83               |
| Senior Magazine             | Magazine Le Bel Age (3)                                               | 6556.47               |
| Public media                | CTV News feature presentation (1)                                     | 0                     |
|                             | Radio (1)                                                             | 0                     |
| Referral                    | Dental professionals, friends and other active study subjects         | 0                     |
| TOTAL COST                  |                                                                       | 19 583.99             |

\* Taxes included

To assess recruitment rate, a method to monitor and evaluate response rates from the five recruitment vehicles was devised. The total number of people attracted from each recruitment strategy was calculated as well as the total cost for each recruitment method (Table 2). The cost associated with each recruited subject was determined by dividing the cost by the number of recruited subjects for each strategy.

A socio-demographic analysis of the population recruited was performed and compared to data from the 2001 Canadian census <sup>6</sup>. Factors such as gender and education were compared. Chi-square tests were used to compare characteristics of the recruited subjects to those of the general population. All statistical analyses were carried out using SAS statistical software (version 8.2). The analysis was limited to a 17-month period (27/1/2003 – 10/6/2004).

## RESULTS

### Socio-demographic Analysis of the Population Attracted

A gender analysis shows that, while more females may have been attracted to the study, there is no significant difference in the gender distribution among the accepted study participants (Table 3).

Comparisons of the population attracted to the study with the general population of Quebec (2001 Canadian census data) confirmed that the study attracted a population with a significantly higher education level (53.5% are high school graduates) than the general population (68.3% are elementary school graduates) ( $p < 0.05$ ) (Figure 1). In addition, further analysis reveals that this study has recruited a population with a significantly lower income level (34.6% <\$20,000) than the general population (9.4% <\$20,000) ( $p < 0.05$ ) (Figure 2).

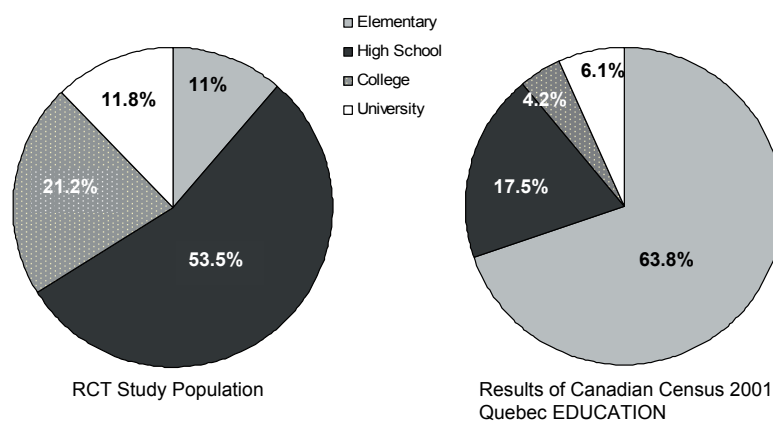
<\$20,000) than the general population (9.4% <\$20,000) ( $p < 0.05$ ) (Figure 2).

### Response to the Advertisement Methods

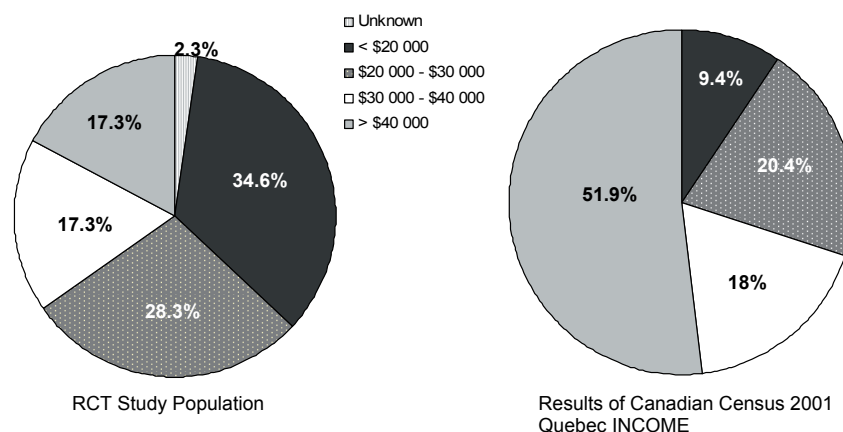
Of all the recruitment strategies employed, the advertisements placed in the major Montreal newspapers attracted the most people (24.3%). The highest acceptance rate (2.6%) was from those that responded to the senior newspaper advertisements although, the number of people originally attracted by these advertisements was lower (18.9%) than by the other means. The senior magazine attracted the lowest number of people (10.5%); however it maintains a relatively competitive acceptance rate (2.4%). The feature television and radio appearance was the second most efficient method in attracting potential participants (22.8%) to the study.

**Table 3.** Population attracted by gender

|         | Total (%)  | Participants Rejected Or Who Refused | Number Screened (%) |            |            |
|---------|------------|--------------------------------------|---------------------|------------|------------|
|         |            |                                      | Total               | Accepted   | Refused    |
| Females | 613 (60.4) | 400 (39.4)                           | 213 (21.0)          | 61 (6.0)   | 152 (14.9) |
| Males   | 397 (39.2) | 240 (23.6)                           | 157 (15.5)          | 66 (6.5)   | 91 (8.9)   |
| Unkown  | 4 (0.4)    | 4 (0.4)                              | 0                   | 0          | 0          |
| TOTAL   | 1014       | 644 (63.5)                           | 370 (63.5)          | 127 (12.5) | 243 (23.9) |



**Figure 1.** Education of accepted study population versus education of general Quebec population.



**Figure 2.** Income of accepted study population versus income of general Quebec population.

Unfortunately, as with the other methods most callers did not meet the initial inclusion criteria (e.g. aged 65 years and older, completely edentulous for the past 5 years), resulting in a lower recruitment rate (2.3%). Referrals from dentists or other study participants attracted the lowest number of people to the study (6.3%) with an acceptance rate of 2.0%. Although great efforts were taken placing advertisements in community papers, the response rate (9.9%) was very low and the number of participants actually eligible for the study proved to be the lowest (0.7%) among all recruitment methods used.

### Recruitment Costs

The most economical recruitment method proved to be advertisements in the senior newspapers (\$73.74 per subject) (Table 4). The most expensive recruitment method proved to be those in the community newspapers (\$847.54 per subject). Taking into account the current number of active subjects and the various methods used to attract these participants, the average cost per recruited subject during the 17 month period of this investigation was \$154.20.

## DISCUSSION

### Socio-demographic Analysis of the Population Attracted

A number of factors may help to explain why this clinical trial attracted a significantly more educated population in comparison to the Canadian census data of the Quebec population collected in 2001. The majority of advertisements were placed in print to ensure that the recruited population was able to fulfil the inclusion criteria, viz to read and respond to the questionnaires as well as to understand the informed consent. All accepted participants were expected to autonomously answer numerous health and nutrition habit questionnaires. The need for participants to answer these questionnaires without help avoids bias that may otherwise be introduced by suggestions from other, such as friends or family.

The clinical trial attracted and accepted a population with a significantly lower income bracket than the general Quebec population, as recorded in the Canadian census data of 2001. It is especially important to note that this clinical trial offered its accepted participants new high-quality dentures at a low cost and may have served as an incentive for people with lower incomes to apply.

### Response to the Advertisement Methods

The advertisements printed in the major Montreal newspa-

pers produced the highest response rate (24.3%) with an acceptance rate of 2.5%. Although the recruitment rate was similar to the others, this method nonetheless proved to be efficient as it attracted the greatest number of applicants.

The feature radio and television appearance attracted the second highest number of people (22.8%) with a final acceptance rate of 2.3%. We were able to benefit from radio and television because McGill University put out a press release about our study that was picked up by some journalists.

These results suggested that in a clinical trial seeking to find elderly people, advertisements in newspapers which directly target the study's population is probably the most appropriate method of recruitment. Advertisements placed in senior magazines also proved to be a useful method in recruiting elderly edentulous people. Trends indicate that these latter advertisements in more specialized newspapers and magazines, such as those written for the elderly, tend to attract a lower number of people but also have a higher acceptance rate. These findings clearly suggest that it is important to use specific advertisement methods directed at the targeted study population.

Community newspapers proved to be among the most unsuccessful methods of recruitment. The aim was to target the greatest number of people in the Montreal and surrounding Laval regions but they were largely unsuccessful and the elderly edentulous population can be better attracted with other newspapers. The use of community newspapers was discontinued once its poor level of success was documented.

### Recruitment Costs

The low mean cost per subject of people attracted from the senior newspapers (\$73.74 per subject) reflects the large number of people attracted together with a reasonable acceptance rate. Despite the potentially large target population the most expensive recruitment method proved to be placement of ads in community newspapers (\$847.54 per subject). The high mean cost per subject can be explained by both the low attraction and acceptance rates for this method. These advertisements were placed during the early months of the study. As is common in initial recruitment, the goal was to make as great a number of people aware of the study as possible. Hence, advertisements were sent out to papers with the largest reading audiences.

The lack of any cost for dentist/participant referral and broadcast public news media events inevitably makes these the most cost effective. However, this method of recruitment must be approached with caution. The research team

**Table 4.** Cost effectiveness of each recruitment method

| Recruitment Method        | Cost (Can \$) | Number Of Subjects Enrolled | Cost/subject (Can \$) |
|---------------------------|---------------|-----------------------------|-----------------------|
| Major Montreal newspapers | 5177.22       | 25                          | 207.08                |
| Senior Newspapers         | 1917.47       | 26                          | 73.74                 |
| Community newspapers      | 5932.83       | 7                           | 847.54                |
| Magazine                  | 6556.47       | 24                          | 273.18                |
| Public Media              | 0             | 23                          | 0                     |
| Referral                  | 0             | 20                          | 0                     |
| TOTAL                     | 19 583.63     | 127                         | Mean: 154.20          |

must be prepared to expect and manage a high volume of response from callers. The initial 48 hours post media coverage were the most taxing to the research team as hundreds of callers responded to the advertisements, a lot of whom did not even meet the initial criteria. The entire team's attention was diverted to responding to the plethora of calls. Therefore, although this method of advertisement is beneficial as it incurs no cost to the research team, one must organize the research facility to handle such a high volume. At the same time, one cannot rely completely on being fortunate enough to have media coverage. Equally large numbers cannot be recruited just by chance referrals, unless arrangements with clinicians and centres have previously been made. Therefore, additional techniques are needed to recruit a sufficient study sample size.

Researchers in Portland, Oregon sought to recruit participants for a Lung Health Study and used various recruitment methods. The cost/person randomized (in US \$) for each method of recruitment, which also included expenses for goods, services and staff, was (1) \$54 for media (TV, radio, newspapers), (2) \$670 for neighbourhood promotion, (3) \$135 for direct mail, (4) \$82 for worksite promotion and (5) \$77 for referrals by other study participants.<sup>2</sup> Due to the US-CAN monetary exchange and the decade of inflation, the cost per subject for the Bjornson-Benson study is comparable to the cost incurred using senior newspapers in this study. The most expensive method of recruitment (neighbourhood promotion) can be compared to the amount expended in this current study for community newspapers.

Taking into account the current number of active subjects and the various methods used to attract these participants, the average cost per recruited subject during the 17 month period of this investigation was \$154.20. This result cannot be directly compared to other research in this field because of the novelty of this study; the clinical trial participants and the inclusion and exclusion criteria are unique. However, the methods of recruitment are comparable with other studies. Adams et al.<sup>7</sup> recruited more than 400 older adults (aged 65 or older) for a clinical trial and used six different methods of recruitment<sup>7</sup>. Those that could be compared with this study were referrals and media which proved to be the least expensive. The average cost per recruited subject was \$99 US. Studies that involved cheaper methods of recruitment, for instance, mailing and telephone based approaches, report significantly lower costs per recruited subject. Taking into consideration supplies, telephone charges and staff time, the total cost was \$8.56 per subject in a study which also recruited older adults (60-7 years)<sup>8</sup>.

The cost per successfully recruited subject in the current study and for each recruitment method is comparable with other studies. One major cause of expense is due to poor response rates both in the current and in other studies<sup>2,7</sup> which in turn, inflates the average cost per subject<sup>8</sup>.

## CONCLUSION

This paper describes the recruitment process and its cost-effectiveness for recruiting into a randomized clinical trial edentulous elderly adults (age 65 or more) in the Montreal region. We highlight the successes and failures of the recruitment methods used and analyze the recruitment rate. When recruiting literate edentulous elderly adults (anglophone or francophone), we suggest using printed advertisements in papers which directly target the elderly. Also, to save on recruitment costs, a well implemented referral system, including physicians or dental professionals involved in the study, as well as recommendations by other study subjects, may help attract participants to the study without further expenditure.

The results of this study influenced subsequent recruitment decisions for an ongoing randomized clinical trial. The recruitment methods that did not attract many eligible participants or that cost too much per recruited subject were discontinued. It supports the concept that a multimethod recruitment plan allows recruitment teams to best evaluate which approaches are most effective in attracting the desired clinical trial population<sup>2</sup>.

## ACKNOWLEDGEMENTS

This research was supported by the Canadian Institutes of Health Research (CIHR), The Network for Oral Research Training and Health (NORTH) and Straumann Canada Limited. Grant Number: UCT 36052.

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