

RESEARCH METHODOLOGY

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The multidimensional study of the elderly in the family health strategy in Porto Alegre, Brazil (EMI-SUS)

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ABSTRACT

Population aging is a global phenomenon never experienced before, which will cause major repercussions for the health area. This paper's main objective is to describe the methods employed in a transversal epidemiological study with a target sample of 1080 elderly people, randomly selected from the Family Health Strategy in Porto Alegre (RS/Brazil). It integrates three key dimensions: epidemiological, clinical and basic sciences. A sub-sample with changes in cognition or mood make up a longitudinal study. The relevance of this work rests primarily on the synergy between research and care; aiming to improve health care for the elderly and making better use of the Brazilian National Health Service structure. In this way, there is a combination of robust methodological tools capable of accurately observing the epidemiological phenomena, associated with research in the areas of basic and multidisciplinary sciences. Research initiatives like this can bring forth benefits to a large proportion of the population who depend on the public health structure.



INTRODUCTION

Over recent decades there have been profound changes in the demographic characteristics of the worldwide population. Among these changes, population aging and its repercussions for health stands out as a major challenge. In this context, developing countries will suffer more intensely from the consequences of this phenomenon as they show a faster aging cohort effect when compared with developed countries¹.

In Brazil, fertility/fecundity remained with the highest growth rates from the 1950's to the 1970's, combined with increasing life expectancy¹. An important portion of these individuals in Brazil will go through an aging cohort effect, such as the north American “baby boom” generation^{2,3}. In the case of Brazil, we suggest a similar term for this population modification, the “Brazilian baby boom”, which will also impact in our midst. However, limited access to civil rights combined with the substantial social inequality that exists in Brazil makes predicting the impact of aging on health unimaginable. This adverse context that affects the more vulnerable individuals in society highlights the relevance of studies aiming to improve the existing public service structure.

Another important aspect of concern is the lack of epidemiological studies conducted in developing country samples, having robust methodologies that combine screening and specialized assessment, planning to improve systematized health care actions using evidence-based knowledge^{4,5}.

The objective of this paper is to present the synthesis of a research project carried out on a random sample of 1080 elderly subjects, selected from the Family Health Strategy (FHS) in Porto Alegre, RS, Brazil (EMI-SUS – *Estudo Multidimensional dos Idosos do Sistema Único de Saúde do Brasil*). Its emphasis is oriented towards the methodology, which integrates three fundamental dimensions: 1) epidemiological: health survey and disease screening; 2) clinical: laboratory and multidisciplinary evaluation for diagnosis and health damage detection; 3) basic sciences: identification of the biochemical and genetic markers of the oxidative metabolism.

METHODS

Study Design

This prospective analytical transversal study had data collected from a random sample of elderly users of the FHS in Porto Alegre (RS/Brazil).

A sub-sample with changes in cognition or mood, dementia and risk of suicide were referred for follow-up at the Brain Aging Outpatient Clinic (AMBEC – *Ambulatório de Envelhecimento Cerebral*) in São Lucas Hospital (HSL) of the Pontifical Catholic University of Rio Grande do Sul (PUCRS), making up a cohort.

Population

According to the Brazilian Institute of Geography and Statistics (IBGE – *Instituto Brasileiro de Geografia e Estatística*), the estimated population of Porto Alegre in 2008 was 1.43 million; about 175 thousand of these were elderly⁶. This demographics estimation was used in the planning of the sampling for this present research protocol, developed between 2009 and 2010. At that time, the FHS in Porto Alegre was composed of 97 family health teams (FHT) covering around 22 thousand registered elderly people. Public health in Porto Alegre is stratified by distribution into eight different geographic areas, called Health Districts (HD).

Recruitment

The inclusion criteria were: aged 60 years old or more and registered in the FHS. The study was projected for a random sample of 1080 elderly – involving 36 individuals selected from each of 30 different teams from the FHS. The FHS participation was selected through a stratified random draw carried out with the teams from the different HD: 4 teams from the North (*Norte/Eixo Baltazar*), 3 from the Northwest (*Noroeste/ Humaitá/ Navegantes /Ilhas*), 2 from the Center (*Centro*), 2 from the South/Center South (*Sul/Centro-Sul*), 6 from the Southwest (*Glória/ Cruzeiro/Cristal*), 2 from the Extreme South (*Restinga/ Extremo Sul*), 4 from the East/ Southeast (*Partenon/ Lomba do Pinheiro*) and 7 from the East/Northeast (*Leste/Nordeste*).

After the random selection of the 30 teams from the FHS, their Community Health Workers (CHW – *Agentes Comunitários de Saúde*) were contacted. The CHW from each team submitted the name of all registered elderly users from their region for the draw of the 36 elderly participants.

Data collection routine

Approximately one month before the scheduled date for data collection, the researchers gave the CHW from each FHS team information on the study design and objectives, as well as training on the application of the instruments they were to apply.

Box 1. Subprojects, objectives and instruments.

| Subproject | | Objectives | Instruments |
|------------|---|---|--|
| 1 | PREVALENCE AND RISK FACTORS FOR COGNITIVE DECLINE, PARKINSONISM, SLEEP DISORDERS AND HEADACHE | <ul style="list-style-type: none"> a) To validate an instrument for identifying cognitive decline in older people with low income and education, which can be implemented by CHW in populations b) To determine the prevalence of cognitive decline, parkinsonism, sleep disorders and headache in elderly users of the FHS in Porto Alegre c) To identify risk factors for cognitive decline, parkinsonism, sleep disorders and headache in a low-income population | Vellore, MEEM, Clock test, list of words and drawings from the CERAD, Boston's naming test (brief version), verbal fluency (F-A-S), verbal fluency (animals), WMS – late recollection, WMS-logic, extension (“Span”) of digits, diagnostic criteria for dementia of DSM-IV, neurological testing for parkinsonism, sleep quality questionnaire, intensity scale of insomnia, sleepiness scale of Epworth, headache questionnaire, Index of Independence in Activities of Daily Living (Katz) and Pfeffer's Functional Evaluation |
| 2 | IDENTIFICATION OF GENETIC MARKERS AND OXIDATIVE METABOLISM BIOCHEMICAL FOR CHRONIC NON-TRANSMISSIBLE DISEASES | <ul style="list-style-type: none"> a) To determine the gene frequencies and genotype of SOD2 gene polymorphism in elderly people with CNTD b) To determine the levels of markers of oxidative stress (TBARS, antioxidant enzymes SOD2, catalase and glutathione peroxidase, protein carbonyls) in elderly patients with CNTD c) To determine if there is an association between the SOD2 gene polymorphism, markers of oxidative stress and lifestyle (diet and physical activity) in elderly patients with CNTD | Minnesota Questionnaire Genetic and biochemical markers of oxidative stress |
| 3 | PREVALENCE OF ENTEROPARASITIC INFECTIONS AND TOXOPLASMA GONDII SEROPREVALENCE | <ul style="list-style-type: none"> a) To evaluate the prevalence of elderly infected by parasites and to describe the enteroparasites found in stool testing b) To determine the relationship between socioeconomic conditions, hygiene habits and the prevalence of elders infected by parasites | General questionnaire Stool testing |
| 4 | PREVALENCE OF METABOLIC SYNDROME AND CARDIOVASCULAR RISK FACTORS | <ul style="list-style-type: none"> a) To describe the prevalence of MS and its components b) To assess the association between MS and the Framingham's Cardiovascular Risk Score | Brief functional assessment, anthropometric measurements, biochemical laboratory tests |
| 5 | ASSESSMENT OF NUTRITIONAL STATUS OF THE ELDERLY | <ul style="list-style-type: none"> a) To determine the frequency of malnutrition risk b) To determine if there is an association between malnutrition and the risk of cognitive decline and depressive symptoms | Mini Nutritional Evaluation, data from the subproject 1, GDS |
| 6 | ANTHROPOMETRIC MEASURES RELATED TO RISK OF DISEASE AND DEATH | <ul style="list-style-type: none"> a) To describe the anthropometric profile b) To investigate the association between anthropometric measures and risk of CNTD | Anthropometric measurements |
| 7 | RELATION BETWEEN BODY IMAGE, NUTRITIONAL STATUS AND SOCIODEMOGRAPHIC CHARACTERISTICS IN THE ELDERLY | <ul style="list-style-type: none"> a) To investigate the association of body image perception, nutritional status, self-esteem and socio-demographic characteristics | Stunkard's Body Image Scale, APQ |
| 8 | PREVALENCE OF PSYCHIATRIC DISORDERS IN THE ELDERLY | <ul style="list-style-type: none"> a) To validate the GDS used by the CHW b) To determine the prevalence of psychiatric disorders c) To investigate the association between psychiatric disorders and quality of life d) To examine distinguishing factors between early and late onset syndromes | MINI PLUS Brazilian version 5.0 GDS – 15 items Flanagan's Quality of Life Scale |
| 9 | IMMUNOLOGICAL RISK RELATED TO THE CNTD IN ELDERS | <ul style="list-style-type: none"> a) Evaluate the immunological risk profile risk and humoral response to the cytomegalovirus and its association with cognitive disorders, psychiatric diseases, and other CNTD | Lymphocytic subpopulation, cytokines and cytomegalovirus serology. |

CHW: Community Health Workers; FHS: Family Health Strategy; MEEM: Mini Mental State Examination; CERAD: Consortium to Establish a Registry for Alzheimer's Disease; WMS: Wechsler Memory Scale; DMS IV: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition; SOD2: Manganese Superoxide Dismutase Dependent; CNTD: non-transmitted diseases; TBARS: Thiobarbituric Acid Reactive Substances; MS: Metabolic syndrome; GDS: Geriatric Depression Scale; APQ: Aging Perceptions Questionnaire; MINI PLUS: International Neuropsychiatric Interview – Plus.

Data collection was developed in three phases: 1) *Screening and general data* collected by the CHW in the subjects' homes using a general questionnaire with epidemiologic questions, and screening instruments for cognitive decline and depression; 2) *Laboratory phase* was carried out by a trained team to collect blood and fecal samples in the units of each FHS. The samples were submitted to the Biochemistry, Molecular Genetics and Parasitological Laboratory of the Institute of Geriatrics and Gerontology (IGG), PUCRS. Analysis of the immunological profile was made by the Immunological Aging Laboratory from the Biomedical Research Institute, PUCRS. The hematological parameters analyses were made by the Clinical Pathology Laboratory from the São Lucas Hospital (HSL), PUCRS; 3) *The expert evaluation* was carried out at the HSL/PUCRS by the project's multidisciplinary team who assessed the elderly subjects about clinical, nutritional and physical aspects – **Box 1** shows the information for the subprojects, better summarizing the objectives and instruments used. The assessments were made by experienced professionals in human aging, such as: geriatricians, neurologists, psychiatrists, nutritionists, occupational therapists, physiotherapists and psychologists. They were helped by Medicine, Physiotherapy and Psychology students, trained to carry out the brief geriatric evaluation, physical activity evaluation and neuropsychological tests (under the supervision of an experienced neuropsychologist). The expert evaluations occurred on Saturdays, in two shifts; comprised of a maximum of 18 elderly people in the morning and 18 more in the afternoon. For those individuals unable to attend the multidisciplinary assessment, a team including neurologists and psychiatrists conducted a mental health assessment at the FHS units or in the homes of the elderly subjects.

Data storage and management

Data is stored in a relational database developed by the researchers specifically for the project, using the software *File Maker Pro Advanced Server*® version 12. As such, the data is handled in a professional and highly secure manner. Furthermore, all the research records are safeguarded on a PUCRS server in a high security environment.

The digitalized forms and database from the cohort study with the sub-sample for changes in cognition or mood, are being developed in a relational manner to the cross-sectional study database, which will work with baseline data added to those generated from the cohort monitoring by the AMBEC/PUCRS. This longitudinal design will make the development of

many future studies in this research line possible, especially in mild cognitive decline, dementia, mood disorders with late onset, the complex relationship between dementia and depression, and the study of suicide risk.

Statistical Analysis

Sample size

The sample size was calculated using the Sample.exe program of the PEPI for DOS statistical package (version 4). A significance level of 0.05 was used.

A minimum sample size of 900 seniors was set, based on a target population of 22 thousand elderly users from the FHS of Porto Alegre and taking into consideration different error rates acceptable for different prevalences, as shown below (Table 1). Allowing for possible sample losses and the maximum assessment capability of the research group in a given data collection day, 1080 seniors were randomly selected, 36 from each of the 30 FHS teams.

Table 1. Sample size calculated according to the prevalence and the acceptable margin of error.

| Prevalence | Margin of error | Sample size |
|------------|-----------------|-------------|
| 0.5% | 0.46% | 868 |
| 1.0% | 0.65% | 865 |
| 3.0% | 1.1% | 887 |
| 5.0% | 1.4% | 894 |
| 10.0% | 2.0% | 832 |
| 20.0% | 2.6% | 874 |
| 30.0% | 3.0% | 862 |
| 50.0% | 3.2% | 900 |

Analytical approach

Data will be analyzed using the software, SPSS version 17. Variables will be described by frequencies, means, medians, standard deviations and interquartile ranges. Quantitative variables will be tested to verify if they have a near normal distribution through the Kolmogorov-Smirnov test. The associations between categorical variables will be tested using Pearson's Chi squared test. In specific cases, the Chi-squared test for linear trend will be used (ordinal variables with few categories). When comparing a dichotomous variable with an ordinal variable or a quantitative variable with a small sample size and not normally distributed, the nonparametric Mann-Whitney test for independent samples or Wilcoxon test for paired samples will be used. When comparing a dichotomous variable with a quantitative variable with a large sample size or normally distributed, Student's t test for paired or independent

samples will be used. For the independent samples, the equality of variance tested by Levene's test will be taken into account.

Prevalence will be inferred by calculating the 95% confidence interval. In order to determine the strength of association of the various risk factors, the odds ratio or the prevalence ratio (for dichotomous variables) with their corresponding 95% confidence interval will be calculated. For the evaluation of the possible confounding variables, the following tests will be conducted: stratified analysis with Mantel-Haenszel's Chi-squared test and multivariate analysis through linear, multiple logistic and Poisson regressions.

Ethics considerations

This project was first presented and approved by the legal representative of the Municipal Health Secretary from Porto Alegre. Hereafter, the project was approved by the Scientific Commission of the IGG/PUCRS and by the two Ethics Committees of PUCRS and Porto Alegre City. It meets the Guidelines and Standards in Research set by Resolution 196/96 of CNS/MS^{7,8,9}.

All participants were informed about the objectives and methods of the research and signed the informed consent¹⁰.

All printed material is filed in a restricted access area in the documentation room for research material at the IGG. Blood samples will remain frozen in the IGG's Biochemistry, Molecular Genetics and Parasitology Laboratory until the end of the analyses; access to this place is also restricted.

FINAL CONSIDERATIONS

Updated epidemiological data is needed to set health priorities and to design and evaluate specific interventions for this age group. In general, it is noted that there are a lack of indicators for the Brazilian elderly population when comparing health data among the elderly with chronic diseases from different countries.

This research work, therefore, can become a valuable and important guiding tool for developing preventive policies in the health area, as well as helping to predict complications and morbidity states in the elderly. This cross-sectional study will allow working with longitudinal subsamples of its subprojects in the mental health area. Therefore, it is worth noting the increasing importance of synergistically applying the acquired scientific knowledge for the benefit of public health users, thus generating further knowledge and enabling improvements in health care and practices.

The main benefit of research like this is to generate knowledge that can be easily translated into clinical practice improvements; benefitting a large portion of the population who depend on the public health care structure. In this context, centers that concentrate greater knowledge, such as universities, have a great responsibility when developing large epidemiological studies that investigate from pre-syndrome and early stage illness through to well established disease.

Therefore, partnerships with the existing public health structure allows knowledge to reach the entire system, beginning in the real environment of an elderly persons home, through to the screening phase and onwards until the specialized multidisciplinary evaluation. Many important indicators are also measured in these phases, such as socio-demographic and lifestyle characteristics, nutritional and functional changes, anthropometric measurements, as well as the identification of abnormal laboratory test results and research of genetic and biochemical markers of oxidative metabolism.

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