# Evaluation of the Experience During a Protocol Visit Compared to a Routine Medical Consultation in Clinical Trial Participants

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## 01. Hypothesis

Participants in clinical trials perceive a better overall experience during protocol visits compared to their usual medical consultations.

## 02. Objective

**To compare five thematic areas: expectation prior to the visit, satisfaction level, motivation to follow medical instructions, perceived organization, and perception of potential benefit, between routine medical consultations and protocol visits among participants of clinical research studies at CIPREC.**

## 03. Materials and Methods

A survey was conducted among 2,140 participants who attended the research center between November 2023 and October 2024. The survey was self-administered, anonymous, and voluntary, completed either digitally or in writing according to participant preference.

Patients of both sexes, over 18 years of age, who had had at least 5 routine medical consultations and five protocol visits in the previous 5 years were included. Participants with any type of vulnerability were excluded.

The questionnaire consisted of ten multiple-choice questions in Likert scale format. Each area was assessed through two identical questions, one referring to the routine consultation and another to the protocol visit, allowing direct comparison between both types of care.

Responses were compared using the Chi-square test for proportions. Test assumptions were verified and met. An alpha level of 0.05 was established.

All analyses were performed using R [R Core Team (2022): A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/] and RStudio [RStudio Team (2025): RStudio: Integrated Development Environment for R. Posit Software, PBC. https://posit.co].

## 04. Results

Results from 2,140 participants, of both sexes, aged between 32 and 83 years, are reported in Table 1.

**Table 1. Participant Responses (n = 2140)**

| | Protocol Visit (1) | Routine Visit (1) | p-value (2) |
|---|---|---|---|
| **1. Rate your expectation toward a consultation** | | | <0.001 |
| No benefit expectation about my health | 20 (0.9%) | 116 (5.4%) | |
| Little benefit expectation about my health | 29 (1.4%) | 322 (15.0%) | |
| Moderate benefit expectation about my health | 178 (8.3%) | 533 (24.9%) | |
| High benefit expectation about my health | 1913 (89.4%) | 1169 (54.6%) | |
| **2. Rate your overall satisfaction with a consultation** | | | <0.001 |
| Dissatisfied | 0 (0.0) | 96 (4.5%) | |
| Slightly satisfied | 38 (1.8%) | 481 (22.5%) | |
| Somewhat satisfied | 163 (7.6%) | 793 (37.1%) | |
| Very satisfied | 1939 (90.7%) | 770 (36.0%) | |

| | Protocol Visit (1) | Routine Visit (1) | p-value (2) |
|---|---|---|---|
| **3. Motivation to follow health team instructions** | | | <0.001 |
| Instructions never clear | 0 (0.0%) | 122 (5.7%) | |
| Instructions sometimes clear | 28 (1.3%) | 546 (25.5%) | |
| Instructions often clear | 288 (13.5%) | 463 (21.6%) | |
| Instructions always clear | 1824 (85.2%) | 1009 (47.1%) | |
| **4. Rate perceived organization when attending a consultation** | | | <0.001 |
| Very difficult access/appointment issues | 9 (0.4%) | 537 (25.1%) | |
| Sometimes difficult access | 37 (1.7%) | 736 (34.4%) | |
| Well-organized access, respecting schedules | 411 (19.2%) | 303 (14.2%) | |
| Always well-organized, respecting schedules | 1683 (78.6%) | 564 (26.4%) | |

## 05. Discussion and Conclusions

In this sample, participants perceived the experience of a protocol visit as superior to that of a routine medical consultation.

The greater expectation of health benefit may be related to the fact that clinical trials often involve novel medications, and many participants may not have found effective solutions with standard treatments.

Having a dedicated medical team available for consultation when needed, more frequent scheduled visits compared to routine practice, free provision of all required medication, reimbursement of travel expenses, and the supply of self-monitoring tools likely contribute positively to the perceived benefit.

The higher satisfaction levels can be explained by several factors: the amount of time healthcare professionals (physicians, laboratory staff, coordinators, etc.) dedicate to each patient, the procedures performed during each visit, and the personalized follow-up.

Patients participating in clinical trials tend to be more motivated to adhere to medical instructions, as these are typically explained in greater detail and with more clarity, facilitating understanding and adherence.

Regarding organization, these results likely reflect that visits are scheduled in advance, transportation between home and the center is arranged, and required medication is dispensed until the next visit.

Finally, the perception of benefit is logically influenced by altruistic motivations inherent to research participation and the consideration of collective well-being.

Figure 1.

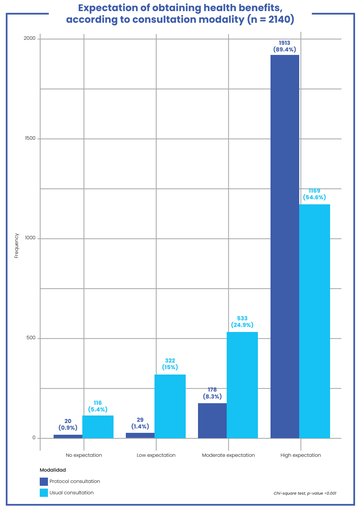


Figure 2.

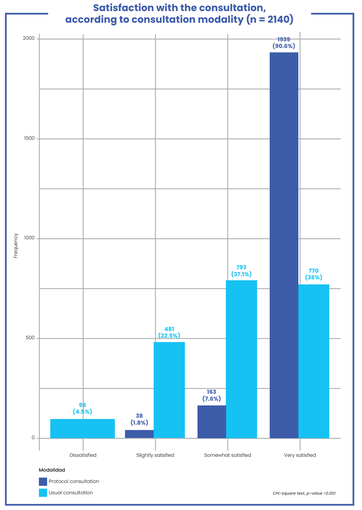


Figure 3.

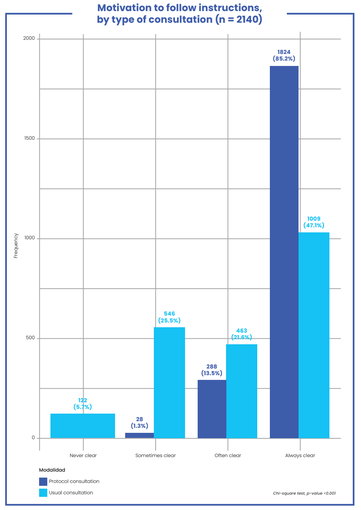


Figure 4.

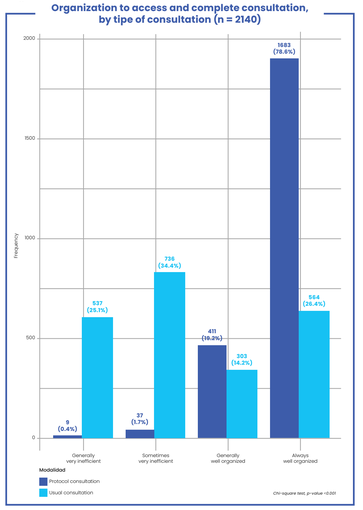


Figure 5.