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REPRESENTATIONS AND PRACTICES OF PREVENTION IN ELDERLY POPULATIONS: INVESTIGATING ACCEPTANCE TO PARTICIPATE IN AND ADHESION TO AN INTERVENTION STUDY FOR THE PREVENTION OF ALZHEIMER'S DISEASE (ACCEPT STUDY) – THE NEED FOR A MULTIDISCIPLINARY APPROACH

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Abstract: *Background:* In the domain of Alzheimer's disease (AD) prevention, various potentially protective factors have been identified in epidemiological studies. Although the results of these observational studies have been relatively consistent, the results of intervention studies remain disappointing. Methodological problems could explain these negative results, like the selection of the population; a plausible assumption is that the older people who agree to take part in these intervention studies differ from those who refuse, and are those that are least likely to benefit from such programs. The aim of this study was (i) to study the determinants of participation in and adhesion to a prevention trial in a population of older individuals via a quantitative approach using a questionnaire, (ii) to study the representations and practices of prevention in this population using a qualitative approach using semi-structured interviews and focus groups. *Method:* The study population for the ACCEPT study was recruited at the time of inclusion of subjects in a prevention trial. The population was made up of persons aged 70 years or older, living at home and demonstrating some form of frailty, defined as a spontaneous memory complaint to their general practitioner or difficulties in carrying out instrumental activities of daily living. We used a quantitative approach based on the administration of a self-completed questionnaire sent to 1680 subjects having accepted to take part in the prevention trial, and to the sample of subjects meeting the inclusion criteria but having refused to take part. The qualitative approach, carried out at the moment of inclusion, involved subjects that having accepted to take part and subjects that having refused. Semi-structured interviews were carried out in order to understand the logic leading to refusal or acceptance. *Conclusion :* The analysis of the results will combine the viewpoints of the different disciplines. It will allow us to better understand the logic at work, to characterise the populations at risk of refusal, and perhaps to remove some of the barriers to participation in prevention programs. The identification of such barriers will provide feedback in terms of the conception and management of prevention measures.

Key words: Recruitment, clinical trial, participation, prevention, dementia.

Introduction

In the domain of Alzheimer's disease (AD) prevention, various potentially protective factors have been identified in epidemiological studies. Some of these factors are lifestyle-related, for example diet (1-3), physical exercise (4-9) and social activities (10-12). Although the results of observational studies have been relatively consistent, the results of intervention studies remain disappointing (13). Aside from a lack of efficacy of the intervention tested, methodological problems could explain these negative results: the implementation of these prevention strategies too late in the disease process, inadequate sample size, the absence of valid criteria for cognitive outcomes, a too short period of exposure/intervention, a lack of consideration of multiple protective factors within the same trial, and a lack of adherence to recommendations (14-20).

One of the main methodological issues might be the selection of the study population in these long term prevention trials. A plausible assumption is that the older people who agree to take part in these intervention studies differ from those who refuse, and are those that are least likely to benefit from such programs (21-23). Thus, this particular selection prior to enrollment in prevention trials may partly explain the failure of

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some interventions. In the past, little attention has been paid to the importance of this potential selection bias in preventive research in the field of Alzheimer's disease and cognitive decline.

From an epidemiological point of view, it has been found that participation in trials is linked to educational level (24). Due to the fact that cognitive status and the rate of cognitive decline before AD diagnosis are linked to a the level of education (25), we can make the assumption that the selection of the population could strongly affect the results of prevention trials in this field.

We report the methods of a multi-disciplinary study whose aims are (i) to analyse the determinants of participation in and adhesion to a prevention trial in a population of older individuals, (ii) to study the representations and practices of prevention in this population.

Methods

Study design

This study is based on a cross-sectional design. All data were collected at one specific point in time: when investigators asked whether or not the subjects agreed to participate in a cognitive decline prevention trial (the MAPT Study). Briefly, this prevention trial is assessing a multidomain intervention (involving physical exercise, nutrition, and cognitive stimulation), either alone or in association with an omega-3 fatty acid supplement, for the prevention of cognitive decline, with a 3 year intervention period and 5 years of follow-up (26).

Participants and recruitment

The study population for the ACCEPT study was recruited at the time of recruitment of subjects for the MAPT prevention trial. The target population was made up of persons aged 70 years or older, living at home and demonstrating some form of frailty, defined as a spontaneous memory complaint to their general practitioner or difficulties in carrying out instrumental activities of daily living or slow walking speed.

Data sources

This study involved both quantitative and qualitative approaches. For the quantitative approach, we addressed a self-completion questionnaire to 1680 subjects having accepted to take part in the prevention trial, and to subjects meeting the inclusion criteria for the prevention trial, but having refused to take part. The questionnaire was designed by a multidisciplinary team involving epidemiologists, sociologists, psychologists and geriatricians. In the preliminary phase, focus groups were used in order to help determine some of the items to be included in the questionnaire, which aimed to explore determinants of acceptance. Data collected included: sociodemographic characteristics (age, gender, lifestyle, income, education), psychosocial characteristics (social network, stressful life events and protective personality aspects), family history of dementia, factors related to the type of prevention strategy tested (drug or life style intervention), the notion of memory impairment and perceived risk of related illnesses, level of knowledge of health and prevention, and relationship with the investigator.

The qualitative approach, also conducted during the recruitment period for the MAPT trial, was carried out in a subsample of 40 subjects from one of the centres involved in the MAPT trial. The sample included 20 subjects who had accepted to participate in the MAPT trial and 20 subjects who had refused to participate. The aim of the semi-structured interviews was to understand the logic that led to rejection or acceptance, as well as exploring perceived issues of prevention in ageing in the context of Alzheimer's disease. During the follow–up period of the MAPT trial, a sample of subjects who dropped out of the study were also interviewed. Therefore, in total, three distinct populations were interviewed: people who refused to participate in the trial, people who agreed to participate in the trial, and those who initially agreed but later dropped out of the trial. Through these three situations, at different levels of the process (acceptance, adherence and compliance), we will study the factors that facilitate or conversely those which constitute obstacles to the establishment of a prevention policy.

Expected Results

This study will provide results on the determinants of acceptance to participate in a prevention trial as well as adherence and compliance, based on different type of factors (socio-demographic characteristics, psychosocial characteristics, the notion of memory problems and the perceived related risk of Alzheimer's disease, the subject's level of health- and prevention-related knowledge, and the duration of the relationship between the subject and the investigating physician). Some authors found that even in the field of aging, the most important reason reported for taking part in a trial was altruism (27).

One of the most important limits in participation in clinical trials remains selection bias. Better informing the entire population (families, patients, GPs) about the availability of clinical trials could certainly decrease this selection biais (28).

Conclusion

Analysis and interpretation of results from the Accept study will be conducted in the framework of the viewpoints of the different disciplines involved in the study. It will allow us to better understand the logic at work, to characterise the populations at risk of refusal, and perhaps to remove some of the barriers to participation in prevention programs. The identification of such barriers will provide feedback regarding the conception and management of prevention measures.

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