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Telephone consent: optimizing the recruitment of research participants

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Abstract

Informed consent aims to protect the autonomy of potential research participants, providing the information necessary to make the right decision. This study reports the experience of collecting the informed consent via telephone from individuals. Telephone contact was successfully achieved for more than 90% of the participants; 1.16% understood the survey, but did not accept to participate; and 0.70% refused to provide telephone consent and required a consent form by mail. Women from all regions of Brazil participated and most had some procedure in the hospital at least 62 days after the date of the call. The results show that telephone consent can be an alternative method of recruiting patients given the high rate of acceptance of the participants and time gains in data collection.

Keywords: Informed consent. Consent forms. Research. Neoplasms.

Resumo

Consentimento por telefone: otimização do recrutamento de participantes de pesquisas

O consentimento informado objetiva proteger a autonomia de potenciais participantes de pesquisas, fornecendo as informações necessárias para a decisão sobre participar ou não. Este estudo relata uma experiência de processo de consentimento informado via telefone. Houve sucesso no contato telefônico com mais de 90% das pacientes elegíveis; 1,16% entenderam as informações fornecidas, mas não aceitaram participar da pesquisa; e 0,70% recusaram dar o consentimento por telefone e pediram que o termo de consentimento fosse enviado por correio. Participaram do estudo mulheres de todas as regiões do país. A maioria tinha algum procedimento marcado em um dos hospitais pesquisados para pelo menos 62 dias após a data da ligação. Os resultados mostram que o consentimento por telefone pode ser um método alternativo de recrutamento de pacientes, tendo em vista a alta taxa de adesão dos participantes e a redução no tempo de coleta de dados.

Palavras-chave: Consentimento livre e esclarecido. Termos de consentimento. Pesquisa. Neoplasias.

Resumen

Consentimiento por teléfono: optimización del reclutamiento de participantes de investigaciones

El consentimiento informado tiene como objeto proteger la autonomía de los posibles participantes de investigaciones, proporcionándoles la información necesaria para que decidan si aceptan o no participar. Este estudio relata una experiencia de proceso de consentimiento informado por teléfono. El contacto telefónico se realizó con éxito con más del 90% de los participantes; el 1,16% entendió la información suministrada, pero no aceptó participar en la investigación; y el 0,70% se negó a otorgar el consentimiento por teléfono y solicitó que se le enviara el formulario de consentimiento por correo. Participaron en el estudio mujeres de todas las regiones de Brasil. La mayoría de las participantes tenía algún procedimiento programado en uno de los hospitales investigados al menos 62 días después de la fecha de la llamada telefónica. Los resultados muestran que el consentimiento por teléfono puede ser un método alternativo para reclutar a los pacientes, una vez que hubo una alta tasa de adherencia de los participantes y reducción en el tiempo para la recopilación de datos.

Palabras clave: Consentimiento libre e informado. Formularios de consentimiento. Investigación. Neoplasias.

The authors declare no conflict of interest.

Research

Research ethics is based on the principles of beneficence, non-maleficence, justice, and autonomy. Consent is a basic requirement for clinical research and a right enforced by the *Declaration of Helsinki*, Resolutions No. 466/2012 and 510/2016 of the National Health Council (CNS) [1-3]. It is intended to protect the autonomy of potential research participants, providing them with the necessary information to decide whether or not to participate in the study. Among the information are highlighted the objectives and duration of the investigation, its risks and benefits, procedures, and the guarantee of anonymity/confidentiality of the information, among others [1-3].

Some types of consent are guaranteed by law: the informed (at the time of inclusion in the study), substitutive (the consent from family members), and deferred (consent from critical patients, at a later time). In some cases, consent may be waived (observational minimum risk surveys) [4]. In studies with follow-up patients, waiting for the potential participant to return for consultation or examination, and only then giving consent, can delay the research and increase costs [5,6]. Thus, other methods, such as recruitment by telephone or multimedia resources can be used as alternatives to bypass this problem [7].

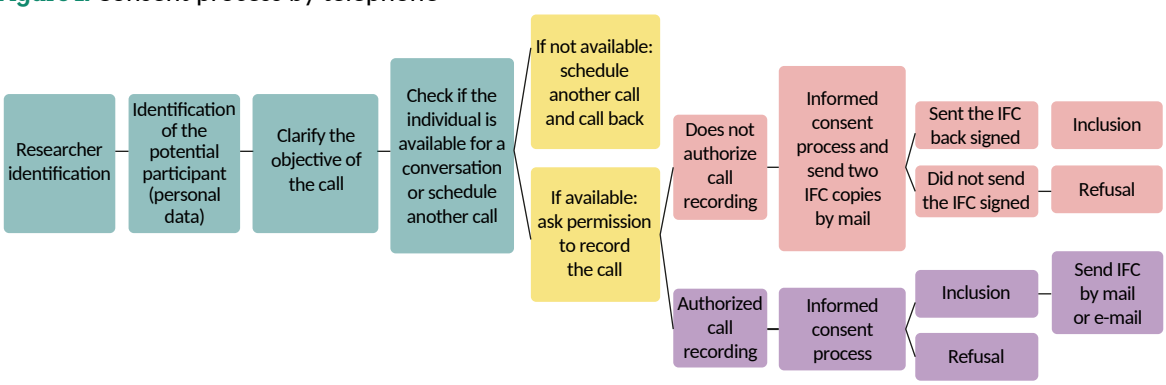
A randomized clinical trial comparing consent by telephone to consent in consultations revealed no reduction in the levels of understanding of the information [8]. Another randomized clinical trial, which investigated consent for colorectal cancer screening, showed greater adherence to the screening visit, as well as a greater number of inclusions, from the group of patients contacted by phone, compared to those contacted by letter [6].

Evidence on recruitment and consent for surveys by telephone is still limited in Brazil. To partially fill this gap, the objective of this study is to report the experience of the informed consent process by telephone with women who are follow-up patients with cervical cancer. The method was intended to expedite patient recruitment.

Consent process by telephone

This study is part of a thesis developed at Hospital de Câncer de Barretos, Barretos/SP, Brazil, and A. C. Camargo Cancer Center, São Paulo/SP, Brazil. The study included 18-year-old or older women suffering from cervical cancer who had started treatment up to 18 months prior. Patients undergoing cancer treatment from another anatomical site, palliative care, or who had undergone cervical cancer screening tests at the hospital were excluded. Eligible patients were identified within the information system of both institutions. The consent process by telephone is presented in Figure 1.

Figure 1. Consent process by telephone



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Patients were contacted on their cellphones by the researchers between 9 am and 7 pm. The call script (Appendix) was approved by a Research Ethics Committee. On the call, the researchers presented the study and asked the patient if they could start the consent process. In the event of an affirmative answer, authorization was requested to record the conversation. The recordings were made using a free mobile application. All elements of informed consent were then read and, if the patient agreed to participate in the study, the informed consent form (ICF) was sent by e-mail or regular mail, according to the recipient's preference.

The cases of six unsuccessful attempts to call, or incorrect or unavailable numbers, were coded as "No contact possible". The Research Electronic Data Capture [9] (REDCap) was used to store the calls and record the data, which were analyzed with the Statistical Package for the Social Sciences software, version 21.0. Simple descriptive statistics (mean and standard deviation, or median) were used, and 95% confidence intervals were provided when appropriate.

430 eligible women were identified within the information system of the two hospitals surveyed. 404 participants (93.95%) were successfully contacted by telephone, while the other 26 fell into the category "No contact possible". Five women (1.16%) understood the information provided, but did not agree to participate in the research. Three women (0.70%) refused to give consent by telephone, and the informed consent form was sent to them by letter (at no cost to the recipient). They were expected to return the signed consent form within three months, but as this did not happen, their responses were considered negative.

The participants were, on average, 46.65 years old (± 13.15 y.o., 95% CI 20.87–72.42). As for their level of education, 40,5% had only completed elementary school. The median number of attempts required for successful contact was two calls. Women from all regions of the country participated. Most participants had an appointment or procedure scheduled at the hospital at least 62 days after the date of consent.

Discussion

The high adherence to the research showed that patients undergoing cancer treatment can be recruited and offer consent successfully by telephone. Over 90% of eligible patients agreed to participate in the study, confirming the initial hypothesis that consent by telephone would be successful in more than 80% of cases. Also, the method helped to shorten recruitment time.

According to article No. 2 of Resolution CNS 510/2016, the consent process is based *on the construction of a relationship of trust between researcher and research participant, in agreement with their culture and continuously open to dialogue and questioning, not being its procurement always necessarily in print* [3]. Besides that, factors such as stress when accessing health services can interfere with the process. Consent, however, is only effective if it is given freely, without limited time for reflection or moral or physical constraints [10,11].

Invitations by telephone are more personal than those made by letter or other electronic means, and the time for recruitment and consent can be adjusted according to the availability of the potential participant [12]. In this study, these characteristics helped patients to understand the information provided, which reflected in the good acceptance of this consent method.

According to Wong and collaborators [6], recruitment by telephone, compared to recruitment made by postal services, can improve the effectiveness of recruitment by 7% up to 12%, with a relative risk of 1.66. The findings corroborate this and other randomized studies comparing the use of consent by telephone and other methods [8,13].

In Brazil, a barrier to this method is the constant change of patients' telephone numbers, as perceived in outpatient clinics. A study that evaluated absenteeism factors in first consultations in an oncology outpatient clinic at a university hospital showed that the rate of invalid numbers was 43.26%, and the cases of patients who did not answer calls, phones turned off, or outside the coverage area amounted to 32.30% [14]. When the health service is provided for people from other states, the change in numbers is even more frequent, as patients seek to reduce costs by purchasing cellphone SIM cards with the same area code of the hospital. However, upon returning to their cities (during the follow-up period), the patients resume the use of their previous

numbers. As a consequence, hospital registries are out of date. The present study being limited to women in treatment for up to 18 months may have been the reason why the outdating perceived by other studies regarding registration information has not been confirmed.

The costs of this type of recruitment include the time spent by the staff during the contacts and the fees for the phone calls themselves [15]. In this study, it took about two calls per participant to get in touch and initiate the consent process. We estimate that the inclusion of participants was advanced by at least 62 days and, although the cost-effectiveness of the method has not been assessed, it is believed it also resulted in some cost reduction.

Researchers should be attentive to how recordings are recorded and archived. According to Law No. 13.709/2018 [16], known as the General Data Protection Law, health-related information is deemed sensitive. Considering the researcher's duty to ensure data privacy and confidentiality [2], it is necessary to choose secure *software* for both recording and archiving audios.

Final considerations

Considering the high rate of adherence and the time saving in data collection observed in this study, the conclusion is that consent by telephone can be an alternative method to recruiting follow-up patients. For that, we must consider the registration update of potential participants and the use of software to guarantee the security of the information obtained, preserving the confidentiality and privacy of the collected data. More research should be carried out with other populations and situations to verify the findings presented here and evaluate the cost-effectiveness of the method.

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Participation of the authors
Lívia Loamí Ruyz Jorge de Paula and Mateus Frederico de Paula collected, organized, and interpreted the data. Levon Badiglian-Filho guided the research. All authors idealized the project, wrote the article, and participated in the critical review.

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Appendix

Script for telephone consent

1. Identification by the researcher and confirmation of the possible participant's identity (personal data).
2. Clarification of the call's purpose.
3. Verification of the possibility of continuing the call at that time or scheduling for another time.
4. Questioning about the possibility of recording the call.
5. Consent process.

CONSENT CONTROL

Name:

Contact information:

Full address:

Attempt 1
Date and time:

Attempt 2:
Date and time:

Attempt 3:
Date and time:

Attempt 4:
Date and time:

Attempt 5:
Date and time:

Attempt 6:
Date and time:

Was the contact successful?
( ) Yes ( ) No

Do you accept consent by telephone?
( ) Yes ( ) No

Do you agree to record the consent?
( ) Yes ( ) No

Do you understand the research?
( ) Yes ( ) No

Do you accept to participate in the research?
( ) Yes ( ) No

Why?

If so, do you want to receive the IFC by:
( ) Email ( ) Regular mail