

Organisational Issues in Implementing Clinical Trials in Primary Care

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Objective. To identify health professionals concerns on the organisational issues of a randomised clinical trial.

Design. A qualitative cross-sectional, descriptive study.

Setting. Primary Care Area 11, Madrid, Spain.

Participants. Twenty-four doctors and nurses from 4 primary care teams.

Method. Three planning meetings with researchers. Design of an anonymous self-administered questionnaire to collect researchers' perceptions on design, method, and organisation during the implementation of a clinical trial.

Results. The prestige of being involved in a multi-centre nationwide project, the training sessions offered, a primary care research topic, a working team model of doctor and nurse, and the support provided by team from the 11th Area, were the main organisational incentives. Lack of time, increased clinic workload, and methodological difficulties are discouraging issues. 79.2% (19/24) of the researchers returned the questionnaire. 94.7% (18/19) considered themselves highly motivated. 84.2% (16/19) of researchers, the time required to complete recruitment was reasonable. The 57.9% (13/19) spent 20-25 minutes collecting data at the interview. Cooperation between doctors and nurses had been effective for 68.4% (13/19) of researchers. 89.4% (17/18) considered that support from the Area 11 organisers was useful.

Conclusions. Organisational barriers for implementation are: complexity of data collection at the recruitment interview, design and methodological issues too unrealistic for a primary care setting, and lack of time and extra workload at consultations. The factors that make organisation easier are: having a high level of motivation, sharing workload with other professionals, and support provided by organisers of the trial.

Key words: Primary care. Clinical trial. Organisation. Research implementation.

ASPECTOS ORGANIZATIVOS DE LOS ENSAYOS CLÍNICOS EN ATENCIÓN PRIMARIA

Objetivo. Conocer la opinión de los investigadores respecto a la organización de un ensayo clínico.

Diseño. Estudio cualitativo, descriptivo y transversal.

Emplazamiento. Área 11 de Madrid. Atención primaria.

Participantes. Participaron 24 médicos y enfermeras de 4 equipos de atención primaria.

Métodos. Se realizaron 3 reuniones de planificación con los investigadores. Se utilizó un cuestionario anónimo autoadministrado respecto al diseño, la metodología y la organización del ensayo.

Resultados. Poder participar en un proyecto multicéntrico nacional, las sesiones formativas ofertadas, un tema de investigación propio de atención primaria, el modelo de trabajo investigador médico-enfermera y el apoyo recibido por la Organización del ensayo son factores organizativos motivadores. El escaso tiempo disponible, una elevada presión asistencial en las consultas y las dificultades metodológicas son aspectos desmotivadores. El 79,2% (19/24) de los profesionales contesta el cuestionario. El 94,7% (18/19) considera que ha estado muy motivado. El 84,2% (16/19) cree que el tiempo de selección es bastante apropiado. Un 57,9% (13/19) invierte 20-25 min en la entrevista. Para un 68,4% (13/19), la colaboración entre médicos y enfermeras ha sido efectiva. Un 89,4% (17/18) estima que el apoyo de la Organización del Área 11 ha sido muy útil.

Conclusiones. Las dificultades organizativas son: complejidad de la entrevista de selección, factores metodológicos y del diseño que distan de la realidad de atención primaria, falta de tiempo y elevada presión asistencial. Los factores organizativos facilitadores son: tener un alto grado de motivación, poder repartir las cargas de trabajo con otros profesionales y recibir apoyo organizativo.

Palabras clave: Atención primaria. Ensayo clínico. Organización. Ejecución del ensayo.

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A commentary follow this article (pág. 379)

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Introduction

Carrying out research in primary care (PC) involves an increase in the care activity of the professionals involved in the scientific project. It requires effort as regards motivation, planning of care activity and training needs. Primary care doctors and nurses have to spend more time in the clinic to carry out research,¹ since there is no time set aside for these tasks. Also, they have a large patient workload and overcrowded clinics that do not have the space to separate these activities from purely care ones.²

When we design a study we must take care in the selection of suitable research professionals, taking into account motivation and the current difficulties as regards recruitment and follow up³ of the patient cohort, the time that has to be invested as well as the human and economic costs.⁴

Some factors that are known to influence the acceptance of the project by researchers in PC are: the training that the professionals receive, the working material and tools, the time required to carry out the intervention, the workload pressure in the clinics, the usefulness of this intervention in a normal clinic, and the expectations generated.^{2,3}

The objective of our study is to find out the overall appreciation of the organisation of the clinical study by the researchers.

Methods

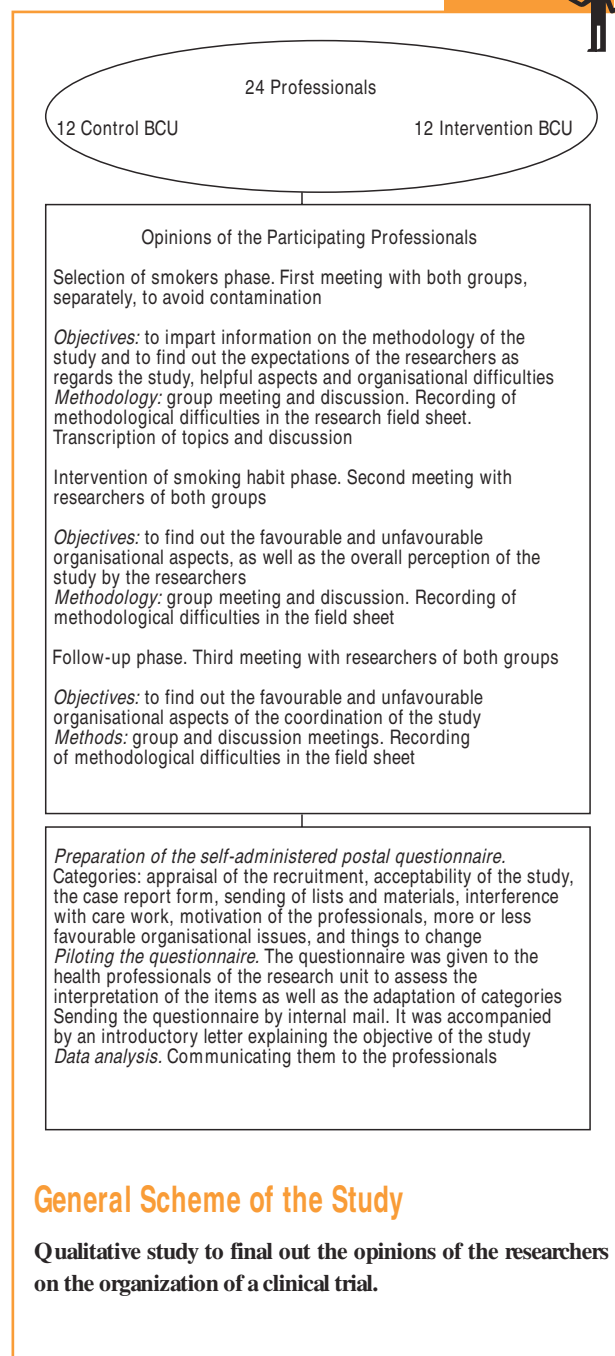
The subjects of the study are 24 professionals who participate in a controlled, randomised by group, multi-centre and open clinical study, for the evaluation of the effectiveness of a stepped primary care smoking cessation intervention programme (ISTAPS).⁵ The randomisation unit in this study is the basic care unit (BCU), which is the doctor and nurse who tend to the same group of patients in the normal clinic.

We chose a qualitative focus. In a first approach to the objective of the study, we had three formal meetings lasting 30 minutes with the control and intervention groups, respectively, in which we discussed aspects regarding the design, organisation and the possible factors that had to be changed in future studies, which we noted in the research information sheet.⁶ From the categories selected we prepared a structured, self-administered questionnaire with 18 items, 15 closed and 3 open (to confirm saturation), which was sent by post to the 24 participants (Annexe 1).

Results

The reliability of the questionnaire has been calculated using the split-half method. The Spearman-Brown coefficient was 0.74 ($P < .010$). The questionnaire was returned by post by 79.1% (19/24) of the participants. For each one of the items, the non-response rate was $\leq 10\%$. Of the 19

Material and methods



researchers who returned the questionnaire, 42.1% (8/19) belonged to the control group and 57.9% (11/19), to the intervention group. 47.4% (9/19) were doctors and 52.6% (10/19), nurses. The distribution by gender was: 63.2% (12/19) male and 36.8% (7/19) female. 63.2% (12/19) worked the morning shift and 36.8% (7/19), the afternoon shift. 68.4% (13/19) had previous experience in smoking problems, and 42.1% (8/19) had participated in clinical studies before.

The closed items provided information on:

1. Motivation and acceptability⁷: 89.5% (17/19) considered that they had been sufficiently motivated. 57.9% (11/19) would have preferred being assigned initially to the intervention group.

The acceptability of the population was very good for 31.6% (6/19) or fairly good for 57.9% (11/19).

2. Design of the study²: the case report forms (CRF) were fairly clear and concise for 63.2% (12/19). To complete the CRF took 20-25 minutes for 57.9% (11/19). Overall, the time dedicated was not quite adequate (31.6%; 6/19), or inadequate (31.6%; 6/19) for their clinics.

3. Organisational issues⁶: the ISTAPS study interfered a lot (36.8%; 7/19) or a little (57.9%; 11/19) with their care activities. The doctor-nurse model (BCU) was very productive (26.3%; 5/19) or fairly productive (47.4%; 9/19) for the investigation. They considered the support of the organiser to be very useful (52.6%; 10/19) or fairly useful (36.8%; 7/19).

4. Methodological aspects⁸: the posting of the completed CRF was not very complicated (36.8%; 7/19) or uncomplicated (42.1%; 8/19). The selection of patients at predetermined time intervals (by protocol) was not very easy (52.6%; 10/19) or not easy at all (21.1%; 4/19).

As regards the open questions in the questionnaire and the discourse analysis, the issues highlighted were:

1. Importance of participating in a national multi-centre project. They appreciated the coordinated organisation of a large project: "the coordination has generally been quite good, taking into account that it was nationwide."

2. Improvement of knowledge.¹ The training received by the intervention group was motivating: "the training of the professional on smoking habits was the best." The control group also expressed interest in being trained about smoking. "When are you going to give us a training course?"

3. Research topic and assigned groups.⁹ The researchers considered that the research topic was important: "I believe that smoking habits aroused motivation and interest." The control group expressed lack of motivation: "I believe that the control does not do very much," "there is less intervention in the control group."

4. Support during the investigation.^{8,10} They emphasised the doctor-nurse work model: "I think working with the BCU model is important." If the doctor-nurse relationship is damaged, it could become an obstacle: "It's because they only think of themselves." They also appreciate the personal contact and external supervision^{8,10}: "the good communication there is between the groups and the organisation of the study is important," "also the availability of the Organiser." The control group needs more attention¹¹: "I feel a bit left aside as regards support and coordination."

5. Accessibility of the patient⁴: "the patient does not have to attend any talks or lectures. They only have to receive telephone calls at a time of their convenience."

6. Applicability in clinical practice.^{1,8} Clinical trial conditions are not the same as in a normal clinic due to there being less time available^{1,7}: "it should stick to the reality of PC as regards clinic times" and a greater clinical workload: "finally, the recruitment phase coincided with the higher clinical workload months with vaccines and all."

7. Methodological and design issues. They disagreed with some of the patient selection criteria and with the wording and thoroughness of some items: "some patients could not enter due to smoking other substances," "the questions on alcohol consumption are not very clear"; they disagreed with methodological aspects of the protocol: "I think the recruitment hours should be more flexible."

Discussion

We obtained a high response rate to the questionnaire. The professionals show a high level of motivation and knowledge of smoking habits. They have previous experience in clinical studies and appreciate being participants of a multi-centre trial. They are concerned professionals, eager to receive the training offered in the clinical trial. These factors could explain the initial wish to be randomised to the intervention group, which is already evident in almost all studies published.

As regards the design, the professionals pointed out that the questionnaire, although extensive and repetitive, was of high quality. The subsequent applicability of the clinical trial, as regards design and methodology, is a factor that causes concerns and decreases motivation in our professionals.⁶ They devote between 20 and 25 minutes to the patient interview, a situation that is not very feasible in clinical practice. The researcher would like more straightforward forms, probably to cut down the time spent on it.⁹ We have to take into account that the average consulting time per patient is around 5 minutes. On the other hand, the acceptability by the population is good. The professional dedicates more time than usual to them, and this gives them satisfaction.

The organisational delays had a negative influence due to the start of the study coinciding with the vaccination campaign and holidays, when there is more pressure in the clinics.¹² Even so, they were able to comply with the protocol as regards sending in the CRF. The demands of the "protocol" to spread recruitment according to specific days and times showed an unfavourable relationship between the expected benefit (to select a representative population sample) and the human cost generated (to devote clinic time to recruitment on days with a heavy workload). The professional devoted time to the research activity "when able," and this time did not necessarily coincide with the

Discussion
Key points

What Is Known About the Subject

- **There are organisational aspects that have an influence on clinical trials:**
 - The topic investigated and the training received.
 - The time required to carry out the intervention, and pressure of care work in the clinics.
 - The clinical usefulness of the trial or intervention.

What This Study Contributes

- **Positively valued organisational aspects:**
 - Doctor-nurse work models with sharing of tasks.
 - External support of the organiser, particularly to the control group.
 - Collaboration of the professionals who will carry out the care activity in PC in the design, to adapt the intervention to the reality of the clinics.

hour or day of the week specified in the trial. We must assess the importance of designing clinical trials in such a way that they are feasible in primary care clinics.

The professionals dissented with some of the selection procedures, the wording of the case report forms and methodology followed in the trial. We believe that when designing a trial we must collaborate with the professionals who carry out their care activities in PC, since it would allow us to adjust them more to the reality of their clinics.¹²

Another factor which appears to influence the obtaining of good results is the doctor-nurse research work group (BCU), since it helps in sharing the tasks involved. However, like any other human relationship, it is subjected to personal and work conflicts. In our opinion, the possible difficulties in the doctor-nurse relationship should be examined,¹⁰ since they could be an obstacle to obtaining the targeted selection of the trial.

Conclusions

The study highlights some organisational factors which we must take into account when designing a clinical trial. The favourable organisational aspects are: to participate in a national multi-centre trial, to receive training in new

skills, to have quality material available, the doctor-nurse work model, the external support of the Organiser and to belong to the intervention group. The unfavourable organisational aspects are: the delays in starting the trial, questionnaires too long, methodological and design aspects which are far from the reality of PC clinics.

The most important limitation of our study lies in the fact that our professionals may not be representative, since they had an increased interest in smoking habits and experience in clinical trials. The results obtained must be verified by other groups to be able to make generalisations.

References

1. Fernández Fernández I. ¿Investigación en atención primaria? *Aten Primaria*. 2003;31:281-4.
2. Prout H, Butler C, Kinnersley P, Robling M, Hood K, Tudor-Jones R. A qualitative evaluation of implementing a randomized controlled trial in general practice. *Fam Pract*. 2003;20:675-81.
3. Rogers S, Humphrey C, Nazareth I, Lister S, Tomlin Z, Haines A. Designing trials of interventions to change professional practice in primary care: lessons from an exploratory study of two change strategies. *BMJ*. 2000;320:1580-3.
4. Wilson S, Delaney BC, Roalfe A, Roberts L, Redman V, Wearn AM, et al. Randomised controlled trials in primary care: case study. *BMJ*. 2000;321:24-7.
5. Cabezas Sanz C. Efectividad de una Intervención Escalonada para Ayudar a dejar de fumar desde la Atención Primaria de Salud (ISTAPS). Red IAPP. Madrid: Instituto de Salud Carlos III; 2006.
6. Bateman H. A Research Information Sheet for Practice (RISP): a tool to facilitate research participation. *Fam Pract*. 2002;19:691-7.
7. Foy R, Parry J, Duggan A, Delaney B, Wilson S, Lewin van den Broek N, et al. How evidence based are recruitment strategies to randomized controlled trials in primary care? Experience from seven studies. *Fam Pract*. 2003;20:83-92.
8. Sellors J, Cosby R, Trim K, Kaczorowski J, Howard M, Hardcastle L, et al, for the Senior Medication Assessment Research Trial (SMART) Group. Recruiting family doctors and patients for a clinical trial: lessons learned. *Fam Pract*. 2002;19:99-104.
9. Bell-Syler SEM, Klaber Moffett JA. Recruiting patients to randomized trials in primary care: principles and case study. *Fam Pract*. 2000;17:187-91.
10. Branson R, Armstrong D. General practitioners' perceptions of sharing workload in group practices: qualitative study. *BMJ*. Available from: 10.1136/bmj.38173.532465.7c
11. Trap B, Todd CH, Moore H, Laing R. The impact of supervision on stock management and adherence to treatment guidelines: a randomized controlled trial. *Health Policy Planning*. 2001;16:273-80.
12. Foy R, Eccles M, Grimshaw J. Why does primary care need more implementation research? *Fam Pract*. 2001;18:353-5.

ANNEXE
1 Evaluation Survey
of the ISTAPS Project

A series of questions relating to the ISTAPS project are listed below. We would like you to read them carefully and mark with a cross the value which fits best with your criteria:

1. The recruitment period (6 months) has been adequate*
2. Recruitment using set times has been straightforward*
3. The recruitment of patients for the ISTAPS Project has been easy*
4. The acceptability of the study by the population has been good*
5. The case report form is written clearly and concisely*
6. To complete the whole case report form required approximately... †
7. The time required to complete the case report form is adequate †
8. It has been complicated to send the list of recruited patients weekly †
9. Participating in the ISTAPS Project has interfered with care work*
10. Working in a team (doctor-nurse) has been productive*
11. At the start of the study, the professional prefers to belong to the... group ‡
12. A high level of motivation has been maintained throughout the recruitment phase*
13. The participation by the professionals by means of detecting problems and/or indicating possible solutions in the ISTAPS Project has been evident*
14. The ISTAPS Project improves training of the professional on smoking habits*
15. Have had support from the quality unit and/or the organiser*
16. The 3 major difficulties for the researcher who participates in the ISTAPS Project are... §
17. The 3 most outstanding features in the design and organisation of the ISTAPS Project are probably... §
18. The 3 aspects in the design and organisation of the ISTAPS Project to change or simplify are probably... §

*Not, not very, fairly, very.

†>25 min, 20-25 min, 5-20 min, <15 min.

‡Control, intervention.

§Free choice.