

RESEARCH METHODOLOGY

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## The Mental Health Research Protocol of the Multidimensional Study of the Elderly in the Family Health Strategy in Porto Alegre, Brazil (EMI-SUS)

### *Protocolo de pesquisa em saúde mental do estudo multidimensional dos idosos atendidos na Estratégia Saúde da Família de Porto Alegre, Brasil (EMI-SUS)*

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#### ABSTRACT

**Introduction:** The rapid aging process in low and middle-income countries poses a major challenge and has special repercussions for mental health. This is especially true for diseases that impair cognition and emotion regulation such as depression and dementia. In Brazil, caring for the elderly is a public health priority. **Aims:** To describe the scientific methodology and practical applicability of a mental health study tailored to seniors; to provide data to improve mental health assessment and care; to describe a primary care methodology that is replicable in other regions. **Methods:** A cross sectional study using stratified randomized sampling. Study participants were residents of Porto Alegre, over 60 years, and enrolled in the Family Health Strategy program. Study prioritized the examination of psychiatric and cognitive characteristics by using multi-professional indicators of mental health. Data was collected in two phases: screening and specialized diagnosis. **Conclusion:** The paper provides a methodological model to assist researchers in similar studies. Striking an adequate balance between assistance and research is a major challenge. Protocols that prospect and examine the leading mental health problems in the elderly could close the gap between identification of older adults with early symptoms and those at risk of developing depression and dementia. A stratified approach to screening and diagnosing cognitive and mood and disorders for all levels in public health that uses low cost instruments in a real setting will benefit communities and can provide local empowerment.

**KEYWORDS:** Research methodology. Mental health. Elderly. Method. Geriatric psychiatry.

#### RESUMO

**Introdução:** O rápido processo de envelhecimento em países de baixa e média renda é um grande desafio que traz importantes repercussões para a saúde mental. Isto é mais intenso para as doenças que afetam a cognição e as emoções, como depressão e demência. No Brasil, cuidar dos idosos é uma prioridade de saúde pública. **Objetivos:** descrever a metodologia científica e aplicabilidade prática de um estudo de saúde mental para os idosos; fornecer dados para melhorar a avaliação e a assistência de saúde mental; descrever uma metodologia de atenção primária replicável em outras regiões. **Métodos:** Estudo transversal com amostragem estratificada e randomizada. Os participantes do estudo eram residentes de Porto Alegre, possuíam idade de 60 anos ou mais e inscritos no programa Estratégia Saúde da Família. O estudo priorizou a análise de características psiquiátricas e cognitivas por meio de mensurações de indicadores de saúde mental por uma equipe multiprofissional. Os dados foram coletados em duas fases: triagem e diagnóstico especializado. **Conclusão:** O manuscrito fornece um modelo metodológico para auxiliar pesquisadores em estudos semelhantes. Alcançar um equilíbrio adequado entre a assistência e pesquisa é um grande desafio. Protocolos que prospectam e examinam os principais problemas de saúde mental na adultez tardia poderiam ajudar a preencher a lacuna existente entre a identificação de idosos com sintomas iniciais e aqueles em risco de desenvolver depressão e demência. Uma abordagem estratificada para triagem e diagnóstico de alterações cognitivas e de humor em todos os níveis de saúde pública utilizando instrumentos de baixo custo em um cenário real beneficiará as comunidades locais e propiciará o seu empoderamento.

**DESCRITORES:** Metodologia de pesquisa. Saúde mental. Idosos. Método. Psiquiatria geriátrica.

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## INTRODUCTION

Demographic transition and the consequent aging of the population is a global phenomenon, but it occurs at different times and rates in different regions. In most developing countries, this process only began in the second half of the 20th century and has occurred very rapidly, with direct consequences for public health systems ill equipped to assist the elderly population.<sup>1</sup>

Human aging is a complex phenomenon and can be defined as the biological and psychological changes that occur as a result of the passage of time with a tendency to become ill.<sup>2</sup> The aging of the brain (normal or pathological) causes a predisposition towards cognitive, behavioral, and emotional diseases. For public health systems tasked with caring for an aging world population, mental illness in the elderly is a major concern. This trend has taken place at an accelerated pace in low- and middle-income countries (LaMIC). This is especially true for high prevalence diseases that impair cognition and emotions, such as Alzheimer Disease (AD) and depression.<sup>3,4</sup>

AD is the leading cause of dementia worldwide, affecting from one half to three quarters of the total number of demented individuals, which is estimated to be nearly 45 million worldwide. Dementia prevalence is expected to increase in the coming decades as a result of the steady growth in the elderly population. This so-called “AD epidemic” will inevitably represent a major public health problem to most nations, because no effective preventative or curative approach has been identified to date.<sup>5</sup>

In Brazil, caring for the elderly (i.e., defined as persons aged 60 or older) is a public health priority. The Ministry of Health has called for an active approach to caring for these individuals, indicating that part of the health assessment must be conducted in the form of home visits.<sup>6</sup> Although the Ministry of Health controls public health at the federal level, the operations and actions of the National Health System (“Sistema Único de Saúde” – SUS) are decentralized and carried out at the municipal level. In recent years the Family Health Strategy (FHS) improved the implementation of public health at the primary care level. This is a modern plan established that each health facility should have a closer and more active relationship with the community. Each FHS health facility consists of a team of at least one medical doctor, one nurse, and four Community Health Workers (CHW) who take proactive actions to prioritize the promotion of health in the elderly. Unfortunately, planning for mental health care and prevention for this age group still needs upgrades.

Although this is a highly relevant topic, few studies in Brazil have focused on the mental health of the elderly. Likewise, there is a lack of epidemiological studies that use robust screenings and specialized assessments specifically tailored to improve systematized health care actions in LaMIC.<sup>7,8</sup> In summary, the combination of aging, prevalent mental disorders with poor mental health assistance, and systems level obstacles to improving the quality of health care for the elderly in Brazil creates an adverse context that affects society’s most vulnerable individuals, and highlights the need for studies aimed at improving the existing public service structure.

The present paper aims to improve existing epidemiological and clinical research methodology and is designed to diagnose the “mental health conditions” of seniors enrolled with FHS. These improvements are essential because of the accelerated aging process, recognized social inequalities, and barriers to civil rights access for vulnerable individuals in LaMIC. The relevance of this work rests primarily on the synergy between research and care; it aims to improve health care for the elderly and improve the Brazilian National Health Service structure. Research initiatives such as this one can benefit the large proportion of the population who depend on the public health structure.

This paper presents the intellectual conception (relevant and rational subjects), the theoretical methodology of the research project, and describes the practical application of the protocol’s multidimensional collection and specialized collection.

## METHODS

This paper describes a mental health protocol that was the main theme of research of a larger interdisciplinary project, previously described by Gomes et al. (2013).<sup>9</sup>

Because of clinical relevance and a lack of epidemiological data in LaMIC, the screening and diagnostic survey phases investigated deep depression and cognitive decline in a representative population-based elderly sample of a multi-cultural urban Brazilian city.

### Study Design

This is a cross-sectional analytical study with data collected prospectively from a random sample of elderly users of the FHS in Porto Alegre, Brazil.

### Population and Recruitment

When the protocol was developed in 2010, the elderly population of Porto Alegre totaled 175,000 (i.e., approximately 12% of the municipality’s population).

The municipality had 97 family health teams (FHT) covering approximately 22,000 seniors. The public health system in Porto Alegre is organized into eight different Health Districts (HD) or geographic areas, all with different coverage areas.

Thirty FSH teams were selected through a stratified random sampling carried out from the eight HD. Within each team, 36 individuals aged 60 years or older were randomly selected, for a total sample of 1,080 seniors.

## Data collection

Data collection for this project occurred in two phases: 1) screening and general data collected by the CHW in the subjects' homes using one general questionnaire and two screening instruments for cognitive decline and depression; and 2) expert evaluation carried out at the São Lucas Hospital of the Pontifical Catholic University of Rio Grande do Sul (PUCRS) that consisted of a neuropsychological evaluation conducted by trained psychology students in consultation with a certified neurologist and a certified psychiatrist. The instruments used in these assessments are described below.

## Instruments

### 1. Instruments used by the CHW in the first phase of data collection

- *General Questionnaire*

For all seniors included in the survey, a general questionnaire collected information about sociodemographic and economic data, spirituality/religion, smoking, alcohol use, and health conditions (including self-reported diagnoses and medications in use).

- *Geriatric Depression Scale (GDS-15)*

The 15 question GDS-15 is the short form of the Geriatric Depression Scale 30 (GDS-30). It screens for presence of depressive symptoms and intensity of depression. It is one of the most used scales in the world, and has been validated for Brasil.<sup>10</sup> The GDS-15 has a minimum score of 0 (i.e., the individual has no depressive symptoms), and a maximum score of 15. Currently, it is the initial assessment tool for geriatric depression recommended by the Ministry of Health of Brazil for use by professionals in the public health level.<sup>11</sup> In EMI-SUS, this scale was administered by the CHW so as to validate its use as a screening tool for depressive symptoms in a community setting; scores will be compared to GDS-15 administered by psychology students, as well as psychiatrist diagnosis of depression.

- *Vellore Questionnaire*

A version of the Vellore questionnaire, which was translated and adapted for Brazil by our group (article in submission process for publication), was used to screen for symptoms of cognitive impairment. This instrument was created and validated in Índia for use in low education populations<sup>12</sup> and has two parts. The first part consists of 10 questions directed at an informant, which can be a son, daughter, spouse or other person who knows the evaluated senior. The questions for which the answer indicates a possible cognitive impairment are scored. Thus the score ranges from 0 (i.e., no deficit) to 10 (i.e., extreme cognitive impairment). The second part of the scale is directed at the patient and covers 10 questions or tasks that are related to daily situations. The score ranges from 0 (i.e., patients who fail to respond or perform any of the questions/tasks) to 16 (i.e., patients who respond properly or perform all tasks). Three questions are scored on a scale from 0 to 3 and the others on a scale from 0 or 1.

### 2. Neuropsychological assessment: instruments applied by trained psychology students

- *GDS-15*

Please see above.

- *Consortium to Establish a Registry for Alzheimer's Disease (CERAD) subscales*

In 1986 CERAD standardized the procedures for evaluating and diagnosing patients with AD. Different neuropsychological tests were used to create this battery for cognitive assessment, which has been translated and validated in Brazil.<sup>13</sup> The subscales below were used in the neuropsychological battery developed for this study.

- Verbal fluency
- Boston naming
- Word list memory
- Constructional praxis
- Word list recall
- Word list recognition
- Praxis recall
- *Other subscales utilized*
- Digit span
- Wechsler verbal memory test

- *Childhood Trauma Questionnaire (CTQ)*

The CTQ is an instrument used in adults to assess for history of child abuse, and has been translated and validated in Brazil.<sup>14</sup> It consists of 28 questions that

allow the respondent to indicate an intensity of abuse through a 5-point Likert scale. The CTQ contains 5 domains: Emotional Abuse, Physical Abuse, Sexual Abuse, Emotional Neglect, and Physical Neglect.

### 3. Neurological evaluation: instruments applied by the neurologist, and diagnostic criteria for cognitive impairment and/or dementia

- *Addenbrooke's Cognitive Examination – Revised (ACE-R)*

ACE-R is a medical instrument used to objectively assess patient cognitive status. This brief cognitive assessment battery consists of a mini-mental state examination (scored 0 to 30), paired with additional tests that have greater cognitive impairment diagnosis sensitivity (i.e., the clock test, verbal fluency test, and additional tests of memory and recognition of figures). It was translated and adapted for Brazil<sup>15</sup> and validated for the diagnosis of disease and AD<sup>16</sup> with normative data according to age and education for the Brazilian population.<sup>17</sup> The score range is 0-100; using the normative data described above, it uses the cut-off points of 50 for 0-3 years of formal education, 60 for 4-7 years of formal education, 70 for 8-11 years of formal education, and 80 for 12 or more years of formal education.

- *Diagnostic criteria*

Seniors were diagnosed with dementia, regardless of etiology, if they met the all-cause dementia criteria recommended by the National Institute on Aging (NIA)-Alzheimer's Association workgroups.<sup>18</sup> The seniors that did not meet the criteria for dementia but had altered ACE-R or one of the subscales of neuropsychological assessment (i.e., 2 standard deviations below the mean for age and education) were considered cognitively impaired. Unfortunately, the cross-sectional evaluations were often conducted without an informant and it was not possible to define precisely Mild Cognitive Impairment (MCI), thus some patients with dementia may have been initially classified as having cognitive impairment – these patients were referred to additional neuropsychiatric or neuropsychological evaluation.

### 4. Psychiatric evaluation: applied instrument and diagnostic criteria for psychiatric disorders

Mini International Neuropsychiatric Interview Plus version 5.0 (MINI Plus 5.0) is a semi-structured interview that investigates major psychiatric disorders Axis I of the 4th edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) of the American Psychiatric Association (APA,

1994)<sup>19</sup> and the 10th publication of the International Classification of Diseases (ICD-10) of the World Health Organization (WHO, 1992)<sup>20</sup>. The tool is intended for use by general physicians and non-clinical professionals and is validated in Brazil, with accuracy similar to more complex psychiatric interviews.<sup>21</sup> At the national and international level its use in public health has been useful, generating diagnoses with moderate to high accuracy.<sup>22</sup> This was the psychiatric evaluation protocol used in this project.

### Data storage and management

The data was stored in a relational database that the researchers developed specifically for the project using the software File Maker Pro Advanced Server<sup>®</sup> version 12. As such, the data was handled in a professional and highly secure manner. Furthermore, all research records were safeguarded on a PUCRS server in a high security environment.

### 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.

Based on a target population of 22,000 elderly users from the FHS of Porto Alegre, and taking into consideration different error rates acceptable to different prevalences, we calculated a minimum sample size of 900 as shown below (Table 1). To compensate for possible loss to follow up, 1,080 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

The data will be analyzed with SPSS version 17. We intend to describe variable means, medians, standard deviations, and interquartile ranges. We will use the Kolmogorov–Smirnov test to verify if quantitative variables have a near normal distribution. We will use Pearson's chi-square test to test the associations

between categorical variables. In specific cases (i.e., ordinal variables with few categories), we will use the chi-square test for trend. When comparing a dichotomous variable with an ordinal variable or a quantitative variable with a small sample size that is 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, the Student's *t*-test for paired or independent samples will be used. For independent samples, the equality of variance tested by Levene's test will be taken into account.

We will infer prevalence by calculating the 95% confidence interval (CI). In order to determine the strength of the association of the various risk factors, the odds ratio or the prevalence ratio (for dichotomous variables) and the corresponding 95% CI will be calculated. To evaluate possible confounding variables, the following tests will be conducted: stratified analysis with Mantel-Haenszel's chi-square test, and multivariate analysis through linear, multiple logistic, and Poisson regressions.

### Ethical Considerations

This project was first presented and approved by the Municipal Health Secretary from Porto Alegre's legal representative. Hereafter, the project was approved by the Scientific Commission of the Geriatrics and Gerontology Institute of the PUCRS and by two Ethics Committees (i.e., PUCRS and the City of Porto Alegre City). It meets the Guidelines and Standards in Research set forth by the Resolution 196/96 of the Ministry of Health of Brazil.

All participants were informed about the objectives and methods of the research project and signed the informed consent form.

All printed materials were filed in a restricted access location within the IGG's documentation room for research material. The blood samples will remain frozen in the IGG's Biochemistry, Molecular Genetics and Parasitology Laboratory until the end of the analysis; access to this location is also restricted.

### DISCUSSION

The lack of research on elder health in LaMIC is well recognized. Many of these nations present similar obstacles to improving knowledge: few funding opportunities, low investment in high standard research, and difficulty accessing the most vulnerable populations (i.e., those with mental disorders, the

elderly, and lower income individuals).<sup>23</sup> This situation is even more critical in light of the paucity of data regarding important and prevalent diseases such as depression and dementia.<sup>24</sup> Globally, most projects fail to reach an adequate balance between assistance and research.<sup>9</sup>

This paper provides a realistic methodological model to assist researchers studying the elderly at the community and primary care levels. We sought to develop a feasible approach that addressed some of the barriers to partnerships between primary care health professionals and highly specialized health professionals at a University Center. A transfer model using evidence-based knowledge was designed and applied that included preliminary conferences about aging and mental health, followed by a training program focused on neurological and psychiatric disturbances.

The scientific rationale was primarily directed towards validating screening and diagnostic instruments for mental health diseases and its predictors in the elderly, as well as to identify the potential advantages of incorporating systematic evaluations of mental health diseases in population-based studies and in clinical practice. The influence of some important factors relating to variations in the outcomes, such as poverty, poor schooling/illiteracy, suicide risk, and childhood trauma were examined as research hypotheses in specific studies.

The majority of the instruments used in the study are important tools for clinical practice; most of them are recommended as a screening or diagnostic tool in primary care.<sup>22,25</sup>

It is noteworthy that currently an ongoing training program similar to the research project is being implemented as a result of an official partnership between PUCRS and the Municipal Health Secretary of Porto Alegre for the professionals of FHS of the University Hospital catchment area. The specific methodology to implement the evidence-based knowledge transfer and training program will be detailed in another paper. Striking an adequate balance between assistance and research is a major challenge. Health care programs and its registries secondarily generate data for research, and research studies find some results applicable to improving health, thereby promoting translational benefits in a shorter cycle of time and not only in the long term.

Finally, research protocols that examine the leading mental health problems in the elderly could close the gap between identification of older adults with early symptoms and those at risk of developing depression and dementia. A stratified approach to screening and diagnosing mood and cognitive disorders for all levels

of Brazilian public health that uses low cost instruments in a real setting is necessary. This paper demonstrates one approach for integrating research protocols into public assistance programs to better address the mental health needs of the elderly.

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