

# BMJ Open Health economic assessment of the Landes public service 'Vivre à Domicile (VIVADOM)' (Living at Home) based on personalised care for frail older adults with human support and digital solutions (telecare, tablet, home automation and connected objects): a Markov model study protocol

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## ABSTRACT

**Introduction** Preventing loss of autonomy has become a public health issue due to the increase in healthcare costs associated with ageing. It has become even more pressing with the arrival of the baby-boomer generation. This has given rise to several initiatives. This is the background to the VIVADOM project. The project provides a complete kit for older adults aged 60 years and over living at home. First, the kit includes a technological package (telecare, light path and digital tablet). Then, these older adults benefit from personalised human support provided by postal workers trained in gerontology. The aim of this study will be to carry out a health economic assessment (HEA) of the VIVADOM project as part of the prevention of frailty and/or dependency (by comparing beneficiaries of the complete kit with non-beneficiaries). The comparator will be the fact of not benefiting from the complete kit. In addition, the efficiency of the project in preventing falls and cognitive problems will be studied. We will calculate three incremental cost-effectiveness ratios (ICER) for these three issues.

**Methods and analysis** The economic model used will be the Markov model. Transition probabilities, average costs and average quality-adjusted life year (QALY) will be calculated for the two groups being compared. The ICER will be obtained by dividing the difference in average costs by the difference in average QALYs. Finally, ICERs will be compared with willingness-to-pay (WTP) to assess the efficiency of the system. Thus, the VIVADOM project will be efficient when these ICERs are lower than the WTP. Univariate and probabilistic sensitivity analysis will be carried out to ensure the robustness of the analysis results.

**Ethics and dissemination** The HEA of the VIVADOM project has been approved by the research unit of the University of Limoges in France. The results will be

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This paper presents a cost-utility analysis protocol for a frailty and/or dependency prevention kit.
- ⇒ Three Markov models are designed to include the entire health status of the frail older adults living at home.
- ⇒ We plan to use a societal perspective that aims to be complete in relation to others.
- ⇒ The paper is based on a non-randomised controlled trial.

published in a peer-reviewed journal and presented at relevant national and international conferences.

## INTRODUCTION

In metropolitan France, there were 16.7 million older adults aged 60 years or over living at home in 2022. Of these, 3–8% were in loss of autonomy, that is, between 500 000 and 1.3 million older adults. In 2015, the rate was 10%. A decline has therefore been observed over the past 7 years. A drop in the proportion of older adults living in nursing homes was also recorded over the same period.<sup>1</sup> Despite this drop in proportion, social protection spending on compensating for loss of autonomy continues to rise. In fact, it rose from €22.6 billion to €27.7 billion between 2015 and 2022. This represents an increase of 22.57%. They are borne by several players: social security, state, departments



and the national solidarity office for autonomy (Caisse Nationale de Solidarité Autonomie).<sup>2</sup>

Faced with rising healthcare costs, it has become essential to prevent older adults living at home from losing their independence. This issue is becoming even more pressing with the arrival of the baby-boomer generation, older adults born between 1946 and 1955.<sup>3</sup> As a result, many local initiatives have sprung up, including the 'Vivre à domicile (VIVADOM)' project, implemented in three French departments (Landes, Eure and Haute-Vienne). The aim is to provide robust or pre-frail older adults living at home with a complete kit. The kit consists first of a technological package (telecare, tablet, home automation and connected objects). Second, older adults benefit from personalised human support. This support is provided by postal workers. The latter have benefited from ongoing training to acquire fundamental knowledge in gerontology. However, before the project can be rolled out to other French departments, it needs to be scientifically proven to be effective. Thus, an economic evaluation of the VIVADOM project has been initiated in the three departments.

Health economic assessment (HEA) is the assessment of the costs and outcomes of interventions, programmes or policies that have an impact on health outcomes. It may be carried out in parallel with individual studies, or as part of decision models summarising evidence from multiple sources. Its aim is to inform decision-making. However, there are divergent views within the health economist community on how to guarantee a social optimum in the allocation of health resources.<sup>4</sup> These points of view are generally characterised by welfarism and extra-welfarism.

Welfarism refers to the neoclassical theory of well-being and its application to situations of market distrust in pure and perfect competition. For the authors of this school of economic thought, social well-being depends exclusively on individual utility functions.<sup>5,6</sup> Applied to healthcare technologies, this involves determining whether a new technology deserves to be financed on the basis of maximising social well-being.<sup>7</sup> Thus, only those people who consume these goods and services, and are therefore affected by the health programme or technology, will be taken into account.<sup>4</sup> On the other hand, the orthodox approach to measuring programme impact would be cost-benefit analysis (CBA), in which the measurement of benefits would be interpreted based on the society's willingness to pay (WTP).

The extra-welfarist approach is linked<sup>8</sup> to Sen's<sup>9,10</sup> capabilities approach. It proposes assessing individual needs using objective measures of the characteristics that define health.<sup>8,11</sup> This approach is more modest than the previous one, in that it claims to inform social decisions about health rather than prescribe a social choice.<sup>7</sup> It opts for cost-effectiveness analysis or cost-utility analysis (CUA).

The aim of this study will be to carry out a CUA of the VIVADOM project as part of the prevention of frailty and/or dependency. In addition, the project's efficiency

in preventing falls and cognitive problems will be studied. We will therefore calculate three incremental cost-effectiveness ratios (ICER) for these three issues (prevention of frailty and/or dependency, falls and cognitive problems). Rather, this paper presents a methodological framework for carrying out the economic assessment of the project after the end of data collection, scheduled for May 2026. It may also serve as a reference for economic assessment of interventions combining technologies and personalised human support. The choice of CUA in this study is explained by the fact that, since the '80s, this method has dominated the practice of health economic evaluation. The trend has been driven by increasing demand for evaluation, improved ability to measure health-related quality of life outcomes and, above all, the adoption of an extra-welfarist perspective by many national health technology assessment agencies (including the Haute Autorité de Santé (HAS) in France, the National Institute for Health and Care Excellence (NICE) in England).<sup>12,13</sup> CBA has fallen out of favour for several reasons: governments have been reluctant to distribute financial resources on the basis of preferences that are likely to be distorted by existing inequalities in income distribution.<sup>7</sup> Moreover, monetary valuations of health do not appeal to the general public.<sup>13</sup>

## METHODS AND ANALYSIS

The proposed method is based on the guidelines of the Professional Society for Health Economics and Outcomes Research.<sup>14</sup>

### Participants

This will be a HEA, CUA carried out in three French departments (Haute-Vienne, Landes and Eure). It will involve a total of 202 older adults living at home. The study investigator will be the University of Limoges.

There will be six inclusion criteria for older adults. They must be aged 60 years or over, live at home, be able to understand and answer the questions, have a level of autonomy between 'Groupe Iso-Ressource (GIR) 3 and 6' and give their oral and written consent to take part in the study. Consent may also be given by a trusted support person and/or by the guardian or curator. The question of consent will be repeated every 6 months, 12 months and 18 months of the elderly person's follow-up. In addition, the person should reside in one of the three departments mentioned above.

However, older adults living in nursing homes will be excluded from the study. The same applies to older adults with severe visual or hearing impairments who may not have been able to perform all the physical tests required as part of the project.

### Regulatory framework

The investigator undertakes to comply with the General Data Protection Regulation. In addition, the data collected will be used in accordance with the reference

methodology (Méthodologie de Référence, (MR)–004 of the National Commission for Data Protection and Liberties), for which the University of Limoges has signed a compliance undertaking. This study is registered in the university's mandatory internal register and is publicly declared in the public directory of studies carried out under the MR of the Health Data Hub (formerly the National Institute for Health Data, Institut National des Données de Santé, INDS) (<https://www.health-data-hub.fr/outil-de-visualisation>). The contract number is: N° F20220214102025 (<https://www.health-data-hub.fr/projets/evaluation-medico-economique-du-service-public-landais-vivre-domicile>).

### Comparators

The older adults in the study will be classified into two groups:

The intervention group will be made up of older adults living in the Landes and Eure departments (France). These older adults will benefit from the complete kit acquired as part of the VIVADOM project, that is, the technological package and human support. The package will include telecare, tablet, home automation and connected objects. The advantage of the complete kit is that it includes three preventive elements: falls prevention, cognitive simulation and breaking the isolation barrier.

- ▶ Modern telecare: there is a broad definition of telecare in the literature. On the 'Telecare Aware' website, it is defined as: '...from simple personal alarms (AKA pendant/panic/medical/social alarms, personal emergency response system (PERS), and so on) through to smart homes that focus on alerts for risk including, for example, falls, smoke, changes in daily activity patterns and 'wandering'. Telecare may also be used to confirm that someone is safe and to prompt them to take medication. The alert generates an appropriate response to the situation, allowing someone to live more independently and confidently in their own home for longer.'<sup>15</sup>
- ▶ Telecare is an umbrella term for different services such as 'pendant alerts' and 'smart homes'.<sup>16</sup> Thus, a wide range of applications and service elements are likely to fall within the scope of this definition of telecare.<sup>17</sup> The term 'generations' of telecare technologies refers to differences in the sophistication of telecare equipment and systems.<sup>16</sup> Based on the evolution of the traditional social alarm model, there are three generations of telecare. This categorisation seems to meet with unanimous approval<sup>16 17</sup>:
  - First generation: these are buttons placed on the wall of the house and easily accessible by the person. When they need assistance, they press them. Alarms can also be worn as watches or pendants. The person activates the alarm by pressing the button to contact the call centre. After a few checks and an analysis of the situation, the call centre alerts the next of kin, the neighbourhood, an intervener, an

ambulance, the police or simply provides reassurance and advice. The alarm is usually linked to a professional call centre. In some cases, it can also be configured to alert caregivers or professionals directly.

- Second generation: this adds a 'passive' or automatic alarm dimension (the older adult does not need to trigger the alarm) by installing sensors such as smoke, fire and flood detectors, among others, in the older adult's home; when a critical situation arises, telecare triggers an alert to the call centre, which takes charge of providing the necessary response.
- Third generation: the telecare generation is more advanced than the other two. This technology automatically collects data on daily activities through various sensors such as front door open/close sensors, refrigerator open/close sensors, pressure mats, bed/chair occupancy and electrical usage sensors. The data are presented to care staff or family carers to monitor well-being and assess the need for help and support.
- The telecare systems covered by the VIVADOM study are first-generation systems. These generations of telecare cannot directly prevent falls (perhaps indirectly, through the assurance and sense of security they provide). On the other hand, they can reduce the consequences, such as prolonged exposure to the ground and its corollaries (dehydration, malnutrition, reduced functional independence and, in extreme cases, death).
- According to the French anti-fall plan, the 'state of telecare' section, there are three types of country in Europe when it comes to the implementation and use of telecare. In first place are countries with a high gross domestic product (GDP) and/or a high level of telecare use: the UK and the Scandinavian countries. The UK, for example, boasts many very small enterprises and very medium enterprises, which serve a dynamic market strongly supported by the public authorities. In second place, we have the countries that are advanced in telecare, but whose GDP is average or even low. Portugal and Spain are good examples. These are countries that have invested heavily in the development of telecare and have voluntary policies in place for its territorial coverage. Spain, for example, has one of the most advanced telecare models, even though its coverage rate remains lower than that of the UK. The first regulatory framework to consolidate certification processes for Spanish suppliers dates to the late '90s. In 2006, the so-called 'dependency law' made telecare a universal right and made access to it conditional on an assessment of the person's degree of dependency. In the last place, we have the countries that are 'lagging behind' when it comes to telecare. In these countries, public authorities are not very active on the subject. What's



more, territorial coverage remains poor. This is the case in countries such as France, the Netherlands, Germany and Italy.<sup>18</sup>

- ▶ Light path/night lighting: the luminous path features a set of light points that light up automatically along the route taken by the older adult at home. It provides appropriate visibility, precisely indicating the right path and enhancing awareness. In this way, the device is likely to reduce falls, especially at night, by providing better adaptation to age-related visual problems (night-time glare when ceiling lights are switched on, poor visual acuity) and by indicating the right path to the toilet and improving awareness (automatically activated light path prevents older adults from getting up without activating the light).<sup>19</sup>
- ▶ In the literature, the presence of light paths coupled with telecare divides by three the risk of falls in older adults living at home: (OR=0.33; 95% CI (0.17 to 0.65); p=0.0012).<sup>19</sup> Another study reported a one-quarter reduction in the risk of functional decline at home (OR=0.24; 95% CI (0.11 to 0.54), p<0.002). As a result, these technologies can reduce the health and social care costs associated with falls in older adults.<sup>20</sup>
- ▶ Digital tablet: these are widespread, low-cost and cognitively accessible digital media.<sup>21</sup> The tablet is frequently used to aid the technological experience of older adults.<sup>22 23</sup>
- ▶ Technologies have four main roles for older adults with cognitive problems: (1) to help these people by limiting cognitive decline, (2) to enable them to carry out daily activities by compensating for cognitive impairment, (3) to ensure their safety and (4) to maintain their involvement in leisure activities and valued social roles. Tablet-based activities take up these four roles by including psychosocial interventions, leisure activities, applications to help with daily living and health applications. They aim to prevent cognitive and psychobehavioural disorders. In addition, these activities promote social inclusion and the maintenance of an active social life, as well as involvement in cultural and leisure activities.<sup>23</sup>
- ▶ Park *et al*, in a meta-analysis, found that digital technologies had significant effects on improving overall cognitive function (standardised mean difference (SMD)=0.31; 95% CI = (0.04 to 0.57); p=0.02). In addition, they had significant effects on people's neuropsychological characteristics, including attention (SMD=1.17; 95% CI = (0.36 to 1.97); p=0.004), visuospatial perception (SMD=0.68; 95% CI = (0.19 to 1.17); p=0.006), visuospatial perception (SMD=0.68; 95% CI = (0.19 to 1.17); p=0.006) and memory (SMD=0.45; 95% CI = (0.19 to 0.71); p=0.0007).<sup>24</sup> The authors argue that these technologies help improve cognitive function in older adults with dementia and mild cognitive impairment.
- ▶ Personalised human support: this is provided by postal workers from XL Autonomie. XL Autonomie is a semipublic company created in March 2019

and equally owned by the Landes department and La Poste. A partnership agreement has been signed with the Eure department to enable the company to provide support services. As part of their support for older adults, postal workers have received training in gerontology. These sessions are repeated every year until the end of the project, enabling postal workers to be better equipped to support older adults daily as part of the VIVADOM project.

Inclusion of participants in the intervention group began in February 2022. A total of 100 older adults are being followed in this group.

*The control group* will be made up of older adults living in Haute-Vienne (France) who do not have the complete kit offered as part of the VIVADOM project.

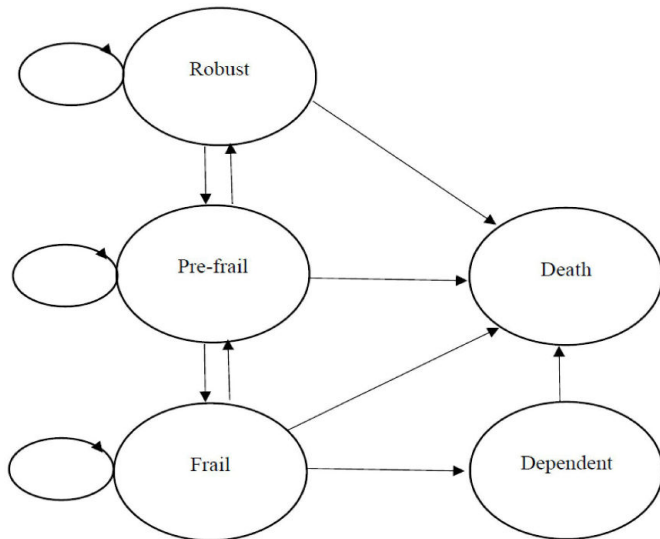
In the control group, participant enrolment began in June 2022. A total of 102 older adults are being followed in this group.

### Markov model

Models are simplified representations of reality. They are used to estimate clinical effectiveness and compare costs. Nevertheless, these models must follow recognised guidelines. Structural assumptions and input data must be fully documented and justified. Economic models are necessary in most HEA.<sup>25</sup> It is impossible to give an exhaustive definition of a high-quality model. In general, estimates of technological performance and organisational processes should be based on the results of systematic examination and modelling, where appropriate.<sup>25</sup> Numerous models can be used to carry out an economic evaluation. These include the decision tree model, the distributional survival model and the multistate Markov model.<sup>26</sup> The decision tree is the most commonly used model.<sup>27</sup>

But it is ill-suited to chronic diseases with long-term prognoses.<sup>26</sup> What is more, it brings together a variety of information from different studies and populations. In this sense, he<sup>28</sup> has even called it 'Frankenstein's monster', as the evaluator (often) combines disparate elements to form a monster (model), while hoping that it will behave in a predictable manner. The distributional survival model is commonly used in cancer treatment.<sup>26</sup>

The Markov model is an analytical framework used in decision analysis. It uses pathological states to represent the possible consequences of a given intervention. These states are exclusive and exhaustive. This means that each person in the model can only be in one and only one pathological state at any given time. People move ('transit') from one pathological state to another as their state evolves over time. Time is considered as a succession of discrete periods called 'cycles'. It is usually expressed in weeks, months or years. Movements from one disease state to another within a period of time are represented by 'transition probabilities'.<sup>29</sup> Markov models make strong assumptions about the absence of process memory. "This means that the transition probabilities depend only on the state of health the patient is in at a given moment, and do not depend on what has happened before. It is



**Figure 1** Markov model for frailty prevention.

difficult to know whether this hypothesis is satisfied in practice”<sup>30</sup>[p 263–264]

Despite these strong assumptions, the Markov model will be used in this study because we find it comparatively the most suitable. Moreover, it is flexible and therefore ideal for creating a methodological framework that can be adapted to any context and environment. The evidence derived from this model can guide decision-makers to improve health outcomes and minimise costs from the perspective of the older adult, health insurance, the healthcare system or society.

There will be three multistate Markov models in this study:

In the first, comprehensive Markov model, frailty and/or dependence will be used to study the impact of the device on beneficiaries (figure 1).

The older adult can be included in the study in a state of robustness, pre-frailty or frailty. He/she will be able to remain in the same state until the end of the 18-month follow-up period. Alternatively, the older adult could die without passing through any of the intermediate states.

It could happen that she passes through these intermediate states. Indeed, from the robust state, the older adult could transit to the ‘pre-frail’ state, thus becoming pre-frail. He/she could remain in this state until the end of the follow-up. On the other hand, this state could continue to deteriorate. In this way, the older adult could move into the ‘Frail’ state, that is, become fragile, and then into the ‘dependent’ state, that is, become dependent. In this same pre-frailty situation, which is reversible, the person could find themselves in a robust state at the end of the follow-up and thus return to the “robust” state.

From the prefrailty state at the start of the study, the older adult could move into the robust state. They could remain in this latter state until the end of the follow-up. On the other hand, from this pre-frailty state, the older adult’s condition could deteriorate. In fact, the older adult could become frail, moving into the ‘frail’ state (and

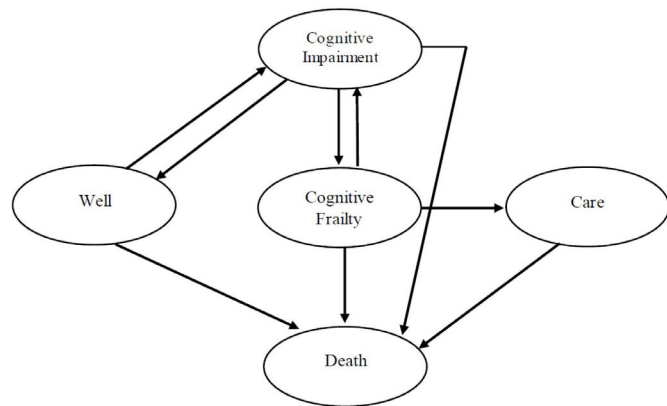
remaining there until the end), then into the ‘dependent’ state (remaining there until the end) and die at the end of the follow-up, in the ‘death’ state.

From a situation of frailty at the start of the study, the older adult could become pre-frail, and thus transit to the ‘frail’ state. They could remain in this situation until the end of the follow-up. On the other hand, from this situation, the older adult could still be in the ‘robust’ state, that is, become robust at the end of the study. From this same state of frailty, a deterioration in the older adult’s state of health could be observed. In fact, the older adult could become dependent, that is, transiting to the ‘dependent’ state (remaining there until the end), and then die, that is, the ‘death’ state.

Dependency is an irreversible state, and the only alternative for the older adult is death.

The second model will deal with cognitive problems and the evolution of the older adult’s condition with the intervention and after 18 months of individual follow-up. It is inspired by Yuang, Xu *et al.*<sup>31</sup> It will assume that the older adult at the start of the study could have no cognitive problems at all, corresponding to the ‘well’ state in figure 2. At the end of the 18 months of individual follow-up, he or she could present minor cognitive problems, in the ‘cognitive impairment’ state, and then die (‘death’) at the end of these problems without receiving care. These problems could also worsen, leading to cognitive frailty. This, in turn, could lead to death without medical care, still a ‘death’ state. The older adult could also die despite having received care, in the ‘care’ state. On the other hand, the cognitively impaired person could switch back to the low cognitive impairment state, that is, the ‘cognitive impairment’ state, and recover completely, that is, land back in the ‘well’ state. Another alternative in this section will be that the older adult could have no cognitive problems at the start of the study, will subsequently present mild problems and will recover, thus returning to the ‘well’ state without receiving care. The older adult, well at the start of the study, could also die after 18 months of individual follow-up without any cognitive problems having been detected.

The last Markov model will deal with the problem of falls (figure 3). It will assume that an older adult in good health (‘well’ state) at the start of the study could suffer a minor fall (‘minor fall’ state). As the consequences of this fall are minimal, this older adult could recover without any ‘visible’ after-effects and thus return to the ‘well’ state. Alternatively, at the end of the 18 months of individual follow-up, the older adult who was well at the start of the study could subsequently fall seriously ill. Despite the absence of care following this fall, the older adult could recover ‘without sequelae’ and return to the ‘well’ state. A serious fall could also lead to the need for social and healthcare. At the end of this care, the older adult could die in the ‘death’ state or will recover ‘without sequelae’ and will return to the ‘well’ state. A serious fall could also lead to the death of the older adult, in the ‘death’ state, without the latter benefiting from social and healthcare.



**Figure 2** Markov model for the prevention of cognitive problems; inspired by Xu *et al.*<sup>31</sup>

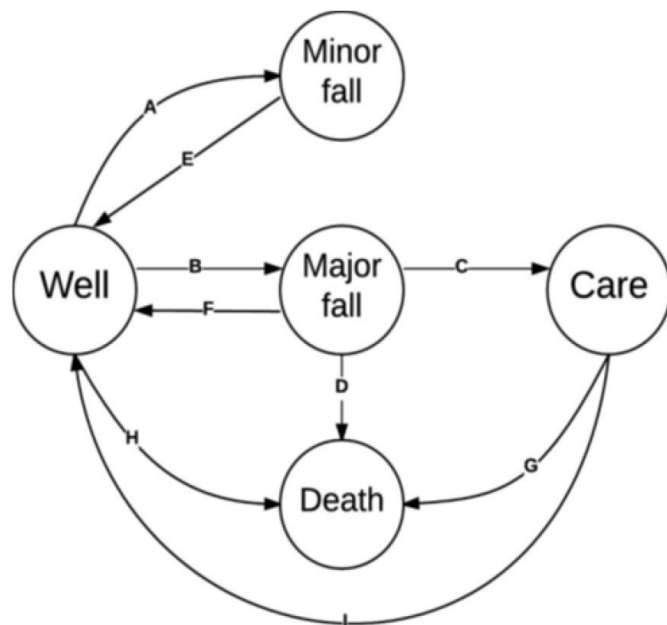
The final cycle in this Markov model will be that the older adult, well at the start of the study, could die at the end of the 18-month follow-up period, in the 'death' state, without a fall event being recorded. The 'death' state is referred to as the 'absorbing state', meaning that no other transition is possible in this state.

Transition probabilities will be attached to the probability of an older adult moving from one state to another. The model cycle period for this study will be 18 months, and each state will be associated with a measure of utility and cost.<sup>32 33</sup>

### Model parameters

#### Transition probabilities

The probability of an older adult participating in the study moving from one state to another is called the 'transition probability', and lies between 0 and 1. To calculate the transition probability in the three Markov models, we will use the following formula:  $r = [-\ln(1-p)]/t$ , where  $r$  denotes the rate,  $p$  represents the probability and  $t$



**Figure 3** Markov model for falls prevention.

denotes the time period. Thus, the transition probability  $= 1 - \exp(-rt)$ , with  $r$ : the rate;  $t$ : the specified period and  $\exp(-rt)$ : exponential of the value  $-rt$ .<sup>34</sup>

#### Outcome measures: instruments

Both generic and health-specific outcomes for older adults will be measured in the study. Generic measures of health-related quality of life will include the European Quality of Life 5 Dimensions 3 Level Version (EQ-5D-3L)<sup>35</sup> and the Short Form - 36 (SF-36).<sup>36</sup>

In the specific measures, we have functional autonomy, which will include the 'Activities of Daily Living',<sup>37</sup> the 'Instrumental Activities of Daily Living',<sup>38</sup> and the GIR.<sup>39</sup> The physical abilities of older adults will be assessed using the Fried criteria,<sup>40</sup> the 'Short Physical Performance Battery',<sup>41</sup> and the 'Integrated Care for Older People'.<sup>42</sup> In addition, in terms of physical tests, grip strength will be collected with a dynamometer. Nutritional status will be assessed using the body mass index. In addition, data on falls and hospitalisations over the last 6 months and the number of medications taken per day by the older adult will be collected in this study.

Generic and specific questionnaires could be administered at the same time. However, it will be recommended to administer the generic questionnaires first, before the specific questionnaires.<sup>43 44</sup>

Measurement data for this study will be collected at baseline, 6 months, 12 months and 18 months. The following generic questionnaires will be used to evaluate the results of the CUA: EQ-5D-3L and SF-36.

#### Utilities

The EQ-5D-3L questionnaire<sup>35</sup> is a generic measure of health-related quality of life.<sup>45</sup> It is based on preferences. The descriptive part of the EQ-5D-3L is used to describe the health status of the older adults surveyed in the study according to five dimensions ('mobility', 'autonomy of the person', 'current activities', 'pain/discomfort' and 'anxiety/depression'). Each dimension of the descriptive system has three response levels ('no problems', 'moderate problems / some problems' and 'severe problems / inability to act').<sup>16</sup> Thus, the instrument can describe a total of 243 ( $3^5$ ) health states. A weighting function (utility function) is associated with each state. It gives a weight (utility) to each health state. Calculation of the quality-adjusted life year (QALY) involves weighting the time spent in each health state by a utility coefficient, ranging from -1 to 1. The latter reflects the value placed by the community on this state, that is, the level of utility associated with the health state. The coefficient 0 is assigned to death. Coefficient 1, on the other hand, reflects full health. Furthermore, states worse than death take on negative values.<sup>4</sup>

In this study, we will use utility scores, estimated from a representative sample of the French population, to convert older adults' responses in the descriptive section into single utility levels.<sup>4</sup> The descriptive part of the EQ-5D-3L is complemented by a visual analogue scale

called 'EQ-5D VAS'. On this scale (in 20cm lines), the older adult is asked to indicate how they rate their current state of health, with 0 being the worst possible state and 100 the best.<sup>45</sup>

### Short Form-36

The SF-36 is a questionnaire for assessing health-related quality of life.<sup>43</sup> It was developed by Ware and Sherbourne<sup>36</sup> on the basis of the medical outcome study. It is a multidimensional, generic scale. It assesses the condition of older adults regardless of their pathology, sex, age or treatment.

The SF-36 comprises 11 questions, with a total of 36 items. The items assess eight dimensions: physical activity ('physical function: PF'), limitations due to physical condition ('role physical: RP'), physical pain ('bodily pain: BP'), general health ('general health: GH'), vitality ('vitality: VT'), social function ('social function: SF'), limitations due to emotional condition ('role emotional: RE') and mental health ('mental health: MH'). The older adult is also asked to evaluate his or her current state of health by comparing it with 1 year earlier ('health thinking: HT').

But this last question is separate from the eight dimensions.<sup>43</sup>

Each item is evaluated on a Likert scale. The Likert scale has 3, 5 or 6 possible response levels. The eight dimensions are used to calculate two quality-of-life scores for older adults: the physical composite score (PCS) and the mental composite score (MCS).<sup>43</sup> The PCS is a global measure of PF, RP, BP and GH. In contrast, the MCS encompasses the domains of VT, SF, RE and MH.<sup>46</sup> But there is little overlap between the dimensions.<sup>47</sup> The PCS and MCS scores are normalised to an average of 50, while the eight dimensions are scored from 0 to 100.<sup>48</sup> Thus, a high score means that the older adult's abilities are important, and vice versa.<sup>43</sup>

### Perspective, resources and valorisation

The costs incurred in this study will be those associated with the various interventions from a societal perspective. These will include the cost of the complete kit (technology and human support), hospitalisations (following a fall, for example, or cognitive problems), drug prescriptions, paraclinical procedures (radiological examinations, biological tests), consultations and paramedical procedures (general practitioner consultations, specialist consultations, hospital consultations, physiotherapy sessions, nursing procedures, medical transport and home help).

From this perspective, we are not going to include production losses, as this will be an older adult, non-active population.<sup>49</sup>

### Technologies

The flat-rate monthly subscription to the VIVADOM kit will be €30 for the older adult (with no special circumstances), €20 for the older adult member of the

'Mutualité Française des Landes', €20 for the older adult who will not be subject to income tax and who will live in the commune of Oeyreluy and € 10 for the older adult who will not be subject to income tax and who will live in the commune of Oeyreluy and is a member of the 'Mutualité Française des Landes'. In the Eure department, the device will be free of charge for all older adults taking part in the project. From XL-Autonomie's perspective, the cost of the device will vary according to the older adult's needs.

The cost ranges from €62.60 (minimum cost) to €130.56 (maximum cost). The average monthly cost is €95.93±SD=12.37, 95% CI (€92.89 to €98.97) (Source: XL-Autonomie database, 2024). These data are available because, at the time of writing the protocol, the older adults' inclusions have been completed.

### Human support and human resources

There are six carers in the Landes and four in the Eure department. The older adults who are part of the VIVADOM project make up some of the people they support. Follow-up times vary considerably from one postal worker to another (from 4–15%). This monthly follow-up time for each postal worker will be included in the gross monthly salary to calculate the cost of the human support provided as part of the VIVADOM project. This information will be obtained from XL-Autonomie. In addition, two full-time researchers have been recruited by the University of Limoges to carry out the telephone follow-ups provided by the project. They are responsible for contacting older adults every month to complete questionnaires (overall geriatric assessment every 6 months, and HEA every month). They are assisted by other staff (interns, clinical research associates, etc.). The total cost of all these people will be recovered from the University of Limoges.

### Hospitalisation

The cost of hospitalisation (fixed cost) will include four expenditure items: salaries (nursing staff, etc.), depreciation and maintenance, logistics (catering, laundry, etc) and structural costs. Data on these costs will be obtained using the medicalised information system programme (Programme de médicalisation des systèmes d'information, PMSI). For each older adult admitted to the medicine, surgery, obstetrics and odontology (Médecine, Chirurgie, Obstétrique et Odontologie, MCO) department, the diagnosis related groups (Groupe Homogène de Malade) and the corresponding tariff, that is, the homogeneous stay group (Groupe Homogène de Séjour, GHS), will be identified. The hospital stay will be classified in a GHS according to PMSI price per activity (Tarification à l'Activité) rules, taking into account the main diagnosis, associated and related diagnoses (comorbidity), age and classifying procedures.<sup>49</sup>

The calculation of the cost of full hospitalisation will consider the actual length of stays: the lower limits (EXB) and the upper limits (EXH). In MCO, a GHS whose

length of stay will be less than EXB will be deprived of part of its valuation.<sup>50</sup>

Rate to be billed = GHS rate – [EXB rate × (low limits – length of stay)].

But when the actual duration will be longer, we will consider the additional cost per day by observing the EXH.

For outpatient hospitalisation, medical consultations and paramedical procedures will be valued on the basis of the general nomenclature for the classification of professional acts (Nomenclature Générale des Actes Professionnels), 'residual' quotations for care not included in the Common Classification of Medical Acts (Classification commune des actes médicaux, CCAM).<sup>49</sup>

The valuation of resources consumed during hospitalisation in geriatric follow-up and rehabilitation care (Soins de Suite et de Réadaptation Gériatrique) will be carried out using medicoeconomic groups (Groupe Médico-économique). These are based on patient stays for full hospitalisation and on the day for partial hospitalisation (without overnight stay). The national cost study (Etude Nationale de Coûts) produces average daily costs for care according to the type of hospitalisation.<sup>50</sup>

#### Admission to emergency

Since 1 January 2022, a patient emergency fee (Forfait Patient Urgences, FPU) of €19.61 has been applied to patients visiting hospital emergency departments (without hospitalisation). It was not introduced for economic reasons. The FPU is also adapted to certain vulnerable populations. For example, for patients with long-term illnesses, such as certain older adults, the FPU is reduced by €8.49. The same applies to patients covered by the industrial injury and occupational disease scheme (Accidents du Travail et Maladies Professionnelles, AT/MP) with a disability of less than 2/3. The FPU also does not apply to insured persons covered by the AT/MP scheme with an incapacity of at least 2/3, to minors who have been victims of sexual violence for treatment resulting from the abuse they have suffered, to organ donors for procedures related to their donation, to insured maternity and newborn babies less than 30 days old, to military or disability pensioners and to victims of acts of terrorism. With this package, anyone who has not been hospitalised will know how much they will have to pay as soon as they arrive at the emergency department. This amount can then be paid in full by complementary health insurance or mutual insurance companies.<sup>51</sup>

#### Medical transport

Scheduled medical transport is mainly carried out by two types of operators: medical carriers and contracted cabs. They are subject to different supervisory authorities and independent regulations. Ambulances and light medical vehicles (Véhicules Sanitaires Légers, VSL) are under the supervision of the Ministries of Labour and Social Security. They must be approved by the Regional Health Agencies (Agence Régionale de Santé) within the framework of a quota. They must

also meet certain professional prerequisites. Their tariffs are set at national level as part of negotiations with the health insurance. Cabs, on the other hand, come under the Ministry of Ecological Transition. They must hold a professional card issued by mayors or prefects. Second, these cabs must have an agreement with the health insurance. Their fares are determined locally by an agreement signed by the cabs and the Sickness Insurance Primary Fund (Caisse Primaire d'Assurance Maladie) based on a national convention. As a result, there is considerable heterogeneity between departments.<sup>52</sup>

In 2023, average expenditure per journey for ambulances was €115, €61 for cabs and €35 for VSL.<sup>53</sup>

For the purposes of this study, the average cost by type of transport and year will be used to assess the cost of transporting older adults to and from emergency services.

#### Consultations

Following the signing of a medical agreement between the health insurance and private practitioners,<sup>54</sup> the cost of a standard consultation with a general practitioner rose from €26.5 to €30 on 22 December 2024. This increase also concerns certain medical specialties. The cost of a consultation with a psychiatrist, neuropsychiatrist or neurologist rose from €51.70 to €55. In July 2025, it will rise by a further €2 to €57. The cost of a consultation with a medical gynaecologist has risen from €33.50 to €37. It will even reach €40 in July 2025. The cost of a consultation with a geriatrician has risen from €31.50 to €37 and will reach €42 in July 2025.<sup>55</sup>

Thus, in our study, the cost of consultations, whether generalist or specialist, will be evaluated according to the cost in force at the time of the consultation.

#### Paramedical examinations and procedures

Biological examinations will be valued based on the medical biology act nomenclature (Nomenclature des Actes de Biologie Médicale) and radiological examinations and functional exploration based on the latest version of the CCAM. Paramedical auxiliary procedures will be valued on the basis of the value of the key letter assigned to their profession, weighted by the coefficient corresponding to their technical nature.<sup>49</sup>

Data on hospitalisation, emergency room visits, medical transport and consultations for this study are collected monthly by interviewing the older adult over the telephone. Occasionally, the interview is conducted face-to-face. The same applies to visits by nurses, physiotherapy sessions, visits by household help or care assistants, emergency room admissions and radiological and biological examinations.

The data collected will be matched with data on the same older adults from the National Health Data System (Système National des données de santé) to ensure the robustness of the data collected over the 18 months of individual follow-up. Matching will also be justified by the fact that, over 18 months of follow-up, we could record a decline in the cognitive abilities of some respondents and therefore collect biased information.

### Discounting

Comparisons of healthcare programmes or organisational initiatives must be made at a specific point in time. The fact that results and costs do not necessarily appear now must be considered when carrying out the medicoeconomic evaluation. Thus, they need to be discounted to a present value.<sup>27</sup>

This discounting is linked to time preference (at both individual and collective levels). People generally have a positive rate of time preference, that is, a preference for immediate rather than deferred benefits. This rate is also known as the psychological interest rate.<sup>30</sup>

This preference is confirmed by the existence of an interest rate. In France, the National Authority for Health (HAS) defines a preference for the present at a rate of 2.5% for time horizons of less than 30 years. Beyond that, the rate is progressively reduced to a floor set at 1.5%. These rates have been fixed since 2013.<sup>56</sup> HAS maintains that the discount rate used in the study is that in force at the time the economic evaluation was carried out.

Thus, the results and costs in this study, collected at different times, but always less than 30 years (since the duration of individual follow-up is 18 months), will be discounted at a rate of 2.5%, in line with HAS recommendations.

### Statistical analysis

Prior to any analysis, we will fill in the missing data. For a given variable, if the proportion of missing data is low (<5%), we will exclude older adults for whom the variable will be missing. This approach is unlikely to significantly bias the results. If this is not the case, we will perform a multiple imputation to complete the missing data.<sup>49</sup>

Quantitative variables relating to the social and health characteristics of the older adults in the study will be presented as means±SD. Qualitative variables will be presented as frequencies with percentages. Comparisons between variables will be made to study the homogeneity of the two groups. For quantitative variables, the student's or t-test will be used when the variable is normally distributed. Otherwise, we use the Mann-Whitney U test. For qualitative variables, the  $\chi^2$  or Fisher test will be used.

Relative risks (RR) of older adults losing their independence at the end of 18 months are calculated from available secondary data. The same applies to falls and cognitive problems. The RR is the ratio of the risk of occurrence of the judgement criterion (loss of autonomy, falls or occurrence of cognitive problems) in the intervention group (Ri) to the risk of occurrence of the same criterion in the control group (Rc).  $RR=Ri/Rc$ . For the adjustment strategy, we will use the multiple linear regression model to find the real effect of the intervention on the outcome indicators.

As part of the HEA, we will calculate the ICER for the three Markov models. ICER is the ratio between the average cost differential between the groups and the average outcome differential between the two groups ( $ICER = \Delta C/\Delta E$ ; with  $\Delta C$ : average cost differential and

$\Delta E$ : average outcome differential expressed in QALYs). It represents the extra cost per QALY gained by implementing the VIVADOM system. This parameter will then be compared with the WTP, generally referred to as lambda ( $\lambda$ ) in the literature. The latter designates the maximum cost that the community is willing to pay for one unit of outcome improvement (here expressed in QALYs).<sup>33 57</sup> Many countries use explicit or implicit thresholds as part of the economic evaluation of healthcare technologies or organisational models.<sup>57</sup>

According to the NICE in England, the expected benefits of a device in the health and social field can be presented using values placed on a QALY gained of £20 000 and £30 000. Thus, if the ICER is less than £30 000, the device is considered efficient.<sup>58</sup> In the USA, the \$50 000 threshold is more often used as a WTP threshold.<sup>59 60</sup> In France, the HAS recognises the importance of this threshold. Nevertheless, it stresses that its definition is fraught with difficulties and calls for the organisation of a national debate to reflect on this issue.<sup>61</sup> The WHO, as part of its 'Choosing Interventions that are Cost-Effective' project, points out that when the ICER is less than three times the national GDP per capita, a device is considered efficient. It is highly efficient when it is less than one times the annual national GDP per capita.<sup>62</sup>

In order to make further progress in the debate on the need to situate the incremental ICER in relation to WTP, the HAS has carried out a literature review aimed at taking stock of the various methods available for estimating WTP. The WHO threshold is cited in this review. While underlining its importance in the context of discussions, the HAS<sup>63</sup> nevertheless considers that the justification for this threshold remains fragile and lacks explicit foundations. As a result, health economists and other professionals are still looking into the issue of WTP in France.<sup>63</sup>

Insofar as the HAS in France has not ruled on a threshold value, we have chosen to use the WHO decision model to interpret the results of this medicoeconomic evaluation, as it is more comprehensive and global than those established by country.

### Sample size

GDP per capita in France in 2020 was €102 849. This figure, combined with the results of other studies, enabled us to calculate the size of the population of older adults to be compared, in order to have significant power in the results of the HEA. In fact, the number of older adults required for this research was calculated based on the following hypothesis. At present, there is no intervention in the literature like VIVADOM (technical and human assistance provided by postal workers) in the context of promoting ageing well at home. However, we chose the study<sup>16</sup> because the population analysed in this study is the closest to our own. The average age in this study was 74.2 years, and the technologies distributed to participants were telecare. Participants also benefited from human support, even if this was not provided by postal workers. We chose telecare because many of the participants in



our study had new-generation telephones on which they could stimulate themselves cognitively through interactive games. In the study by Henderson *et al*, the cost differential was £1014 (approximately €1220.37) and the QALY differential was 0.003. The SD of costs and QALYs was 352.2 and 0.016, respectively. The intragroup correlation coefficient was 0.05.<sup>16</sup>

The WTP chosen here was that of the WHO, that is, €102 849. With a power of 80% and risk  $\alpha$  of 0.05. The number of older adults required comes from the formula of Glick.<sup>64</sup> It is based on the difference in cost and QALY for the chosen CAP threshold. The calculation yields a small sample size of around 30 older adults.<sup>16</sup> It has been multiplied by 2.86 to account for possible increases linked to clusters of varying size. Thus, the total size found is 200 older adults, with 100 in the intervention group and 100 in the control group.

### Sensitivity analysis

Detsky has stressed the importance of sensitivity analysis when carrying out HEA, in order to: “assess the robustness of qualitative conclusions and identify areas where further research is needed to accurately estimate the values of variables for which the result is sensitive”.<sup>65</sup> The principle of this analysis is to measure the effect of variation in an input variable on an output variable of a model with a given structure. This means testing the robustness of a result to variations in a chosen parameter. The result is robust when it varies little in response to a change in the value of a parameter. There are several types of sensitivity analysis.<sup>27</sup>

### Univariate sensitivity analysis

Unidimensional (‘one-way’) analysis studies the effect on the result of variation in one parameter (taken in isolation), all other things being equal (point estimates for other parameters remain unchanged). This means defining reasonable ‘bounds of variation’ and calculating the result for parameter values between the bounds. The extremes represent the values most favourable and most unfavourable to the decision-maker’s objectives. As the response to the result is not identical from one parameter to another, univariate sensitivity analysis also enables us to rank them according to their degree of influence on the final result and to visually represent this hierarchy in the form of a Tornado diagram.<sup>27</sup>

Thus, in this study, variation rates of  $\pm 20\%$  will be used for the costs of human resources, hospitalisations, emergency admissions, medical transport, consultations, examinations and paramedical procedures. On the other hand, for the discount rate, the variation scales will be 0% and 4%.<sup>43</sup>

### Probabilistic sensitivity analysis

Stochastic or probabilistic sensitivity analysis enables the uncertainty of all study parameters to be assessed jointly. It is considered to be the most highly developed form of sensitivity analysis.<sup>7</sup> These analyses use several techniques:

Monte Carlo, Fieller, bootstrap or Taylor to reiterate the calculation of the results a very large number of times by varying the parameters according to predefined statistical laws between the bounds themselves predefined.<sup>27</sup>

We will use Monte Carlo simulation in this study. First, we randomly sample the values of the selected parameters in their simultaneous distribution. We will then calculate the incremental cost-efficiency ratios. These exercises will be repeated 10 000 times.<sup>66</sup> In the literature, cost and utility parameters follow the gamma and beta distributions, respectively. Transition probabilities follow the Dirichlet distribution insofar as polytomous transitions are concerned ( $>2$ ). RRs follow the lognormal distribution.<sup>34 67</sup> In Markov models, to validate the transition probabilities relative to the different states, we first use Monte Carlos to make an uncertainty reading. Then, the data found will be compared with empirical data. The main objective will be to ensure that the different models faithfully reflect the dynamics observed in the data.

Probabilistic sensitivity analysis is used to produce acceptability curves for ICER. The acceptability curve will represent the probability that the VIVADOM device will be efficient compared with no intervention, as a function of WTP. The greater the uncertainty, the greater the efficiency of VIVADOM compared with ‘doing nothing’ at higher WTP. This curve will also facilitate interpretation of the results: decision-makers could set their own WTP and assess the risk they would be taking, assuming the new system will be efficient.<sup>49</sup>

## DISCUSSION

This article describes the protocol of the first HEA of the provision of technology and support by postal workers trained in gerontology as part of the VIVADOM project. It provides a transparent presentation of the data collection and analysis methods used.

More generally, the results will be used to study the effectiveness of the system before considering its extension to other departments, or even to the whole of France.

These results will be presented at national meetings and conferences and submitted to peer-reviewed journals.

## ETHICS AND DISSEMINATION

This study involves human participants, but an Ethics Committee(s) or Institutional Board(s) exempted this study.

This study is registered in the university’s mandatory internal register and is publicly declared in the public directory of studies carried out under the MR of the Health Data Hub (formerly the National Institute for Health Data, INDS).

The contract number is: N° F20220214102025.

The results of this research will be presented at meetings with project partners and funders. They will also be presented at national and international symposiums and conferences. Articles will be submitted to peer-reviewed

journals. In addition, the results of this research will be communicated (1) to participants in the form of a leaflet summarising the main results and their interpretations, (2) to the general public through conferences organised in the various local communities where the study was conducted, (3) to professional organisations working in the field of healthy ageing, (4) to learnt societies in the field of gerontology and (5) to organisations active in the medicoeconomic field (eg, HAS, CNAM, etc).

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