

## Projecto de investigação no âmbito do estudo EpiReumaPt

**(Project Research under EpiReumaPt study)**

### Processo de submissão à Comissão de Ética

**(Ethics Committee Submission)**

#### 1. Identificação do Projecto **(Project identification)**

##### a. Título do Projecto **(Name of the Project)**

The Impact of Rheumatic Diseases on Early Retirement

##### b. Investigador Principal **(Principal Investigator):**

**Nome/Name:** Pedro Lares

**Instituição/ Departamento Institution/Department:**

Centro Académico de Medicina de Lisboa

##### c. Co-Investigadores **(Co-Investigators):**

###### 1. Nome **(Name)** and Instituição/ Departamento **(Institution/Department):**

Professora Doutora Helena Canhão (Centro Académico de Medicina de Lisboa)

###### 2. Nome **(Name)** and Instituição/ Departamento **(Institution/Department):**

Professor Doutor Miguel Gouveia (Católica Lisbon School of Business and Economics)

#### 2. Instituições/locais onde se irá realizar o projeto

**(Department(s), Laboratory(ies), Institution(s) where the study will be developed)**

### 3. Sumário (Summary) (Max: 150 palavras/words)

**Introduction:** The old-age dependency ratio is rising steadily in most western countries, which are currently facing a shrinking number of economically active people supporting a growing economically dependent elderly population. Despite the recent overall increase in the median age of retirement, this has happened at a much slower pace than the increase in life expectancy. Still, early exit from work continues to occur frequently accelerating the sustainability challenge. In fact, the “early exit from employment” trend is hardly feasible and provides a major challenge to social and health policies. There are several factors affecting early retirement and health problems are at the forefront, with rheumatic diseases (RD) being some of the most relevant. Rheumatic diseases are characterized by pain and physical disability that may lead to early withdrawal from paid employment, generating substantial economic costs to society.

**Objectives:** 1) To examine the association between RD with early exit from paid employment in the Portuguese population. 2) To measure indirect costs associated with early exit from work attributable to RD in Portugal. 3) To analyse possible cost-effective community interventions targeting early retirement due to RD.

**Methods:** Health and sociodemographic data will be retrieved from 2 main national databases: the 4th National Health Survey (INS) and the national rheumatic diseases epidemiology study – EpiReumaPt/CoReumaPt. Other official national databases will be used, namely to estimate productivity values by gender, age-group and region, using the human capital approach. The effects of RD on the likelihood of early exit from paid employment and attributable fractions estimates will be assessed at the individual level by logistic regression. Systematic review will be performed to analyse cost-effective interventions aiming to reduce early retirement.

**Conclusions:** This study should build evidence on the socioeconomic impact of RD in the early exit from paid employment in Portugal. It will also present

recommendations to prioritize investments and interventions targeting patients with rheumatic conditions in order to better address sustainability issues and social protection effectiveness.

#### 4. Estado de Arte (State of Art): (Max: 1500 palavras/words)

##### **Rheumatic Diseases and Early Exit from Work**

Portugal is already among countries with the oldest population in the world, with one of the highest old-age dependency ratio.<sup>1</sup> Thus, this trend is hardly feasible and early exit from paid employment in Portugal generates a serious problem for social and economic sustainability. In fact, it might just be at the very forefront of a general European concern with premature exit from work of its potential labour force. Identification of relevant determinants of early exit from paid employment is clearly a prerequisite to delineate strategies and interventions aiming to shift from early exit to the virtuous cycle of active aging.<sup>2</sup>

There is a large literature on this issue and it is possible to identify some variables that might explain the retirement decision. First, the financial incentives, imbedded in the rules governing disability and old-age pensions;<sup>3,4</sup> second, the type of work;<sup>5,6,7</sup> third, sociodemographic factors, such as gender, education and marital status<sup>8</sup> and lifestyle factors, such as alcohol consumption,<sup>9</sup> smoking<sup>10</sup> and obesity;<sup>11,12,13</sup> and lastly, health-related determinants, such as comorbid conditions.<sup>14,15,16,17,18,19,20,21,22</sup> Previous research has suggested associations of exit from work with diseases like cancer,<sup>23</sup> heart disease,<sup>24</sup> depression,<sup>25</sup> disorders of the nervous system,<sup>26,27</sup> and others.<sup>28</sup> The association with RD is particularly interesting. These diseases are highly prevalent in the western world, and their clinical and functional impact may be profound, representing major causes of disability among workers. Some studies have analysed the RD effect on early retirement,<sup>29,30</sup> but its isolated role is inconclusive, reflecting differences on the type of study performed, the population under study, and the explanatory variables included in the analysis. Besides, most studies of early retirement and health status have been carried out in the United States and northern European countries, but little is known about

Southern European countries, where disability due to RD may represent a quantitatively relevant reason for exit from the labour market.

### **Rheumatic Diseases and Indirect Costs due to Early Exit from Work**

Rheumatic disorders are characterized by pain and physical disability that may lead not only to a substantial consumption of health resources, but also to productivity losses and early retirement.<sup>31,32,33</sup> Knowledge about the economic burden of this group of disorders has progressed during recent years confirming that the total economic burden of RD is often more substantial than other chronic conditions, including cardiovascular diseases and cancer; and that the impact of the disability caused by these conditions is significant on both direct and indirect costs, such as early exit from work.<sup>34</sup>

Nowadays, in developed countries, about a third of the population approaching the statutory retirement age suffers some type of RD.<sup>35,36,37,38,39</sup> This situation is meant to rise in the coming future and therefore RD are expected to have a growing impact in indirect costs, in particular those caused by premature departure of rheumatic patients from the labour market. This makes RD good candidates to be the target of specific public health policies, which in turn should be preceded by research supporting informed decision-making. Calculating this specific type of indirect costs attributable to RD help to prioritize not only the disease itself but also to identify particular subgroups at higher risk, thereby justifying higher investments on activities to reduce their risk of early withdrawal from work.

## **5. Objectivos (Aims): (Max: 300 palavras/words)**

The following hypotheses underline the objectives of the proposed work:

- Health status might have a significant impact in the early exit from paid employment in the Portuguese population.
- Rheumatic diseases, in particular the most prevalent forms, might have a role in this occupational phenomenon.

- Substantial indirect costs to society are expected to follow from early retirement attributable to rheumatic conditions.
- Strategies and interventions aiming to control RD-disability might be cost-effective by reducing significantly this sort of production losses.

Thus, the primary objectives of this study are the following:

- 1) To examine the association between RD and early exit from paid employment in the Portuguese population.
- 2) To measure the indirect costs associated with early exit from work attributable to RD in the Portuguese population approaching the statutory retirement age.
- 3) To analyse and recommend possible cost-effective community interventions targeting early retirement due to RD.

The following secondary objectives will also be considered:

- To characterize early retirees in Portugal, according to sociodemographic characteristics, lifestyle factors and health status (e.g. self-reported and confirmed prevalence of RD).
- To characterize the Portuguese population with RD, namely regarding occupational status.
- To identify relevant determinants of early exit from paid employment in Portugal, by different exit channels (i.e. official retirement, unemployment, other forms of early exit from work).
- To assess how the association between RD with early exit from paid employment is affected by other factors (including personal, financial, socioeconomic and working conditions).
- To analyse the evolution of this association in 2 periods (2005/2006 vs. 2012/2013), by using distinct databases (INS and EpiReumaPt/CoReumaPt).
- To measure the indirect costs attributable to RD by the abovementioned channels of early exit from work.

- To calculate indirect costs attributable to RD for different sub-populations, according to age, gender and region.
- To estimate indirect costs attributable to specific forms of RD (e.g. osteoarthritis, osteoporosis, inflammatory arthritis, etc.).
- To list already tested interventions aiming to reduce early retirement due to RD and rank them according to expected effectiveness.

## 6. Desenho do estudo (Study design) (Max: 300 palavras/words)

Cross-sectional analysis to estimate the association between RD and early exit from work. The effects of RD on the likelihood of early exit from paid employment and attributable fractions estimates will be assessed at the individual level by logistic regression.

Indirect costs will also be estimated. Other official national databases will be used, namely to estimate productivity values by gender, age-group and region, using the human capital approach.

Systematic review of the literature will be performed in order to list already tested interventions aiming to reduce early retirement due to RD and rank them according to expected effectiveness. It will also allow gathering valuable information to analyse and recommend possible cost-effective community interventions targeting early retirement due to RD. If local information is available, authors will try to estimate incremental cost-effective ratios (ICER) of given interventions in Portugal, applying standard health economics techniques, such as modelling (e.g. Markov simulation models). Therefore, if possible, cost-effectiveness analyses will be run using literature inputs and country-specific data (e.g. PT early retirees characteristics) in order to evaluate expected value for money following the implementation of these interventions in Portugal.

## 7. População/amostra (explicitar se o estudo envolve menores): (Population/sample: clarify children enrollment, if applicable)

For the purposes of this study, subsamples of all EpiReumaPt subjects approaching the statutory pension age, between 50 and 64 years old, will be analysed.

### 7.1. Critérios de inclusão (inclusion criteria)

All EpiReumaPt subjects who have signed EpiReumaPt informed consent with ages between 50 and 64 years old will be analysed.

Since this analysis will be based on the EpiReumaPt dataset, it follows its inclusion and exclusion criteria.

### 7.2. Critérios de exclusão (exclusion criteria)

Same as above.

## 8. Descrição Detalhada (Metodologia) / Detail Description

**(Methodology):** (Max: 2500 palavras/words)

**Deverá incluir: (including)**

- a) tipo de estudo (transversal, longitudinal)/ Type of study
- b) descrição das variáveis independentes (exposição) e como serão medidas (variables description and how they will be measured)
- c) potenciais confundidores e como serão avaliados (confounders and how will be assessed)
- d) outcomes e a sua avaliação (outcomes and how will be assessed)

Cross-sectional analysis.

Health and sociodemographic data will be primarily retrieved from 2 main national databases: the 4th National Health Survey (INS) and the national rheumatic diseases epidemiology study – EpiReumaPt/CoReumaPt.

- INS was conducted in 2005 and 2006 in all regions of Portugal. The methodology of the INS has been detailed elsewhere.<sup>40</sup> Briefly, the sampling frame was built on census data and included all subjects living in individual housing during that period (collective housing such as hospitals, prisons, military barracks, or retirement houses was excluded). The sample was

considered representative of the main regions of mainland Portugal (North, Center, Lisbon region, Alentejo, and Algarve) and the autonomous regions of the Azores and Madeira. The primary sampling unit (PSU) was the housing unit, and sampling built on the population and housing census. Within each main region, two strata were defined: the freguesias (corresponding to townships) and, within the freguesias, geographically defined units of 240 lodgings. The PSUs were then randomly selected within each geographically defined unit. Subjects living in the sampling unit were then surveyed. Data were collected using face-to-face interviews by trained staff and the questionnaire included self-reported information about perceived health, chronic diseases, lifestyle, social and demographic conditions.

- The EpiReumaPt survey is a recent national epidemiologic cross-sectional study (2012-2013) with the main aim of estimating the prevalence of different RD in Portugal, but full characterization was also performed, namely regarding occupational status. The 10,000 participants in this project (a random sample of the Portuguese population) were also invited for a long-term follow-up (CoReumaPt). This database provides detailed information for each of the main rheumatic pathologies (confirmed by a rheumatologist) in Portugal.

For the purposes of this study, subsamples of all people approaching the statutory pension age, between 50 and 64 years old, will be analysed.

#### *Exit from Work Definitions*

Early retirement will be considered as being out of paid work before age 65 (statutory retirement age in Portugal). There are different channels of exiting from the labour market and entering into early retirement, including long-term unemployment, disability and pure early retirement. These pathways are related to the same economic behaviour, which implies an exit from the labour market in the later stages of working life and subsequent loss of productivity for society. Results might be presented in the aggregated form of generic “exit from work” and separately by main types, including official retirement and other forms of exit from paid employment.

### *Indirect Costs and Statistical Analyses*

The human capital approach will be used to estimate productivity costs by valuing healthy time lost due to the disease in monetary terms, using information on employers' labour costs estimated on the basis of market wage rates. Thus, the value of lost production will be assessed by obtaining the market wage rates from national public sources (e.g. *Quadros de Pessoal - Ministério do Trabalho e da Solidariedade Social*). All unit values of lost production will be stratified by age-range, gender and geographic region.

### *Cost-Effectiveness of Possible Interventions*

A systematic revision of literature will be done to identify relevant works with results on effectiveness / cost-effectiveness of intervention programs aiming to either delay work withdrawal or to enhance return to work.

These possible interventions specifically addressing rheumatic patients may be diverse.<sup>41</sup> For example, vocational rehabilitation delivered to RD patients at risk for job loss, but while they were still employed, delayed job loss.<sup>42</sup> Work factors are potentially important modifiable risk factors. On this regard, Chorus AM et al. found that individuals with rheumatoid arthritis who had received at least one form of workstation accommodation (included shortening work hours, slowing pace of work, changing tasks, and being allowed to manage work) were 2.5 times less likely to be work disabled.<sup>43</sup> In Spain, Abásolo L and colleagues reported a successful case in which rheumatologists following detailed proceedings in a specialist-run early intervention program had an effect on work disability, at least for some forms of RD.<sup>44</sup>

In order to address specifically our third objective we aim to systematically explore this sort of studies so that valuable interventions might be recommended for Portugal and, if possible to gather required inputs, to build a simulation model to estimate the ICER for Portugal of specific interventions. EpiReumaPt database might provide some of the required model inputs, for instance, the early retirees characteristics.

Among other data, simulation models require definition of relevant states (e.g. at work, retiree), transition probabilities between states (e.g. annual probability of a RD employee for early retirement), costs of each state (e.g. annual cost of early

retirement in Portugal per RD patient), and effectiveness of the studied intervention (e.g. reduction in the annual probability of a RD employee for early retirement following the implementation of that intervention). Since some of these data might be not available, feasibility of applying this technique for this topic in Portugal is still to be determined along the project, namely following the abovementioned systematic revision of the literature.

***EpiReumaPt Variables: detailed in attached document.***

#### **9. Análise estatística (statistics analysis)** (Max: 150 palavras/words)

**Deverá incluir** uma descrição sumária da metodologia a efectuar de acordo com as características do(s) outcome(s) e avaliação das covariáveis e confundidores. Deverá incluir também a dimensão da amostra e o power do estudo.

**Should include:**

- . a brief description of the methodology according to the characteristics of the(s) outcome(s)
- . the assessment of covariates and confounders.
- . the sample size and the power of the study.

Estimation of the impact of RD on the probability of early exit from paid employment will be assessed using logistic regression models. The following relevant covariates are expected to be included in the models: Age, gender, region (North, Center, Lisbon, Alentejo, Algarve, Azores and Madeira islands), RD, other comorbidities, self-perceived health status, QoL, lifestyle factors, marital status, socioeconomic characteristics, and occupational social class.

A good measure of the impact of RD in the early exit from paid employment may be the population attributable fractions (PAF), which take into account both the strength of the association between RD and early exit from work, as measured in the logistic models, and the prevalence of RD in the surveyed population. PAF can be calculated as the resulting proportional change in the probability of exit from paid employment after a counterfactual exercise where the presence of RD is artificially eliminated from the sample. This recalculated

probability of early work exit can be used to estimate the indirect costs attributable to RD. Consequently, annual indirect costs associated with early exit from work and attributable to RD can be obtained after multiplying each observation's probability change with the corresponding unit value of production.

Standard descriptive and inferential statistics will be used to characterize the studied sample and to test hypotheses and make estimations using sample data. Prevalence of RD, exit from work and other characteristics will be computed as weighted proportions, in order to take into account the sampling design of each survey.

All statistical analyses will be carried out using Stata 12.

## 10. Cronograma (Time line)

### I – Causes of early exit from work:

Main milestones:

- Preparation of databases.
- Selection of eligible sample.
- Descriptive analysis of INS and EpiReumaPt databases  
(Including characterization of Portuguese early retirees and RD population).
- Multivariate models (logistic regression with different clusters of covariates).
- Analysis of the results *and paper publication*.

*Timelines: 2H2014-2015 (18 months).*

### II – Consequences of early exit from work:

Main milestones:

- Individual values of production  
(Following average wages by gender, age and region).
- Estimation of PAFs (for each observation of both databases).
- Annual indirect costs by type of early exit from work.

- Annual indirect costs by sub-groups (region, gender and age-group)
- Analysis and publication of 1-2 articles.

*Timelines: 2H2015-1H2016 (12 months).*

III – Solutions for early exit from work:

Main milestones:

- Systematic review of the literature regarding effectiveness of possible interventions aiming to reduce early retirement, as explained before.
- List of already tested interventions aiming to reduce early retirement due to RD and rank them according to expected effectiveness.
- Cost-effectiveness analysis of potential interventions in Portugal (If possible with available data).
- Recommendations / List of proposed actions for community interventions.

*Timelines: 2H2016 (6 months).*

## **11. Orçamento (Budget)**

Not estimated

## **12. Financiamento (se já existir) / Sponsors (if applicable)**

Not applicable

## **13. Publicações (deverá incluir a informação se os dados obtidos constituirão propriedade exclusiva do promotor; quem terá acesso aos dados e se a responsabilidade da publicação é da exclusiva responsabilidade do promotor):**

**Publications (including information of data property, who will have access to the data and if the promoter is the only responsible by the data publication):**

(Max: 300 palavras/words)

We intend to publish results in indexed peer-review scientific journals. This project is included in the PhD project from the first author and results will be used for due PhD thesis.

Any other purposes related with EpiReumaPt data should be subject to explicit appraisal and approval by the scientific EpiReumaPt scientific team.

Raw data (individual observations) will not be disclosed to any other person or third party.

We won't have any primary data property rights.

**14. Estratégia de protecção dos dados do participante (Strategy of data protection)** (Max: 300 palavras/words)

Only aforementioned authors will have access to EpiReumaPt data and will be fully liable for the protection of this data. This means ensuring measures of protection for the security, confidentiality and integrity of EpiReumaPt data, namely by excluding any access to other people or third party. Also, no further analyses will be done without explicit approval by the EpiReumaPt scientific team.

**15. Outras questões éticas relevantes (se aplicável) (Other relevant ethics issues, if applicable):**

**Anexos:**

. carta de apresentação

. Declaração de Financiamento e Conflito de Interesses, caso existam.

- . CVs da equipa de investigação
- . protocolo (versão integral)
- . Consentimentos informados
- . Declaração do responsável do serviço de que aceita a realização do estudo

**Attachments:**

- . cover letter
- . Statement of Funding and Conflict of Interest, if any.
- . Research team CVs
- . Protocol (full version)
- . Informed consents
- . Declaration of the Head of the Department authorizing the study

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