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# Usability, efficacy, and perspectives of an Internet-based psycho-educational program for informal caregivers of persons with Alzheimer's disease: the contributions of an iterative user-centered design and a randomized clinical trial

Victoria Cristancho-Rocha Lacroix

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# Université Paris Descartes

Ecole doctorale 261 « Cognition, Comportements, Conduites Humaines »

Equipe d'Accueil 4468 « *Maladie d'Alzheimer : facteurs de risques, soins et accompagnement des patients et familles* »

## Usability, efficacy, and perspectives of an Internet-based psycho-educational program for informal caregivers of persons with Alzheimer's disease

*The contributions of an iterative user-centered design  
and a randomized clinical trial*

Thèse de Doctorat en Psychologie, Université Paris Descartes

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# **Usability, efficacy, and perspectives of an Internet-based psycho-educational program for informal caregivers of persons with Alzheimer's disease:**

*The contributions of an iterative user-centered design and a randomized clinical trial*

## ABSTRACT

Given the major repercussions of caregiving on the overall health and wellbeing of informal caregivers, the WHO and the French NHA strongly recommend the implementation of interventions devoted to them. Although Internet-based programs represent a promising tool for isolated and overburdened caregivers, little research has been conducted about their design and efficacy. The purpose of this PhD dissertation was to contribute to the knowledge and understanding of the development, evaluation, and implementation process of these programs. For this purpose, we involved forty-nine participants (12 healthcare professionals, 6 caregivers, and 31 healthy older-adults) in the iterative user-centered design process for the development of the Diapason program. The latest version of this program was evaluated in an unblinded randomized clinical trial, based on mixed methods research. Forty-nine informal caregivers of persons with Alzheimer's disease were randomly assigned to the experimental (n=25) or control group (n=24). Although the results were inconclusive about the program's efficacy, the experimental group significantly improved their knowledge of the disease ( $p=0.008$   $d=0.79$ ) in comparison with controls. Furthermore, the results of qualitative analysis showed that patients' children reported more positive appreciations of the usefulness of the program than female spouse caregivers. The findings of this research offer promising perspectives for this kind of interventions, particularly when individualized, centered on the needs of caregivers and based on social support. This work allows for the understanding and analysis of specific methodological features to develop and evaluate caregiver interventions.

# **Utilisabilité, efficacité et perspectives d'un programme psycho-éducatif en ligne pour les aidants informels de personnes atteintes de maladie d'Alzheimer :**

*Contributions d'un design itératif participatif et d'une étude clinique randomisée*

## RESUME

*(voir Annexe 1 pour un résumé extensif en français)*

Compte tenu des risques non-négligeables liés à la prise en charge des personnes souffrant de maladie d'Alzheimer sur la santé globale et le bien-être des aidants informels, l'OMS et la HAS recommandent fortement la mise en place d'interventions à leur égard. Bien que les programmes en ligne représentent un outil prometteur pour les aidants isolés ou surchargés, peu de recherches ont été menées sur leur conception et leur efficacité. Le but de cette thèse de doctorat était de contribuer à la connaissance et la compréhension des processus du développement et d'évaluation de ces interventions. Pour cela, quarante-neuf participants (12 professionnels de la santé, 6 aidants et 31 personnes âgées) ont participé au processus itératif de conception du programme Diapason centrée sur l'utilisateur. La dernière version a été évaluée dans un essai clinique randomisé, basé sur des méthodes de recherche mixtes. Quarante-neuf aidants informels de personnes atteintes de maladie d'Alzheimer ont été randomisés soit dans le groupe expérimental ( $n = 25$ ) ou soit dans le groupe de contrôle ( $n = 24$ ). Bien que les résultats portant sur l'efficacité du programme ne soient pas concluants, les personnes du groupe expérimental ont significativement augmenté leurs niveaux de connaissance de la maladie ( $p = 0,008$   $d' = 0,79$ ). Par ailleurs, l'analyse qualitative a montré que les enfants des patients avaient donné un avis plus favorable que les épouses sur l'utilité du programme. Les résultats de ces travaux offrent des perspectives prometteuses pour ce type d'interventions, en particulier quand elles sont personnalisables, centrées sur les besoins des aidants et basées sur le support social. Ce travail permet de mieux appréhender les spécificités méthodologiques liées au développement et à l'évaluation des interventions des aidants.



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## GENERAL INTRODUCTION

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Due to the worldwide aging population, the increased incidence of dementia in the future and the likely unavailability of economic and human resources are foreseen. As a result, families could be more called upon to support their relatives with Alzheimer's disease, helping them in daily activities, and often delaying their institutionalization. Nevertheless, several studies have shown the non-negligible consequences of informal caregiving on the physical and psychological health, as well as on the quality of life and social network of informal caregivers. Indeed, they have a higher risk to develop chronic diseases, chronic stress, depression, burden, anxiety, and mortality than non-caregivers (Amieva et al., 2012), or than caregivers<sup>1</sup> of patients with other pathologies (Schulz & Sherwood, 2008).

Most of these consequences are described in **Chapter 1**, as well as major theoretical models inspired from the Lazarus and Folkman's cognitive model of stress and coping. They have been used to analyze the causes and consequences of mental and physical weakness in informal caregivers. At the end of this chapter we present an overview of protective and predictive factors from caregivers' distress, which may guide the development of preventive and therapeutic interventions for them.

In fact, over the last decades various non-pharmacological interventions have been developed in order to improve caregivers' wellbeing, to prevent stress and its consequences on health. The studies evaluating the efficacy and effectiveness of these programs have found positive, albeit "small", benefits for caregivers. Nevertheless, one of the limits of these interventions is that they have often been delivered in-person and on-site. As a result, when caregivers are unable to go to health centers (often as side consequence of caregiving demands) (de Rotrou et al., 2010), they rarely have other alternatives, and turn out to be unintentionally excluded from these interventions. In this context, Internet-based, and generally technology-driven programs may supply the needs of isolated and overwhelmed

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<sup>1</sup> For the purpose of this work and in the sake of readability, the word "*caregiver*" will be used instead "informal caregivers".

<sup>2</sup> The "Personnes âgées QUID" (PAQUID) cohort is a prospective population-based study, which included at baseline 3,777 community-dwelling older adults aged 65 and over, recruited in two administrative areas of south-

caregivers. In **Chapter 2**, we describe the current trends and recommendations for the evaluation and implementation of caregivers' interventions, and provide a brief overview of usability methods and the user-centered design approach. Based on a literature review, on earlier sets of experience, and on caregivers' needs, the geriatric service of the Broca hospital developed a web-based psycho-educational program for caregivers of persons with Alzheimer's disease, called Diapason. In **Chapter 3**, we described the development process based on an iterative user-centered design approach as well as usability tests using mixed methods in order to adapt the contents and ergonomics to the needs of end-users (**Paper 1**). In **Chapter 4**, we summarized the theoretical basis, and methodological, logistic and ethical considerations that we took into account in designing the study protocol to evaluate the efficacy of the Diapason program. The in-depth description of the study protocol is available in **Paper 2**. We then summarize and discuss the qualitative and quantitative results of this unblinded randomized clinical trial in **Chapter 5**, as well as the limits, strengths and scientific and clinical implications of this study (**Paper 3**). Finally, based on an iterative approach of this work, we conducted an ancillary descriptive study for the evaluation of caregivers' needs and expectations towards web-based interventions devoted to them. The methodology and the preliminary results of this study are described in the second section of Chapter 5.

The overall goal of this thesis is to contribute to the knowledge and understanding of the development, evaluation, and implementation process of Internet-based interventions for caregivers of persons with dementia.

#### **Note to readers**

The present PhD dissertation is article-based. Chapters 1 and 2 present the theoretical framework for the topic of this thesis. Chapters 3 to 5 present the empirical and experimental work that I conducted during the thesis. Each study is presented as a scientific article that has either already been published or has been submitted to international peer-reviewed journals. It is important to note that only papers where I am first author, in which I played a main role during the design, plan, execution and analysis, were presented in this document. In total, three papers are included: two published papers (Chap. 3 and 4); and one submitted paper (Chap. 5). My contribution is described at the end of every one of them.

The Diapason program content was created in its majority by the multidisciplinary team of the Broca hospital, before I joined in this project in 2010. The areas in which I mainly contributed were the design of the relaxation training section, the edition of contents, the supervision and

coordination of website design, as well as the scientific and logistic management of the project.



# **Part I**

Theoretical introduction

## CHAPTER ONE

---

# INFORMAL CAREGIVING IN ALZHEIMER'S DISEASE

### ALZHEIMER'S DISEASE: THE PUBLIC HEALTH VIEWPOINT

With the continuous growing worldwide aging population, the number of persons with dementia (35.6 millions) is expected to double by 2030 (WHO, 2012). In Europe, Alzheimer's disease is the most frequent type of dementia (Lobo et al., 2000). Each year the number of new cases of Alzheimer's in the world is estimated at 7.7 million, which means one new case every four minutes. In France, it is estimated that 860,000 persons over 65 suffer from Alzheimer's disease and this population will raise to two million in the next twenty or thirty years (Ankri & Van Broeckhoven, 2013). Given these figures, many public and international authorities, as well as patients' associations, have expressed their worry. In 2012, the World Health Organization (WHO) named Alzheimer's disease the biggest public health challenge for the 21<sup>st</sup> century (WHO, 2012). They underline the lack of awareness and knowledge about the illness in many countries, which induces stigmatization of patients and limitation of diagnosis, and impacts the patients and their families, as well as professional caregivers, "*psychologically, physically and economically*". From this growing interest in Alzheimer's disease over the last years, policies and resources have been specially assigned to the research and development of science and technology to improve diagnosis, understanding, care, and support for patients and their families (Ankri & Van Broeckhoven, 2013; Robert, 2010, 2012; INPES, 2010; Thies & Bleiler, 2013).

### ALZHEIMER'S DISEASE: A NEURODEGENERATIVE DISORDER

Alzheimer's disease is a progressive neurodegenerative brain disorder, characterized by brain atrophy, particularly of hippocampal regions, temporal amygdala, and the temporal

pole. The loss of cortex volume is also associated with a moderated ventricular dilatation observed in 57% of patients. Nevertheless, no such macroscopic modifications observed in Alzheimer's disease evolution are specific to the disease. Thus, it is only after a microscopic brain examination that the diagnostic can be affirmed (INSERM, 2007).

The lesions observed and described in autopsied Alzheimer's disease brains include, "positive" lesions such as the amyloid plaques and neurofibrillary tangles, and "negative" modifications such as neuronal and synaptic loss. The positive lesions allow the diagnosis, whereas the negative ones are less disease specific (Serrano-Pozo, Frosch, Masliah, & Hyman, 2011). At the beginning of the 20<sup>th</sup> century, Aloïs Alzheimer provided the first description of the *neurofibrillary tangles*. These are due to the accumulation of hyperphosphorylated tau proteins within the neurons. In contrast, *amyloid plaques* are aggregating in the extra-cellular space, resisting different brain elimination systems for an unknown reason. This accumulation of senile plaques leads to local inflammation. The *neuronal and synaptic loss* is correlated with the presence of neurofibrillary tangles. The hypothesis of researchers is that accumulation of A $\beta$  might interfere with the inter-neuron synapsis, contributing to cell death (Braak, Thal, Ghebremedhin, & Del Tredici, 2011). Although multiple research studies consecrated to Alzheimer's disease have uncovered some of its underlying mechanisms, the causes of these features remain poorly understood (Amieva et al, 2007).

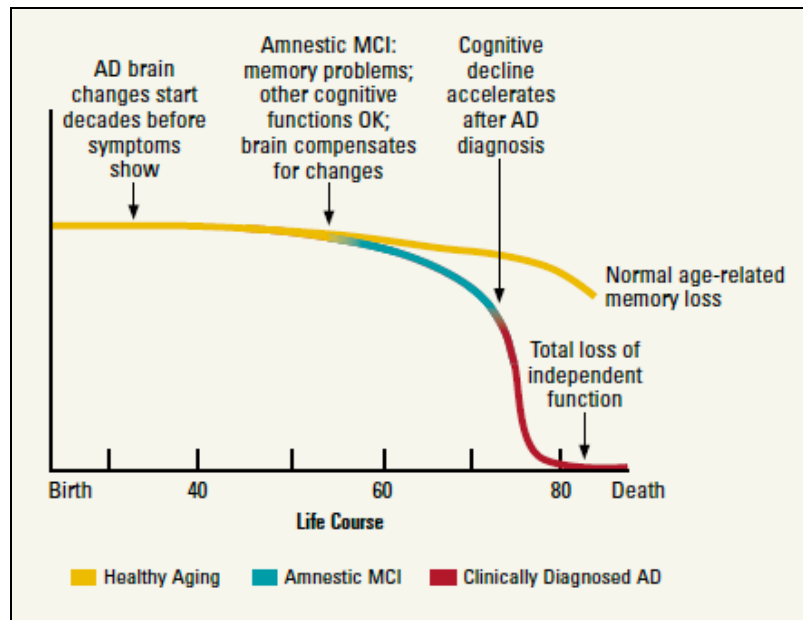
## CLINICAL ASPECTS OF ALZHEIMER'S DISEASE

The evolution from healthy aging to Alzheimer's disease occurs over many years. This insidious and progressive process resulting from the interaction of biological, genetic, lifestyle and environmental factors in some individuals, may trigger a Mild Cognitive Impairment (MCI), and possibly Alzheimer's disease. Other persons, sharing or not the same genetic makeup, having experienced a different combination of factors, might continue the course of normal aging (Figure 1) (National Institute of Aging & National Institutes of Health, 2008).

Alzheimer's disease and other dementias affect each individual in a different way, depending on the progression of the disease and the person's pre-morbid personality. Based on clinical descriptions, dementia, including Alzheimer's disease, may progress through three clinical stages: a) early stage, during the first two years, b) middle stage, between the second and fourth or fifth year and c) late stage after the fifth year (see Table 1). Nevertheless these periods are approximate guides, and persons can experience a more rapid or slower

progression of symptoms. Indeed, “not all persons with dementia will display all the symptoms” (WHO, 2012).

**FIGURE 1. CHART OF COURSE FROM HEALTHY AGING TO ALZHEIMER'S DISEASE**



Source: NIA & NIH, 2008

The first stage of the illness is often overlooked, delaying its diagnosis and treatment. Most families and friends misunderstand the early symptoms of dementia, and attribute them to a normal aging process (WHO, 2012), In fact, since at this stage the patients retain a relative autonomy, and only need help with housekeeping or daily activities (Van der Roest, 2009), it is difficult for the relatives or for the general practitioner to perceive or ascertain their pathological nature.

**TABLE 1. COMMON SYMPTOMS EXPERIENCED BY PEOPLE WITH DEMENTIA**

Early stage	Middle Stage	Late Stage
<p>The early stage is often overlooked. Relatives and friends (and sometimes professionals as well) see it as “old age”, just a normal part of the aging process. Because the onset of the disease is gradual, it is difficult to be exactly sure when</p>	<p>As the disease progresses, limitations become clearer and more restricting.</p> <ul style="list-style-type: none"> <li>• Become very forgetful, especially of recent events and people’s names</li> <li>• Have difficulty comprehending</li> </ul>	<p>The last stage is one of nearly total dependence and inactivity. Memory disturbances are very serious and the physical side of the disease becomes more obvious.</p> <ul style="list-style-type: none"> <li>• Usually unaware of time and</li> </ul>

<p>it begins.</p> <ul style="list-style-type: none"> <li>• Become forgetful, especially regarding things that have just happened</li> <li>• May have some difficulty with communication, such as difficulty in finding words</li> <li>• Become lost in familiar places</li> <li>• Lose track of the time, including time of day, month, year, season</li> <li>• Have difficulty making decisions and handling personal finances</li> <li>• Have difficulty carrying out complex household tasks</li> <li>• Mood and behavior: may become less active and motivated and lose interest in activities and hobbies may show mood changes, including depression or anxiety may react unusually angrily or aggressively on occasion</li> </ul>	<p>time, date, place and events; may become lost at home as well as in the community</p> <ul style="list-style-type: none"> <li>• Have increasing difficulty with communication (speech and comprehension)</li> <li>• Need help with personal care (i.e. toileting, washing, dressing)</li> <li>• Unable to successfully prepare food, cook, clean or shop</li> <li>• Unable to live alone safely without considerable support</li> <li>• Behavior changes may include wandering, repeated questioning, calling out, clinging, disturbed sleep, hallucinations (seeing or hearing things which are not there)</li> <li>• May display inappropriate behavior in the home or in the community (e.g. disinhibition, aggression)</li> </ul>	<p>place</p> <ul style="list-style-type: none"> <li>• Have difficulty understanding what is happening around them</li> <li>• Unable to recognize relatives, friends and familiar objects</li> <li>• Unable to eat without assistance, may have difficulty in swallowing</li> <li>• Increasing need for assisted self-care (bathing and toileting)</li> <li>• May have bladder and bowel incontinence</li> <li>• Change in mobility, may be unable to walk or be confined to a wheelchair or bed</li> <li>• Behavior changes, may escalate and include aggression towards caregiver, nonverbal agitation (kicking, hitting, screaming or moaning)</li> <li>• Unable to find his or her way around in the home</li> </ul>
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Source: World Health Organization, 2012

The progression of Alzheimer's disease presents three hallmark features: cognitive impairment, behavioral troubles and functional disabilities provoking a progressive dependency and loss of autonomy. A quick overview is presented below.

#### COGNITIVE IMPAIRMENT IN ALZHEIMER'S DISEASE

The most frequent symptoms reported by the patients or their relatives (75%) concern memory impairment and disorientation in time and space (Amieva et al., 2005). The impairment of episodic memory affects specific autobiographical memories, and thus, their individual identity. Semantic memory impairments may alter functions in naming objects or



persons, while working memory troubles alter capacities to execute daily activities, such as cooking, or managing their medications without help (Belin, Ergis, & Moreaud, 2006). Nevertheless, recent studies estimated that up to 7% of cases of Alzheimer's disease can preserve normal verbal and nonverbal memory, and 6% can have normal verbal memory with abnormal nonverbal memory (Lopez, McDade, Riverol, & Becker, 2011).

The impairment of executive functions in Alzheimer's disease has substantial repercussions on patients' daily life, and sometimes on their social relationship. Indeed, executive functions allow people to anticipate, plan, organize, and execute daily life activities (Amieva et al., 2005) as well as, inhibit maladjusted social behaviors. Other cognitive impairments affect decision-making, judgment and reasoning of patients (McLaughlin et al., 2010).

In the middle and late stages of the disease, the patients may further present with cognitive dysfunctions affecting their language, (i.e. aphasia, impairment of the comprehension and/or formulation of language), gestures (i.e. apraxia, loss of the ability to perform specific voluntary tasks or movements), and recognition (i.e. agnosia, inability to recognize sound, persons, shapes or smells) (Belin et al., 2006).

#### BEHAVIORAL TROUBLES

Behavioral and psychological symptoms of dementia (BPSD) are observed in almost 90% of persons with Alzheimer's disease (PWAD) at different stages of the illness. Nevertheless, the presence of these symptoms is quite heterogeneous between them (Robert et al., 2005). Apathy is the most frequent BPSD followed by anxiety, and mood/depression symptomatology, while hallucinations and elation are the least frequent (Fauth & Gibbons, 2014; Robert et al., 2005). Depression and apathy may be observed in early stages of the illness, while aberrant motor behaviors, disruptive behaviors, and resistance to care frequently emerge in the last stages of the illness. Other manifestations such as insomnia/hypersomnia, delusions, hallucinations, agitation and appetite disorders, could appear at different stages of the disease, (Leperre-Desplanques et al., 2013; Robert et al., 2005).

The BPSD are attributed to brain lesions of dementia, but are strongly associated with psychological, social, and environmental contexts (INSERM, 2007; Robert et al., 2005). For instance, it was noted that: *"non-adapting caregivers were most likely to encounter patients' hyperactivity symptoms during the course of dementia"* (Robert et al., 2005, p. 491).

## FUNCTIONAL IMPAIRMENT AND DEPENDENCE ON OTHERS

The cognitive, behavioral, and functional impairments due to Alzheimer's disease, lead the patients to different levels of dependency and an increased need for assistance (McLaughlin et al., 2010). According to the PAQUID cohort study<sup>2</sup>, functional impairments may even be described in pre-clinical stages, sometimes three to five years before the Alzheimer's disease diagnosis. In fact, in this study, individuals diagnosed with Mild Cognitive Impairment having an alteration of daily life activities, had a significantly higher risk to develop dementia during the following 2 years, in comparison with other MCI participants (INSERM, 2007).

In the first stages, the PWAD may begin with subtle symptoms of the disease, and may need help with social activities (e.g. hobbies, community affairs and home) (Bläsi & Brubacher, 2005). Over time, cognitive impairment may lead to increased reliance on others for coping with memory-related impairments (e.g. schedule appointments), disorientation (e.g. navigation and temporal orientation), and executive impairments (e.g. manage finances or medications, and apraxia). Functional impairment, defined as the patient's inability to perform specific activities, induces dependence on others and loss of functional autonomy (McLaughlin et al., 2010).

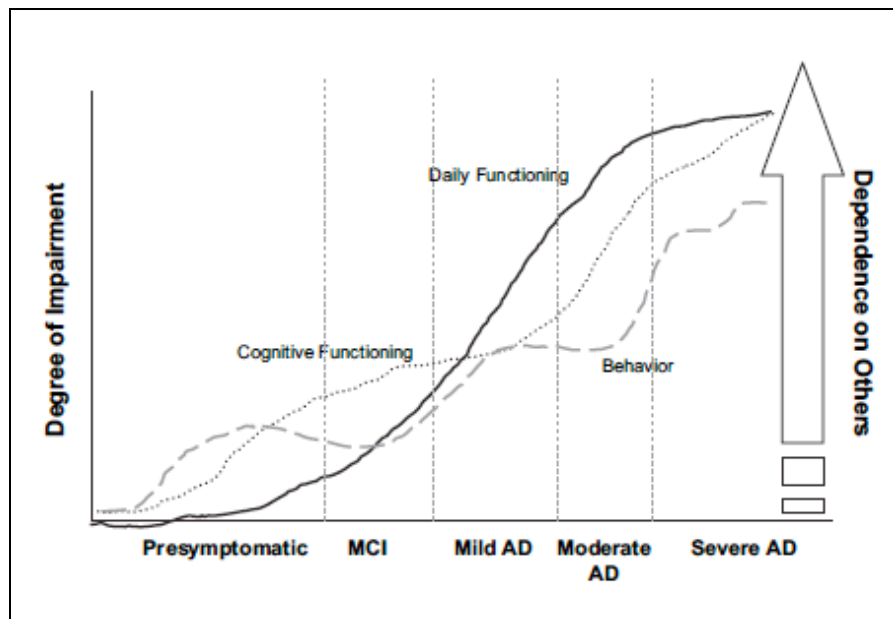
The apparition of behavioral troubles, such as wandering, often leads to increased personal risk of injury and demands more management strategies and assistance needs (e.g. supervision to avoid harm, from the patients or other persons). In fact, Murman and colleagues (2007) found significant correlations between the measures of behavioral troubles (measured with the Neuropsychiatric Inventory) and the level of dependence (measured with the Dependence scale).

As observed in Figure 2, the overall level of dependence is more or less associated to each domain of impairment (i.e. behavioral, cognitive or functioning), depending on the stage of the disease. For instance, in the first stage, cognitive impairment might be the main contributor to dependency, while daily functioning impairment might have more impact on dependence with the disease progression. In addition, the levels of dependency may be provoked by other factors than those related to Alzheimer's disease severity, such as patients' "*comorbid conditions, physical handicap, or environmental factors*" (McLaughlin et al., 2010).

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<sup>2</sup> The "Personnes âgées QUID" (PAQUID) cohort is a prospective population-based study, which included at baseline 3,777 community-dwelling older adults aged 65 and over, recruited in two administrative areas of south-western France (González-Colaço Harmand et al., 2014).

**FIGURE 2. IMPACTS OF IMPAIRMENTS IN COGNITION, FUNCTION AND BEHAVIOR ON PATIENT DEPENDENCE ON OTHERS**



Source: McLaughlin et al., 2010

### ALZHEIMER'S DISEASE DIAGNOSTIC CRITERIA

In the last 25 years, the criteria for the Alzheimer's disease diagnosis have evolved along with scientific and technological advances. The updated version of the diagnostic criteria (from the National Institute on Aging – Alzheimer's Association, NIA-AA) includes the presence of insidious and "clear-cut history of worsening of cognition", affecting at least one cognitive domain. In fact, the new classification expands the definition to non-memory forms of Alzheimer's disease (language, visuospatial and executive). Furthermore, these criteria stress the importance of biomarkers and genotypes supported by multiple studies (e.g. atrophy in medial temporal lobe structures in Magnetic Resonance Imaging (MRI) or autosomal dominant mutation in immediate family) (Lopez et al., 2011; McKhann et al., 2011) (Table 2). In this version the role of expert professionals is highlighted (e.g. geriatrists, neurologists, neuropsychologists, neurophysiologists): they are the sole persons able to pronounce the diagnosis, by underlying the pathological nature of Alzheimer's disease (Espace Ethique Alzheimer, 2013).

**TABLE 2. CLINICAL DIAGNOSIS CRITERIA FOR PROBABLE ALZHEIMER'S DISEASE, MCKHAN ET AL. 2011**

<p><i>The patient meets criteria for dementia, and in addition, has the following characteristics:</i></p> <p><i>A. Insidious onset</i></p> <p><i>B. Clear-cut history of worsening of cognition by report or observation</i></p> <p><i>C. Initial and most prominent cognitive deficits are evident on history and examination in one of the following categories.</i></p> <p><i>a. Amnesic presentation: Deficits include impairment in learning and recall of recently learned information. Evidence of cognitive dysfunction in at least one other cognitive domain.</i></p> <p><i>b. Nonamnesic presentations:</i></p> <ul style="list-style-type: none"><li><i>• Language presentation: Prominent deficits in word-finding, and deficits in other cognitive domains.</i></li><li><i>• Visuospatial presentation: Prominent deficits in spatial cognition (object agnosia, impaired face recognition, simultanagnosia, and alexia). Deficits in other cognitive domains should be present.</i></li><li><i>• Executive dysfunction: Prominent deficits are impaired reasoning, judgment, and problem solving. Deficits in other cognitive domains should be present.</i></li></ul> <p><i>D. Diagnosis of probable AD dementia should not be applied when there is evidence of (a) substantial concomitant cerebrovascular disease; or (b) core features of Dementia with Lewy bodies other than dementia itself; or (c) prominent features of behavioral variant frontotemporal dementia; or (d) prominent features of semantic variant primary progressive aphasia or nonfluent/agrammatic variant primary progressive aphasia; or (e) evidence for another concurrent, active neurological disease, or a non neurological medical comorbidity or use of medication that could have a substantial effect on cognition</i></p>
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Source: Adapted from McKhann et al., 2011

## DIAGNOSIS ANNOUNCEMENT

In France, Alzheimer's disease is under-diagnosed, with an estimated one in two cases actually diagnosed. Most of the non-diagnosed cases seem to concern the youngest or oldest persons, due to different factors. As previously described, given the insidious progression of Alzheimer's disease, the first troubles are often interpreted as consequences of normal aging. In some cases the PWAD may compensate for the troubles for a while, making the detection of impairments by their relatives or by themselves more difficult (Solomon & Murphy, 2005). Finally, a few PWAD suffer from anosognosia or from denial of the illness and its symptoms, limiting their access to medical institutions (INSERM, 2007). Therefore, the diagnosis is often disclosed at advanced stages, delaying the medical and psychosocial care management of patients, and adding burden and stress to caregivers (Van der Roest, 2009; World Health Organization, 2012). On the other hand, establishing a clear diagnosis in the last stages of the disease is also difficult. Indeed, with the progression of the illness the symptoms become less specific to determine the etiology of troubles (INSERM, 2007).

Once the previous difficulties have been overcome, the practitioners must disclose the diagnosis to patients (excepted when they explicitly refuse it) (In France: Article L.1111-6, loi

n°2002-303 du 4 mars 2002). The announcement of the diagnosis is a critical moment for patients and caregivers. The way the disclosure of the diagnosis is run, will usually determine the understanding of the disease by patients and relatives, the observance of care, and can facilitate the active participation of patients to planning for the future (Espace Ethique Alzheimer, 2013). The recent recommendations of the National Health Authority (2011) (NHA, in French: Haute Autorité de Santé-HAS) underline the necessity for an individualization of the diagnosis disclosure process. As a consequence, this process must be reviewed for every patient depending among others on their lifestyle, medical and familial background, social network, and awareness of symptoms. Based on this approach, specialists are advised to identify the right moment and manner to disclose the diagnosis. It could be announced in one or more appointments, with or without the caregivers. Moreover, the NHA recommends to provide both patients and caregivers with physical, emotional, and educational care management, during and after the diagnosis disclosure (Haute Autorité de Santé, 2012).

If the NHA extends these recommendations of care to the relatives of PWAD, it is likely due to the non-negligible consequences of caregiving on the caregivers' wellbeing and on their general health status. In the following section, we will address the demands associated to caregiving for a PWAD, the positive and negative consequences for relatives, and some of the theoretical models devoted to their study. Finally, we will summarize various protective and predictive factors of stress that may guide us to various preventive and therapeutic intervention clues.

## WHO ARE THE INFORMAL CAREGIVERS?

The so-called “informal”, “natural”, or “family” caregivers remain the most common source of assistance for older adults with physical or cognitive impairment (Steffen, Gant, & Gallagher-Thompson, 2008). They can be relatives or friends, and are non-trained and unpaid. They often begin by providing “temporary” help or support to a close relative who is frail, ill, or disabled.

The Confederation of Family Organizations in the European Union defines the informal caregiver as:

*“...a non-professional person who provides primary assistance with activities in daily life, either in part or in whole, towards a dependent person in his / her immediate circle. This regular care may be provided on a permanent or non-permanent basis and may assume various forms, in particular: nursing, care, assistance in education and social life, administrative formalities, co-ordination, permanent vigilance, psychological support, communication, domestic activities, etc.”* (Confederation of Family Organizations, 2007-2013)

As noted in this definition, caregivers play a crucial role in maintaining the patients at home, helping them with instrumental activities of daily living (IADL) (e.g. cooking, cleaning, transporting) and/or activities of daily living (ADL) such as bathing or dressing.

In France, in the past decade, the role of caregivers has been underlined in various national public health programs, mainly for the caregivers of older persons (Valette & Membrado, 2004). After the heat wave of 2003 and its terrible consequences for older people (14.802 heat-related deaths), the French government drafted a plan to prevent similar tragedies. As a result, national reports and recommendations centered their attention on the “inter-generational solidarity”, defining it as an essential tool for the support and protection of the elderly (Caisse Nationale de la Santé pour l’Autonomie, 2012). Thus, the role of the family began to be publicly recognized in the society (e.g. Plan Solidarité - Grand Age in 2006 or Plan Alzheimer 2008-2012).

A similar scenario was observed in other developed countries, in which families and relatives are called upon to help and support the elderly people. These persons frequently assume multiple roles (grandparents, children, workers, spouses, etc.), and experience the consequences of caregiving on both their private and professional lives. In the next section, we describe the critical consequences on the health and wellbeing of caregivers of patients with Alzheimer’s disease, as well as provide an overview of some of the models designed to

improve our understanding of the mechanisms underlying informal caregiving. Some of these models have served as grounds for the development of interventions supporting, educating, and helping caregivers.

## CAREGIVERS OF PATIENTS WITH ALZHEIMER'S DISEASE

Given that most PWAD and other dementias generally live at home a relative or family member has to support and take care of them in activities of daily life. Without their help, patients might have a poorer quality of life and might have to be more rapidly institutionalized. Caregivers of PWAD are not only facing the steady loss of their relatives' cognitive faculties, but they also endure the emotional burden that accompanies it (Brodaty & Donkin, 2009). In contrast with professional caregivers, informal caregivers have lived alongside the PWAD, and their relationship has been built based on memories of shared experiences. Thus, when one of them loses these memories, changes behavior and becomes dependent on the other, their respective roles in the relationship tend to be altered. This situation is emotionally demanding for both the care-recipient and the caregiver.

In France, most caregivers of PWAD are spouses (51%) or children (25%) of PWAD. Most of them are women (62%), aged between 55 and 64 y/o (25%) or between 75 and 84 y/o (28%). Frequently they are already retired (66%) (Alzheimer Europe, 2006, cited by Villez, Ngatcha-Ribert, & Ariel, 2008). Most of the caregivers live at home with the PWAD, and on average dedicate more than 40 hours per week to provide them care. The studies have demonstrated that consequences for caregivers of PWAD are more severe than for caregivers of other pathologies (Schulz & Sherwood, 2008; Vitaliano, Zhang, & Scanlan, 2003). In Alzheimer's disease, due to the steady progression of cognitive impairment, the demands in time and effort continuously rise, and over time may prevent caregivers from taking time for leisure activities, self-care or free time (Brookmeyer, Corrada, Curriero, & Kawas, 2002; Vitaliano et al., 2003). Furthermore, and in contrast with other diseases, care for PWAD requires a higher assistance with ADL and IADL, for instance:

*“getting in and out of bed (54% vs. 42%), dressing (40% vs. 31%), toileting (32% vs 26%), bathing (31% vs. 23%), managing incontinence (31% vs. 16%) and feeding (31% vs. 14%)” (Thies & Bleiler, 2013).*

Moreover, caregivers are often responsible for the organization of care with the government agencies and service providers (64%), and for the management and supervision of paid

caregivers (46%) (Thies & Bleiler, 2013). Furthermore, most of them take on the role of caregiver on top of other responsibilities (work, children, friends, spouses, grandparents, social relationships, etc.). Despite the difficult situations encountered in caring for a PWAD, in most cases, only one caregiver often assumes most of the responsibilities linked to care (Carretero, Garcés, Ródenas, & Sanjosé, 2009) over many years (from three to 10 or 15 years (Brookmeyer, Corrada, Curriero, & Kawas, 2002; Vitaliano, Zhang, & Scanlan, 2003)).

### INFORMAL CAREGIVERS' MOTIVES FOR HELPING

In order to better understand the motivations of caregivers, it would be useful to know how caregivers come to assume this role. Relatives and friends who care for a PWAD (or any other illness) regularly see in this action a natural extension of their relationship (O'Connor, 2007). Deborah O'Connor conducted in-depth interviews with thirty-three family caregivers in order to understand the process of self-identifying as caregiver. She found that seeing oneself as a caregiver is a social-based process. It was through interaction with others that they learned a *"new language, for understanding and making sense to their actions"* (O'Connor, 2007, p. 168). Indeed O'Connor described various perceived benefits from self-positioning as caregivers. For instance, it fosters a sense of connection with other family caregivers, an increased empathy towards other caregivers and it positions them within a community. Moreover, they also reported an increased ease with which services could be accessed and utilized. For example, one daughter had repeatedly driven by a "caregiver" banner promoting a support group over one month, before recognizing herself as a caregiver, and finally joining the support group. Nevertheless, the author underlines that even if benefits emerged most prominently, contradictions and tensions were also evoked as a result of self-positioning as caregiver. For instance, they reported an overall feeling of guilt, present when taking care of them and when not doing so, as evoked by one of the caregivers *"...you feel guilty about feeling guilty"* (p. 172). Another tension was due to difficulties of balancing the responsibilities, and to the feeling of having to *"take over everything"* (O'Connor, 2007).

Several reasons have been reported in the literature about caregivers' motivations to provide care for loved-ones: *"a sense of love or reciprocity, spiritual fulfillment, a sense of duty, guilt, social pressures, or in rare instances, greed"* (Brodaty & Donkin, 2009, p. 2). Schulz and his colleagues (2000) described two explanations for providing care to relatives. The first one is based on egoistic or self-serving motivations, while the second one is centered on altruistic or empathic feelings. The egoistic motivations are explained by the anticipation of punishment or the reward obtained by the individual externally (e.g. a laud) or internally (e.g. avoiding guilt). In fact, between spouses or children-parents caring were described feelings



of indebtedness: *"I know I'm doing everything I can for my mother, but somehow I still feel guilty"* (Brody, 1985, p. 26, in Schulz et al. 2000), or the idea that caregiving was a kind of "repayment" for the care provided earlier by parents. From the other perspective, the altruistic motivations are based on the capacity of an individual to adopt the perspective of the other, experiencing an emotional response (empathy) congruent with the other's welfare, and triggering the motivation to reduce the other's needs (Schulz, Gallagher-Thompson, Haley, & Czaja, 2000).

From another perspective, cultural origin also plays a crucial role in the representation of care, as well as in the caregiving styles and responsibilities. For instance, it was described that African-American caregivers are less likely to place their relatives in nursing-homes, or in Cuban-American families where there is an extremely strong culturally-based expectation that daughters should provide care to impaired relatives (Schulz et al., 2000).

However, the studies have demonstrated that caregivers who are motivated by negative feelings, such as guilt, social pressure, or cultural norms, suffer more psychological distress. In contrast, caregivers that identified more beneficial aspects, experienced less depressive symptoms, less burden and better self-assessed health (Cohen, Colantonio, & Vernich, 2002).

## CAREGIVING BURDEN AND STRESS

Stress and burden have been extensively used and often indifferently interchanged to conceptualize caregivers' outcomes (Brodaty & Donkin, 2009; Campbell et al., 2008; Del-Pino-Casado, Frías-Osuna, Palomino-Moral, & Pancorbo-Hidalgo, 2011).

Some authors have defined caregiving burden as all physical, emotional, economic, social, and familial consequences of providing care (Aneshensel, Pearlin, Mullan, & Zarit, 1995; Carretero et al., 2009). In spite of many years of research in the field of family caregivers, the caregiver's burden remains a vast construct with many definitions. Indeed, research findings have demonstrated that burden is not a unique and static concept, but an evolving concept through caregivers' changing situations, individual variability and caring periods (Carretero et al., 2009).

While clear theoretical differences between stress and burden remain inconclusive, attention should be drawn to the instruments used by different studies measuring burden or stress, since their implications are not the same. For instance, some authors (Gallagher-Thompson et al., 2010; Mausbach et al., 2012) have measured stress with the Revised Memory

Behavioral Problems Checklist (Teri et al., 1992), a scale evaluating behavioral and cognitive problems, and their emotional impact for caregivers. Thus, they measured the burden or stress provoked by behavioral and cognitive troubles, but other areas and sources of stress were neglected. Another factor to highlight is the difference between “subjective” and “objective” burden. Sometimes they are treated like one and the same construct, provoking inconsistent results. In fact, objective burden is measured by observable events or circumstances (e.g. money, time, frequency, etc.), whereas subjective burden refers to emotional and cognitive reactions or attitudes (e.g. feelings of frustration or guilt).

However, the majority of models developed to explain stress in caregiving have been based on Lazarus and Folkman's transactional model of stress and coping. An overview of this model and other models adapted to caregiving is presented in the next section.

## DEFINITIONS AND MODELS OF STRESS

Cannon developed one of the first definitions of stress in 1932. It was centered on the autonomous nervous system's physiological reaction of “fight or flight” in a stressful situation. This model suggests that external threats trigger a response of fight or flight, provoking a physical and emotional activation. Although this approach was interesting and useful to understand the physiological mechanisms of stress, it has two main limits. Firstly, it suggests a direct relationship of stimulus-response, without taking into account the inter-individual characteristics. Secondly, the model described the same physiological stress activation independently of the source of stress, and consequently described individuals as passive entities responding automatically to external demands (Ogden, 2012).

Afterwards, the "Life Theory Events" was developed in order to study stress as a consequence of life events. In fact, in an attempt to evaluate the psychological impacts of stress, Holmes and Rahe in 1967 created a list of life events (i.e. Schedule of Recent Events) that might provoke important changes in individuals' lives. The first studies using this scale showed a correlation between having stressful changes in life and one's health status. One of the limitations of this model was to rank the stressful events, regardless of the subjective appraisals of individuals. Another (methodological) limitation was that most of the scales evaluating the stressful events of life demand a retrospective evaluation (from months or years). Thus, the current context of individuals (e.g. health status, stress levels) might influence their memories, skewing the causal analysis between life events and stress levels, and the consequences on their health (Ogden, 2012).

## COGNITIVE STRESS AND COPING MODEL (LAZARUS AND FOLKMAN, 1984) (FOLKMAN, 2008, 2010)

The cognitive (transactional) stress and coping model has been the most frequently used, and has inspired various models of caregiving (Pearlin et al 1990; Aneshensel et al 1995, Schulz and Martire, 2004). While in previous models the individual was considered as an agent responding to stress passively, in this model the person actively interacts with the potentially stressful events. The **appraisals** are the main component parts of this model. The **primary appraisal**, conducted at the outset of an (potentially stressful) event, concerns the personal significance attributed by subjects, while the **secondary appraisal** is focused on the evaluation of available resources to cope with the event.

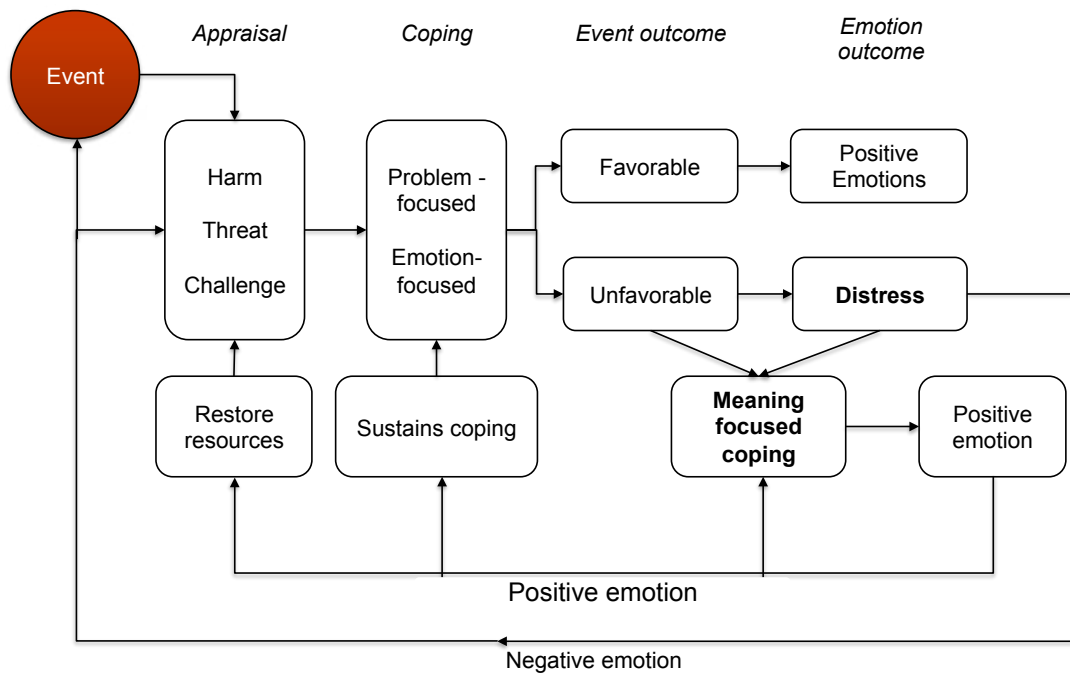
The authors mention that the confluence of personal and situational factors determines the appraisal or the manner in which the person will perceive the encountered event. According to the model, **two personal factors** (commitments and beliefs) determine appraisals by defining what is salient for the individual, and by influencing their understanding of the event. Firstly, **commitments** define the aspects that are important to people, in other words what is meaningful for individuals. As motivational factors, they underlie the choices people make. Secondly, **beliefs** are: “(the) preexisting notions about reality, which serve as perceptual lens (...)” (Lazarus and Folkman, 1984, p. 63). They may be formed individually or culturally (socially), and determine how the individual perceives what is happening. Although various beliefs may influence the appraisals on a situation, the model allocates a special interest to beliefs of control and existential beliefs.

Moreover, there are **situational factors** (e.g. novelty and uncertainty) that create their potential for being threat, harm or challenge. For instance, the authors explain that a **novel situation** is appraised as stressful only if there is previous experience or general knowledge associating this with harm, danger, or mastery. Incidentally, a novel situation could provoke ambiguous feelings when they have not a clear meaning for the person. Furthermore, an event which could be predictable and controllable is appraised as less stressful than **uncertain** and **less controllable** events (Lazarus & Folkman, 1984; Ogden, 2012).

Based on appraisals, persons may conclude whether the transaction with the event is harmful, threatening, or challenging. The event can be evaluated as stressful when the situation is significant for the individual, and requiring resources that the individual does not have. Situations evaluated as harmful or threatening are accompanied by **negative feelings** such as anxiety or fear, while challenging situations produce **positive emotions** such as excitement, eagerness, and confidence (Folkman, 2008) (Figure 3). Afterwards, individuals

select **coping strategies** to face stressful situations. The model proposes different kinds of strategies that may be problem-focused, emotion-centered or meaning-focused.

**FIGURE 3. STRESS AND COPING MODEL FROM LAZARUS AND FOLKMAN (1984) REVIEWED BY FOLKMAN (1997)**



Source: Folkman, 1997 Cited By Folkman, 2008

### COPING STRATEGIES

"Coping" has been defined as *"constantly changing cognitive and behavioral efforts to manage specific external and/or internal demands that are appraised as taxing or exceeding the resources of the person"* (Lazarus & Folkman, 1984, p. 141). Nevertheless, later, S. Folkman has underlined that "managing the demands" suggested that to effectively cope with an event, individuals have to succeed in mastering the situation, while the most difficult and stressful situations cannot be solved. Most of the time, coping strategies are used to try and find a successful way to solve them (Folkman, 2009).

There are two major categories of coping that can be used depending on the level of control of the situation. On the one hand, **problem-focused coping** is more adapted to controllable situations. This type of coping is centered on the management of problems causing distress and includes information gathering, instrumental coping (i.e. fixing the problem), and problem solving strategies. When the situations are not controllable, individuals should accept them. The strategies centered on the regulation of distressful and negative emotions belong to

**emotion focused-coping.** This category includes using humor, seeking emotional support, "looking on the bright side", distancing oneself from the problem (distracting oneself), and escape-avoidance strategies. Most of the time, using humor and seeking emotional support are adaptive ways for mitigating emotions, while escape-avoidance strategy is mal-adaptive. People use both kinds of coping virtually in all kinds of situation (Folkman, 2008).

Several years after the first version, Folkman added meaning-focused coping and positive emotions to the model. **Meaning-focused coping** may explain how persons are able to give another sense to difficult situations, based on their beliefs, values, and existential goals. In this way, distressful situations (even unmanageable ones) may offer positive outcomes. This coping strategy is less situation-specific than emotion-focused or problem-focused coping. It is based on four individual dimensions: a) **values**, guiding individuals in evaluating the prominence of situations for them; b) **goals**, helping individuals to organize their actions and identify a purpose; c) **expectations**, in other words person's hopes about themselves and the world; d) spiritual and religious beliefs, including existential meanings related with forgiveness and gratitude. Folkman distinguished five types of meaning-focused coping, based on qualitative results of 2,000 interviews and recent studies: benefit finding, benefit reminding, adaptive goal processes, reordering priorities, and infusing ordinary event with positive meaning (for a description see Folkman, 2008).

### POSITIVE FEELINGS IN CAREGIVING

Although the majority of research has been centered on the negative feelings of caregivers, different studies have shown that caregivers also experience positive feelings. For instance, Sarah Sanders (2005) found that 81% of caregivers experienced both strains and gains from caregiving, while 19% experienced only strains. The feelings of gains were produced by spiritual growth, personal growth, and feelings of mastery (Sanders, 2005). In a more recent study, Habermann and her colleagues (2013) interviewed 34 caregivers, mostly daughters (82%) of patients with Alzheimer's (76%) and Parkinson's disease (24%). Of them only 6 persons could not identify positive experiences from caregiving. During interviews, participants described positive experiences that were grounded in their relationship with care-recipients. After content analysis they found three main categories "*spending and enjoying time together; appreciating each other and becoming closer; and returning and giving back care*" (Habermann, Hines, & Davis, 2013).

Positive emotions have shown a protective and therapeutic value for caregivers. For instance, they are significantly correlated with better self-regulation performance, they help restore physiological and psychological coping resources, and are related with survival in

some chronic diseases such as Diabetes type II and HIV/AIDS (Moskowitz, Shmueli-Blumberg, Acree, & Folkman, 2012). Furthermore, some authors argue that caregivers are not using the services created for them, since these are merely focused on the negative aspects of caregiving (Coudin & Mollard, 2011).

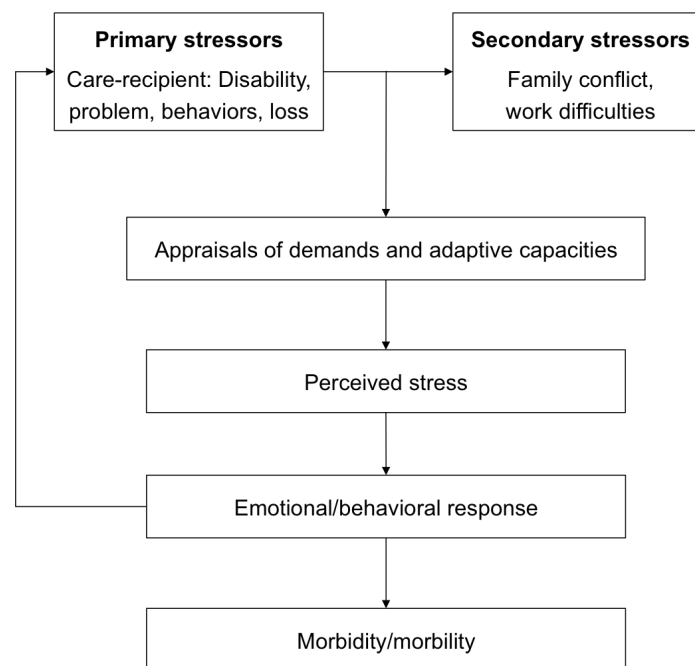
Lazarus and Folkman's model has inspired various models to explain caregiving stress (Del-Pino-Casado et al., 2011). These models highlight risks and stress consequences for caregivers. Among others, the most frequently used are the Stress/Health Process model (Schulz and Martire, 2004), and the Stress Process model (Pearlin et al 1990, Aneshensel, Pearlin, Mullan, & Zarit, 1995).

#### STRESS/HEALTH PROCESS OF SCHULZ AND MARTIRE (2004)

According to this model, primary stressors in caregiving include the cognitive impairment of care-recipients, their behavioral problems, or the loss of autonomy, as well as the time spent directly (e.g. assistance in ADL or IADL) or indirectly in caregiving activities (e.g. negotiating healthcare system, appointments, medicines, etc.). The secondary stressors can be defined as the repercussions of primary stressors, less evident for professionals who have limited contact with patients and caregivers. These include the conflicts with other family members, as well as the consequences in social and professional areas (e.g. less-performing at work, or missing new job opportunities, etc.) (Figure 4).

Based on both categories of stressors, caregivers evaluate whether the situation is a potential threat and whether they have enough resources to cope with it. Stress is experienced when caregivers evaluate the situation as threatening, and when their coping strategies are inappropriate. This contributes to negative physical, psychological, and behavioral responses, increasing the individual's risk of physical and psychiatric disease. The model also proposes different loops between a reaction at any level of the model and the repercussion in earlier stages. For instance, the reaction of a caregiver could change the patient's behavior, and this change might in turn modify the caregiver's appraisal of the situation, and so on (Schulz & Martire, 2004).

**FIGURE 4. STRESS/HEALTH MODEL, SCHULZ & MARTIRE (2004)**



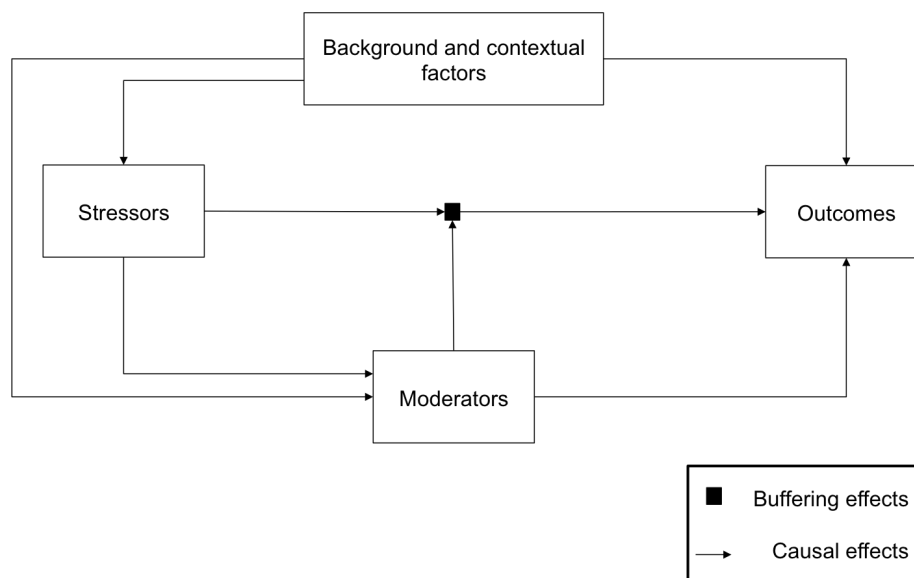
Source : Schulz & Martire, 2004

#### THE STRESS PROCESS MODEL (PEARLIN ET AL 1990; ANESHENSEL ET AL 1995)

This model was used to explain the complexity of stress processes, based on three components (Figure 5): stressors, outcomes, and moderators. The **stressors** are the problematic conditions and difficult circumstances encountered by the caregivers that are above their capacities to adapt. The authors propose the term “stress proliferation” to describe an observed phenomenon, in which a first stressor tends to generate other stressors, and reach other life fields than that where the original stressor had appeared. For caregivers, stressors are directly linked with care (**primary stressors**) or they may originate from other stress factors, outside the caregiving role (**secondary stressors**) (Aneshensel, Pearlin, Mullan, Zarit, & Whitlatch, 1995).

Thus, the **outcomes** are the consequences of the intrapsychic strain provoked by stressors. They include a) effects on individual health and wellbeing, b) transitional events, such as the premature institutionalization of the care-recipient, and c) behavioral changes, such as accepting support by paid care. Finally, **moderators** involve social, personal and material resources that help to regulate the relationship between the stressors and the outcomes. These three dimensions are complexly interrelated and constantly evolving.

**FIGURE 5. STRESS PROCESS MODEL FROM PEARLIN ET AL (1990) & ANENSHENSEL ET AL. (1995)**



Source : Aneshensel, Pearlin, Mullan, & Zarit, 1995

The components of this model are in relation with the social, economic, cultural, and political contexts, as well as with the background of individuals, which determine how subgroups of individuals are exposed to stressors, the type and the quantity of resources available for them, and the resulting outcomes (Aneshensel, Pearlin, Mullan, & Zarit, 1995).

## EFFECTS IN CAREGIVERS' HEALTH AND WELLBEING

Caring for a PWAD is often a highly demanding, unpredictable, and uncontrollable situation, often cumulated with other responsibilities (work, family, social relationships). Given their significance for caregivers, many decisions are strongly permeated by emotions, and sometimes provoke ambivalent feelings. Over time, imbalance between resources of caregivers and multiple demands may lead to chronic stress (Carretero et al., 2009; Vitaliano et al., 2003), and to its devastating consequences: “*psychiatric illness, physical illness, and even death*” (Schulz & Sherwood, 2008).

### MENTAL HEALTH OF CAREGIVERS OF PWAD

Caregivers of PWAD are more prone to depressive symptoms and likely to meet clinical criteria for **depression** than non-caregivers in CES-D scale (40% vs. 5%) (Mausbach et al.,



2013) or than other populations of older persons living in community (22% to 30% vs. 11%) (Vitaliano et al., 2003). In a retrospective survey including 200 caregivers of PWAD selected randomly, depressive symptoms were predicted by patients' behavioral problems (OR= 5.2), low income (OR= 3.4), or when patients were less than 65 y/o (OR=2.9) (Ferrara et al., 2008). Moreover, depressive symptoms were also **associated with high burden and perceived stress**, as well as with decreased life satisfaction and self-esteem (Cooper, Katona, Orrell, & Livingston, 2008). In fact, the impact of stress on depressive symptoms has been consistently demonstrated in the literature. There are four predictive mediators in the pathway stress-depression. These are personal mastery (relates to one's belief that the situation is controllable), self-efficacy (confidence in the ability to perform specific actions), as well as higher activity restriction and the use of avoidance coping strategies. As previously introduced, the BPSD provoke highly deleterious consequences for caregivers in terms of psychological wellbeing. In fact, they demand the constant adaptation of caregivers; moreover, they are less predictable and less controllable than other situations in caregiving.

In a cross-sectional study, Mausbach and his colleagues (2013) compared the psychological outcomes of stress, coping, and mood of 125 dementia caregivers with 60 older adults with non-caregiver spouses. Caregivers endorsed greater levels of **global stress** (n.b. assessed as role overload) ( $p < 0.001$   $d' = 1.36$ ), depression symptoms ( $p < 0.001$   $d' = 1.15$ ), utilized **fewer positive coping strategies** (i.e. engagement in pleasant events, seeking social support, reducing sense of personal mastery and self-efficacy), and more negative coping (i.e. activity restriction, avoidance coping, wishful thinking) than the control group (Mausbach & Chattillion, 2013). Moreover, in the retrospective study of Ferrara and her colleagues (2008), **stress** was proportional to the **severity of the care-recipient's disease**. Moreover, memory disorders (OR=8.4), engine disorders (OR=2.6) and perception disorders (OR=1.9) of patients were predictive of caregivers' stress (Ferrara et al., 2008).

A systematic review of the literature on the prevalence and covariates of **anxiety** in caregivers of people with dementia (Cooper, Balamurali, & Livingston, 2007) showed that a quarter of caregivers included in the studies experienced clinically significant anxiety. Authors found that psychiatric antecedents of caregivers were the only factor predicting anxiety disorder. However, **dysfunctional coping strategies** (confrontative and escape-avoidance coping) were associated with high levels of anxiety, while positive reappraisal strategy was not consistently related with anxiety levels. These authors also found that caregivers with greater self-esteem and self-concept presented less anxiety. In another study, Cooper and her colleagues (2008) interviewed 126 caregivers of PWAD and measured their anxiety symptoms with the Hospital Anxiety and Depression Scale at baseline and one year later. They found that caregivers who used **problem-focused**

**strategies** were more anxious one year later, while those using emotion-focused strategies were less anxious one year later.

## PHYSICAL HEALTH OF CAREGIVERS OF PWAD

Various outcomes of health in caregivers “*including cellular and organ-based physiologic measures, global physical and psychiatric health status indicators, and self-reports on health habits*” (Schulz & Scherwood, 2008, p. 3) have been linked to primary stressors (i.e. duration and type of care, care-recipient’s functional and cognitive impairment) and secondary stressors (i.e. financial strain, family conflicts) of caregivers (Schulz & Scherwood, 2008).

One of the main concerns for researchers and clinicians is caregivers' **negligence of health habits**, and their **inability to care for themselves** (Vitaliano et al., 2003). They forget more frequently their own health care appointments, and have a poorer-quality diet (Schulz & Sherwood, 2008) than other populations. This disengagement from self-care may be linked with the appearance of cardiovascular, gastric, or mental diseases.

Although the physical effects of caregiving are globally less important than psychological ones, caregivers report a greater number of physical health problems, and a **worse overall health** than non-caregivers. They have an increased **risk of cardiovascular problems**, and **chronic illnesses** such as diabetes and ulcers, have a poorer response to vaccines, slower healing, and less practice of preventive activities (Brodaty & Donkin, 2009). Compared with non-caregivers, the caregivers of PWAD reported **poorer subjective sleep** (as evaluated by the Pittsburg Sleep Quality Index), as well as a shorter total sleep-time, and lower sleep efficiency measured by in-home polysomnography (von Känel et al., 2013). Moreover, caregivers with higher levels of stress are more likely to die during the course of a 4-year follow-up than caregivers with low stress levels (Schulz & Beach, 1999).

However, one recent study mitigated the results found earlier (Mausbach et al., 2007). In a large sample of nearly 8.000 caregivers (men and women) followed over almost two decades, Buyck and his colleagues did not find “clear evidence of greater risk” of coronary heart disease among caregivers. Only caregivers self-reporting a poor health at the beginning of the study presented increased risks of coronary heart disease (hazard ratio = 2.00; 95% CI: 1.44, 2.78). This relation was found independently of the caregiver's variables (i.e. "gender, age, ethnicity, marital status, socioeconomic position, health behaviors, chronic disease, and risk factors") (Buyck et al., 2013, p. 4).

Although few studies have evaluated the cognitive status of caregivers, they have shown an **increased risk of poor cognitive performance**, which might be mediated by depression, distress and psychosocial factors (Vitaliano et al., 2005, 2009). Moreover, male caregivers with higher burden reported having more cognitive problems than other caregivers or than non-caregivers (Buyck et al., 2011). Furthermore, they are more worried about having Alzheimer's disease (52% of caregivers) than older adults non-caregivers of PWAD (16%) (Alberts et al, 2011).

## CAREGIVERS' STRESS AND ILLNESS: PREDICTORS AND PROTECTORS

Whilst the effects of caregiving on caregivers' health and wellbeing have been extensively demonstrated, most studies have also noted that not all caregivers presented the same risks. Various individual or contextual factors may protect or predict the risks of caregivers. For instance, caregivers' economic status, social support resources and other individual characteristics, such as gender, personality, coping strategies, and quality of relationship with the care-recipient, may interfere with the stress levels of caregivers. Supported by the literature Brodaty and Donkin (2009) propose a review of these factors, which are overviewed in this section.

### FROM CAREGIVERS OF PWAD AND OTHER DEMENTIAS

**Burden** has been extensively associated with the weakness of the mental and physical health of caregivers. Recently, Buyck and his colleagues (2011), in a French cross-sectional study involving 10.687 caregivers from the Gazel cohort, evaluated the impact of burden in self-reported caregivers' health. Burden was measured with the Zarit Burden Inventory. The results showed that regular caregivers with the highest burden scores had **significantly worse self-reported health** in both physical and mental health than non-caregivers (Buyck et al., 2011). As introduced earlier in this chapter, persons who did not choose to be caregivers, were at increased risk of stress (Winter et al, 2010).

Some **socio-demographical and economic factors** were also associated with health weakness in caregivers (Table 3). Older caregivers, or with a low socio-economic status, or having a limited support network, had a poorer psychological and physical health than younger caregivers having more economic or social resources (Schulz & Sherwood, 2008). In contrast, caregivers having more positive feelings were older, non-Caucasian, had higher social relationships, and a lower educational level (Brodaty & Donkin, 2009).

Caregivers with **increased stress** were more likely to report **reduced personal mastery** and self-efficacy, as well as **higher activity restriction** and the use of **avoidance coping** (Mausbach et al., 2012). Similarly, caregivers with high levels of burden, and with high **self-efficacy for controlling upsetting thoughts** reported significantly lower levels of distress than caregivers with low self-efficacy for controlling upsetting thoughts (Romero-Moreno et al., 2011). Finally, Campbell and colleagues (2008), who evaluated personality in caregivers using the Eysenck Personality Questionnaire, found that **higher levels of neuroticism** were associated with higher levels of burden, confirming the results of previous studies (Robert et al., 2005).

As described in previous sections of this chapter, some coping strategies may be more effective than others. **Adaptive emotion-focused coping** (e.g. getting emotional support from others, using humor, and religious coping, among others) predicted reduced caregiver depression (Gallagher et al 2011). **Positive affects** have also shown positive effects on caregivers' health. For example, increased levels of positive affects (measured with the Positive and Negative Affect Schedule – PANAS, 1988) were significantly associated with better subjective sleep, even though actigraphy measures did not show significant relations with positive affects (von Känel et al., 2013). In addition, Gallagher and her colleagues (2011) showed that self-efficacy for patients' symptom management, for the use of community support, and for their ability to pay for services, had significant negative correlations with symptoms of depression and burden (Gallagher et al., 2011).

**TABLE 3. PREDICTORS AND PROTECTORS FROM CAREGIVERS' DISTRESS**

<b>Variables associated with</b>	<b>Greater strain and psychological morbidity</b>	<b>Lower strain and psychological morbidity</b>	<b>Comments</b>
<b>Demographic</b>	Female gender Spousal caregivers, particularly those of younger patients Cohabiting with the care recipient Lower income or financial inadequacy	Male gender Non-spousal (e.g. child or child-in-law) caregivers Living separately to the care recipient Better financial position/resources	Gender may have no effect when allowance is made for the increased likelihood of behavioral disturbances in men Evidence about the relationship between age, gender and psychological morbidity is inconclusive
<b>Dementia variables</b>			
<b>Severity</b>	More neuropsychiatric	Fewer	Most studies in the

	disturbances and behavioral problems Impairment in basic activities, particularly incontinence in the developing world	neuropsychiatric disturbances and behavioral problems Preservation of basic functions in the developing world	developed world have found no significant relationship between cognitive decline and caregiver psychological health
<b>Relationship factors</b>	Poorer relationship quality and low levels of past and current intimacy	Positive current and previous relationship between caregiver and care receiver	Cultural differences may mediate these associations
<b>Caregiver variables</b>			
<b>Personality</b>	High level of neuroticism High expressed emotion Less secure (or avoidant) attachment style	More secure attachment style Higher self-esteem	Depression levels can predict neuroticism levels
<b>Perception and experience of caregiving role</b>	A low sense of confidence in the caregiver role High "role captivity" caregivers feelings of being trapped in their role	Increasing caregivers' confidence in their competence as caregivers, reduced burden levels	
<b>Coping strategies</b>	Emotion-based coping strategies Confrontative coping strategies	Problem-focused coping strategies Positive reappraisal (reframing)	Coping style may be more associated with anxiety than depression, which is related to factors such as burden and poor health Cooper and colleague found inconsistencies in the evidence regarding problem-based versus emotion-based coping strategies.

Adapted from Brodaty and Donkin (2009)

## FROM PWAD AND OTHER DEMENTIAS

The **BPSD** have important repercussions on caregivers' health and wellbeing, compared with cognitive and functional impairments (Bergvall et al., 2011; Schulz, O'Brien, Bookwala, & Fleissner, 1995). The apparition of the behavioral problems of PWAD (e.g. wandering, disruptive or aggressive behaviors, apathy) (McLaughlin et al., 2010) are highly correlated with caregiver burden and stress (Fauth & Gibbons, 2014). In a recent study evaluating the impact of BPSD in caregivers, they rated the least frequent symptoms (delusions, agitation and irritability) as the most stressful, while the most frequent problems (memory problems) were the least distressing for them (Fauth & Gibbons, 2014). Moreover, the **comorbidity of dementia and mood disorders**, more specifically depression, was associated with higher levels of caregiver burden (Schulz & Martire, 2004).

Although there is a relative lack of research about the current and **previous relationships** between the PWAD and the caregiver, they have an important effect on caregiving, (Mahoney, Cloutterbuck, Neary, & Zhan, 2005). In addition, the **lack of awareness of PWAD** may be an important mediator of caregiver burden (Seltzer, Vasterling, Yoder, & Thompson, 1997). In contrast, PWAD aware of the distress of their caregivers were more likely to be supportive of them (Ablitt, Jones, & Muers, 2010).

As noted in this first chapter, caregivers play a crucial role in assuring the quality of life and wellbeing of PWAD. Nevertheless, the psychosocial and physical consequences for caregivers may be devastating. Researches have demonstrated the protective role of some factors, which is a promising perspective for therapeutic and preventing initiatives. As presented in the next chapter, over the past years various interventions for caregivers have been developed, showing the diversity of possibilities and the growing interest of adapting Information and Communication Technologies (ICT) to this field. We will present a quick review of outcomes and contents of non-pharmacological interventions for caregivers, as well as authors' recommendations for the development of interventions and methodologies to evaluate the interventions devoted to them.

## CHAPTER TWO

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# DEMENTIA CAREGIVER INTERVENTIONS. TRENDS AND RESULTS

### A PUBLIC HEALTH PRIORITY

In Europe the care and support provided to the elderly is substantial. According to the data of the 2001 United Kingdom census, half of the caregivers spent more than 50 hours per week caring for a person over 85 (Doran, Drever, & Whitehead, 2003). In the United States of America (USA) an estimated 15 million people were informal caregivers of a PWAD or another dementia in 2013. Their cumulated roles represented 17.5 billion hours of unpaid care, or 216 billion dollars (Thies & Bleiler, 2013). In France, the implication of caregivers may delay the institutionalization of PWAD, reducing private and public costs. Annually the cost of a community-dwelling PWAD is around 15,000 euros, while the cost jumps to 21,000-24,500 euros for an institutionalized PWAD (Rieucou, 2013). Indeed, as regards the estimated socioeconomic impact of Alzheimer's disease in 2008, 55% of the total costs of care corresponded to informal caregiving (Gervès, Bellanger, & Ankri, 2013; Kenigsberg et al., 2009).

Caregiving is one of the intangible and indirect costs of caring for the person with dementia. Usually the cost of caregiving is calculated based on the unpaid time spent in caregiving or on the negative effects of caregiving, but a recent and original approach consists in evaluating the intangible costs of caregiving, which encompass the suffering and pain associated with the illness (Gervès et al., 2013). Kenigsberg and her colleagues (2009) attempted to calculate this and included the functional status (activities of daily living) as a hypothetical indicator of the indirect cost of informal caregiving. In France, they estimated that the indirect cost of informal caregiving was 15,206 euros per year and per PWAD or another dementia, while the direct cost was 9,914 euros. However, beyond these numbers, there is a complex and costly reality for our societies and for individuals (caregivers and

patients). As described in Chapter 1, caregivers face challenging situations for many years and are often devoid of support.

The worrisome effects of Alzheimer's caregiving regarding the health and well-being of individuals and the impact in the societies (summarized in Chapter 1) have led national and international organizations to recommend the implementation of strategies and the development of policies in order to reinforce the financial and social support to caregivers, as well as the implementation of care services and preventive programs for them (Vasse et al., 2012). The World Health Organization (WHO) (World Health Organization, 2014) and the French National Health Agency (NHA) (Haute Autorité de Santé, 2008) recently published their recommendations to support caregivers of people with dementia. Among others, they advocate for the development and implementation of psycho-educational interventions, to offer knowledge of the disease, train caregivers in skills to manage patients' daily care, and address psychological strain with counseling or cognitive-behavioral interventions (World Health Organization, 2012). The WHO's "Guideline Development Group" have determined the strength of each recommendation (Table 4) based on the quality of the evidence, the balance between positive and undesirable effects, and the feasibility issues among other factors (World Health Organization, 2014).

**TABLE 4. RECOMMENDED INTERVENTIONS FOR INFORMAL CAREGIVERS OF PERSONS WITH DEMENTIA, WHO (2014)**

<p><i>"Psycho-educational interventions should be offered to family and other informal carers of people with dementia at the time when diagnosis is made.</i></p> <p><i><u>Strength of recommendation:</u> STRONG</i></p> <p><i>Training of carers involving active carer participation (e.g. role playing of behavioural problem management) may be indicated later in the course of illness for carers who are coping with behavioural symptoms in people with dementia.</i></p> <p><i><u>Strength of recommendation:</u> STANDARD</i></p> <p><i>Carer psychological strain should be addressed with support, counselling, and/or cognitive-behaviour interventions.</i></p> <p><i><u>Strength of recommendation:</u> STRONG</i></p> <p><i>Depression in carers should be managed according to the recommendations for depression (see depression guidelines).</i></p> <p><i><u>Strength of recommendation:</u> STRONG »</i></p>
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Source: WHO (2014). [http://www.who.int/mental\\_health/mhgap/evidence/dementia/q9/en/](http://www.who.int/mental_health/mhgap/evidence/dementia/q9/en/).



They also suggest that interventions for families and other relatives of PWAD be integrated in the holistic care system for PWAD. Indeed, studies have shown that interventions targeting caregivers may impact patients too. For instance, the improvement of caregivers' wellbeing might delay institutionalization of their relatives, and this effect is most important when the intervention for caregivers is proposed in the early stages of the disease (Mittelman, Haley, Clay, & Roth, 2006). Furthermore, burden and strain of caregivers are risk factors for the mistreatment of patients (Haute Autorité de Santé, 2008). Therefore, interventions targeting the reduction of burden might be useful to prevent maltreatment.

Since this thesis is focused on caregivers' interventions, the latter are addressed in this Chapter. Nevertheless other formal services such as care centers, day care organizations or community services providing respite, which are also recommended in the caring of patients and caregivers, are will not be addressed in this work.

## CAREGIVER INTERVENTIONS

As described by Brodaty and Donkin (2009), the three main types of support to caregivers are instrumental (helping with daily life needs and housework), emotional, and informational support (Brodaty & Donkin, 2009). Interventions supporting caregivers are particularly important because caregivers seem to be protected from burden and stress when they perceive that resources are available for them to handle stress. Nevertheless, these relationships are complex; they depend on the type of support and on how the caregiver perceives it. For instance, unwelcome support may be more stressful than helpful (Bloch, 1994 cited by Brodaty & Donkin, 2009).

In this section we present the results of literature reviews and meta-analysis of studies evaluating the efficacy of interventions for caregivers. The first part is dedicated to in-person interventions, while the second section presents the studies devoted to Internet-based or technology-driven interventions for caregivers. We focus our interest on the aims of programs as well as in their methodology and overall findings.

### IN-PERSON INTERVENTIONS FOR DEMENTIA CAREGIVERS

Although public health authorities have only recently issued recommendations for supporting caregivers, the first interventions for them date back to the 1980s (Schulz, 2000). Most of them are psycho-educational interventions, behavioral-cognitive therapies, care-management, or support groups, and individual or in-group counseling. In a systematic

review of evidence-based studies, Gallagher-Thompson and Coon (2007) have classified the interventions for caregivers in three categories: psycho-educational/skills-building programs, psychotherapy, and multicomponent interventions.

In sum, the **psycho-educational and skills-building programs** targeted the improvement of knowledge of a specific disease and acquisition of skills to manage common emotional and behavioral problems linked with the disease. The **psychotherapeutic interventions** included cognitive-behavioral studies in which the therapeutic relationship was part of the treatment process. Finally, the **multicomponent programs** included two or more conceptually different approaches embedded in one intervention. For instance, the interventions that combined family counseling, respite, and technological equipment were included in this category. In this review were included 14 psycho-educational programs, three psychotherapies, and two multicomponent interventions (Gallagher-Thompson & Coon, 2007). Although the main outcome differed across the studies, most of them were **grounded in the theoretical models of stress and coping** (Lazarus & Folkman, 1984). The findings of this review have shown that the strongest effects were found for the interventions focused on skills training, cognitive-behavioral therapies and multicomponent programs combining at least two theoretical approaches.

Other meta-analyses and systematic reviews which included non-evidence-based studies, showed a mild to modest efficacy in reducing the burden and distress of caregivers (Brodaty, Green, & Koschera, 2003; Olazarán et al., 2010; Pinquart & Sorensen, 2006; Schoenmakers, Buntinx, & Delepeleire, 2010; Thompson et al., 2007; Vernooij-Dassen, Draskovic, McCleery, & Downs, 2011a). However, some characteristics of interventions seemed to improve their efficacy. For instance, interventions targeting multiple domains (e.g. skills, information, and social support), and those administered in a structured and intensive setting have shown higher impacts (Pinquart & Sorensen, 2006; Spijker et al., 2008). Pinquart and Sorensen (2006) used weighted multiple linear regressions to evaluate the influence of moderator variables on positive effects of interventions. In their results, longer interventions were more likely to improve depression and to decrease the risk of institutionalization. In addition, studies with a greater percentage of women were more likely to show an improvement of knowledge, and the improvement of burden was more frequent in the recent studies. Concerning the studies' characteristics, the randomized clinical trials and the studies with little samples and greater dropout rates have shown larger effect sizes.

In order to illustrate the content and structure of different interventions we chose to describe three of them, based on different settings: a psycho-educational program, a cognitive-behavioral therapy and a multi-component program. When possible we selected French

projects to offer an overview of local trends in this domain. We also tried to identify the main strengths and limits of each one of them, based on methodological and theoretical recommendations (Vernooij-Dassen & Moniz-Cook, 2014; Zarit & Femia, 2008), which are extensively described later in this chapter.

### PSYCHO-EDUCATIONAL PROGRAM: THE AIDMA PROGRAM<sup>3</sup> (DE ROTROU ET AL., 2010)

This program was developed based on clinical experiences of psychologists and practitioners from the Geriatrics team at the Broca hospital (Paris, France) (De Rotrou et al., 2006) and evaluated in a randomized clinical trial (De Rotrou et al., 2010). The AIDMA intervention was developed for caregivers in order to provide them with information and support. The program aimed to improve their care management of the disease, benefiting both caregivers and PWAD. The AIDMA intervention is delivered in small groups from 6 to 10 caregivers. The caregivers had to attend twelve onsite sessions of two hours once a week. In each session a different health professional (geriatrician, psychiatrist, psychologist, social worker, speech therapist, and occupational therapist) provided caregivers with detailed information.

The program contents were focused on “*education, problem-solving techniques, emotion-centered coping strategies, management of patient’s behavioral problems, communication skills, crisis management, resource information and practical advice*” (de Rotrou et al., 2010). Each session followed three structured steps: a) information, b) debriefing, in which caregivers evoked their experiences in the past week, then solutions were proposed by other caregivers, and c) ecological stimulation, in which caregivers received training in how to stimulate their relative in social and daily life activities, according to personal interests during 20 minutes (De Rotrou & Wenisch, 2009).

The multicenter RCT, including 15 national recruitment centers, evaluated 167 dyads of caregivers-PWAD at the baseline, at M3 (i.e. at the end of the program) and at M6 (i.e. after follow-up). The main outcome measures were the functional status of patients, evaluated with the Disability Assessment Scale for Dementia; and depressive symptoms of caregivers assessed with the Montgomery and Asberg Depression Rating Scale (MADRS). The results did not show significant improvement of the main outcomes. Nevertheless, significant improvements were obtained by the experimental group in the knowledge of the disease at

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<sup>3</sup> AIDMA : Aide dans la maladie d’Alzheimer

M3 ( $p = 0.007$ ) and M6 ( $p = 0.0001$ ) and in coping strategies at M6 ( $p = 0.02$ ), both evaluated with visual analogical scales. Qualitatively, caregivers reported at each session a better understanding of the disease and of the behavioral and cognitive symptoms, and reported feeling less stress and anxiety in spite of patients' mood fluctuations, which was cited as the most difficult aspect to manage and understand.

Based on this first experience and in response to the recommendation of the French NHA, the team adapted the contents in a program of "therapeutic education". This program called "Entr'aidants" has been running since 2012 and is also dedicated to caregivers. The program consists of six thematic and weekly sessions, with the participation of a multidisciplinary team of professionals (a different professional per session) and a psychologist who moderates everyone. The program provides caregivers with information about the disease, social and financial support, and nutritional advice, as well as skills to customize the patients' living environment, to promote their autonomy, and stimulate their language, memory, and communication skills. Although the informal feedback collected by moderators is positive, the impact of "Entr'aidants" has not been objectively evaluated yet.

**Main strengths:**

- Professionals were trained with homogeneous material
- Intervention was delivered as planned
- Allows the participation of caregivers during sessions leading to content adaptation
- Evaluated by a single blinded, randomized clinical trial

**Main limits:**

- No pilot study conducted before the RCT
- Undefined implication of caregivers to design the program
- Program was not (explicitly) theory-driven
- Cut-off values for primary outcomes were not defined in inclusion criteria
- Delivery modality might be constraining for caregivers (12 weekly sessions)
- Qualitative data were not formally collected

## COGNITIVE-BEHAVIORAL PROGRAM: THE STRUCTURED MULTIDISCIPLINARY PROGRAM (NEGOVANSKA ET AL., 2011)

This program is structured on the basis of behavioral and cognitive theories and was designed by the memory center team from the Pitié-Salpêtrière hospital (Paris, France). It was focused on information about the disease, psycho-educational advice on the understanding of patients' behavioral problems, problem-solving techniques inspired from D'Zurilla and Goldfried (1971), adaptation strategies to reframe familial relationships, and the prevention of depression and anxiety troubles.

The program was evaluated by a non-randomized study (ELMMA study), comparing two groups (multidisciplinary program vs. usual care) of dyads of spousal caregivers-PWAD (Negovanska et al., 2011). Depending on the previous care received at the institution in the preceding two years, the dyads were recruited in multidisciplinary or usual care. Participants receiving the multidisciplinary program (n=8) attended three-hour multidisciplinary sessions every six months for two years, in which each dyad received: a) neurological consultation with the patient, then with the caregiver, b) neuropsychological assessment of the patient, c) a psychological interview with the caregiver, then a psychological interview with the patient to evaluate anxiety, anosognosia, and delusions. In addition, they attended two annual caregivers meetings. Participants who received usual care were followed every 6 months in a neurological consultation with the patient, then with the caregiver.

Assessments were conducted after two years (at the end of the program). They measured clinical depression (Mini International Neuropsychiatric Inventory, version lifetime), the severity of depressive symptoms (MADRS), trait-state anxiety (State Trait Anxiety Inventory), burden (Zarit Burden Interview, Zarit et al., 1980), perceived stress (PSS), and locus of control (Hierarchical Scale of Internality for elderly people). The results have shown significantly lower scores in anxiety-state scale in the group receiving the multidisciplinary program than those receiving usual care ( $p = 0.02$ ). Non-significant differences were found for the other measures.

### **Main strengths:**

- Grounded in specific and renowned theories
- Embedded in regular clinical practice increasing feasibility over time
- Individual follow-up improving the flexibility and adaptability of contents to caregivers' needs

- May serve as preliminary study before an RCT
- Control group

**Main limits:**

- Non-randomized, non-blinded study
- Unreported involvement of caregivers in program's design before implementation
- Low control of program's implementation
- Unreported training of professionals with homogenous material
- Cut-off values for primary outcomes were not defined in inclusion criteria
- Short exposure to the program (enough to be efficient?)
- No follow-up measuring the sustainability of benefits.
- No collection of qualitative data

**MULTI-COMPONENT PROGRAM: RESOURCES FOR ENHANCING ALZHEIMER'S  
CAREGIVER HEALTH - VETERANS AFFAIRS (REACH VA) (NICHOLS ET AL., 2011)**

This program is the clinical translation of the REACH program: it was designed in the United States and modeled from the National Institute on Aging and the National Institute of Nursing Research programs, and has been tested in various states. The 6-month intervention consisted of nine 1-hour individual home-sessions, three 0.5-hour individual telephone sessions, and five 1-hour monthly telephone support group sessions. Contents focused on information, skills training and support. Skills training targeted five caregiving risk areas: safety, social support, problem behaviors, depression, and caregiver health. The interventionists were trained in problem-solving strategies and in action-oriented behavioral strategies to address caregiver or patient problems, identified using a caregiver notebook. The notebook was written "at a fifth-grade reading level". This included educational information, and practical strategies for 30 behavioral and 18 stress/coping topics adaptable to caregiver situations. Moreover interventionists trained caregivers in stress management techniques (e.g. breathing centered, relaxation, stretching, mood management). The telephone group support sessions with 5 or 6 caregivers were conducted by a leader who provided caregivers with support, skills and education on self-care, resources, financial and legal issues, and communication with patient and service providers (Nichols, Martindale-Adams, Burns, Graney, & Zuber, 2011).

Investigators condensed materials of REACH II in an operation/training manual for interventionists and leader groups, as well as notebooks for caregivers. Over a period of two years 78 staff members were certified as interventionists (n=35), group leaders (n=12) or both (n=31). They conducted a field study, without control group. From 24 facilities were enrolled 127 caregivers. One hundred and five caregivers were evaluated at the baseline (M0) and six months after (M6), at the end of the program. The estimated improvement between M0 and M6 was significant for burden ( $p = 0.01$   $d=0.33$ ) measured by the Zarit Burden Inventory, depression ( $p = 0.009$   $d=0.26$ ) evaluated with the Patient Health Questionnaire (PHQ-9) (Kroenke, Spitzer, & Williams, 2001), the impact of depression on daily lives ( $p = 0.01$   $d=0.26$ ), and caregivers' frustrations ( $p = 0.003$   $d=0.30$ ) informally assessed with closed-ended questions. Caregivers reported a subjective benefit; the program helped them to better understand the disease and their role, and increased their ability to provide care. Although both individual sessions and group support were positively accepted, caregivers reported that they would like more in-home sessions.

**Main strengths:**

- Grounded in previously validated interventions
- Professionals were trained with homogeneous material
- Multicenter study improving external validity
- Embedded in regular clinical practice increasing feasibility over time
- Individual follow-up improving the flexibility and adaptability of contents to caregivers' needs

**Main limits:**

- Non-randomized, non-control study, non-blinded study
- Undefined implication of caregivers to design the program
- Cut-off values for primary outcomes were not defined in inclusion criteria
- Short exposure to the program (enough to be efficient?)
- No follow-up measuring the sustainability of benefits.
- No formal analysis of qualitative data

The interventions illustrated in this section demonstrate the relevance of each type of intervention for specific domains. The psycho-educational program showed an improvement in knowledge and coping, while the cognitive-behavioral program, in accordance with the

literature, was efficient to reduce caregivers' anxiety-trait. Finally, and in coherence with literature review findings (Gallagher-Thompson & Coon, 2007), the multicomponent program showed more substantial results, reducing burden, depression, the impact of depression in daily lives, and caregivers' frustrations, all with a higher effect size (ranging from 0.20 to 0.33).

In these studies we also noted that the information and details available from the various interventions were quite dissimilar, making the replication of interventions or studies difficult. In order to homogenize the reported features, the members of the REACH team suggested a taxonomy of interventions (Schulz, Czaja, McKay, Ory, & Belle, 2010). This work resulted in two checklists adaptable to any kind of intervention, in order to describe the same characteristics of delivery and the goals of them. (see Appendices 1 and 2).

## INTERNET-BASED INTERVENTIONS FOR DEMENTIA CAREGIVERS

Although most of the currently available programs are delivered "in-person" and "on-site", over the last years various e-health interventions have been developed, targeting broader populations of caregivers. For institutions and caregivers they may represent lower costs (e.g. fewer human resources, lower costs of care engaged so as not to leave the PWAD alone, lower transportation fees), and are more flexible and adaptable to caregivers' needs. In fact, they are more accessible for overwhelmed caregivers, or for those living in remote regions or who cannot leave their relative alone at home or who have difficulties finding respite (Boots, de Vugt, van Knippenberg, Kempen, & Verhey, 2013; Martin-Carrasco et al., 2009). Furthermore, in recent years the digital generation gap was reduced (Gombault, 2013), and older adults (including spousal caregivers) have become more engaged in the use of technologies. Thus, incoming generations of caregivers should be more comfortable with and willing to use Internet-based programs and their e-health literacy<sup>4</sup> should likely be greater (Colantonio, Cohen, & Pon, 2001).

The studies evaluating the efficacy of online interventions for caregivers remain less frequent than in-person ones. In a literature review, Boots and her colleagues (2013) analyzed 12 published studies. The sample sizes ranged from 11 (Lai & Thomson, 2011) to 700 subjects (Kelly, 2003). The contents and setting varied between the **Web-based programs**. Those providing the caregivers with **information and support** were the most frequent, followed by

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<sup>4</sup> e-Health literacy is "the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem" (C. D. Norman & Skinner, 2006)



those **combining a website with individual counseling (by mail or phone)**, and others **combining individual and social support online**. Only one program focused on **information and skills training**.

Interestingly only five studies included a control group: one was assigned to a waitlist, others received usual care, or participated in on-site workshops, or online training to identify local services and resources (considered as placebo). The most frequently evaluated constructs included “*self-efficacy, stress/burden, depressive symptoms, coping, social contact/support, knowledge, utilization of health services, and general (mental) health*” (Boots et al., 2013). Overall, a (small) significant effect was found in measures of depression, stress, sense of competence, self-efficacy, and burden. Increased intentions in looking for support, and self-control were also observed. Nevertheless burden was not reduced in all the studies (Chiu et al., 2009; Lai & Thomson, 2011). Nevertheless, Chiu and her colleagues (2009) found a significant difference in caregivers' burden between users and non-users of the program. The other studies did not report any such analysis.

However, none of the studies included in the literature review of Boots et al (2013) reported blinded treatment allocation, likely due to the usual impossibility in psychosocial interventions to conceal the nature of the treatment to participants (Zarit & Femia, 2008). Finally, Internet interventions focused on providing information were less likely to show a positive impact in comparison with programs based on multiple components (Boots et al., 2013).

Recently, Godwin and his colleagues (2013) reviewed all the publications based on RCTs of technology-driven interventions for dementia caregivers from 1990 to 2012 (Table 5). Only 8 studies were published in this period (Bass, McClendon, Brennan, & McCarthy, 1998; Beauchamp, Irvine, Seeley, & Johnson, 2005; Brennan, 1995; Casper, Calvitti, Brennan, & Overholt, 1995; Eisdorfer et al., 2003; Finkel et al., 2007; Gitlin et al., 2003; Feeney Mahoney, Tarlow, & Jones, 2003), representing four RCTs and **three intervention programs** (an additional RCT was published in 2013, see description below: Kajiyama et al., 2013).

**TABLE 5 RANDOMIZED CLINICAL TRIALS OF TECHNOLOGY-DRIVEN INTERVENTIONS FOR CAREGIVERS (1990-2012)**

<b>Authors</b>	<b>Aims</b>	<b>Participants</b>	<b>Outcome variables</b>	<b>Results</b>
Beauchamp et al	To evaluate the efficacy of a	n = 299, 46.9y/o (avg),	Stress; self-efficacy; coping	Significant improvements in depression, anxiety, stress, strain,

	multimedia support program delivered over the Internet to employed family caregivers of PWD	73% female, 80% white, 4% African American, 8% Hispanic	skills, intention to get support; caregiver strain; caregiver gain; depression symptoms ; state anxiety	self-efficacy, intention to seek help, and perceptions of positive aspects of caregiving.
Bass et al	To determine whether access to ComputerLink had greater reductions in caregiver strain	n = 96, 60 y/o (avg), 68% female, 28% African American	Caregiver strain; activity restriction; ComputerLink use	No reduction in overall strain. Reduction in relationship strain for spouses and in emotional strain and activity restriction for caregivers with more informal support. Decrease in activity restriction was greater for caregivers not living alone with PWD.
Brennan et al	To examine the impact of ComputerLink use on caregiver's decision-making confidence, skill, and isolation	n = 102, 64 y/o (median), 67% female, 72% white	Decision-making confidence; decision-making skill; social support; depression; burden; service utilization; patient's functional status	Significant improvement in decision-making confidence. Functional status declined similarly in both the groups. No significant changes in decision-making skills or perception of social isolation.
Casper et al	To examine the impact of ComputerLink on caregiver's decision confidence and skill	n =102, 60 y/o (avg), 67% female, 28% African American	Decision-making confidence; decision-making skill	Significant improvement in decision-making confidence. Access to and length of time on ComputerLink were correlated with decision-making confidence.
Eisdorfer et al	To examine efficacy of SET and SET. CTIS to reduce depressive symptoms	n = 225, 69 y/o (avg), 75% female, 51% Cuban Americans, 49% white Americans	Depression; burden; satisfaction with social support	Combined family therapy and technology intervention (SET . CTIS) resulted in significant reduction in depressive symptoms at 6 and 18 months
Finkel et al	To evaluate the effectiveness of	n = 46, 64.6 y/o (avg), 68%	Depression; burden;	Caregivers in the intervention had a significant decrease in burden

	technology-based caregiver psychosocial intervention modeled after the REACH intervention	female, 92% white, 8% African American	caregiver's health behavior; social support; change in problem behaviors	over time. Compared with controls, those with high depression at baseline had improvement in depression; those with high support at baseline were able to maintain support and had improved caregiving confidence and ability to provide care.
Gitlin et al	To determine the pooled treatment effect of 15 different REACH interventions on burden and depression	n =1222, (age, gender, and ethnicity not reported in this article)	Depression; burden	Intervention improved caregiver's burden. The family therapy plus computer technology intervention reduced depression.
Mahoney et al	To determine the main outcome effects of a computer mediated automated interactive voice response intervention	n = 100, 62 y/o (avg), 80% female, 79% white	Bother; anxiety; depression	Significant intervention effect on bother, anxiety, and depression for caregivers with low mastery at baseline. Wives also had a significant intervention effect in reducing bother.

Adapted from : Godwin et al. (2013)

The sample sizes of these studies ranged from 46 to 1,222 participants. Although every program addressed information and social-support components, the content and delivery differed across the studies. The small number of RCTs and the high variability in content and method, as well as the inconsistency between measures and the variability in outcomes, prevented the authors from concluding on the robust effects of technology-based interventions. They pointed out the greater gap between the number of feasibility studies of these interventions and the number of studies evaluating their efficacy, as well as the little use of control groups (Godwin, Mills, Anderson, & Kunik, 2013).

In order to illustrate Internet-based interventions and study protocols to evaluate them, we describe four of these in this section.

“CAREGIVER’S FRIEND: DEALING WITH DEMENTIA” (BEAUCHAMP ET AL., 2005)

This program was grounded in the stress and coping model of Lazarus and Folkman (Lazarus & Folkman, 1984) and in the Bandura’s concept of self-efficacy (Bandura, 2005). This is a web-based multimedia intervention based on text material and videos that model positive coping strategies (Beauchamp et al., 2005). The program was funded by the National Institute of Aging and developed by scientists and designers, based on literature reviews, interviews with gerontology specialists, nurses, and social workers, and focus groups with 60 informal caregivers. To evaluate the efficacy they carried out a pretest-posttest randomized clinical trial with 30 days of follow-up. At the beginning of the program, users filled out an online questionnaire targeting the interests of each caregiver, allowing for the individualization of contents. For instance, spousal caregivers received information “*on finances, socializing, and losing a companion, whereas adult children are offered information on losing a parent, long-distance caregiving, and helping the parent’s spouse*” (Beauchamp et al., 2005). Three thematic modules included multiple components: information, cognitive and behavioral skills, “affective learning”, and problem-focused strategies and social support skills. Caregivers received a personalized report describing difficulties encountered by the families depending on the patients’ level of cognitive impairment, how long the caregiver provided care, and the stage of the illness. Pre-screened caregivers completed an online consent and the pretest (T1). Upon completion of the pretest, caregivers received a \$20 check. They were then randomly assigned to the Website program or to a waitlist control (no attention-placebo). The contact with both groups was ensured by mail. All participants were evaluated 30 days after their enrollment (T2). After this, the control group received free access to the program. Immediately after the experimental group viewed the first module, they filled out a “manipulation check survey” including self-efficacy assessment. Thirty days later they filled out the same follow-up questionnaire as controls (T2). All caregivers received a \$30 check after completion of T2 (Beauchamp et al., 2005).

Interestingly, in this study the researchers used only the parts of questionnaires (subscales) that matched their domains of interest. In fact, they selected “an ambitious set of measures” based on the stress and coping model of Lazarus and Folkman (Lazarus & Folkman, 1984), the theory of reasoned action (Ajzen & Fishbein, 1980), the transactional model of behavior change (Prochaska & DiClemente, 1983). They explained they intended to limit the number of questions so as not to overwhelm already overburdened caregivers. Thus, no standardized instrument of measure was completely used. The primary appraisal was stress evaluated with two screening questions: “*In the past four weeks, how often have you felt stressed by your caregiving activities?*” (4-point scale from never to regularly) and “*When that happened, how stressed did you usually feel?*” (7-point scale from not at all stressed to

*extremely stressed*)” (Beauchamp, et al. 2005, p. 5). The secondary appraisal was self-efficacy, assessed with six questions designed by researchers and centered on self-efficacy in the intervention. Additionally they measured the intention to get support, coping skills, caregiver strain, caregiver gain, depressive symptoms and state anxiety. The double multivariate repeated measures analysis of variance showed a significant effect by time effect and by condition ( $F(8, 290) = 4.25, p < 0.001, \eta^2 = 0.11$ ). The website group improved self-efficacy, intention to get support ( $p = 0.002$ ) and caregiver gain ( $p = 0.021$ ). Were also found significantly greater reductions in caregiver stress ( $p < 0.001$ ), caregiver strain ( $p = 0.028$ ), depressive symptomatology ( $p = 0.009$ ) and state anxiety ( $p = 0.030$ ) compared with control participants. The only measure that did not differ between the groups was the Ways of Coping scale, evaluating the self-reported frequency of using stress-reduction strategies ( $p = 0.971$ ). Concerning the dose-response analysis, they reported positive outcomes with a minimal exposure to the program for 32 minutes, which was explained by authors as a positive secondary effect of the program (Beauchamp et al., 2005).

**Main strengths:**

- Grounded in a clear theoretical framework
- Involvement of professionals and caregivers in the development process
- RCT with follow-up
- Individualization of contents by screening caregivers’ needs before starting the program
- Multiple components
- Economic retribution for participants after each evaluation (T1 and T2)
- Reported analysis of time and rate of program’s utilization

**Main limits:**

- No standardized questionnaires were used completely
- Cut-off values for primary outcomes were not defined in inclusion criteria
- Low utilization of the program
- No formal analysis of qualitative data

## THE I-CARE PROGRAM (KAJIYAMA ET AL., 2013)

This program is an adaptation of an evidence-based treatment program called “Coping with Caregiving” developed by Gallagher-Thompson and her colleagues. The original version of this intervention was evaluated in multiple randomized trials, which reported decreased depression symptoms, and caregiver bother, in the USA (Gallagher-Thompson, Gray, Dupart, Jimenez, & Thompson, 2008), Hong Kong (Au, Koo, & Cheung, 2009) and Spain (Márquez-González, Losada, Izal, Pérez-Rojo, & Montorio, 2007). The intervention aimed at teaching caregivers skills for stress management, focusing on four components: a) relaxation training, b) learning to increase pleasant daily activities, c) cognitive restructuring, and d) communication skills on how to effectively seek help from the family, the community, or medical institutions.

During the first year of the project, they conducted extensive interviews and focus groups with caregivers and professionals, in order to determine the protocol and the contexts of the Web-based program. The final version of the iCare program was displayed in six modules: a) an overview on dementia course, facts and stages, b) stress detection and management, cognitive reframing, c) rationale and techniques of relaxation, d) identification and planning of pleasant activities, e) communication skills training, f) training in understanding and handling of behavioral problems based on the Trigger – Behavior – Response model, g) learning to monitor healthy habits and h) planning for the future, identifying national and local resources. For the study, the program contents had to be visualized as described above. Nevertheless, caregivers did not have time constraints to complete each module, but they were encouraged to practice specific assignments 7-10 days after visualizing the module, and before moving on to the next topic. The web-based program (Figure 6) included videos illustrating the components described above, in which actors embodied different types of relationship (e.g. daughters, sons, wives, etc.). In videos, the typical responses from caregivers were shown first (e.g. frustration, guilt, depression, etc.), followed by more efficacious ways to respond, thus promoting role modeling for caregivers in different skills. The caregivers also received a DVD with the Website contents, in case they were not available (none of them used it). They were also provided with a workbook, offering exercises and practice examples, in which the participants were encouraged to write down their own individual strategies and “action plans”. The control group was provided with access to a Website, in which contents were focused on information about dementia, obtained from renowned national institutions. A booklet compounding health agencies materials was also provided to control caregivers.

The caregivers were informed of the study thanks to notices placed in family associations or other referral agencies. Interested participants contacted the researchers (by mail or phone). Volunteers signed the consent sent by regular mail or by e-mail, and filled out a

questionnaire on caregiver and PWAD characteristics, as well as depression symptoms of caregivers. Caregivers presenting a clinical level of depression were not included, as well as those offering fewer than 8 hours of care per week.

Of the 354 who initially contacted the researchers, only 150 caregivers were enrolled and randomized in the experimental group (EG, n=75) and the control group (CG, n=75). They completed a set of questionnaires at baseline before beginning the programs, and at post-evaluation, three months later.

**FIGURE 6. I-CARE HOME PAGE**



Source : <http://www.icarefamily.com/>

The primary outcome was the perceived stress measured with the Perceived Stress Scale (Sheldon Cohen & Williamson, 1988). They also evaluated the level of bother due to disruptive behaviors with the Revised Memory Behavior Problems Checklist (Teri et al., 1992), the level of depressive symptoms with the Center for Epidemiological Studies Depression scale (Radloff, 1977), and the Perceived quality of Life (PQoL) (Patrick, Danis, Southerland, & Hong, 1988).

A mixed between-within subjects ANOVA showed a significant interaction between conditions over time (Wilks'  $\lambda = 0.945$ ,  $F(1,101) = 5.88$ ,  $p = 0.017$ , partial  $\eta^2 = 0.055$ ) for the primary outcome. Paired t-tests from pre-post in the control condition were not significant, whereas the reduction in perceived stress was significant in the EG ( $t(45) = 3.18$ ,  $p = 0.003$ ).

Even if authors described a diminution in secondary outcomes in the iCare group, it was not significant. They pointed out the great number of ineligible cases and dropouts (nearly 30%) before the end of the study. The latter might be due to the fact that the program did not match all the caregivers' needs. Finally authors also advocated the development of more user-friendly programs, and more accessible to a broader range of caregivers.

**Main strengths:**

- Grounded in a previously validated program
- Involvement of professionals and caregivers in the development process
- Evaluated with an RCT including follow-up
- Intervention with multiple components and multiple materials
- Reported analysis of time and rate of program's utilization

**Main limits:**

- Difficulties in recruitment and higher percentage of dropouts
- Cut-off value for primary outcomes were not defined in inclusion criteria
- No formal analysis of qualitative data

DEMENTIA-SPECIFIC DIGITAL INTERACTIVE SOCIAL CHART (DEM-DISC) (VAN DER ROEST, MEILAND, JONKER, & DRÖES, 2010)

DEM-DISC is a web-based "social chart", developed on the basis of caregivers' and PWD's needs, evaluated by Van der Roest and her colleagues (Van der Roest, 2009). In order to improve the usability and accessibility of the program, researchers adopted a human-centered design approach, involving end-users in different stages of the development (Van der Roest et al., 2008). Caregivers were guided by the three-step system to the identification of their specific demands. The version used for the study was a prototype of the program, which included, a) information on diagnosing dementia, b) practical support, c) coping skills, and d) finding company. The content (practical services and contacts) was restricted to two regions in Amsterdam.

The study was conducted in a pre-post control group design. The participants were enrolled through meeting centers, associations and memory clinics for persons with dementia (PWD) and their caregivers, as well as through advertisements in a public weekly newspaper. Only caregivers caring for a person with dementia for at least four hours per week, and



experiencing needs in areas addressed by the DEM-DISC were included in the study. Additionally, participants in the experimental group (EG) had to have experience in using Internet, and live in one of two districts of Amsterdam included in the program. Thus, a convenience sample of 29 participants was recruited (EG,  $n=14$ ). The EG used the program for 2 months, while the control group did not receive access to DEM-DISC, and relied on their usual information channels (e.g. newspapers, internet, care consultants, etc.). Both groups were evaluated at baseline and after two months. The primary outcome measures were caregivers' needs assessed with the Camberwell Assessment of Need for the Elderly (CANE) (van der Roest, Meiland, van Hout, Jonker, & Dröes, 2008), the actual care and welfare, which was measured with the "Use of service List" (Dröes, et al 2003), caregiver burden with the Short Sense of Competence Questionnaire (Vernooij-Dassen et al., 1999), and caregiver self-efficacy with the Pearlin Mastery Scale (Pearlin & Schooler, 1978).

The ANCOVA included different confounder variables: type of dementia, relationship, gender of person with dementia and number of services used by people. By comparing the groups over time, they showed significant results for some of the primary outcomes. EG reported more met needs at post-test ( $F=3.26$ ,  $df=1$ ,  $p=0.05$ ;  $d=1.20$ , and  $F=9.93$ ,  $df=1$ ,  $p=0.00$ ;  $d=1.44$ ), and fewer unmet needs ( $F=3.93$ ,  $df=1$ ,  $p=0.03$ ;  $d=-1.31$ ), presented higher feeling of competence than controls ( $F=4.11$ ,  $df=1$ ,  $p=0.03$ ;  $d=0.93$ ) and reported having received more information from general practitioners ( $p=0.02$ ) and their pharmacist ( $p=0.03$ ) after the program.

The program was used on average 5.14 times, and 14min36 per session. The most consulted questions concerned the general information about dementia and about support for practical problems. Users found the program easy-to-learn and user-friendly. Nevertheless their satisfaction about the program and their opinion of its usefulness were neutral. Two caregivers reported some problems using the website, and the navigation problems were also due to caregivers' unfamiliarity with the browser. Caregivers reported that the program was not detailed enough. They wished to receive direct contact with case managers and information about finances. Despite limitations in sample size and program duration, it is important to underline the interesting idea of using the measure of number of met or unmet needs to evaluate the impact of the program.

#### **Main strengths:**

- Development based in a human-centered design approach
- Involvement of caregivers in the development process

- Individualization of contents by screening caregivers' needs before starting the program
- Intervention based on multiple components
- Reported data on time, rate and contents used from the program

**Main limits:**

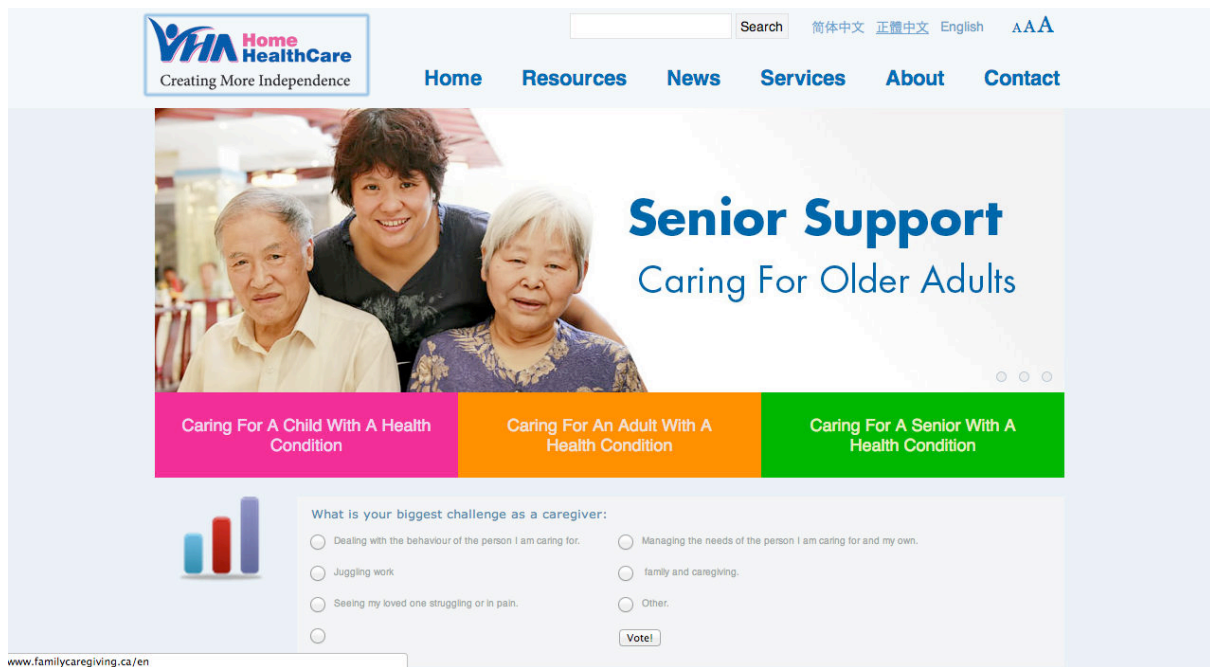
- Small sample size
- Cut-off values for primary outcomes were not defined in inclusion criteria
- No formal analysis of qualitative data

INTERNET-BASED CAREGIVER SUPPORT SERVICE (ICSS) (T. CHIU ET AL., 2009)

In this study the targeted population was the Chinese Canadian caregivers. The cultural differences described by the authors underlined the necessity of a specific program for this population. The ICSS is a system based on two main components. Firstly, a caregiver information handbook with more than 400 pages of information, designed by experienced social workers and occupational therapists. A professional translator translated the document in Chinese, and then it was reviewed and edited by bilingual clinical staff to ensure the pertinence and relevance of translations. The second component of the program was personalized e-mail communication between caregivers and clinicians. It was password-protected and accessible through the secure Web site. By e-mail, two experienced therapists provided psychosocial, educational intervention, advice regarding self-care as well as how to access specific services agencies, and helping caregiver to manage burden more effectively.

The design of the website (<http://www.familycaregiving.ca/>) (Figure 7) was adapted from a well-tested program for caregivers of persons with neurodegenerative disease (Marziali & Donahue, 2006). It was designed to meet four requirements: a) functionality, proposing multiple components, b) usability, following the recommendations of the National Institute of Aging (Chiu & Henderson, 2005), adapting the contents for a greater readability from people without a high level of education, c) security, password protection of the website and data encryption assured for the e-mails, d) language, all interfaces were available in English, simplified Chinese or traditional Chinese.

FIGURE 7. HOME PAGE OF THE ICSS PROGRAM



Source: <http://www.familycaregiving.ca/>

Researchers conducted a laboratory usability evaluation with three caregivers and a heuristic evaluation (see User-centered design section). The intervention study was conducted in pre-post design without control group. The researchers used convenience sampling to recruit caregiving adults from a Day Care Program, who had to speak, write, and read Chinese, as well as have access to the Internet. Invitation to participate, the consent form, and baseline questionnaires were sent and returned by regular mail. The main outcome was the perceived burden, measured with the 28-item Burden Scale for Family Caregivers (BSFC) (Gräsel, Chiu, & Oliver, 2003). Seven additional measures were used in this study: the RMBPC, the CES-D, the Self-rated Health (SRH), The Multidimensional Scale of Perceived Social Support (MSPSS) (Zimet, Dahlem, Zimet, & Farley, 1988), The Positive Aspects of Caregiving (PAC) (Cohen, Colantonio, & Vernich, 2002), a measure of care-recipients' functioning level (the OARS Multidimensional Functional Assessment Questionnaire – OARS, Older Americans Resources and Services, 1978), and the Caregiver Competence Scale (CCS).

Of 132 eligible caregivers, only 35 were actually recruited, and 28 finished the study. Most participants were women, worked full-time, and were aged between 40 and 50. Older participants tended to be non-users ( $n=9$ ), while younger participants were more likely to be occasionally (1 or 2 times,  $n=8$ ) or frequently users (3 or more times,  $n=11$ ) ( $\chi^2= 9.96$ ;  $df= 4$ ;  $p= 0.041$ ). The study did not find significant differences between the pre-post evaluations for all participants. Nevertheless, the subgroup of caregivers who frequently used the program

presented a significantly lower burden than those who did not use the program ( $t=2.50$ ,  $df=17$ ,  $p=0.02$ ). However, the results in ANOVA comparing the three groups were not statistically significant ( $F=1.78$ ,  $p=0.19$ ). Authors concluded among others on the necessity to conduct more studies to enhance the technologies' design, and to evaluate the effectiveness and cost-effectiveness of using an experimental design.

**Main strengths:**

- Individualization of contents by professionals' personalized e-mail messages
- Conducted usability tests, adapted readability to low education level
- Involvement of caregivers in the development process
- Based on multiple components
- Reported data on time, rate and analyzed the correlations with psychological outcomes

**Main limits:**

- No control group
- Small sample size
- Cut-off values for primary outcomes were not defined in inclusion criteria
- No formal analysis of qualitative data

From the previously described Internet-based intervention studies, we retained the following aspects. The use of RCT was not always considered necessary or feasible. Instead of this, researchers conducted quasi-experimental studies with a design in pre-post with or without a control group (Chiu et al., 2009; Van der Roest et al., 2010). Two RCTs evaluating perceived stress as a main outcome found significant results (Beauchamp et al., 2005; Kajiyama et al., 2013). They were based on the Lazarus and Folkman model, and on a cognitive and behavioral approach. The programs were delivered using the Internet, with a certain individualization of contents (for instance, Beauchamp et al., 2005; Kajiyama et al., 2013; Van der Roest et al., 2010). Most of the programs targeted three domains of action: knowledge, skills, and social support. Moreover, four studies provided the experimental group with additional material such as workbooks, e-mail accounts or video modeling training. Interestingly, one of the studies showing the most significantly positive results did

not use standardized measures, but a fragment of them, or closed-ended questions designed by researchers (Beauchamp et al., 2005).

All the programs described have involved caregivers in the development of contents. In some of them, caregivers also participated in the design and iterative tests of the interfaces (Van der Roest et al., 2010), as well as in usability tests, yet this practice was less widespread (Chiu et al., 2009). In the next part of this chapter we present an overview of recommendations to develop and implement interventions, as well as evaluate their efficacy.

## RECOMMENDATIONS TO EVALUATE AND DEVELOP INTERVENTIONS FOR CAREGIVERS

In an attempt to explain the overall trend of psycho-educational program studies (i.e. in-person and technology-driven programs) showing mostly "small" positive effects, various authors have analyzed distinctive features of this field of study. In fact, methodological issues in evaluating and implementing caregivers' interventions would be a likely reason for this (Vernooij-Dassen & Moniz-Cook, 2014; Zarit & Femia, 2008).

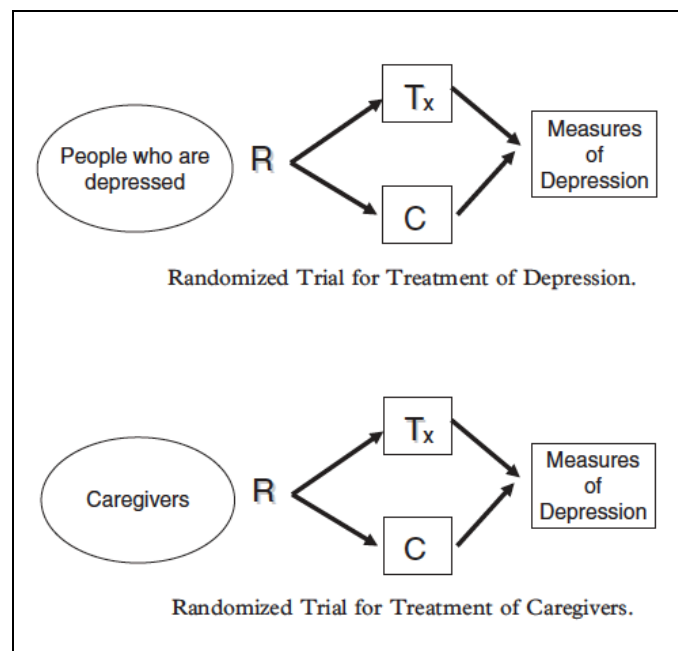
Zarit & Femia (2008) provide a critical analysis of the methodological issues noted in earlier studies, and suggest possible strategies to overcome or avoid them. According to them, the caregiving intervention studies, being a relatively new domain of study, follow the established methodological principles for conducting research, the "gold standards". Nevertheless, they are often not adapted to the specific features of the population or to the questions posed. Researchers have to take into consideration the specific features of their intervention and the aims of the study and attune them to the selection criteria, the measuring instruments, the implementation protocol, and all the other factors, which may affect the internal or external validity of the study. In sum, it means that the good study design "X" might well be unadapted to evaluate the program "Y".

In addition, and although it may seem obvious, **a frequent mistake is to consider the "caregiving" as a clinical entity** (see example in Figure 8). In fact, some studies selected the participants only based on the fact that they were "caregivers". The inclusion criteria were mainly centered on care-recipient characteristics (e.g. functional or cognitive status, diagnosis), or on characteristics confirming the role of caregiver (e.g. number of hours caring, helping with daily life activities). Therefore, the caregivers are recruited regardless of whether they have or not the dependent variable (e.g. depression, burden, stress, or anxiety). With this approach researchers are claiming that all caregivers are depressed, or have burden,

when in fact it is not true. For instance, only 20 to 50% of caregivers have clinically significant depression symptoms, meaning that 50 to 80% do not suffer from it (Aneshensel, Pearlin, Mullan, Zarit, et al., 1995; R Schulz & Sherwood, 2008). As a result, it would be useless to propose a treatment against depression to all of them, and in any case, no benefit of such treatment can be demonstrated for them. To avoid this issue Zarit & Femia (2008) suggest that minimum thresholds for the main outcome measures should be included in the selection criteria, in coherence with hypothesized effects of the intervention

Like studies focused on outcomes (e.g. depression symptoms), some studies follow a similar pattern to evaluate the effect of interventions on risk factors (e.g. behavioral troubles of PWAD could heighten risk of depression in caregivers). Due to the considerable variability among caregivers in their risk factor profile, they may not benefit equally from a treatment, which targets one specific domain. Although behavioral troubles may provoke great levels of depression and burden in caregivers, not all caregivers are depressed, not all patients exhibit behavioral problems and these are not always bothering for caregivers (S. H. Zarit & Femia, 2008).

**FIGURE 8. ZARIT AND FEMIA (2008), COMPARISON OF RCTS FOR DEPRESSION AND FOR CAREGIVING INTERVENTIONS**



Source: Zarit & Femia (2008)

Furthermore, depending on the construct's definition the result may diverge drastically between studies. For instance, Fauth and Gibbons (2014) demonstrated inconsistencies in identifying the most problematic BPSD. The authors concluded that inconsistencies were due to the diversity of "problematic" meanings, depending on the instrument used to evaluate it. They may be centered on the frequency, intensity, distress rating or the outcomes of caregivers, such as the resulting depression levels (Fauth & Gibbons, 2014).

In addition, **caregivers are a heterogeneous population**, with different socio-demographic characteristics that could affect their response to treatment. They are exposed to different caregiving contexts, and differ in the resources they have to manage or contain the stressors (Steffen et al., 2008; Zarit & Femia, 2008). For instance, male caregivers (in contrast with female caregivers) prefer informational or skills-based interventions, rather than emotional-focused ones (Gant, Steffen, & Lauderdale, 2010). Thus, Zarit and Femia (2008) remind us that "one size does not fit all". It means that interventions that target all caregivers have to be flexible and adaptive enough to be beneficial for different profiles of caregivers, as implemented in some programs overviewed in the present work (among others: Beauchamp et al., 2005; Kajiyama et al., 2013; Nichols et al., 2011). Otherwise the intervention has to be tailored or individualized.

A critical condition for the design of protocols is that **the mechanisms of the intervention and the outcomes should be functionally related**. As exemplified by Zarit and Femia (2008), "*there is (...) considerable research that demonstrates the link between selected neurotransmitters and depressive symptoms and so medications that affect these neurotransmitters are a rational choice for treatment*". Nevertheless, some psychosocial interventions use less obvious or known relationships with the outcome measures. In this perspective, it is necessary to have a clear theoretical framework, allowing the researchers to identify what the mechanisms and the expected results are.

As pointed out by various authors, the way in which some studies are conducted or the programs designed may satisfy researchers' interests, but not caregivers' needs. Zarit and Femia (2010) explain it by the trend of various studies to target the results of epidemiological studies. Based on these studies, some researchers conclude that caregivers suffer from higher burden, depression and anxiety than comparable populations, and that interventions need to target them. In this perspective, **the needs and wishes of caregivers should be listened** to more closely (such as in recent studies, e.g. Amieva et al., 2012; Herr, Arvieu, Aegerter, Robine, & Ankri, 2013; Van der Roest et al., 2007; Van der Roest, 2009). This stage will facilitate attuning interventions to the wishes of caregivers.

The additional recommendations of Zarit and Femia (2010) are centered on the necessity to **ensure the correct implementation of interventions**. Vernooij-Dassen and Moniz-Cook (2014), who also highlighted the importance of implementation error, suggest adding different considerations to the Medical Research Council Framework (a checklist/guideline for implementing and evaluating complex interventions) (Craig, Dieppe, Macintyre, & Michie, 2008). From their perspective the current methodological trends make it difficult to determine whether the lack of effect of assessed interventions is not due to their erroneous implementation. In fact, different factors may alter the application of the interventions, several of which being linked to the variability between practitioners.

Like Zarit and Femia (2008), they question the pertinence and suitability of current methodologies used to evaluate the programs. Although RCTs have improved the standards and quality of psychosocial intervention research, controlling type I errors (rejecting the hypothesis when it is true), and type II errors (accepting the hypothesis when it is false), RCTs rarely permit the control of type III errors (failure of internal validity, due to implementation error) (Vernooij-Dassen & Moniz-Cook, 2014).

In fact, Vernooij-Dassen and Moniz-Cook (2014) suggest that by firstly conducting an explanatory trial<sup>5</sup>, the intervention would be better monitored, and practitioner variations would be controlled and analyzed. Thus, once the efficacy of programs is demonstrated, they can be evaluated in real-life conditions, using a pragmatic trial design (contrary to that suggested by Craig et al., 2008). In fact, explanatory trials may help researchers and practitioners to identify the “ideal” setting, the barriers and risks from initial stages of implementation, as well as the strategies to improve the adoption of the intervention. In coherence with this, Curran, Bauer, Mittman, Pyne, & Stetler, (2012) have recently published the “Effectiveness-implementation hybrid design”, a model which also underlies implementation conditions, supporting Vernooij-Dassen and Moniz-Cook's suggestion of a final large-scale pragmatic design. Nevertheless, this model does not include the study of barriers experienced by stakeholders, varying between settings and contexts, which would be precious for the successful implementation of interventions in real-life (Vernooij-Dassen & Moniz-Cook, 2014).

The particular challenges in the implementation of caregiver support programs are the low rates of adoption and the high attrition (Chiu et al., 2009; Kajiyama et al., 2013). An

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<sup>5</sup> *Explanatory vs. Pragmatic trial*: The research question of explanatory trials concerns the efficacy of interventions in an ideal setting with a closely monitored intervention, while pragmatic trials evaluate the effectiveness under real-life conditions (e.g. in routine healthcare settings) (Myrra Vernooij-Dassen & Moniz-Cook, 2014).



interesting study has recently analyzed the factors associated to the “readiness”, a construct which determines when caregivers are “ready” to learn about the techniques proposed (i.e. skills to manage dementia-related behavioral problems), since this may affect the viability of intervention programs. The results have shown that readiness is not a trait but a “malleable state”. Only persons with important financial strain were unable to increase their readiness level (Gitlin & Rose, 2014). Therefore, a detailed analysis of participants’ characteristics related with adoption or attrition might be useful if integrated in the studies. The results may allow practitioners to take into account socio-demographic characteristics, health conditions, timing (when the intervention was proposed), as well as the suitability of interventions for the targeted populations? , and the contextual factors which may constrain or favor the implementation of the program (Vernooij-Dassen & Moniz-Cook, 2014), bearing in mind that unwelcome support might be more stressful than helpful (Brodaty & Donkin, 2009).

## USABILITY AND DESIGN OF WEB-BASED PROGRAMS

Complementing these recommendations, two fundamental aspects should be considered during the development of Internet-based programs: the iterative user-centered design and usability of the program. In a utopic scenario all methodological and implementation issues might be overcome. However, if caregivers have to face many difficulties using the program, the latter causing burden and frustration, they will most likely not use it again. A non-user-friendly web-based program is misused, or is not used at all, resulting in a costly failure for researchers, as well as a disappointing experience for clinicians and caregivers, who may have created expectations towards this program (Chiu & Eysenbach, 2010; Schulz, Gallagher-Thompson, Haley, & Czaja, 2000).

Thus it seems important to recall that most caregivers of PWAD are spouses, aged over 65 (INSERM, 2007). In fact, the French technological generation gap is greater after 70 years old. For instance, after 75 y/o only 23.4% of the population has Internet at home, and out of them only 16.5% have used the Internet in the past three months (Gombault, 2013). Because this generation is not “digital-native”<sup>6</sup>, it is more difficult for them to adopt the latest technologies. Most older persons may not benefit from the transfer of knowledge resulting from the use of other similar technologies, as younger users can. But the reluctance towards new technologies is also due to designs, which are not attuned to typical changes

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<sup>6</sup> *Digital-native*: Defined as the generation born after 1980, significantly affected by the apparition of Internet technologies (Shah & Abraham, 2009).

accompanying normal aging (i.e. sensorial, perceptive, cognitive and motor age-related declines) (Demiris, Finkelstein, & Speedie, 2001; Fisk, Rogers, Charness, Czaja, & Sharit, 2009).

These aspects have to be taken into consideration during the development process of a web-based program. As described early in this chapter, few technology-driven programs have been designed based on a user-centered design. We will present an overview of this approach and some methods to improve the usability of programs.

## THE USER-CENTERED DESIGN APPROACH

Until the end of the 1980s, many products were designed based from the perspective of manufacturers or designers. This was the “product-centered design”, in which the product is derived from a set of specifications previously defined (Denning & Dargan, 1996), and is based on principles of innovation and productivity. One of the criticisms leveled at this approach was that users have to adapt their behavior to accommodate new products and not inversely (Norman, 1993). Actually, the involvement of users was limited to the documentation of requirements and specifications (Denning & Dargan, 1996).

The user-centered design appeared at Bentley College, in the early 1980s. A team of students and professors were interested in the study of human behavior, research methods, design, and testing. Although they attributed value to business, the main aim was to understand how to “serve” users (Gibbons, 2013). The user-centered design includes the techniques, processes, and procedures to place the user in the core of the design process, in order to develop them from a user-friendly approach (Rubin & Chisnell, 2011). The main characteristics of the user centered design are the following: a) the design is based on the explicit understanding of users and their contexts; b) users are involved throughout design and development; c) the design is driven and reviewed by users' feedback; d) the process is iterative (cyclic); and e) the design team includes multidisciplinary skills and perspectives (Pino, 2012).

Over the last years, the designers of systems and products targeting older persons have taken into account sensorial, perceptual, and cognitive changes due to normal aging, in order to “*make human-system interaction error-free, productive, safe, comfortable and enjoyable*” (Fisk, Rogers, Charness, Czaja, & Sharit, 2009, p. 13). The usefulness of a product can thus be defined from two perspectives: utility and usability. The utility is relative to the capacity of a product to respond to users' needs, whereas usability refers to the manner in which the

user may access that functionality. Fisk and his colleagues (2009) identified five main components of usability:

*Learnability and memorability.* They imply the facility to learn how to use the product (ease-to-learn), and the easiness to remember the manner to use the product after long periods of non-use, in minimizing the effort necessary to relearn. A critical point in designing products for older people is to avoid the cognitive overload. In fact, older persons may have difficulties to learn how to use a new product if the instructions are long or complex, overloading the working memory. These negative experiences may reinforce negative self-stereotyping, and affect future adoption of other technologies.

*Efficiency.* It concerns the capability for matching the functions of the product with the users' needs. Thereby, an efficient product would allow users to reach the intended objectives in a reasonable amount of time, without frustration, fatigue, or dissatisfaction.

*Errors.* Although the "ideal" product is error-free, in real life it is likely that not all errors are controlled. In this case, the system has to be designed to provide the user with a quick and easy manner to regain the "right path".

*Satisfaction.* It addresses the pleasure of users when using, or interacting with the product.

The methods in a user-centered design approach are diverse and could be applied in different stages of design (Table 6). The majority of these are inspired by psychological methods of measure, such as is the case with behavioral observations, questionnaires, interviews, or focus groups (Fisk et al., 2009).

**TABLE 6. STAGES, GOALS AND METHODS IN USER-CENTERED DESIGN**

Phase	Goal	Methods
Conceptual design	Definition of user profile	Interviews Cognitive assessment Questionnaires Socio-demographic surveys
	Needs and requirements gathering	Collaborative workshops Ethnographic research Focus groups Interviews Prototyping Questionnaires Use case scenarios
Formalization, design and prototyping	Prototype design, layout and validation	Cognitive walk-through Behavioral observations Heuristic evaluations

		Prototyping Storyboards Task analysis Thinking-aloud / Verbal protocols User tests Use case scenarios
Final prototype	Final product assessment, operation and maintenance	Safety and environmental analysis Behavioral observations Task analysis Questionnaires Interviews Focus groups

\* Methods that do not require user involvement *Adapted from:* Pino, Cristancho-Lacroix, et al. (2012) and Fisk et al., (2009)

Some methods for usability inspection include:

- *Task analysis:* This method consists in identifying and defining a cluster of tasks, divided in a sequence of steps required achieving a goal. The selected tasks represent the main actions that users can perform with the final product. The evaluator has to identify the steps in which the users make mistakes, have difficulties, or those which turn out to be useless (Pak & Price, 2008).
- *Think-aloud verbal protocols:* Users are asked to think aloud while interacting with the product. They have to focus their verbalizations on what they are doing and why they are doing it. This method provides excellent qualitative data and contributes to avoiding evaluator bias (i.e. interpretations or rationalizations of user's actions). The purpose of this method is to discover the problems that users encounter when using a product, which information can be used to improve the design (Fisk et al., 2009).
- *Heuristic assessment:* Three or more specialists in usability (single experts) and at least one specialist in the domain of the program and in usability (double experts) evaluate the usability of the product or system thanks to a checklist of usability heuristics, created on the basis of usability recommendations (Or & Tao, 2012).

## SOME EXAMPLES OF USABILITY TESTING

We noted a growing use of usability testing in e-health, mainly for designing Internet-based interventions in other pathologies and with younger populations. For instance, Voncken-Brewster and colleagues (2013) evaluated and improved the usability of an Internet-based

self-management intervention called “**MasterYourBreath project**” (AdemDeBaas in Dutch), which targeted the change in behaviors (i.e. smoking cessation, medication adherence, and physical activity) of **patients suffering from chronic obstructive pulmonary disease**. The individual lab-evaluations were conducted in successive series of tests (three iterations), involving eight patients. Scientists had previously defined a test scenario, in which the participant had to log on the website, and then follow the instructions presented in the program until he/she had completed all of them. During the evaluation the participant was asked to think aloud. The researchers observed and recorded the sessions for the subsequent qualitative analysis. As a result, most of the usability issues were fixed and qualitative data guided the researchers to adapt some behavior change techniques that had turned out to be frustrating for patients (Voncken-Brewster et al., 2013).

In the domain of **caregiving for PWAD**, Chiu and her colleagues (2009) recruited three Chinese caregivers to participate in a usability study of the program ICSS (see description in the section “Technology-driven interventions”). Individually the participants completed a series of tasks on the Website and in the e-mail tools in a laboratory (e.g. sending a mail, or browsing the website to examine the workbook). After this, they were interviewed and completed a questionnaire. Finally, researchers conducted a heuristic assessment. Based on the results, the authors redesigned the layout and the functionalities of the program, and identified four variations on the language preferences depending on the task. For instance, Chinese was preferred when speaking with the therapist in face-to-face, whereas English was preferred for sending e-mails, to avoid inputting Chinese characters (Chiu et al., 2009).

These examples stress the feasibility and pertinence in conducting usability studies that should be embedded in a user-centered design, in order to ensure iterative development of programs, and the involvement of end-users through the overall design process.

## WHAT IS MISSING?

As highlighted in this review, although public health organizations recommend the development and implementation of interventions to support and inform caregivers of PWAD (Haute Autorité de Santé, 2008; World Health Organization, 2012) many of them have not yet shown conclusive results. In fact, methodological issues (Zarit & Femia, 2008) or implementation mistakes (Vernooij-Dassen & Moniz-Cook, 2014) have made it more difficult to obtain clear evidence of their efficacy. Moreover, while web-based programs represent a promising and flexible alternative for overburdened or isolated caregivers, few studies have been conducted to evaluate their efficacy (Boots et al., 2013; Godwin et al., 2013). In fact,

only four Internet-based programs have been tested using an RCT design (Godwin et al., 2013; Kajiyama et al., 2013), with a limited control of implementation error. Furthermore, in spite of the critical relevance of usability for the adoption of these programs (Chiu & Eysenbach, 2011), not all of them described this stage in the development process.

## PRINCIPAL QUESTIONS OF THE PRESENT THESIS

In this thesis we aim to contribute to the knowledge and understanding of the processes of development, evaluation, and implementation of Internet-based interventions for caregivers by considering the following: the application of a user-centered design approach, the design of an RCT protocol study founded in methodological and theoretical recommendations, and the application of mixed methods of research. The ultimate aim of this work is to better understand the process and the limits underlying the development and assessment of Internet-based interventions, the impacts and benefits for caregivers, as well as to try and answer the following questions:

1. *How can a user-centered design approach be applied to the development of the Diapason program, a web-based psycho-educational program?*

**Chapter 3** aims to clearly describe the development and adaptation of the program, from the conception until the iterative usability tests, the whole process being based on the user-centered design approach. A multidisciplinary team of health professionals participated in regular workshops, while end-users were involved during the proof of concept and the usability tests. We present the use of mixed methods for the usability tests including interviews and behavioral observations, which were compared with the results in a satisfaction survey. Results are discussed and compared to previous works.

2. *How can we design an RCT to evaluate the Diapason program?*

In **Chapter 4** we report the design process of the RCT for the evaluation of Diapason program. As a project funded by the Minister of Health, different stakeholders including clinicians, sponsors, methodological advisers and researchers participated in the study protocol design. We present in this chapter the contextual and theoretical basis for defining the protocol, as well as the hypothesized effects of the program, which formed the grounds of the selection of a set of outcomes and measuring instruments. We also describe the methodological, logistic, organizational and ethical

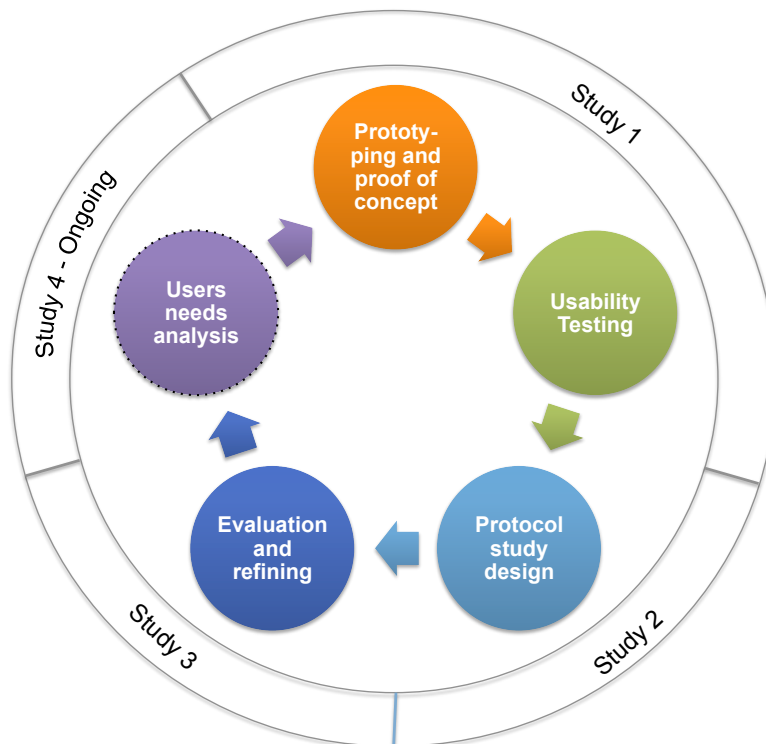
considerations required in this RCT as well as an in-depth description of the final study protocol.

3. *Is the Internet-based program Diapason useful and acceptable for caregivers of PWAD?*

The evaluation of the efficacy of the Diapason program was carried out according to an unblinded RCT among caregivers (n=49) of community-dwelling PWAD. Qualitative analysis was conducted based on interviews and open-ended questionnaires. The results of this mixed methods analysis are described in **Chapter 5**. As a perspective of this work we present in the second section of this chapter the preliminary results of an ancillary study aiming at the evaluation of the needs and expectations of caregivers towards a web-based intervention using a methodological triangulation design.

Throughout this work and in the following chapters we describe the different stages of the cyclic process for the iterative development, evaluation, and improvement of the Diapason program (Figure 9).

**FIGURE 9. STUDIES CONDUCTED DURING THE CYCLICAL PROCESS OF THE DIAPASON PROGRAM'S DEVELOPMENT AND EVALUATION**



V. Cristancho-Lacroix

## **Part II**

### Empirical and experimental work



## CHAPTER THREE

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# THE DIAPASON PROGRAM DEVELOPMENT PROCESS

As described in Chapter 2, intervention programs based on the Internet represent a promising alternative for complementing the usual care of caregivers, in particular attuning to the needs of those living in remote areas or those unavailable to follow on-site interventions. In spite of the growing interest popularity of these programs, the literature reviews revealed the scarcity of programs based on the Internet (Gallagher-Thompson & Coon, 2007; Godwin et al., 2013), and the absence of these programs in France.

Nevertheless, the implementation of these interventions turns out to be useless if the targeted groups do not use or underuse them (Chiu & Eysenbach, 2010b). Thus, the usability of programs may affect the measurability of interventions' effectiveness. As described in the previous chapter, although the user-centered design approach and usability testing are highly recommended for the iterative design of Internet-based programs, they are not systematically reported and/or applied by researchers. In this project, we adapted the usability and end-user centered design approach to the development of the Diapason program. Our main concern was the improvement of the accessibility and usability of materials (content and website) for older caregivers having less experience with the Internet, as well as cognitive, sensorial, and perceptual deficits associated to normal aging.

In this chapter we describe the background, aims, and contents of the Diapason program designed by a multidisciplinary team. In the second part of this chapter we describe the iterative user-centered design approach used for the development and adaptation of the Diapason program.

## BACKGROUND OF THE DIAPASON PROGRAM

Between 2004 and 2008, the professionals of the Broca hospital conducted a clinical trial to evaluate the effects of a psycho-educational program called AIDMA (de Rotrou et al., 2010) (described in Chapter 2). The findings showed that caregivers who received the program significantly improved their knowledge and their ability to cope with caregiving difficulties ( $p < 0.05$ ) in comparison with the control group. This program was revised, and is still proposed to families of PWAD, in the form of six weekly sessions at the memory center of the Broca hospital.

In spite of benefits for various caregivers, De Rotrou and her colleagues (2010) noted that some of them were less available and less likely to be present at every session, and dropped out of the study or did not complete the program. After a literature review of Internet-based caregiver support interventions (Rigaud et al., 2011; Wu, Faucounau, de Rotrou, Riguet, & Rigaud, 2009), they adapted and designed an Internet-based program for caregivers of PWAD. Several professionals (i.e. physicians, psychologists, speech language therapists, nurses, social workers, occupational therapists, among others) participated in writing the contents, making or performing in the videos, and providing interviews for the program. Caregivers were also involved in this process, as described in the second part of this chapter.

## TARGET GROUP DEFINITION AND CAREGIVERS' NEEDS

The Diapason program was designed for the informal caregivers (family members or friends) who prefer or are more available for an online program rather than for face-to-face support programs proposed at the hospital as a complement to the usual follow-up. The needs of this target group were informally identified based on experiences of healthcare professionals, during the AIDMA study. Caregivers who improved their understanding of cognitive and behavioral symptoms reported feeling less stressed and anxious. During the program they were frequently in search of information and counseling, particularly on *“how to stabilize patients' condition, what to propose to the patient at home, how they can stimulate him/her in order to maintain residual resources. They are also in search of psychological and financial support”* (de Rotrou et al., 2010, p.8).

In fact, the literature describes similar results. Caregivers wish to receive further information and skills to better cope with caregiving demands (Amieva et al., 2012). Moreover, the lack of understanding of their relative's reactions frequently leads to distressing emotional reactions

(i.e. guilt, anger, anxiety, and depression) (Vernooij-Dassen, Draskovic, McCleery, & Downs, 2011b; Zwaanswijk, Peeters, van Beek, Meerveld, & Francke, 2013). A second goal of the team was to maintain and reinforce the social network, and the help-seeking behaviors of caregivers. In fact, stress, burden, and depression are more frequent in caregivers with a perceived personal time restriction or a poor social support (Croog, Burlison, Sudilovsky, & Baume, 2006; Lai & Thomson, 2011; Rodakowski, Skidmore, Rogers, & Schulz, 2012).

## CONTENT OF THE DIAPASON PROGRAM

While being aware that this online intervention could not respond to all the needs and wishes of caregivers, the team defined the main aims of Diapason as the following: reducing caregivers' stress, favoring their self-care, self-efficacy, social support, and help-seeking behaviors. The contents and strategies were inspired by a cognitive approach, matching the main concepts of model of stress and coping of Lazarus and Folkman (Lazarus & Folkman, 1984) and self-efficacy of Bandura (Bandura, 2009).

Thus, the contents were focused on: a) **caregivers' beliefs**, about the illness and the caregiving role, b) **caregivers' skills**, to manage daily life difficulties, and to improve communication with the relatives, and c) **caregivers' social support and help-seeking behavior**, giving information that may help caregivers obtain respite or financial support if necessary, as well as offer a space to meet and discuss with other caregivers through a private and anonymous forum. Table 7 summarizes the action fields, the targeted areas, the strategies, and some examples of the program's content.

The Diapason program retained the same structure as the AIDMA program, providing a new topic every week once the previous one was validated. The twelve sessions were run in sequential topics. Every one of them included theoretical and practical information, videos of health professionals, and at the end of every session a practice guide for applying the session's content in real life (e.g. in "Avoiding falling" session we recommend caregivers to list the physical risks of falling in their relatives' home based on the session information) was proposed.

**TABLE 7. OVERVIEW OF DIAPASON PROGRAM CONTENTS**

<b>Action fields</b>	<b>Targeted area</b>	<b>Program strategy</b>	<b>Example</b>
<b>Beliefs</b>	Knowledge and beliefs about the illness (AD)	Giving clear information on illness progression and causes	Videos of specialists explaining AD symptoms
	Knowledge and beliefs about patients' emotional and behavioral problems	Offering strategies to understand patients' reactions  Guiding the CGs to explore optional reactions adapted to their relative	Explanation on why the relative becomes aggressive by analyzing situational and individual factors
	Beliefs about « caregiving role » - Reducing CGs' feeling of guilt	Affirming and reinforcing help-seeking behaviors	In the stress management session, explanation on why CGs should ask for help and consult a physician when necessary
<b>Skills</b>	Self-efficacy to manage patients' emotional or behavioral problems	Providing practical advice to manage critical situations in daily life	The section "Caregivers' stories" shows realistic scenarios of frequent problems and proposes ideas on how to react
	Self-efficacy to manage their own emotional or behavioral reactions	Providing practical advice to cope with stress, strain, and anger	The relaxation training includes guidelines and videos for different types of relaxation
<b>Social support</b>	Help-seeking behavior	Providing information on state subsidies and public organizations offering respite	A list of public institutions which support patients and their families is provided
	Networking and Social support	Providing reasons and advice to obtain more social support	A forum to discuss with peers on their respective experience and feelings

CG= Caregivers, AD= Alzheimer's disease.

Source: Cristancho-Lacroix et al (submitted)

In brief, the twelve sessions of the program are:

- a) **Session 1. Caregiver stress.** This session presents a definition of stress, its causes and consequences on caregivers, the risk factors for chronic stress, and the mechanisms and effects of relaxation (includes a link towards the relaxation training in the Diapason website), as well as strategies for managing stress, underlining the importance of looking for respite.
- b) **Session 2. Understanding the disease.** In this session the Alzheimer's disease diagnosis procedure, the symptoms, and the progression of the illness, as well as the consequences on daily life activities for PWAD, are explained.
- c) **Session 3. Maintaining the loved-ones' autonomy.** This session presents the reasons and strategies to involve the loved-ones in their process of care, to stimulate the preserved functions and compensate for the lost ones. The session underlines the importance of maintaining the self-esteem of PWAD.
- d) **Session 4. Understanding their reactions.** In this session, the most frequent BPSD, as well as their characteristics are succinctly described and illustrated by examples from daily life. The contextual and intrinsic factors that might be associated to them are also described.
- e) **Session 5. Coping with behavioral and emotional troubles.** This session presents practical advice on how to cope and react vis-à-vis the BPSD described in the previous session.
- f) **Session 6. Communicating with loved-ones.** This session includes the description of the most frequent language troubles and the strategies to modulate and adapt communication to the preserved skills of PWAD.
- g) **Session 7. Improving their daily lives.** This session presents strategies to facilitate the performance of activities that become difficult or impossible to execute due to apraxia troubles, illustrating them with examples adapted to daily life.
- h) **Session 8. Avoiding falling.** The session includes practical advice for maintaining and stimulating the relative's balance, and actions to adopt in case of falling. In addition various actions are described to adapt the relative's home.
- i) **Session 9. Pharmacological and non-pharmacological interventions.** This session includes a brief presentation of different interventions available for caregivers in France, with pharmacological treatment as well as cognitive and psychological support.

- j) **Session 10. Social and financial support.** This session presents the different stakeholders and services that may help caregivers in daily life. The financial and social support provided by the French government is also overviewed.
- k) **Session 11. About the future.** This session explains to caregivers' the role of anticipation of the disease progression, inviting them to try and foresee solutions keeping a prospective vision, encouraging them to look for further sources of information, and social support, in order to reduce the uncertainty of caregiving situations (described in Chapter 1).
- l) **Session 12. In a nutshell.** The last session encompasses a summary of the Diapason program, emphasizing the acceptance of support and help, and the importance of obtaining more information to anticipate and avoid stressful circumstances.

Additionally the website contains other sections which can be consultable at every moment:

- I. **Relaxation training:** guidelines for learning relaxation, as well as two videos for the modeling of Schultz's Autogenic Training and Jacobson's method,
- II. **Life Stories:** stories about four couples of spouses, written based on testimonials of caregivers, in which difficult situations are illustrated, and possible solutions to manage them are discussed (e.g. apathy of patient, caregivers' isolation),
- III. **Glossary:** a glossary for technical words (e.g. neuropsychological assessment, aphasia),
- IV. **Stimulation:** practical activities to stimulate autonomy and share pleasant activities with the relatives in daily life, and
- V. **Forum:** a private and anonymous forum to discuss with peers, to express their concerns, discuss solutions to daily problems, share their feelings and experiences. The participants use nicknames to protect their privacy. A clinical psychologist participates in discussions if necessary (i.e. avoiding aggressive or inappropriate commentaries).

## TO SUMMARIZE

Based on the taxonomy proposed by Zarit, Czaja et al (2010) the delivery and contents characteristics of the Diapason program are summarized as follows (Appendices 1 and 2).

Diapason is an Internet-based program, delivered in an individual fashion, to be used at home by the participants. The length of the intervention is 3 months, with 12 weekly sessions that individually last 15 to 30 minutes on average, but there is no time limit and the participants may access the website as much as they want. In order to guarantee the homogeneity of the program, the professionals received a specific protocol concerning the contact with the participants, adapted for the research. Moreover, the program is fully automated. Only forum contents are updated depending on topics addressed by participants. In the future, a more active participation of professionals in the forum could be easily implemented. In order to measure the implementation characteristics, the website was coded to calculate the time and rate of the program's utilization anonymously. The strategies of the program were the provision of information, skill-building techniques, stress-management techniques, and facilitation of social support. The key processes and goals were to improve the ability to assess risks/goals, increase caregivers' knowledge, behavioral skills, problem-solving skills, self-efficacy, and social support.

The latest version of the Diapason program is the result of an iterative and participative process described in the next section. In that order, we conducted a proof of concept, two usability tests and multiple workshops, in which end-users and professionals were at the core of the process and decisions.

## ITERATIVE USER-CENTERED DESIGN OF DIAPASON PROGRAM

### (PAPER 1)

The following article was published in September 2014 in the *Journal of Medical Internet Research: Research Protocols*. The material cited in the paper (i.e. questionnaires, interview guide) is available in Appendices 4-7.

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Original Paper

# A Web-Based Program for Informal Caregivers of Persons With Alzheimer's Disease: An Iterative User-Centered Design

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## Abstract

**Background:** Web-based programs have been developed for informal caregivers of people with Alzheimer's disease (PWAD). However, these programs can prove difficult to adopt, especially for older people, who are less familiar with the Internet than other populations. Despite the fundamental role of usability testing in promoting caregivers' correct use and adoption of these programs, to our knowledge, this is the first study describing this process before evaluating a program for caregivers of PWAD in a randomized clinical trial.

**Objective:** The objective of the study was to describe the development process of a fully automated Web-based program for caregivers of PWAD, aiming to reduce caregivers' stress, and based on the user-centered design approach.

**Methods:** There were 49 participants (12 health care professionals, 6 caregivers, and 31 healthy older adults) that were involved in a double iterative design allowing for the adaptation of program content and for the enhancement of website usability. This process included three component parts: (1) project team workshops, (2) a proof of concept, and (3) two usability tests. The usability tests were based on a mixed methodology using behavioral analysis, semistructured interviews, and a usability questionnaire.

**Results:** The user-centered design approach provided valuable guidelines to adapt the content and design of the program, and to improve website usability. The professionals, caregivers (mainly spouses), and older adults considered that our project met the needs of isolated caregivers. Participants underlined that contact between caregivers would be desirable. During usability observations, the mistakes of users were also due to ergonomics issues from Internet browsers and computer interfaces. Moreover, negative self-stereotyping was evidenced, when comparing interviews and results of behavioral analysis.

**Conclusions:** Face-to-face psycho-educational programs may be used as a basis for Web-based programs. Nevertheless, a user-centered design approach involving targeted users (or their representatives) remains crucial for their correct use and adoption. For future user-centered design studies, we recommend to involve end-users from preconception stages, using a mixed research method in usability evaluations, and implementing pilot studies to evaluate acceptability and feasibility of programs.



**KEYWORDS**

usability; caregivers; Alzheimer's disease; psychoeducational program; psychological stress inclusive design

## Introduction

### Background

Psycho-educational interventions have shown benefit in relieving the burden of caregivers of people with Alzheimer's disease (PWAD), and associated manifestations of caregivers' distress [1,2]. However, these programs are often implemented on-site in individual or group sessions, and may thus not be available for many caregivers who are overwhelmed or isolated, are unwilling to resort to available community help [3], live in remote regions [4], or are still in active life.

With the proliferation of information and communication technologies, there has been a growing interest in developing distance-based interventions that might be useful for this particular population of caregivers. Internet-based interventions have shown promising improvements in psychological [5-7], and physical outcomes [8]. Among these interventions, Web-based programs have shown to better respect the caregiver's privacy and respond to availability issues than telephone-based interventions [9]. Moreover, the recent assessment report of the French Alzheimer's Plan 2013 [10] recommends the use of Web-based interventions in order to inform and support family caregivers.

### User-Centered Design Approach

However, one limitation of Web-based programs resides in the obstacles caregivers face adopting and making correct use of them [11]. The majority of caregivers of PWAD are over 65 years of age [12]. The typical changes accompanying aging (sensorial, perceptive, cognitive, and motor age-related declines), make it even more difficult for them to interact with technological systems [13]. Moreover, most of the older adults are also limited by their narrow experience with the Internet and by the lack of usability of some websites [14]. These aspects have been taken into consideration during the development process of our Web-based program.

In fact, the user-centered design approach fosters the conception of accessible products, and targets the needs of end users. Usability testing is a user-centered design method, which aims to identify the problems users are confronted with when using (technological) products, and to find the means of solving them [13]. To our knowledge, despite the benefit of usability testing in favoring the adoption and correct use of Web-based programs intended for caregivers of persons with dementia, few authors reported the use of this method or the adoption of a user-centered design approach in the development of their programs [6]. In contrast, usability studies are more frequent for programs

targeting other populations, such as adolescents with overweight [15], or patients with chronic obstructive pulmonary disease [16]. To our knowledge, this is the first published work describing the user-centered design applied in the development of a program for caregivers of PWAD before it is tested in a randomized clinical trial.

### The Present Study

In fact, we aimed the application of user-centered design approach in developing a fully automated Web-based psycho-educational program called Diapason. This program was adapted from a face-to-face intervention, developed and tested by our team in order to reduce or prevent caregivers' stress [17]. The Diapason program delivers: (1) disease information in twelve weekly sessions, (2) relaxation guidelines with training videos, (3) caregivers' testimonials, and (4) stimulation activities for the relatives. This program is available in a free fully automated computerized and password-protected website. In this paper, we describe the iterative process that allowed for the adaptation of the program's content and design.

## Methods

### Design

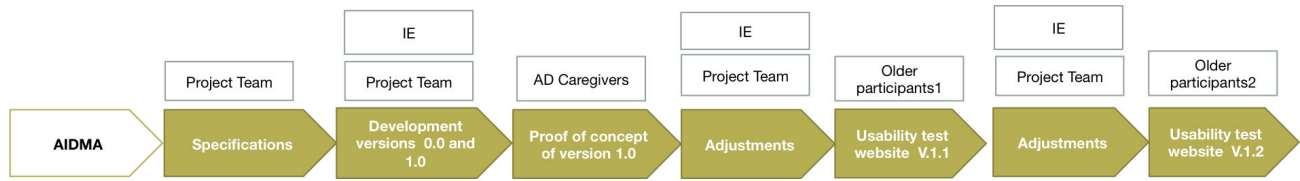
This was an exploratory-descriptive study, which consisted of a double iterative design allowing for the adaptation of the content and usability of the website. A group of health professionals (project team) participated in the iterations for determining the content, layout, and program design in the different stages of development through the workshops. In parallel, we conducted a proof of concept with caregivers and two usability tests with healthy older adults. The latter were based on a mixed research method with a convergent parallel design. Indeed, the protocol of the usability tests consisted of qualitative and quantitative data that were collected concurrently, but analyzed separately, and finally merged during the interpretation [18]. We used this method in order to obtain a more comprehensive analysis of data, and to raise the reliability of results. All the participants gave their written informed consent prior to their inclusion in the study.

### Diapason Program Development Process

#### Overview

The program development process took place from 2009 to 2011 and included the following component parts: (1) design and development of the first two versions of the website, (2) proof of concept, and (3) two iterative usability tests (Figure 1 shows the development process).

**Figure 1.** Face-to-face program, AIDMA=Aide dans la maladie d’Alzheimer, AD=Alzheimer’s disease, IE=Informatics engineer.



**Project Team Workshops**

**Participants**

The project team comprised twelve health care professionals and researchers who participated in the regular meetings, 2 physicians, 8 psychologists, and 1 sociologist, all from the same geriatric department, as well as an informatics engineer.

**Procedure**

Throughout the whole development process, two psychologists (FM or VCL) moderated and conducted regular workshops in an informal setting with the project team. During each workshop, their specifications and recommendations were collected by one of the moderators. Based on their feedback, the informatics engineer built the website prototype (V.0.0), and its successive versions for the proof of concept and usability tests.

In addition, the project team analyzed the offline prototypes during the workshops. The analyses were focused on the following criteria inspired from usability guidelines [13,14,19,20]: (1) avoiding technical terminology (neither medical- nor informatics-related); (2) ameliorating accessibility for nonexperienced users, providing a familiar look (eg, looking like a printed notebook); (3) improving readability (including font size and contrast); (4) facilitating navigation (eg. providing visual cues); and (5) adapting the content to the target users (privileging condensed, clear, quick, and easily accessible information).

**Proof of Concept**

**Participants**

We recruited six informal caregivers of PWAD who attended the memory clinic, including three children, mean (SD) age

50.3 (12.4) years, and three spouses, mean (SD) age 73.4 (7.5) years, having at least once used the Internet. A purposive sampling approach was used to recruit the same number of children and spouses. Purposive sample techniques involve selecting certain units based on specific purposes rather than randomly. These techniques are used when the researcher wants to “set up a comparison between different types of cases”; it allowed us to compare the opinions of younger and older users about the program.

**Procedure and Evaluation Tools**

Each participant received a clear explanation of the program’s aim, and then browsed the Diapason website offline v1.0. After that, a semistructured in-person interview carried out by a psychologist (≈ 40 minutes) was recorded in order to evaluate the opinions of caregivers. Semi structured interviews have a flexible and fluid structure, organized around an interview guide [21]. Questions regarding website usability and appearance were covered in the course of the interview.

**First Usability Testing (Test 1)**

**Participants**

As mentioned in the Introduction, since older people experience more difficulties with Internet use than other caregivers, we targeted them for usability testing. In order to avoid the learning bias, we recruited two different groups for each prototype version. There were 16 self-reportedly healthy persons 60 years and older (age mean 73.81, SD 7.03), having at least once used the Internet, that were recruited from three seniors associations in Paris. Sociodemographic information is summarized in Table 1.

**Table 1.** Sociodemographics of usability test participants.

Characteristics	Test 1 mean (SD) or n (%)	Test 2 mean (SD) or n (%)
<b>Participants gender</b>		
Male	4/16 (25)	2/15 (13)
Female	12/16 (75)	13/15 (87)
Participants age (years)	73.81 (7.03)	72.12 (7.03)
Internet experience (years)	8.32 (6.79)	8.91 (8.07)
Frequency of Internet use (days per month)	25.31 (10.22)	22.33 (10.32)

**Procedure and Evaluation Tools**

A research psychologist conducted a one hour individual usability test with each participant. The session was divided into four steps:

1. The participant filled out a questionnaire on sociodemographic data, Internet experience, and the monthly frequency of Internet use.
2. The participant was asked to follow written instructions (Textbox 1) of navigation on the offline version of v1.1 (Figure 2 shows this version) using a “think aloud” method

- [22]. In the “think aloud” method, which is common in usability testing, the users are asked to think aloud while using the system, allowing the evaluator to understand what they are doing and the reasons for their actions [13]. The five tasks were selected to cover the main functions of the website. The test sessions were video-recorded for a behavioral analysis. Moreover the psychologist noted the participant’s mistakes, difficulties or comments, and avoided to interfere with the evaluation.
- The participant’s opinions of website usability were assessed with a five point Likert scale (0= negative to 4= positive) designed by our team (VCL). The survey evaluated five topics: (1) overall impression about the website; (2) easy-to-use perception; (3) pleasant to use perception; (4) coherence of website layout; and (5) satisfaction with the website design (font, colors).
  - At the end, the participant was asked to answer a semistructured interview on the following topics: (1) positive and negative aspects of the website, (2) difficulties when using the website, (3) discomforting situations during navigation on the website, and (4) advice to improve the appearance and design.

**Textbox 1.** Five step usability test.

- Please enter to the website: [www.etreaudiapason.com](http://www.etreaudiapason.com)
  - Username: *Participant*
  - Code: 123456
  - Go back to the home page
- Go to the session “*Managing the caregivers stress*”
  - Watch the video “*caregiving-related stress*” and change to full-screen
  - Go back to the home page
- Search the glossary
  - Read the meaning of the word “*hippocampus*”
  - Go back to the home page
- Go to the stories
  - Read the story of “*Lucia*”
  - Go back to the home page
- Go to the forum
  - Post the message: *I’m using Diapason*
  - Go back to the home page

## Second Usability Testing (Test 2)

### Participants

We recruited 15 healthy volunteers over 60 years old, age mean 72.12; SD 7.03, through three seniors associations in Paris. They had at least once used the Internet. Sociodemographic information is summarized in [Table 1](#).

### Procedure and Evaluation Tools

With the second usability test, we evaluated the offline v1.2 ([Figure 2](#)). The protocol was identical to the first usability test.

### Analysis Methods

Qualitative data from the workshops (ie, moderator’s notes), the proof of concept (ie, interviews), and the usability tests (ie, interviews and mistakes, difficulties or comments; observed

and collected by the evaluator) were analyzed based on the thematic analysis method [23]. After being familiarized with data JW and VCL coded the relevant extracts of material concurrently. Then, they analyzed the themes based on the recommendations of various usability authors [13,14,24,25]. Finally, they corroborated the pertinence of the selected topics, comparing them with initial verbatim.

Assisted by the software “The Observer XT” and an observation grid, two trained psychologists (VCL and JW) collected, coded, and analyzed videos of usability tests. We measured the frequency of mistakes, requests for help, and the duration of task performance.

Finally, we analyzed the satisfaction survey results using descriptive statistics.

Figure 2. Diapason website program versions.



Results

Participants

In total, 49 persons were involved in the Diapason program development: 12 health care professionals, 6 caregivers, and 31 healthy older adults. The development process resulted in four successive website versions as shown in Figure 2 for which the qualitative results of the iterative design are provided in Table 2.

Qualitative Results

Project Team Workshops

The results of the first workshops showed that most professionals were motivated by the new project. They proposed interesting and creative ideas to develop the Web-based program. They stated that the Diapason program should be made easily and rapidly accessible to overwhelmed caregivers who may have only fifteen or twenty minutes to spend with the

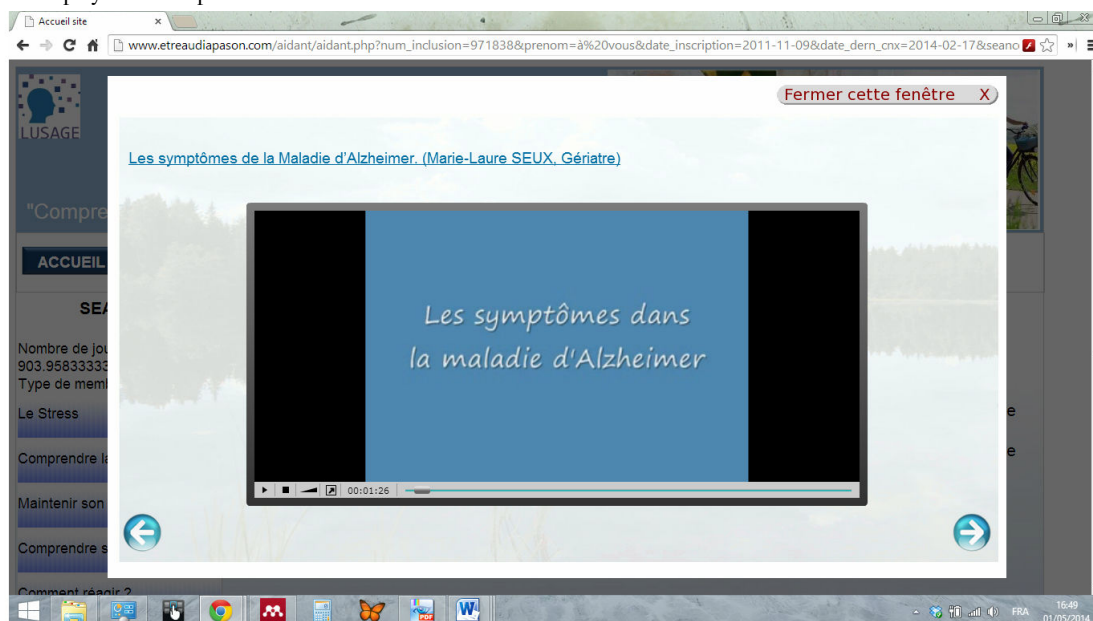
program. Some professionals also expressed concerns about the suitability of Internet use for caregivers, since most of them were spouses of patients and likely inexperienced with this technology. Some also thought that computers might increase caregivers' isolation.

Based on the criteria selected by the team (described above in the Procedure of Workshops), the website v0.0 was not retained. The content was too long, complex, and technical for nonprofessionals. The appearance was dark, sad, and stigmatizing (Figure 2). As for v1.0, the project team suggested the use of a more "common" language for the button sections. They also recommended using a "light box" effect, to facilitate navigation (Figure 3 shows this display). Concerning v1.1, the team found "My journey" functionality unnecessary or infeasible. It was also suggested to add a "Relaxation training" in the program. As regards v1.2, the professionals supervised the consistency of changes made by the informatics engineer on the website following the demands of end-users, and prioritized them, based on their feasibility and relevance.

**Table 2.** Qualitative results.

Website version	Category	Problem reported	Actions and/or solutions
<b>PT<sup>a</sup> workshops</b>			
0.0	Readability	Content too complex, using technical jargon	Contents were simplified, avoiding medical or informatics jargon
		Content too long, adapted for professionals caregivers	Contents and the layout were reedited
	Appearance	Black and gray colors, photo suggestive of sadness	The website was redesigned with “flashy” colors
<b>Proof of concept and PT<sup>a</sup> workshops</b>			
1.0	Readability	Low contrast between characters and background of some website pages	The color of website background was modified
		Font size too small (12 point)	The font size was increased (16 point)
		Unfamiliar terminology	The terms were replaced, eg, “resources” by “document”, “search engine” by “glossary”, “me/he/she” by “life’s testimony”, among others
Ergonomics	Complex actions to access the “sessions”	Action was simplified	
<b>Usability testing #1 and PT<sup>a</sup> workshops</b>			
1.1	Ergonomics	Participants clicked twice on the hyperlink, but flash screen closed with the second click	Explanation in the Internet and printed user manual
		Lack of an icon to close the flash screen	Add the icon “close this window”
		Small characters at the forum section	[no quick solution]
		“Send the message” option is at the bottom of the website, and requires use of the vertical scrollbar	[no quick solution]
		Some participants are not familiar with video-player icons	Explanation in the Internet and printed user manual
<b>Usability testing #2 and PT<sup>a</sup> workshops</b>			
1.2	Ergonomics	Dimensions of the website vary depending on Internet browser and computer models	[no quick solution]
	Navigation	Hyperlinks text was unfamiliar for some of participants	Explanation on the Internet and in a printed user manual

<sup>a</sup> PT = project team

**Figure 3.** Screen display in the Diapason website.



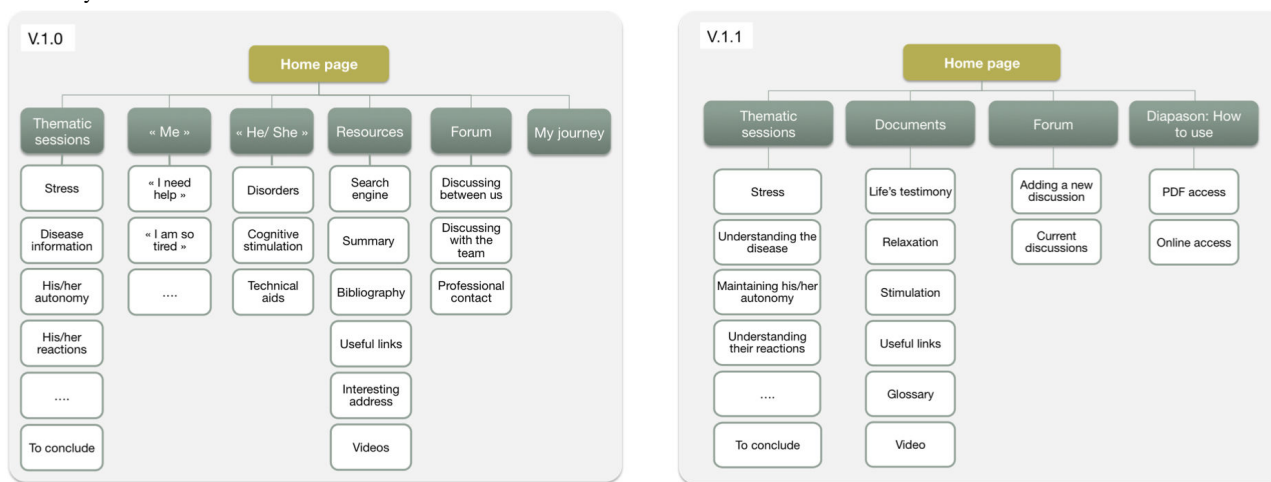
## Proof of Concept

### Overall Opinion of Caregivers

The caregivers found the website prototype (v1.0) clear and understandable. All of them, and especially the PWAD's spouses, appreciated the aims, the topics, and the website's layout. Although the participants thought the Web-based program likely to be useful for isolated caregivers, most of them underlined the need to communicate with professionals and to maintain face-to-face contact.

The suggestions to change the look (adding photos and modifying colors) were implemented in the following version

**Figure 4.** Layout for versions 1.0 and 1.1 - PDF=Portable document forwards.



### Font Readability

The younger caregivers found the font size too small and thought it would constitute an obstacle for older users. By contrast, older participants did not raise this issue, but reported that some pages were difficult to read due to the lack of contrast between the background and the font. In the subsequent version (v1.1) the font size was increased and the contrast enhanced.

### Ergonomics

To access the sessions, the user had to click on a button, and then confirm their choice by clicking on another one. This condition was simplified.

### Simplified Layout

Based on the project team and on caregivers' suggestions, the website's layout was simplified (Figure 3). The version v1.1 and the final version only offered three main sections: (1) thematic "sessions", (2) a "forum", and (3) the "documents" providing access to other content (eg, relaxation or glossary).

Unfortunately the option "contact a professional" and the videoconferencing options were not implemented, owing to a lack of resources. Moreover, the section "My journey", a private diary for caregivers, was removed because the system could not encrypt the data.

### Usability Test of v1.1

In this version, the overall program content was added to the website. Moreover, the readability improvements performed

(v1.1). Moreover, the caregivers pointed out important usability issues.

### Unfamiliar Terminology

Although the project team aimed to avoid jargon (from informatics or medical areas), some of the terms used remained confusing for the participants in this version. For instance, the "Resources" button (ie, "Ressources" in French), giving access to additional sections (eg, relaxation training, glossary, etc), was understood as giving access to financial help. Consequently, the website was reorganized, and potentially confusing words or expressions were replaced by more commonly used website terminology (Figure 4 shows this layout).

during the proof of concept phase were appropriate, as no participant reported any visual discomfort while browsing the website (except for the forum, as described in this section). Concerning the easy-to-learn perception, many participants asserted that they would have performed better if they had used the website more than once.

*Using the website would be easy provided I received training or that I spend more time using it. [Mrs. H, 71 y/o]*

However, various ergonomics issues were identified. Although the website home page was kept accessible using a script (jQuery Superbox) to display a screen with a light box effect (Figure 3), most participants did not know how to go back to the previous page.

*To go back to the home page sometimes I had to click in a grey zone or sometimes click on the close button, this is not practical. [Mme GG, 69 y/o]*

To correct this, we added an icon at the top right of the screen with the message "Close this window" (in Figure 3, the button "Fermer cette fenêtre"). Some other issues remained unsolved due to technical or logistical reasons: (1) the font size and symbols in the forum and video-player interfaces did not facilitate reading; (2) the post button for forum messages was at the bottom of the screen, requiring the use of the scrollbar; and (3) the least experienced participants often double clicked in the website, which was in conflict with the one-click activated "light box" effect, as the second click immediately closed the

window. For each of these problems, a clear explanation was provided in the user's manual.

**Usability Test of v1.2**

There were two additional problems that were identified during the second usability test. The website display varied according to the Internet browser and/or the computer model, and some participants did not know how to use the hyperlinks in the website. We adapted the Internet and printable version of the user's manual, taking into account the results of both usability tests, including the issues without a quick or easy solution (Table 2).

**Additional Findings From the Usability Tests**

Although during the usability tests the evaluators found most of the problems reported by users in the interviews, the evaluators also identified additional problems regarding the computer interface, and the Internet browsers. The mouse cursor and the scrollbar were not visible enough on the screen (lack of contrast or small size), and some participants did not distinguish the website settings from the Internet browser or

computer interface. For instance, a participant recommended changing the order of icons of the Internet browser because he thought that the latter was part of the website. When asked to go back to the "home page" of the website, another participant closed the browser window, then could not find, unaided, the icon of the Internet browser to continue the task. These problems were observed even for the people with more than one year of experience of Internet use.

**Quantitative Results of Usability Tests**

**Behavioral Analysis of v1.1 and v1.2**

There were two psychologists using an observation grid who analyzed the videos of usability tests sessions with The Observer TX. The three main variables analyzed are presented in Table 3: (1) the duration of the task, (2) the total of errors, and (3) requests for help during the evaluation. We observed an important reduction in completion time and the total of requests for help after the website improvements were made between the first and the second iteration. However, the overall number of errors remained similar in the two versions, possibly owing to unsolved usability problems.

**Table 3.** Total performance in five step usability test (for v1.1 and v1.2).

Usability tests	Mean task completion time, seconds	Total group errors (n*error) <sup>a</sup>	Total group requests for help (n*help) <sup>b</sup>
v1.1, n=16	1866.14	103 (15)	36 (6)
v1.2, n=15	1042.40	96 (15)	5 (4)

<sup>a</sup> n\*error, number of persons who made at least one error

<sup>b</sup> n\*help, number of persons who asked for help

**Usability/Satisfaction Survey**

As shown in Table 4, the two website versions yielded similar scores. Overall the participants' opinions of the website were positive. The lowest scores were for the system's "ease of use". A plausible explanation was that most of the participants

evaluated website ease of use for themselves, but not for other seniors. During the semistructured interviews, the most prominent argument was that the "other seniors" might be in poorer health and cognitive status than the participant himself. This suggests that this item reflects the participants' perception of older adults more than their experience using the website.

**Table 4.** Results of the usability/satisfaction 5 Likert questionnaire.

Satisfaction questionnaire items	Version 1.1 mean (SD)	Version 1.2 mean (SD)
Overall website evaluation	3.19 (0.54)	2.80 (0.68)
Easy-to-use	2.75 (0.68)	2.47 (1.06)
Pleasant to use	2.94 (0.68)	2.60 (0.63)
Website structure	3.31 (0.70)	3.13 (0.83)
Website layout	3.07 (0.70)	3.00 (0.76)
Website font	3.19 (1.05)	2.87 (1.06)
Website colors	3.19 (1.28)	3.67 (0.40)
Overall mean score	21.63 (2.90)	20.53 (3.40)

**Discussion**

**Program Development**

In this paper, we describe the iterative development of a Web-based psycho-educational program (Diapason) aiming to

reduce or prevent stress in caregivers of PWAD. To our knowledge, this is the first published work describing a user-centered design process for the development of a program addressed to caregivers of PWAD. To that end, we involved end-users and health care professionals in a double iterative design, allowing for a cyclic adaptation of the content and design

to the targeted population. During the whole process, our project team elaborated tailored guidelines for the engineer's mission, based on their own professional experience, but also taking into accounts the feedback from end users.

In fact, the involvement of end-users was decisive in the development of our program. The caregivers and healthy older adults pointed out various website usability deficiencies which had been unnoticed by the professionals. In agreement with the user-centered design approach, our aim was to prevent users lacking the necessary cognitive (experience or abilities) or physical resources from having to deal with the maladjusted and imposed technology devices [13]. Various authors have demonstrated the relevance of this approach to design eHealth interventions. For instance, Chiu and Eysenbach [11] found that caregivers attracted to a service which they considered useful, could eventually stop using it if they perceived the service as nonuser-friendly. Furthermore, focusing on caregivers' needs (and their representatives) during the development process is a critical aspect for the acceptability and adoption of interventions [6].

### Principal Findings

The Proof of Concept evaluated the program's content and website usability, and was carried out with a group of caregivers of PWAD, consisting of children and spouses. As hypothesized by our team, and in accordance with the literature [13], the difficulties linked to usability issues were preeminent in older participants. Thus, the usability tests were focused on adapting the program in a senior-friendly website. As a consequence, we decided to privilege the recruitment of a group of healthy older persons rather than the (overwhelmed) caregivers for usability tests.

In order to obtain a more comprehensive appraisal of usability tests' results, we designed a mixed research method combining behavioral analysis with think aloud method, individual interviews, and questionnaires [13]. In this study, the questionnaire was the least sensitive and informative of the three methods. A plausible explanation is that closed-ended questions offer answers on "what" the users' opinions are, or "how" difficult the website is to use, but they do not give information as to "why" this might be. For example, researchers may obtain information on the degree of disagreement about an item, but not "why" the subject disagrees with it. In contrast, interviews and behavioral analysis (using thinking aloud) provided us with valuable and accurate data about the difficulties that users encountered in the website. For instance, additionally to usability issues described elsewhere, we observed that the participants confused the website and the Internet browser interfaces, and some had many difficulties with the computer interface or Internet browser themselves. As stated by Nielsen, even the most recent and popular operating systems Interfaces could present important usability issues, which entail cognitive overhead and add memory load [26]. Therefore, designers and evaluators of website usability should effectively disentangle website conception issues from problems due to computer and Internet environments (eg, Windows 8, Internet browser...).

It is also noteworthy that most of the older adults who filled out the satisfaction questionnaire during usability tests considered

the website easy-to-use for them, but not for other seniors. They argued that they thought about older adults with poorer health and more perceptual and cognitive deficits than themselves. This result matched those of previous studies by our team [27]. In both projects we explained to the participants (older adults) that the study aimed to identify their needs to create a senior-friendly technology. As described in this study, older adults rarely identified themselves as the "target" of gerontechnology, which was not intended for them, but for "other" older adults who may be (much) older, frailer, and more isolated than they are. This attitude may be due to "negative self-stereotyping", described in the literature [28,29]. In our study, children of PWAD (see in Proof of Concept section) also expressed this stereotyping of aging people. These results prove the advantage of observation methods, which provide an objective basis for the (un)necessary improvements.

As regards the program's content, the project team designed the Web-based Diapason program based on the Aide dans la Maladie d'Alzheimer (AIDMA) program content, retaining the most pertinent information and making it more accessible and easier to use. In fact, the AIDMA program was proposed in 2 hour face-to-face sessions, while we adapted the Web-based program to be used 15-20 minutes per week. Nevertheless, slight changes in topics were required through the development process, since some of them had already been tested by our team in the AIDMA project [17], and improved based on professionals' and caregivers' feedback.

Finally, although most of the professionals and end-users judged the Web-based program likely to be useful for isolated caregivers, some of them also worried that these interventions might increase (or reinforce) caregivers' isolation. We also encountered health care professionals who rule out the use of technologies and claim face-to-face interventions are the only way to help patients and their families. In our team, even if we recommend the use of face-to-face interventions, we also consider it appropriate to propose additional support for caregivers or for patients who cannot benefit from on-site psycho-educational programs.

### Limitations and Lessons Learned

The acknowledged limitations of the present work might be useful for methodological and logistic considerations in future projects. First, even if our usability questionnaire was more adapted to our project context, it did not include items intended to measure "learnability" and "usefulness" perceptions [30], instead, we conducted the interviews at the end of the evaluations exploring these constructs. To improve the analysis of both dimensions, we recommend to conduct a field study during the development process, such as pilot tests in which the users have access to the program for one or two weeks [31]. In fact, these two measures would be valuable if some usability issues remained unsolved, as in our study. The difficulties encountered by the users may demand a learning process, and the developer has to know whether the website facilitates this process. Additionally, a pilot test may be a reassuring step before a clinical trial.

In this work, the involvement of both professionals and end-users was critical to develop a ready-to-use eHealth program



[13,14,32]. Moreover, this work provides additional arguments supporting the effectiveness of using usability guidelines to increase Internet accessibility for older adults [20]. Nonetheless, based on our current knowledge about website usability for seniors, we think that some ergonomic mistakes in the first versions of our website could have been prevented earlier in the development process, with the help of an expert in ergonomics at these stages. For instance, we recommend avoiding the use of open source “ready-to-use” programs, since they do not always respond to the universal design criteria.

Finally, and in accordance with other studies [20], our findings highlighted the relevance of using a mixed method approach, combining subjective and objective methods, such as observation analysis and interviews, to obtain complementary data.

## Conclusions

The implementation of Web-based programs requires the adaptation of the system, including content and ergonomics, to match the needs of target populations. In fact, even when the content and aims are well established and tested, the face-to-face programs need to be reviewed and adapted for Internet use. Only the optimal usability and readability of interventions may prevent the underuse or incorrect use of these programs. Through usability iterative evaluations, the latest website version of our program has been improved, and is currently being tested in a randomized clinical trial [33]. For future user-centered design studies we recommend the following: (1) involving end-users from preconception stages, (2) using a mixed research method (mainly based on interviews and observations) in usability evaluations, and (3) implementing pilot studies to evaluate acceptability and feasibility before a clinical trial.

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## Authors' Contributions

VCL managed, contributed to the design, implementation, and results analysis of the study, as well as edited the paper. FM contributed to the adaptation and rewriting of the program content, and moderated the project team workshops. JW participated in the data analysis and the editing of the paper. BB developed the latest versions of the website, fixed most of the usability issues, and edited the paper. MP contributed to the editing of the paper and the results analysis. JDR contributed to the adaptation of the program content and editing of the paper. IG contributed to the data analysis and editing of the paper. ASR is the main investigator, supervised the study, oversaw the implementation of the project, and edited the paper.

## Conflicts of Interest

None declared.

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**Abbreviations**

**AIDMA:** Aide dans la Maladie d'Alzheimer

**PWAD:** people with Alzheimer's disease

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## CHAPTER FOUR

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# RATIONALE, CONSIDERATIONS, AND STUDY PROTOCOL DESIGN

### INTRODUCTION

Chapter 3 described the process encompassing the development and iterative improvement of the Diapason program. In order to determine the efficacy of this program, we evaluated the latest version resulting from this iterative process in a randomized clinical trial. The first version of the protocol study was developed with the methodological support of physician V. Faucounau. The project was partially funded by the National Ministry of Health (Programme de Recherche en Qualité Hospitalière) in 2009 (Appendix 11). From this moment the project was sponsored by the Assistance Publique des Hôpitaux de Paris (APHP) and regularly monitored by the *Département de la Recherche Clinique et du Développement* (DRCD) and the *Unité de Recherche Clinique de Cochin* (URC Paris Centre). A-S. Rigaud (research director), V. Cristancho-Lacroix, J de Rotrou, and H. Kerhervé, in collaboration with the DRCD, contributed to the methodological design of the randomized clinical trial. The project received complementary funding from the Association Médéric Alzheimer in 2011 (Appendix 12).

As described in Chapter 2, the methodological design for evaluating the effectiveness of caregiver interventions requires the consideration of specific features in order to limit methodological and implementation issues, which may skew the overall results (Vernooij-Dassen & Moniz-Cook, 2014; Zarit & Femia, 2008). In the first section of this chapter we describe the different considerations (i.e. methodological, ethical and logistical) that we have taken into account throughout this process. The final version of this study protocol is described in-depth in the second section of this chapter (Paper 2).

## METHODOLOGICAL CONSIDERATIONS

### BLINDED VS. UNBLINDED DESIGN

This study was originally designed to use a simple blinded design of evaluations, in which the evaluator could not know in which group the participants had been randomized. Nevertheless, in line with the research sponsor concerns, and based on scenario analysis, we found two main limitations for the effective implementation of a blinded design in this study. Firstly, owing to limited human resources in this project, the professionals involved in the recruitment phase would have had to also conduct the assessments. Secondly, even if the human resources were sufficient, controlling the participants' commentaries referring to the program during the assessments would have been quite difficult. According to Zarit and Femia (2008), the use of blinded studies was promoted by pharmacological studies, in which the control group receives a placebo, in appearance comparable with the treatment (i.e. the participant may believe that he/she receives the treatment). However in psycho-educational programs it is almost impossible to conceal the real nature of the treatment to participants, not to mention to evaluators. Thus, while being aware of the risk of bias associated to unblinded studies (Hróbjartsson et al., 2013), we considered that the implementation of a double or single blinded design would be unrealistic in this protocol.

### ONSITE VS. DISTANCE-BASED EVALUATIONS

An important decision concerned the conditions of the evaluation. On the one hand, onsite assessments (i.e. conducted at the hospital) may discourage some of the participants belonging to the targeted populations (i.e. isolated, overburdened, and living in remote regions) to participate in the study. Besides, this modality could be considered inconsistent with the intervention properties (i.e. proposed online, accessible at home). On the other hand, we had the possibility to conduct distance-based evaluations, in which the instruments of measure are sent to participants by regular mail or are delivered online. Although this option may motivate the targeted populations, they can reduce the fidelity of measures. Indeed, the evaluators cannot control the conditions in which the individual fill out the surveys (e.g. while watching TV, helped by someone, filled out by someone else). Moreover, as noted by some authors (e.g. Kerhervé, 2010), various mistakes are recurrently committed by the subjects (e.g. missing data, questionnaires incorrectly filled or non returned), affecting the validity of the analysis. Our final decision on this topic was mainly determined by the sponsor demands to control the reliability of answers, and the conditions of evaluations. Only a

satisfaction questionnaire that had to be completed each week was filled out by the participants at home (Appendix 8).

## CONSTRUCTS AND MEASURES

### EXPECTED EFFECTS OF THE PROGRAM

Although the Diapason program was not strictly grounded in a theoretical framework, the contents and strategies were inspired by a cognitive approach, and evolved from two renowned concepts: Lazarus and Folkman's model of stress and coping (Lazarus & Folkman, 1984) and Bandura's self-efficacy (Bandura, 2009).

As described in Chapter 3, the main aim of the program was to **reduce (or prevent) caregivers' stress**, by three means: by improving caregivers' understanding and anticipation of Alzheimer's disease symptoms; by training them in skills (e.g. training in relaxation) to favor caregivers' self-care; and finally by fomenting and favoring help-seeking behaviors (e.g. participating in a forum with peers) and social support. In sum, the intervention focused on three secondary aims (described in depth in Chapter 3):

a) **Reframing caregivers' beliefs**, about the disease's diagnosis, progression, and symptoms, as well as about the caregiving role and the consequences of non-self-care (Vernooij-Dassen et al., 2011)

b) **Improving skills**, to manage the daily life difficulties, to improve communication with the relatives, which may improve their self-efficacy and favor caregivers' self-care (Bandura, 2009).

c) **Favoring and fomenting social support and the help-seeking**, by providing information that may help them obtain respite or financial support if necessary, as well as offer a space to meet and discuss with other caregivers through a private and anonymous forum (Lai & Thomson, 2011; Rodakowski et al., 2012).

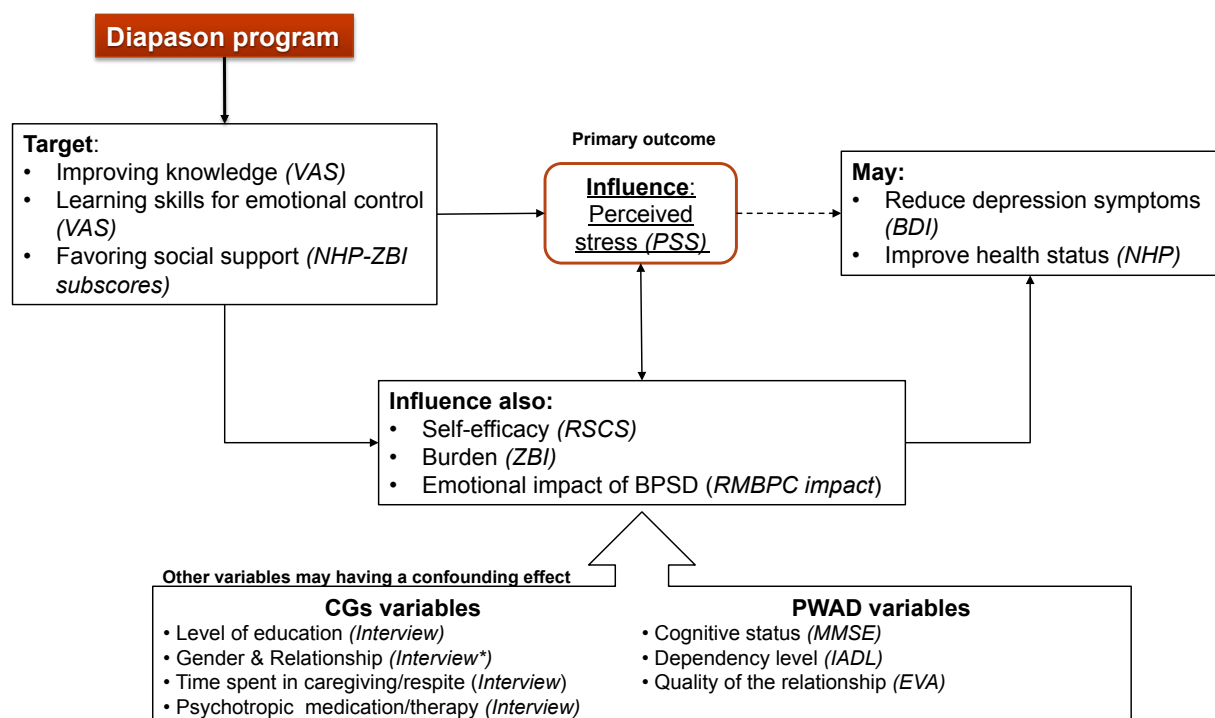
Measuring the impact of a program is a complex mission, because evaluating all desirable variables in a study would be infeasible and highly costly (Schulz, Czaja, McKay, Ory, & Belle, 2010). By selecting a set of constructs and outcome measures, the evaluator may in a way not account for all the effects of a program. Thus, based on a literature review, on the team's experiences with the AIDMA project (de Rotrou et al., 2010), and the hypothesis of

the likely effects of the Diapason program, we selected the main and secondary outcomes of this randomized clinical trial.

### CAREGIVERS' OUTCOMES

Figure 10 schematizes our hypothesis about the expected direct and indirect effects of the program on the psychological outcomes of caregivers. According to the stress and coping model and to cognitive theories, the three main action fields of this program (i.e. knowledge, training skills, and social support) could positively influence the caregivers' **perceived stress**, thanks to the reframing of appraisals and coping skills acquisition. In fact, improving the knowledge and understanding of the disease might help caregivers to reframe their beliefs and goals concerning the illness and the caregiving role (Vernooij-Dassen et al., 2011).

**FIGURE 10. SCHEMA ON THE EXPECTED EFFECTS OF THE DIAPASON PROGRAM**



\*Variable controlled by stratification in randomization. In parenthesis the outcome measures. PWAD: Persons with Alzheimer's disease, caregivers: Informal caregivers, VAS: Visual analogical scale. PSS: Perceived Stress Scale, RSCS: Revised Scale for Caregiving Self-Efficacy, RMBPC: Revised Memory and Behavior Problem Checklist, ZBI: Zarit Burden Interview, NHP: Nottingham Health Profile, BDI-2: Beck Depression Inventory, second version, MMSE: Mini-Mental State Examination, IADL: Instrumental Activities of Daily Living.

Nevertheless, and given the complexity of stress (see description in Chapter 1) (Lazarus & Folkman, 1984), other variables may be affected by stress and may affect stress levels. As is described in Lazarus and Folkman's model, the loops between individuals' outcomes, their coping strategies, and appraisals are endless. The experiences of persons, and outcomes using determined coping strategies might reinforce their beliefs, or alter their appraisals of a defined situation.

Besides, we thought that increased knowledge, skills training, and social support might also provoke direct effects on other psychological outcomes of caregivers. We selected the following three: **burden, self-efficacy, and emotional strain** or upset associated to relatives' BPSD.

As described in Chapter 1, **burden** and stress are often used indistinctively. Nevertheless, burden covers a broad scope of consequences associated to caregiving. As will be described in the next section, we decided to keep burden as a secondary outcome, measured with the ZBI, since the latter might show different or complementary results than those obtained by the stress levels instrument (PSS-14).

Secondly, caregivers' **self-efficacy** might be improved thanks to the additional skills and social support provided by the program (Bandura, 2009; Steffen, McKibbin, Zeiss, Gallagher-Thompson, & Bandura, 2002). Moreover, based on its definition and demonstrated interaction with stress and depression, we considered that self-efficacy could be a moderator variable between stress and depression. Perceived self-efficacy "*refers to beliefs in one's capabilities to organize and execute the courses of action required to manage prospective situations*" (Bandura, 2009, p. 2). Studies are consistent in showing that beliefs of self-efficacy significantly contribute to human motivations and achievements, and have diverse effects on psychosocial functioning: a) determines whether the use of coping will be initiated, and how much and how long the efforts will be sustained to deal with obstacles and aversive experiences, and b) affects vulnerability to emotional distress and depression (Steffen et al., 2002). Importantly, self-efficacy is a modifiable attribute which can be learned and enhanced, hence the interest regarding its role in determining health outcomes in caregivers (Gallagher et al., 2011). Although scarcely studied in caregiving research, self-efficacy studies have demonstrated its predictive and moderator role in burden, stress, and depression in dementia caregivers (Gallagher et al., 2011; Gilliam & Steffen, 2006; Mausbach et al., 2012).

The third aspect that we expected would be directly affected by the intervention was the **emotional impact of BPSD**. In fact, the Diapason program might help caregivers to improve and reframe their understanding on the nature of BPSD (Vernooij-Dassen et al., 2011),



leading to a reduced emotional impact associated to BPSD (e.g. caregivers of AIDMA have reported feeling less affected by the behaviors that they understood were not targeted at them, but were symptoms of Alzheimer's disease).

Other variables frequently assessed in the efficacy studies of caregiver interventions are the impact on mental and physical health. Although we did not hypothesize such a direct impact, we found it plausible that the reduction in stress could impact these variables. In fact, the relationship between stress, depression symptoms, burden, self-reported health, and the emotional impact of BPSD has been demonstrated. For instance, **depressive symptoms** were associated with high burden and perceived stress (Cooper et al., 2008), and caregivers with the highest **burden** scores significantly suffer from worse **self-reported health** in most of the areas (in both physical and mental health) than non-caregivers (Buyck et al., 2011).

To finish, we selected a set of variables that have been identified by other works as **moderators or mediators** of stress in caregivers, for instance, care-recipients' cognitive and functional impairment, caregivers' social support resources, gender, quality of relationship with the care-recipient, among others (Schulz & Martire, 2004; Steffen et al., 2008). The aim was to include them in the analysis to ensure the comparability of the groups.

## INSTRUMENTS OF MEASURE

The purpose of the following section is to concisely explain the reasons that motivated our choices about the instruments of measure. Further details of outcome measures will be exposed in the second section of this chapter (Paper 2).

### PRIMARY OUTCOME: THE PERCEIVED STRESS

Given that the main objective of the program was to reduce or prevent stress levels in caregivers, we defined self-perceived stress as the primary outcome of this study. As described in Chapter 1, the lack of conclusive studies to clearly define burden has led authors to use stress or burden without distinction. Evidence of this is shown by various works that have used the Zarit Burden Inventory (Zarit, Todd, & Zarit, 1986) in order to measure caregivers' stress in the context of dementia (e.g. Gaugler, Mittelman, Hepburn, & Newcomer, 2009).

Given its broadness, the ZBI might not be sensitive to the effects of our intervention. In coherence with the definition of burden, the items of the ZBI cover a broad scope of domains on which caregiving may have an impact (i.e. financial or emotional domains, social life, psychological well-being, relationship between caregiver and care-recipient). The analysis

factors have found all in all three dimensions in the 22-item version of the ZBI. Siegert and his colleagues (2010) evaluated 222 caregivers of people after acquired brain injury with the ZBI. The exploratory factor analysis revealed three factors: a) personal strain, b) role strain, and c) the third, including only two items, specifically centered on guilt (Siegert, Jackson, Tennant, & Turner-Stokes, 2010). In a second analysis factor, Ankri and his colleagues (2005) evaluated 152 primary caregivers of community-dwelling older adults with dementia. They analyzed the results of the ZBI, with principal component factors and varimax rotation. Five factors accounted for the 66.2% of total variance, the authors retained three because of their clinical relevance: social and personal consequences of caregiving explaining 41.5% of variance, psychological burden and emotional reactions (8.6% of variance), and feelings of guilt (6.2% of variance) (Ankri, Andrieu, Beaufile, Grand, & Henrard, 2005). As described later we included this scale in our protocol as secondary outcome.

Another scale used to measure stress in caregivers of PWAD is the Revised Memory Behavioral Problems Checklist (Teri et al., 1992) (Gallagher-Thompson et al., 2010; Mausbach et al., 2012). This scale evaluates the frequency of BPSD and the bother or upset caused in caregivers by the presence of BPSD. The main limit of this scale (for our study) resides in the fact that the measure of stress is exclusively associated to dementia symptoms, while other sources of stress like the lack of self-efficacy, or helplessness, among others, are not measured. Nevertheless, since this scale allows for an interesting measurement of the emotional impact of dementia symptoms, we included it in our secondary outcomes.

Finally, we selected the 14-item version of the Perceived Stress Scale (PSS-14) (Cohen, Kamarck, & Mermelstein, 1983) as primary outcome of this study. To our knowledge, this is the only stress scale validated in France (Bellinghausen, Collange, Botella, Emery, & Albert, 2009). Translated into French by Bruchon-Schweitzer (2002), this scale is grounded in the stress model of Lazarus and Folkman (Lazarus & Folkman, 1984). Seven out of the fourteen items are considered negative, and the remaining seven are positive, representing perceived helplessness and self-efficacy respectively (Andreou et al., 2011). Items are rated on 5-point Likert scales (0=never and 4=very often). Its internal consistency has ranged from 0.70 to 0.85 in prior research.

In order to focus the evaluation on the stress associated to caregiving experiences, we adapted the scale instruction by adding the following text in bold: "this scale asks you about your feelings and thoughts **about your experience with your relative during** the last four weeks". Interestingly, a recent RCT also used the PSS as primary outcome to evaluate the

impact of a web-based program on the perceived stress of caregivers of persons suffering from dementia (Kajiyama et al., 2013).

## SECONDARY OUTCOMES

As illustrated earlier, we expected the program to improve the self-efficacy of caregivers in asking for help, or in controlling their emotional reactions (Merluzzi, Philip, Vachon, & Heitzmann, 2011; Steffen et al., 2002). Since self-efficacy is not a global entity, but varies depending on the domains of activity, on subjective tasks demand, and on situational characteristics, we selected a scale specially designed to evaluate self-efficacy in caregivers of persons with dementia (the Revised Self-efficacy Caregivers Scale, RSCS), focusing on three types of self-efficacy depending on related goals: obtaining respite, controlling upsetting thoughts, and responding to disruptive patients' behaviors (Steffen et al., 2002).

As previously introduced, we selected the ZBI (Zarit et al., 1980) as secondary measure, because of its broad scope to measure different areas of caregiving which are not measured by other scales (e.g. feelings of guilt, social impact of caregiving), and which could be improved by the program (social support and reframing beliefs). Moreover, to measure the impact of the program on the emotional reactions provoked by the BPSD of care-recipients we chose the RMBPC. Nevertheless, and mainly based on the results of AIDMA, we did not expect a reduction in the frequency of BPSD the other variable measured by this questionnaire.

To measure the secondary impact of the program on the perceived health (mental and physical) of caregivers we selected a well-known scale, the Beck Depression Inventory. Although the authors warn against the use of this scale as sole instrument for the diagnosis of depression, it is well recognized and recommended to evaluate depressive symptoms consistent with the criteria of the DSM-IV (Beck, Ward, Mendelson, Mock, & Erbaugh, 1961; Beck, Steer, & Brown, 1996). In addition, to evaluate the perceived health in other areas we selected the Nottingham Health Profile (NHP, Bucquet, Condon & Ritchie, 1990), a self-administered scale considered as a measure of distress evaluating the perceived health in different domains: pain, physical mobility, energy, social isolation, emotional reactions, and sleep. Unlike other generic measures of the health status, the NHP items were generated from hundreds of interviews, making it suitable for use with a wide range of people, including informal caregivers. Moreover it is the only measure of perceived health, which was extensively tested and adapted to be used in Europe. In fact the language in the different

translations of this scale was embedded in culture and usage, resulting in conceptual rather than linguistic equivalences between the different versions (Garcia & McCarthy, 2000).

### ADDITIONAL MEASURES

As recommended by various authors (e.g. Steffen, Gant, & Gallagher-Thompson, 2008), and in order to control the balance of these variables between the groups during statistical analysis, we measured the cognitive status (MMSE, Folstein, Folstein, & McHugh, 1975) and dependency of care-recipients (IADL, Israël, 1996), as well as other caregiver variables that have shown an impact on stress levels in the overall population (Cohen & Janicki-Deverts, 2012) and in caregivers. For instance, we included the measure of socio-demographic variables (level of education, gender and relationship), the time spent in caregiving, the respite obtained, and the services used, including psychotherapies and psychotropic treatments (Ferrara et al., 2008).

The Visual Analogical Scales (VAS) are already validated in domains like anxiety and pain (van Duinen, Rickelt, & Griez, 2008; Williamson & Hoggart, 2005). Based on the results of the AIDMA program, which showed the interest of VAS to evaluate caregivers' knowledge and coping strategies (de Rotrou et al., 2010), we included them to evaluate the perceived knowledge of the disease and caregivers' self-efficacy in coping with caregiving situations in our protocol. Finally, we included a third VAS to measure the current quality of the relationship between caregivers and PWAD, as perceived by the caregiver.

In order to complement de quantitative results of this RCT we collected qualitative data from the open-ended items of satisfaction questionnaire, and from semi-structured interviews conducted at the end of the last visit.

## ETHICAL CONSIDERATIONS

In addition to methodological considerations, the ethical aspects of this study were largely discussed and treated by the team in collaboration with the sponsor. During the pre-screening phase, practitioners would propose both the online and onsite programs to caregivers in order to give them a choice. Moreover, in line with Mahoney and her colleagues (2007) and respecting concerns of “truthfulness, prudence, and humility”, we included a clear description of the program, in the information notice provided to volunteers before their inclusion. In addition, caregivers with important physical or psychological health weaknesses

(based on practitioners' evaluation) were not included in the study, but were offered more individualized help (Mahoney et al., 2007). At any rate, they were given access to the program outside the protocol. For recruited caregivers, if they felt the need for another type of support or help after beginning the protocol, they only had to inform the research psychologist, who then decided with the DRCD if the participant should be withdrawn or not from the study.

Finally, in agreement with the article L.1123-6 of the “Code de Santé Publique”, the study protocol was submitted to an independent Protection to Persons Committee (PPC). Before starting the study, the protocol was approved by the PPC in July 15, 2011 (Appendix 13), and received the approval from the French Office for the safety of Health Products (Appendix 14). The Diapason website was also declared to the National Commission for Data Protection and Liberties (CNIL-France) in September 2011 (Appendix 15). In addition, a procedure was implemented to ensure confidentiality and anonymity of the participants during the transcription of data. For that end, the data of participants only mentioned the initials of their last and first names as well as a number. All participants read the information form and signed the consent before the randomization (Information and consent forms in Appendix 16).

## LOGISTICAL CONSIDERATIONS

In order to homogenize the recruitment and assessment processes different actions were carried out. Firstly, before starting the recruitment, physicians and paramedical professionals were informed about the study protocol, including the inclusion and exclusion criteria, and the recruitment process. Secondly, we designed a retro planning of inclusions schedule. These projections were calculated based on sample size calculations provided by bio-statisticians. Thirdly, we designed a guide for the inclusion interviews carried out by psychologists. The non-eligible caregivers were offered use of the Diapason program outside the formal protocol. Finally, we designed a guide for the evaluation protocol. The evaluators were also trained in using the electronic case report form, the evaluation protocol, and the training/demo offered to participants of the experimental group, about how to use the website (Appendix 18).

# STUDY PROTOCOL TO EVALUATE THE DIAPASON PROGRAM

## (PAPER 2)

Although few research protocols are published they are useful for various audiences. For instance they enable systematic reviewers, funders, and researchers to have an overview of ongoing studies. Moreover, with these publications, patients and caregivers are informed about studies in which they could wish to participate. Additionally, publications on trials results rarely allow the in-depth presentation of the methodology used, limiting the replication of studies (Skogvoll & Kramer-Johansen, 2013). The following article was published in December 2013 the *Journal of Medical Internet Research: Research Protocols*. The material used for this study (i.e. user's manual, leaflets promoting the study) is available in Appendices 10 and 17.

Cristancho-Lacroix V, Kerhervé H, de Rotrou J, Rouquette A, Legouverneur G, Rigaud AS. (2013). Evaluating the Efficacy of a Web-Based Program (Diapason) for Informal Caregivers of Patients With Alzheimer's Disease: Protocol for a Randomized Clinical Trial. *Journal of Medical Internet Research Protocol*. 2(2):e55. DOI: 10.2196/resprot.2978

Protocol

# Evaluating the Efficacy of a Web-Based Program (Diapason) for Informal Caregivers of Patients With Alzheimer's Disease: Protocol for a Randomized Clinical Trial

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## Abstract

**Background:** Informal caregivers (CGs) of patients with Alzheimer's disease are at risk of suffering from psychological and physical weakening. Several psychoeducational interventions have been designed to prevent stress and burden of caregivers. In France, despite health authorities' recommendations, to our knowledge there is no rigorously assessed Web-based psychoeducational program to date.

**Objective:** The objective of our study was to assess the efficacy of a French Web-based psychoeducational program (called Diapason) with an unblinded randomized clinical trial.

**Methods:** In this protocol, 80 informal caregivers of patients followed at Broca Hospital are recruited offline and randomized in the experimental condition (EC) or the control condition (CC). The volunteers in EC have to visit a closed online user group at least once a week and validate one new session of this fully automated Web program, during 12 weeks. Each week a new thematic is added to the website. The participants in the CC receive usual care, and have access to the Diapason program after their participation (6 months). Face-to-face evaluations for both groups are planned every 3 months (M0-M3 and M6). The main objective of this program is to provide CGs with information on the disease process, how to prevent psychological strain (using anticipation and relaxation techniques), and offering a virtual space (forum) to discuss with other caregivers. The primary outcome of this study is the self-perceived stress, while self-efficacy, burden, depression, and self-perceived health status are defined as secondary outcomes. Other variables that might have an impact on the program efficacy are collected.

**Results:** This protocol was accepted for funding. The enrollment began in October 2011, and participants currently recruited will finish their evaluations in January 2014. The results are expected for June 2014.

**Conclusions:** Findings might provide empirical evidence on: (1) the feasibility of an Internet-based program in the French context, (2) the effectiveness of a Web-based program for informal caregivers, and (3) the identification of caregivers who will benefit from this type of intervention.

**Trial Registration:** Clinicaltrials.gov NCT01430286; <http://clinicaltrials.gov/ct2/show/NCT01430286> (Archived by WebCite at <http://www.webcitation/6KxHaRspL>).

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**KEYWORDS**

family caregivers; Alzheimer's disease; Internet; program effectiveness; psychoeducational program; psychological stress; randomized clinical trials

## Introduction

### Background

Informal caregivers (CGs) of patients with dementia have an important role in the prevention of patients' institutionalization. Unfortunately, CGs are prone to high levels of stress and are at higher risk of weakening mental and physical health, lower life expectancy, and lesser economic security than people who are not confronted with such stressful situations [1]. In order to prevent these consequences various programs have been developed for them, which have shown a positive effect on caregivers' burden, depression, or stress [2-4]. Furthermore, several studies have demonstrated the protective role of resilience and coping factors for this population [5].

The new recommendations following French Alzheimer's Plan 2013 [6] underlined the use of Web-based interventions in order to inform and support family caregivers.

### Distance-Based Interventions

There are many reasons for caregivers to use or to prefer a distance intervention instead of a face-to-face one. In fact, CGs spend a lot of their time in care activities, supporting directly (eg, cooking, housekeeping, supervising their loved ones) or indirectly (eg, doing administrative, financial, or logistic management) their relatives. Furthermore, the time requested for caring increases with the disease progression, and finding time for their own respite can be quite difficult. In fact, several CGs fulfill many roles, such as being parent, grandparent, worker, and friend. Finally, some of them live in remote regions and other CGs do not feel at ease with face-to-face interventions or prefer a flexible time/content intervention [7].

Distance interventions, based on information and communications technology (ICT), appeared in the earlier part of the 21st century in order to propose an alternative intervention to caregivers unable to access health centers delivering face-to-face programs. Distant programs have shown a positive effect on self-perceived stress, burden, depression symptoms, and social support of caregivers [7-14].

In the case of caregivers of patients with dementia, several websites exist in France, but these programs have not been, to our knowledge, subjected to a randomized clinical trial.

It is therefore relevant to evaluate the impact of ICT-based or distance-based interventions on the mental and physical health status of caregivers in a controlled experimental study with a French population. It could represent a base for the health care policies and facilitate financial support for these initiatives.

*Diapason* [15] is a fully automated Web-based version of a psychoeducational program, inspired by the group intervention sessions from the geriatric service of Broca Hospital called Aide dans la Maladie d'Alzheimer (AIDMA) program, or in English: Help in Alzheimer's disease. AIDMA was assessed in a previous study including 167 dyads "patient-caregiver" and showed a

significant improvement in disease understanding and in the ability to cope with care-recipients' disease [16,17]. The difficulty to schedule and attend all sessions (once per week during 12 weeks) for some of the caregivers was the main reason to adapt the program into an Internet-delivered version. Thus, we have adapted and designed a Web-based program in order to improve the accessibility for caregivers.

The purpose of this article is to present the study protocol of a randomized clinical trial designed to evaluate the efficacy of Diapason, a Web-based psychoeducational program for caregivers of patients with Alzheimer's disease (AD). Our hypothesis is that the Diapason program reduces the caregiver's perceived stress and burden and enhances his/her self-efficacy and self-perceived health. This study protocol has received approval from the French competent authorities (ie, Agence Française de Sécurité Sanitaire des Produits de Santé, Centre de Protection de Personnes-CPP, Commission nationale de l'informatique et des libertés).

## Methods

### Study Design

This is a pragmatic and unblinded randomized controlled trial (NCT01430286) of a Web-based psychoeducational program for the CGs of patients diagnosed with AD. Two parallel groups are compared. The experimental group receives immediate access to a Web-based program, and the comparison group is given the information usually delivered to the patient by the geriatrician during follow-up consultations. In addition to the baseline visit, two follow-up visits at the hospital are planned at 3 and 6 months.

### Participant Eligibility

Eligible participants are informal French-speaking caregivers (family or not, providing care to the patient at least 4 hours per week) of an AD patient diagnosed at the Memory Center of the Broca Hospital, Paris, France, and who meets the criteria in the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition [18] or National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's disease and Related Disorders Association criteria [19]. To be included in the trial, caregivers have to be 18 years or older or to be able to provide an informed consent, to score 12 or over on the Perceived Stress Scale of 14 items (PSS-14) [20] during screening, and to have a computer with an Internet access at home with an email address regularly used. If participants (CGs) are on psychopharmacological treatment or therapy, they are required to keep the same treatment at least two months before inclusion in the protocol.

### Exclusion Criteria

Exclusion criteria include being a professional or paid caregiver, a volunteer suffering from a physical or mental health status incompatible with patient's care, or following another psychoeducational program.



## Recruitment

Strategies to communicate about the program include flyers and posters in medical waiting rooms of the Memory Center as well as in other places in the Broca Hospital. An information meeting for the hospital staff has been organized before starting the inclusions in order to explain the study protocol. Then, the contact forms are available in every counseling room and in the waiting room.

The participants are recruited either during the follow-up consultation of a patient: (1) the geriatrician/neurologist delivers the general information about the protocol and gives a contact form to fill in and drop off at the Memory Center's reception desk, or (2) the CGs fill in the contact form available in the waiting room and drop it off at the Memory Center's reception desk.

One of the two research psychologists previously trained in the protocol contacts the caregiver, checks his/her eligibility criteria and explains the benefits, constraints, and schedule of the protocol. The psychologist gives an information notice to the caregiver and proposes to contact him/her a few days later. If the caregiver agrees with the protocol and meets the criteria for inclusion, the screening session (M0) is scheduled with the caregiver.

## Randomization

A computer-generated randomization list is used to assign the participants in the experimental condition (EC) group or in the control condition (CC) group after assessment with PSS-14 and all the inclusion and noninclusion criteria are checked. Blocking and stratification by gender and relationship (spouses versus nonspouses) were used to generate the randomization list.

## Interventions

### *Experimental Condition*

The Diapason program is an adapted fully automated computerized version of a psychoeducational program (AIDMA) created by the Geriatric Service of Broca Hospital. Usability of Diapason program was evaluated in a previous experimental study (pre/post). The study involved the assessment of 30 volunteer participants 60 years or older, with various levels of expertise in Internet use, during a guided visit. After

modifications and adaptation of the website, the performances of beginners and experts were similar [21].

Diapason is a free password-protected website. Figure 1 shows the home page. The program is run in twelve thematic weekly sessions organized in the following order: (1) caregiver stress, (2) understanding the disease, (3) maintaining the loved ones' autonomy, (4) understanding their reactions—how to recognize behavioral and emotional troubles, (5) coping with behavioral and emotional troubles, (6) communicating with loved ones, (7) improving their daily lives, (8) avoiding fall risks, (9) pharmacological and nonpharmacological interventions, (10) social and financial support, (11) about the future, (12) in a nutshell—a summary of Diapason program.

Globally, these twelve sessions cover the following areas: (1) information about AD diagnosis, symptoms, treatment, and progression, (2) how to cope with stressful situations, and (3) information about socioeconomic support and preventive gestures. A new session is available each week, after the validation of the previous session. Furthermore, the website also contains: (1) relaxation guidelines and training videos (based on Schultz's Autogenic Training and Jacobson's method) [22,23], (2) stories based on testimonials of caregivers, used to show critical situations and possible solutions to manage them (eg, apathy of patient, caregivers' isolation), (3) a glossary for the technical words (eg, neuropsychological assessment, aphasia), (4) stimulation guidelines and entertainment activities to do with the patients, and (5) a forum allowing users to establish contact with other caregivers anonymously, express their concerns, discuss solutions to daily problems, and share their feelings and experiences. The participants use nicknames to protect their privacy. A clinical psychologist takes part in discussions if necessary (ie, aggressive or inappropriate comments).

Participants involved in experimental group have to validate one session per week during 12 weeks (about 10 minutes per session), and complete a satisfaction survey corresponding to each session. During the first evaluation (M0) the participant is trained by a psychologist in how to use the website. At the second visit (M3) the participant is requested to provide the satisfaction paper-based survey filled out.

Figure 1. Home page.

### Control Condition

Participants randomized in the CC group receive usual care. It consists of a geriatric semiannual follow-up appointment during which the caregiver obtains illness information from the geriatrician. The volunteers receive the access code to the Diapason website at the end of their participation in the research protocol. Every participant of the CC group is advised to look for more specific help (ie, that of a psychologist or a physician) when he/she feels it necessary and then to report it to the main investigator.

### Measures and Procedures

#### Participant Recruitment

The physicians of the Memory Center have been informed on the study protocol and have received training in inclusion criteria screening. They provide the caregiver with some information about this study at the end of the consultation with the patient. Then the physician gives a contact form to the volunteers interested in participating in the study. The research psychologist contacts the person, presents the protocol study, and provides the caregiver with the information sheet. When the participant delivers a positive answer, the first visit (M0) at the hospital is scheduled together with the psychologist.

#### Assessment Protocol

The duration of each visit (M0-M3 and M6) is estimated to 90 minutes. The baseline visit is usually conducted as follows:

1. The research psychologist answers the questions on the information notice and the participant signs the informed consent if he/she agrees.
2. Evaluation with PSS-14 (primary outcome).
3. Randomization if PPS-14 total score is 12 or over.
4. Demographical interview and control questions of caregiver and patient's variables.
5. Assessment of secondary variables (researcher-administered, and then self-administered surveys).
6. The participants randomized in the EC receive the material (weekly paper-based survey, a journey book, and a user's manual of the website) and a personal access code to the website. Then, they are trained on how to use the Web-based program.
7. The CC participants are notified that they will receive a website access at the end of their participation to this protocol (6 months after M0).
8. Planning follow-up visits (M3-M6).

For the CC and EC groups, the assessments at M3 and M6 visits are similar, and go as follows: (1) evaluation of caregiver variables (time spent on caregiving, use of respite resources, stressful events, etc) and patient status (hospitalization or other unexpected event occurred in the last three months), (2) measurements with self-administered scales or administered by an interviewer. The measures used in this RCT are summarized in [Table 1](#).

**Table 1.** Overview of measures in the baseline and follow-up visits.

Variables (instruments/measures)	Administration	M0	M3	M6
<b>Caregivers' measures</b>				
Self-perceived stress (PSS-14)	<sup>a</sup> ABI	x	x	x
Self-efficacy <sup>b</sup> (RSCS)	ABI	x	x	x
Caregiver perception of troubles <sup>c</sup> (RMBPC)	ABI	x	x	x
Burden <sup>d</sup> (ZBI)	<sup>e</sup> SA	x	x	x
Self-reported health <sup>f</sup> (NHP)	SA	x	x	x
Depressive symptoms <sup>g</sup> (BDI-2)	SA	x	x	x
Knowledge about illness <sup>h</sup> (VAS)	SA	x	x	x
The quality of the relationship with the patient (VAS)	SA	x	x	x
Time spent on caregiving <sup>i</sup> (RBC)	Interview	x	x	x
Other sources of stress (ie, work, health status, financial status) (RBC)	Interview	x	x	x
Respite or social help (ie, psychotherapy, associations, technical help, etc) (RBC)	Interview	x	x	x
Time and frequency using the program (website statistics)	Website	x	x	x
Satisfaction towards the program content (weekly paper-based survey filled at home)	Weekly survey (M0-M3 for <sup>j</sup> EC)	x	x	x
<b>Patients' measures</b>				
Cognitive status <sup>k</sup> (MMSE)	Medical data	x	-	-
Degree of dependency <sup>l</sup> (IADL-RBC)	Interview	x	-	-
Duration of symptoms (RBC)	Interview	x	-	-

<sup>a</sup>ABI=Administered by the interviewer, <sup>b</sup>RSCS=Revised Scale for Caregiving Self-Efficacy, <sup>c</sup>RMBPC=Revised Memory and Behavior Problem Checklist, <sup>d</sup>ZBI=Zarit Burden Interview, <sup>e</sup>SA=Self-administered, <sup>f</sup>NHP=Nottingham Health Profile, <sup>g</sup>BDI-2=Beck Depression Inventory-second version, <sup>h</sup>VAS=Visual Analogical Scale, <sup>i</sup>RBC=Reported by caregiver, <sup>j</sup>EC=Experimental condition, <sup>k</sup>MMSE=Mini-Mental State Examination, <sup>l</sup>IADL=Instrumental Activities of Daily Living

### Primary Outcome Measure: PSS-14

Stress perceived by the caregiver is measured by the French version of the Perceived Stress Scale, the version of 14 items from Cohen et al [20], translated into French by Bruchon-Schweitzer in 2002 [24]. The PSS-14 is a widely used self-reported scale evaluating the general appraisal of stress in the last month. It consists of 14 items, with scores ranging from 0 (never) to 4 (very often). This scale has demonstrated a high reliability and validity in several studies [25]. The total score range for this scale is 0-56. Due to numerous roles of caregivers (as mentioned above) and in order to target stress specifically related to a caregiving role, we adapted the instruction of the PSS-14 by proceeding with hetero evaluation and adding the following text in bold: "this scale ask[s] you about your feelings and thoughts about your experience with your relative during the last four weeks." The rest of the instruction is similar to that proposed by Cohen in 1983.

### Secondary Outcomes Measures Administered by an Interviewer

#### Self-Efficacy

The Revised Scale for Caregiving Self-Efficacy was validated in 2002 by Steffen et al [26] and translated into French by Marziali and Garcia in 2011 [27]. This scale offers a simple and effective way to evaluate caregivers' self-efficacy on: (1) obtaining respite, (2) controlling upsetting thoughts, and (3) responding to disruptive patient behaviors. Each section has five items arranged from easiest to most difficult (based on research results) [26]. For each item the participants choose a score between 0 and 100, based on their degree of confidence for each situation. This scale should be administered by an interviewer [26].

#### Perceived Behavioral and Cognitive Problems

The Revised Memory and Behavior Problem Checklist [28] is a widely used scale that rates the caregiver's perceived frequency of occurrence of behavioral and cognitive problems and the caregiver's perceived distress facing these problems. It explores 24 situations in which the caregiver estimates: (1) the frequency of situations/problems during the last week, and (2)

the caregiver's response to each situation/problem. Satisfactory internal consistency coefficients of reliability have been reported (for frequency of behaviors .93 and for reaction .90) [29].

### **Secondary Outcomes Measures Self-Administered**

#### **Zarit Burden Interview**

The Zarit Burden Interview (ZBI) is a subjective measure of burden that includes 22 items exploring the caregiver's perception and feelings about care situations. There are three factors that could explain 56.3% of global score variance: (1) caregiver's social and personal life, (2) psychological burden, and (3) caregiver's guilt [30]. The score range is 0-88, a higher score indicating a higher burden level.

#### **Depressive Symptoms**

Depressive symptoms will be evaluated with the second version of Beck Depression Inventory [31]. This widely used scale comprises 21 items, and the total score range is 0-63 [32].

#### **Self-Perceived Health**

Bucquet et al [33] validated the Nottingham Health Profile in France. We use this scale to evaluate the self-reported morbidity of caregivers. There are 38 items that are grouped in 6 dimensions: (1) physical mobility, (2) social isolation, (3) emotional reactions, (4) pain, (5) sleep, and (6) energy. In the French validation study, weights were calculated using Thurstone's Paired Comparisons [33]. The addition of this item totals a hundred per dimension and corresponds to the percentage of the illness impact perceived by each individual.

### **Additional Measures**

#### **Caregivers' Measures**

The sociodemographic variables and general information on caregiver situation collected are age, sex, educational level, relationship with the patient (spouse versus nonspouse), current psychopharmacological treatment, current psychosocial services and respite care (daycare centers for the patient, in-home care services, etc), time spent per week with the patient, and their "free time". Moreover, the quality of the relationship with the patient, the caregiver's confidence in his/her ability to cope with the consequences of the disease, and the caregiver's level of knowledge about AD are evaluated with the Visual Analogical Scales.

Participants in the EC complete a satisfaction survey each week, after watching the weekly program. Therefore, qualitative information about perceived utility of this program is obtained during the face-to-face interviews in the visits M3 and M6. Moreover, the frequency and duration of the Web-based program use for each participant is stored and anonymously analyzed at the end of the study.

#### **Patients' Measures**

The global cognitive status of patients is evaluated with the Mini-Mental State Examination (MMSE) [34] and obtained from the patients' medical file, if the patient accepts it (during follow-up at the Memory Center the patients with AD are evaluated with neuropsychological batteries, including the MMSE evaluation). The degree of dependency from the patient is evaluated by the French version of the Instrumental Activities

of Daily Living [35] reported by the caregiver at M0, and the duration of symptoms is also based on the caregivers' report.

### **Data Management and Statistical Analysis**

#### **Monitoring/Security Issues**

Data are collected via an electronic case-report form, then centralized, and stored on a secured server using the "CleanWEB" system [36]. A monitoring of records is planned every two months and done by an external agent to control the respect of protocol and procedures according to Clinical Best Practices guidelines [37].

#### **Ethical Proceedings**

This study protocol was submitted to the French ethical CPP and received approval on July 2011. Before they enter the study, all participants receive an information sheet and sign a written consent form.

The study provides equal opportunity to access the program. Caregivers who do not meet the inclusion criteria can access the website and program as external participants. Also, every participant is asked to search another form of help (ie, that of a psychologist or a physician) if he/she feels the need to, and to report it to the main investigator.

#### **Sample Size**

The sample size has been calculated by the Biostatistics and Epidemiology Department of the Hôtel-Dieu Hospital (Paris). Based on the literature [38], a 6-point difference on PSS-14 scale is expected between EC and CC at the posttest evaluation (M3). With an assumed standard deviation of 9, 40 participants per group should be included to be able to detect such a difference with an 80.0% power (Cronbach alpha=.05; two-tailed).

#### **Data Analysis**

The Biostatistics and Epidemiology Department of the Hôtel-Dieu Hospital will perform statistical analysis. All the analyses will be conducted according to the intention to treat principle and to handle with missing data; multiple imputations will be used if the missing at random or missing completely at random hypothesis holds. Otherwise sensitivity analysis will be done. No interim analysis will be performed.

A description of the characteristics of the two groups will be performed using percentages for categorical variables and means with standard deviation for quantitative variables. For primary and secondary outcomes, student *t* tests or a Wilcoxon test if required, as well as covariance analysis to take the regression to the mean into account, will be used to compare means between experimental and control groups. Percentages will be compared using chi-square test or Fisher's exact test if required. Calculations will be performed using SAS software.

Qualitative data obtained during visits M3 and M6 from EG participants' perception on the program's utility and satisfaction will be analyzed by Broca's research team, using thematic analysis [39].

Statistical analysis will exclude data from: (1) caregivers performing less than two thirds of the online program



(participant validates fewer than 8 out of 12 sessions), (2) dropouts due to mental or physical state of the caregiver becoming incompatible with this research protocol.

## Discussion

### Distinctive Features

This study protocol is quite innovative. To our knowledge, it is the first French Web-based program evaluated with a randomized clinical trial. The Diapason program has been conceived to offer a primary access to basic information about the illness progression and practical advice to reduce stress and manage the daily life for Alzheimer's CGs. In coherence with other studies, we are convinced that the Internet for health is an interesting tool to inform and support the isolated CGs [40], at a reduced cost, but with increasing convenience for users [41].

We are interested in evaluating the program effectiveness on self-perceived stress. Although the ZBI is often used to measure the CG stress in the context of dementia [42], the burden construct is relatively complex and not specific enough. In fact, two factor analyses of the ZBI identified three dimensions: (1) personal strain, (2) role strain, and (3) guilt [43], or (1) social impact, (2) psychological burden, and (3) guilt [30]. Based on these results we decided to use a PSS 14-item version and to adapt the main instruction of PSS to caregivers' strain. However, in this protocol we use the ZBI as a secondary outcome, and it would be interesting to compare the results obtained with each of these measurement instruments.

### Strengths of the Study

In our opinion, four main strengths are identifiable in this protocol.

First, since most elderly caregivers (spouses) do not have sufficient experience with the Internet, 30 elderly volunteers participated in the usability tests, which allowed us to modify and adapt the website prior to the present study. The usability tests increase the likelihood of inexperienced Internet users to use Web-based programs and offers access to a widespread population who has never navigated on the Internet because it was considered as too complex or difficult to use.

Second, our Web-based program (Diapason) keeps a structure that is similar to an on-site psychoeducational program, such that it proposes a thematic session weekly. In this way, we control the information viewed by the caregiver according to a specific schedule. In fact, the EC is not completely controlled if the access to the information is determined by the choice of the patient. In our opinion, controlling the order and access to main thematic areas should improve the reliability of results because all the participants receive the same information.

Third, we are aware of the positive impact of social networking and communication between peers for CGs. We did not have enough human resources to offer a virtual presence or face-to-face participation, nevertheless we integrated a forum in the website which enables the CGs to ask and share experiences, feelings, and advice with their peers, with the participation of a psychologist as moderator. This initiative represents a first step towards more comprehensive and interactive Web-based initiatives that our team has scheduled to build, optimizing social networking perspectives, as advised by recent works [44,45].

Fourth, we will analyze the data of Web server utilization from each user and compare it with their satisfaction and appraisal of the effectiveness of the program. This objective information will help us to know the system use, and its acceptability. Our purpose with these results is also to identify the "user profiles" with a highest adherence to or benefit from the program. For instance, do spouses or nonspouses benefit more from the program? Is the time spent on the program website associated with the level of stress after the 12 sessions? Or is there minimum time duration of navigation to observe some benefit from the program?

### Conclusions

In conclusion, the results of this study will allow a better targeting of beneficiaries, for whom the intervention will be more efficient. The results will provide strong support to influence health care policies and facilitate the financial support of these initiatives.

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## Authors' Contributions

VCL is the trial manager of the study, contributed to the study design, conception, and preparation of the manuscript. HK contributed to the study design and edited the paper. JDR provided methodological advice, oversaw the adaptation of psychoeducational program, and contributed in the edition of the paper. AR provided statistical and methodological advice, undertook the randomization process, and revised the paper. GL participated in the project group. ASR is the main investigator, contributed to the study concept, to the supervision of the study, oversaw the implementation of the project, and revised the paper. All authors read and approved the final manuscript.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.2 [46].

[[PDF File \(Adobe PDF File\), 996KB - resprot\\_v2i2e55\\_app1.pdf](#)]

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## Abbreviations

**AD:** Alzheimer's disease  
**AIDMA:** Aide dans la Maladie d'Alzheimer program  
**CC:** control condition  
**CGs:** Informal caregivers  
**CPP:** Centre de Protection de Personnes  
**EC:** experimental condition  
**ICT:** information and communications technology  
**MO:** month 0  
**M3:** month 3  
**M6:** month 6  
**MMSE:** Mini-Mental State Examination  
**PSS-14:** Perceived Stress Scale of 14 items  
**ZBI:** Zarit Burden Interview

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## CHAPTER FIVE

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# DIAPASON PROGRAM EFFICACY, ACCEPTABILITY, AND PERSPECTIVES

Throughout this document we have described the long and challenging development process of Internet-based interventions for caregivers, and the design of the study protocol. As mentioned in Chapter 2, various technology-driven interventions for caregivers have been developed in the last two decades (e.g. Brennan, 1995; Chiu & Eysenbach, 2011; Lewis, Hobday, & Hepburn, 2010). Nevertheless the gap between the number of published studies dedicated to the evaluation of feasibility and those assessing the efficacy of this type of interventions is considerable, preventing reviewers from concluding on the robustness of Internet-based programs' effects (Godwin et al., 2013). Indeed, over the past twenty years, only four Internet-based programs have been evaluated in an RCT (Beauchamp, Irvine, Seeley, & Johnson, 2005b; Brennan, 1995; Kajiyama et al., 2013). Moreover, none of them has formally used mixed methods to analyze the data.

In the first section of this chapter (Paper 3) we expose the results of the RCT evaluating the efficacy of the Diapason program, based on a mixed analysis. Our results and discussion confirm the complexity and heterogeneity of caregiver populations and the features that have to be taken into account to correctly evaluate interventions addressed to them. The second part of this chapter is an attempt at giving continuity to the iterative design, improvement, and assessment of the Diapason program. Although other studies have already addressed the needs of PWAD's caregivers (Amieva et al., 2012; Van der Roest et al., 2007), to our knowledge no study so far has specifically evaluated caregivers' expectations towards Internet-based interventions. In fact, caregivers report a broad scope of unmet needs in different domains (e.g. financial or social domains, respite, wellbeing, physical care) which cannot be addressed by the exclusive use of the Internet. While being aware of these limitations, and based on the qualitative results of the Diapason RCT, we have designed and conducted an ancillary study to the Diapason RCT, aiming at a better understanding of the

expectations and wishes of caregivers, towards the contents and functionalities of an Internet-based program. In the second section of this chapter we briefly describe the methodology and provide a preliminary overview of this study based on a methodological triangulation (Guion, Diehl, & McDonald, 2011).

## EFFICACY OF THE DIAPASON PROGRAM: RESULTS OF A RANDOMIZED CLINICAL TRIAL (PAPER 3)

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**Original paper: Efficacy and acceptability of a Web-based psycho-educational program for informal caregivers of patients with Alzheimer's disease: a randomized controlled trial.**

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## **Abstract**

### **Background**

Due to the worldwide aging population, dementia has become a major public health concern. Most people with dementia live at home with only a relative or a friend caring for them. Consequently, the prevention of psychological, physical, and social consequences of informal caregiving has become a growing priority. Although several onsite programs are dedicated to them, they are not easily accessible to overburdened or isolated caregivers. Thus, Internet-based interventions may meet caregivers' needs, and their efficacy needs to be demonstrated from an evidence-based approach.

### **Objective**

This study evaluated the efficacy and acceptability of a Web-based psycho-educational program for caregivers of persons with Alzheimer's disease (PWAD) using a mixed research method embedded in an unblinded randomized clinical trial.

### **Methods**

We recruited forty-nine caregivers in our memory center and randomized them in two parallel groups. The experimental group (EG) received the Web-based intervention as well as usual care during 6 months, while controls received usual care, and were provided with the Web-based intervention at the end of the protocol. In three face-to-face evaluations (our baseline, at the end of the program at M3, and after follow-up at M6), we measured caregivers' self-perceived stress (primary outcome), self-efficacy, burden, perceived health status, and depression (secondary outcomes). Additionally, EG caregivers were interviewed at M6 and were administered a satisfaction questionnaire. Qualitative results were treated based on the thematic analysis method.

### **Results**

Intention-to-treat analysis did not show significant differences in self-perceived stress between EG and CC. EG significantly improved their knowledge of the illness ( $P = 0.0008$ ,  $d = 0.79$ ) from M0 to M3. Most participants considered the program useful, clear and comprehensive. The husbands and sons evaluated the program positively, while daughters had mitigated feelings, and female spouses expressed negative or neutral opinions. Caregivers expected more social interaction (with staff and peers), and asked for more dynamic and deeper contents than those provided by the Website.

### **Conclusions**

In this study, quantitative results were not conclusive. However, qualitative analysis disclosed optimistic perspectives for the Internet-based interventions, mainly for incoming generations of caregivers. This study underlines the need for iterative assessment and adaptation of interventions in order to match caregivers' needs and expectations.

### **Keywords**

*Informal caregivers, Psycho-education, Internet intervention, Alzheimer's disease, Stress, Caregiving, Mixed Method, Web-Based Program, Randomized Clinical Trial*

**Trial Registration:** Clinicaltrials.gov NCT01430286;

<http://clinicaltrials.gov/ct2/show/NCT01430286>

(Archived by WebCite at <http://www.webcitation.org/6KxHaRspL>).

## Introduction

Due to the worldwide aging population, the number of persons with dementia (35.6 million currently) is expected to double by 2030 [1]. However, the number of professionals will not increase proportionally. Thus, more help and support should be provided to informal caregivers [2]. In 2013, caregiving provided by informal caregivers was estimated at 17.5 billion hours of unpaid care by the Alzheimer Association, representing 216 billion dollars [3]. Their contribution delays or avoids institutionalization for the care-recipient [4].

Today, the majority of persons with Alzheimer's disease (PWAD) living at home, are cared for by their spouses, children or friends [5]. In contrast with some other illnesses, the care for a PWAD requires higher assistance with daily-life activities [3]. Caregivers have to deal with the progression of the disease as well as the behavioral and emotional troubles characterizing it. Thus, time spent providing care, physical efforts and strong emotional involvement may provoke chronic stress, affecting physical and mental health, [6–9]. Moreover, the deleterious effects of stress associated with caregiving may trigger negative consequences in other domains of life (e.g. professional or social domains) [10].

A recent study showed that a majority of caregivers wish to receive further information about the illness, as well as acquire skills to cope with caregiving situations [11]. However, most information and support programs are mainly available onsite [12]. Attending a face-to-face program is impossible for some of the caregivers, due to a lack of respite, behavioral problems or physical limitations. Thus, technology may represent an interesting complementary strategy to regular care management [2].

We developed the Diapason program, a free fully automated Internet-based psycho-educational program for caregivers of PWAD. It is based on an onsite intervention that was previously tested by our team [13]. Although other recent Internet-based programs have been tested [14–16], to our knowledge one single study using a randomized clinical trial (RCT) design has previously evaluated an online intervention the design of which was based on the results of a face-to-face program [17]. Despite recommendations, the use of qualitative analysis remains rare in association with RCT [18]. In fact, qualitative analysis may facilitate interpretation of results, help “trialists” become more sensitive to individual differences, and save money “by steering researchers towards interventions more likely to be effective in future trials” [19].

## The present study

The main aim of this RCT was to evaluate the impact of the Diapason program on caregivers' perceived stress. We hypothesized that this Internet-based program, offering information, skills training and a forum, provides significant benefits for informal caregivers, mainly by reducing perceived stress, enhancing self-efficacy, diminishing burden, and improving self-perceived health as well as knowledge of the illness. Qualitative analyses may facilitate identification of subgroups, which benefit from the program, and may guide us in improving a future version. Since the program was designed from a user-centered design approach, we hypothesized that the website would be easy to use for aged caregivers, and that mainly spouses would find it useful and adapted, in comparison with children who may be more familiarized with other informative websites (Figure 1).

## Methods

We carried out an unblinded monocentric RCT (NCT01430286) between 2011 and 2014 in the memory center of the Broca hospital. Informed consent was obtained before participation, and competent authorities approved the protocol. The in-depth description of this study protocol has been reported previously [20], and will be presented here briefly.

**Figure 1.** Homepage of the Diapason program's website



## **Participants**

Eligible participants were required to be French-speaking caregivers of community-dwelling AD patients who met the criteria of the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (APA, 2000). Caregivers had to spend at least 4 hours per week with their relative, to be aged 18 or more, to score 12 or more on the Perceived Stress Scale (PSS-14), and to have access to a computer with Internet connection. Professional caregivers were ineligible.

## **Procedure**

Recruitment strategy included flyers and posters disposed in waiting rooms of the memory center in the Broca Hospital. Caregivers of PWAD were invited to participate in this study, as well as in a group-based onsite program on the occasion of follow-up consultations. If caregivers were interested by the study, the geriatrician gave them a contact form. Then, psychologists contacted them to confirm inclusion criteria and to schedule the M0 visit.

Participants were assigned in two parallel groups, the experimental group (EG) or the control condition group (CC), based on a computer-generated randomization list, using blocking and stratification by sex and relationship (spouses vs. non-spouses).

At baseline (M0) the subjects of EG received access to the Diapason program. They benefited from a 10-minute training session on how to use the website, and a printed Diapason user's manual. Participants validated one session per week, over 12 weeks (about 10 minutes per session), and completed a satisfaction questionnaire corresponding to each session. Additionally, other website contents were available at any time (relaxation training, caregivers stories, forum, and guidelines for stimulating activities). The program content is summarized in Table 1.

The CC and EG participants received usual care, i.e. caregivers were provided with information on the illness during geriatric semiannual follow-up. The CC participants were given access to the Diapason program after M6. All participants were advised to look for additional help if necessary, but they had to inform the researcher.

The follow-up consisted of three individual face-to-face assessments, every three months (M0-M3-M6), conducted at the Broca hospital by research psychologists (VCL or JW). Each 90-minute assessment consisted of a structured interview, standardized questionnaires and visual analogical scales.

Additionally, EG volunteers participated in an optional one-to-one semi-structured interview at M6.

**Table 1.** Overview of Diapason program contents

Action fields	Targeted area	Program strategy	Example
Beliefs	Knowledge and beliefs about the illness (AD)	Giving clear information on illness progression and causes	Videos of specialists explaining AD symptoms
	Knowledge and beliefs on patients' emotional and behavioral problems	Offering strategies to understand patients' reactions  Guiding the CGs to explore optional reactions adapted to their relative	Explanation on why the relative becomes aggressive by analyzing situational and individual factors
	Beliefs on « caregiving role » - Reducing CGs' sense of guilt or feelings of guilt?	Affirming and reinforcing help-seeking behaviors	In the stress management session, explanation on why CGs should ask for help and consult a physician when necessary
Skills	Self-efficacy to manage patients' emotional or behavioral problems	Providing practical advice to manage critical situations in daily life	The section "Caregivers' stories" shows realistic scenarios of frequent problems and proposes ideas on how to react
	Self-efficacy to manage themselves emotional or behavioral reactions	Providing practical advice to cope with stress, strain and anger	The Relaxation training section includes guidelines and videos for different types of relaxation
Social support	Help-seeking behavior	Providing information on state subsidies and public organizations offering respite	A list of public institutions which support patients and their families is provided
	Networking and Social support	Providing reasons and advice to obtain more social support	A forum to discuss with peers on their respective experience and feelings

CG= Caregivers, AD= Alzheimer's disease.

## Measures

Primary and secondary outcomes were collected at each visit (M0-M3 and M6). The primary outcome was the perceived stress of caregivers, measured by the Perceived Stress Scale 14-items (PSS-14) [22]. The total score ranges from 0 to 56, higher scores representing higher stress levels. In order to target the caregiving stress, we added the following text in bold to the instruction of the PSS-14: "This scale asks you about your feelings and thoughts

**about your experience with your relative** during the last four weeks". The secondary outcomes were:

- a) Self-efficacy, measured by the Revised Scale for Caregiving Self-efficacy (RSCS) [23], distinguishing three self-efficacy domains: obtaining respite, responding to disruptive behavior, and controlling upsetting thoughts. Scores in each domain range from 0 to 100, higher scores indicating a higher degree of confidence for each situation.
- b) Perception and reaction to cognitive or behavioral symptoms of PWAD were evaluated by the Revised Memory and Behavior Problems Checklist (RMBPC) [24]. This instrument proposes 24 problems to be rated on two scales. They evaluate (five-point): frequency and caregiver's distress or 'bothering' for each problem. A global score ranging from 0 to 4 was calculated for both scales. Higher scores indicate higher frequency or higher emotional effects.
- c) Subjective burden was evaluated with the French version of the Zarit Burden Interview [25]. The total score ranges from 0 to 88, a higher score meaning a higher burden level.
- d) Depressive symptoms were measured with the second version of the Beck Depression Inventory (BDI) [26] including 21 items, in which the total score ranges from 0 to 63. Higher scores indicate higher levels of depressive symptoms.
- e) Self-perceived health was measured with the French version of the Nottingham Health Profile (NHP) [27]. We analyzed social isolation, emotional reactions, and sleep quality sub-scores, and rated each from 0 to 100, which provided a percentage of the perceived illness impact.

At each visit we collected information on received professional support, time spent providing care (structured questionnaire). On four visual analogical scales (VAS) caregivers evaluated their current levels of a) knowledge about Alzheimer's disease (0= low, 100=high), b) stress, c) coping, and d) the caregivers-PWAD relationship quality.

In particular, as to EG, web metrics (session length and rate of visits) were collected for each participant automatically and anonymously. Participants completed a weekly satisfaction questionnaire focused on utility, clarity, and comprehensiveness (5-Likert scale). They rated from 0 to 100 the applicability and positive emotional impact of each session and reported their opinion of the program (open-ended question). At the end of their participation, we proposed a semi-structured interview exploring their opinion of the program.



Concerning the PWAD we collected at M0: Mini-Mental State Examination (MMSE) [28] from the medical record, and Instrumental Activities of Daily Living (IADL,[29]) and the date of symptom onset (reported by the caregiver).

## **Data Analysis**

All available data at baseline were analyzed by intention-to-treat. Descriptive statistics (means and percentages) were calculated for caregivers' and AD patients' characteristics. Moreover, t-tests (or Mann-Whitney tests) and Spearman or polyserial correlations were used to assess associations between variables. The missing data within each scale were treated according to the recommendations of the literature, when available. Otherwise, simple mean imputation was used. The last observation carried forward method was used for dropped out participants. After checking normality and homoscedasticity of primary outcome (PSS), we conducted an analysis of covariance (ANCOVA), controlling for regression to mean phenomenon and effects of potential confounders at baseline on primary outcome. All analyses were conducted using R Software for Windows (version 3.0.0).

Interviews and open-ended questions as to satisfaction were concurrently analyzed by two trained psychologists following thematic analysis method, using a semantic approach, driven by analytic interests, and an essentialist/realist approach [30].

## **Sample size**

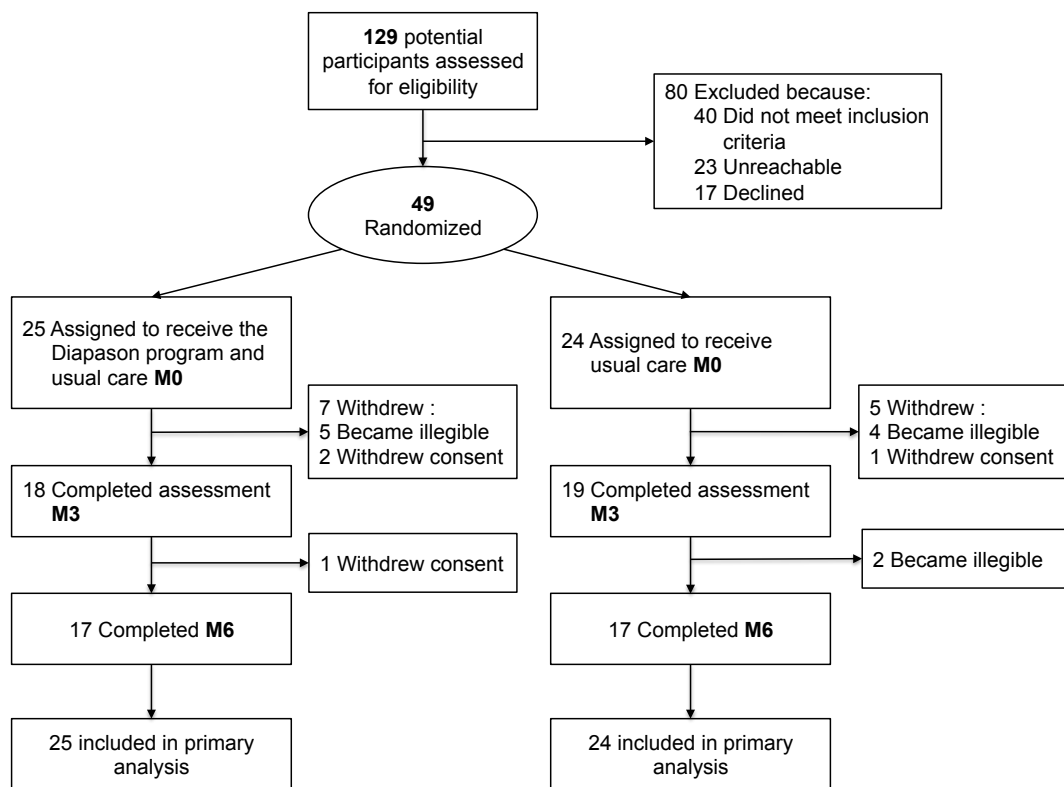
Based on the literature, a 6-point difference on PSS-14 was expected between EG and CC at M3 [31]. With an assumed SD of 9, 40 participants per group needed to be included to detect such a difference with an 80 % power (Cronbach alpha=0.05; two-tailed).

## **Results**

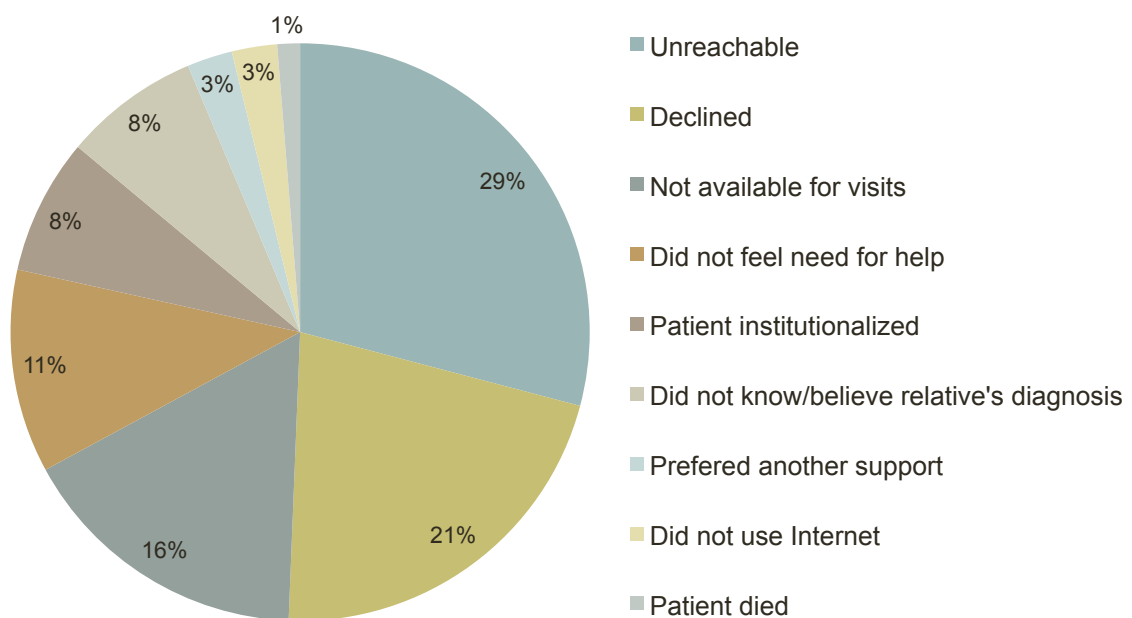
As summarized in the flowchart (Figure 2) of the individuals met by the physicians, 129 subjects were actually pre-screened between December 2011 and August 2013. Among them, 40 did not meet inclusion criteria (i.a. did not use internet, did not accept/know (yet) the diagnosis, were not available for three assessments at the hospital), 23 were unreachable, and 17 declined (Figure 3). After an eight-month extension, the main investigators (ASR and VCL) stopped recruitment (in total 20 months), since the rate of inclusions did not exceed two persons per month on average.

We recruited 49 participants. They were randomly assigned to EG (n=25) or to CC (n=24). Of the 25 participants allocated to EG, 17 (70,83%) finished the protocol and validated at least 10 of the 12 online sessions.

**Figure 2.** Flowchart of the Diapason RCT.



**Figure 3.** Grounds for non-inclusion of caregivers



Demographics and other characteristics of participants are summarized in Table 2. At baseline (M0) the groups were imbalanced as to the number of weekly hours of professional help, IADL and BDI scores. We found significant correlations between PSS scores and

weekly professional help received (Rho = 0.33), and BDI scores (Rho = 0.49), whereas the correlation (Rho = -0,11) for IADL scores was weak.

**Table 2.** Demographics and key characteristics at baseline by group

	Experimental Group N=25	Control Group N=24
<b>Caregivers' characteristics</b>		
Caregiver age, yrs., mean (SD) <sup>1</sup>	64.2 (10.3)	59.0 (12.4)
Female caregiver, n (%)	16 (64.0)	16 (66.7)
Children of PWAD <sup>2,3</sup> , n (%)	16 (64.0)	13 (54.2)
High level of education, n (%)	19 (76.0)	18 (75.0)
Middle level of education, n (%)	6 (24.0)	3 (12.5)
Living with the PWAD, n (%)	12 (48.0)	10 (41.7)
Visiting the PWAD daily, n (%)	4 (16.0)	2 (8.3)
Visiting the PWAD at least once per week, n (%)	9 (36.0)	9 (37.5)
Psychological/ psychiatric treatment, n (%)	3 (12.0)	2 (8.3)
Psychotropic treatment, n (%)	6 (24.0)	7 (29.2)
Caregivers with at least another source of stress different to caregiving (work, relationship, family)	18 (72.0)	14 (56)
Caregivers with at least one professional help <sup>4</sup> , n (%)	18 (72.0)	18 (75.0)
Weekly hours of professional help <sup>5</sup> , mean (SD)	26.7 (28.7)	8.2 (9.7)
Suffering from a chronic pathology, n (%)	9 (36.0)	8 (33.3)
<b>Patients' characteristics</b>		
Onset of symptoms, yrs., range, mean (SD)	0.55-14.05, 4.62 (3.53)	0.39-12.03, 4.11(3.28)
MMSE <sup>6</sup> , mean (SD)	18.5 (5.4)	19.0 (4.6)
IADL <sup>7</sup> scale, mean (SD)	0.6 (0.8)	1.1 (1.1)

<sup>1</sup>SD=Standard deviation, <sup>2</sup> PWAD= Persons with Alzheimer's disease, <sup>3</sup> Two participants were not children or spouses (one daughter-in-law and one friend), <sup>4</sup>Professional help= housekeeper, nurse, day care, meal delivery, <sup>5</sup>Among caregivers receiving respite help, <sup>6</sup> MMSE= Mini-Mental State Examination, <sup>7</sup>IADL= Instrumental Activities of Daily Living.

### Primary outcome: Self-perceived stress

T-tests (or Mann-Whitney tests) did not show significant differences between EG and CC over time (Table 3). An ANCOVA was conducted with PSS-14 score at M3 as a dependent variable, and as independent variables: PSS-14 at baseline, intervention, stratification factors (sex and relationship), and baseline characteristics found to be potential confounders (BDI and hours of weekly professional help received). Only PSS-14 at baseline ( $P<0.001$ ) and weekly help received ( $P=.013$ ) were significantly associated with PSS-14 at M3. Thus, no significant relationship was found with the intervention ( $P=0.3$ ).

**Table 3.** Mean (SD) of the score at each assessment (M0, M3 and M6) for primary and secondary outcomes in experimental group (EG) and control condition (CC)

Scales	Sub-scores	Group	M0	M3	M6	Mean difference M3 - M0	P-value M3 - M0
<b>PSS-14</b>		<b>EG</b>	24.2(9.0)	23.7(9.2)	25.0(9.9)	-0.5(8.0)	.98
		<b>CC</b>	24.5(6.7)	23.8(6.2)	23.8(6.9)	-0.7(4.5)	
<b>RSCS</b>	Obtaining respite	<b>EG</b>	55.0(26.9)	51.7(29.3)	54.7(30.6)	-3.3(18.3)	1
		<b>CC</b>	49.2(22.4)	48.9(26.8)	48.6(24.5)	- 0.4(24.1)	
	Responding to patients' behaviors	<b>EG</b>	72.2(17.0)	69.0(19.7)	71.5(23.1)	-3.2(14.1)	.52
		<b>CC</b>	66.3(18.2)	65.8(22.7)	68.4(15.3)	-0.5(15.5)	
	Controlling upsetting thoughts	<b>EG</b>	62.6(21.3)	63.2(19.7)	63.4(20.8)	0.5(17.0)	.83
		<b>CC</b>	64.7(18.1)	66.3(14.9)	64.0(13.7)	1.5(16.1)	
<b>RMBPC Frequency</b>		<b>EG</b>	1.6(0.5)	1.8(0.6)	1.8(0.6)	0.1(0.4)	.72
		<b>CC</b>	1.5(0.6)	1.6(0.6)	1.6(0.7)	0.0(0.3)	
<b>RMBPC reaction</b>		<b>EG</b>	2.2(0.4)	2.2(0.6)	2.3(0.5)	0.0(0.4)	.66
		<b>CC</b>	2.2(0.6)	2.1(0.6)	2.1(0.6)	-0.1(0.5)	
<b>ZBI</b>		<b>EG</b>	38.0(14.5)	38.3(14.9)	39.6(15.7)	0.3(6.6)	.74
		<b>CC</b>	35.0(15.0)	33.5(15.3)	34.8(15.9)	-1.5(6.1)	
<b>BDI-II<sup>7</sup></b>		<b>EG</b>	11.2(10.1)	11.5(9.2)	12.4(11.6)	0.3(4.6)	.56
		<b>CC</b>	9.0(7.4)	8.9(6.5)	8.8(7.2)	-0.1(2.7)	
<b>NHP</b>	Social Isolation	<b>EG</b>	14.1(20.4)	15.9(21.7)	16.5(23.4)	1.9(9.7)	.79
		<b>CC</b>	12.5(17.2)	15.5(19.9)	14.8(20.7)	3.0(14.9)	
	Emotions	<b>EG</b>	20.6(22.4)	18.6(18.09)	26.6(25.6)	-2.07(16.4)	.84
		<b>CC</b>	18.6(20.3)	19.0(19.5)	17.2(19.2)	0.36(12.9)	
	Energy	<b>EG</b>	27.9(39.1)	25.3(33.6)	35.9(39.4)	-2.6(30.6)	.22
		<b>CC</b>	26.6(31.7)	38.5(38.8)	35.6(41.6)	11.9(34.2)	
<b>VAS Knowledge</b>		<b>EG</b>	45.4(23.2)	59.2(25.9)	58.56(24.4)	13.8(15.1)	.008
		<b>CC</b>	44.5(23.5)	44.4(21.6)	51.67(18.8)	-0.0(17.4)	
<b>VAS Coping</b>		<b>EG</b>	67.4(15.8)	67.6(13.3)	67.2(17.6)	-0.2(13.8)	.71
		<b>CC</b>	61.4(21.8)	61.4(15.7)	61.8(17.5)	0.0(16.5)	
<b>VAS Stress</b>		<b>EG</b>	40.7(23.0)	48.6(24.3)	50.6(23.2)	7.9(23.8)	.053
		<b>CC</b>	50.2(15.3)	46.7(16.7)	50.3(17.0)	-3.5(16.5)	
<b>VAS QR</b>		<b>EG</b>	71.4(20.5)	73.8(21.5)	72.7(17.9)	2.4(13.5)	.36
		<b>CC</b>	72.1(16.9)	69.0(23.8)	69.3(18.0)	-3.0(19.5)	

PSS-14= Self-perceived stress, EG= Experimental group, CC= Control condition, RSCS=Revised Scale for Caregiving Self-Efficacy, RMBPC=Revised Memory and Behavior Problem Checklist, ZBI=Zarit Burden Interview, BDI-2=Beck Depression Inventory-second version, NHP=Nottingham Health Profile, VAS=Visual Analogical Scale, QCR= Quality of relationship between caregiver and the patient.

## Secondary outcomes

Means of each assessment for the secondary outcomes are shown in Table 2. The only measure showing significant change at M3 was VAS evaluating knowledge of the disease which gained 13.8 points (+/-15.1) in the EG, whereas score was decreased -0.04 points (+/- 17.4) in the CC ( $P=.008$ ) scoring a high effect size (Cohen's  $d = 0.79$ ). However, these changes were not found to be significantly different between the groups from M0 to M6.

Almost all participants considered Diapason topics useful (95.31%), clear (99.57%), and comprehensive (89.24%). Only one user reported problems watching the videos (demanding the installation of Flashplayer®) (Mrs. R, daughter, 72 y/o) and another (Mrs. M, spouse, 85 y/o) with a poor Internet experience was not able to use the Website unaided. Among the twelve topics, those describing strategies to maintain autonomy of relatives, and coping skills with PWAD's behavioral troubles, provoked the higher levels of positive emotional impact (61.50 and 61.90/100). The most applicable session (72.25/100) was focused on coping skills of PWAD's behavioral troubles. In contrast, the session focused on consequences and actions to prevent caregiver stress received the lowest scores for positive emotional impact (score 49.25/100) and applicability (61.00/100).

On average, participants used the website 19.72 times (+/- 12.88) and were connected for 262.20 minutes (+/-270.74) during the first 3 months. The most frequently visited section was the forum (mean= 24.86 +/- 40.95). Interestingly, only ten discussions and ten answers were posted throughout the study. Proportionally, in this time-slot the top users of the website were spouses. Four spouses (44.45%) and four daughters (33.34%) visited the website 26 times or more (3<sup>rd</sup> quartile). No significant correlation was found with website use frequency ( $Rho = -0.15$ ) or duration ( $Rho= -0.05$ ) and PSS-14 score change from M0 to M3. After M3 time of connection was near zero.

## Qualitative Analysis

We focused the analysis on EG participants' opinions of the program. We identified four trends: caregivers without a clear opinion ( $n=5$ , 20%), and caregivers with a clearly positive ( $n=3$ , 12%), mitigated ( $n=11$ , 44%) or negative ( $n=6$ , 24%) opinion. As summarized in Table 4, most of the wives had a negative opinion, while daughters expressed a reserved opinion on the program. The only ones expressing a positive opinion were men (a son and two husbands). As is shown in Figure 4, reasons varied between caregivers of a single category.

**Table 4.** Caregivers' profiles and opinions of the Web-based program

	<b>None</b>	<b>Negative</b>	<b>Mitigated</b>	<b>Positive</b>
Age, mean (SD)	58.00 (4,24)	66.83 (11.81)	62.45 (9.36)	72.00 (13.45)
<b>Relationship</b>				
Wife, n	1	3	0	0
Husband, n	1	1	1	2
Daughter, n	2	2	8	0
Son, n	1	0	2	1
<b>Total, n (%)</b>	5/25 (20.00)	6/25 (24.00)	11/25 (44.00)	3 (12.00)

Moreover we distinguished four topics comprising caregivers' opinions (Examples in Table 5):

***"It was useful for me"***: A few participants recognized having benefited from the program. They noted that the topics improved their understanding of the disease or changed their initial beliefs of the disease or diagnosis.

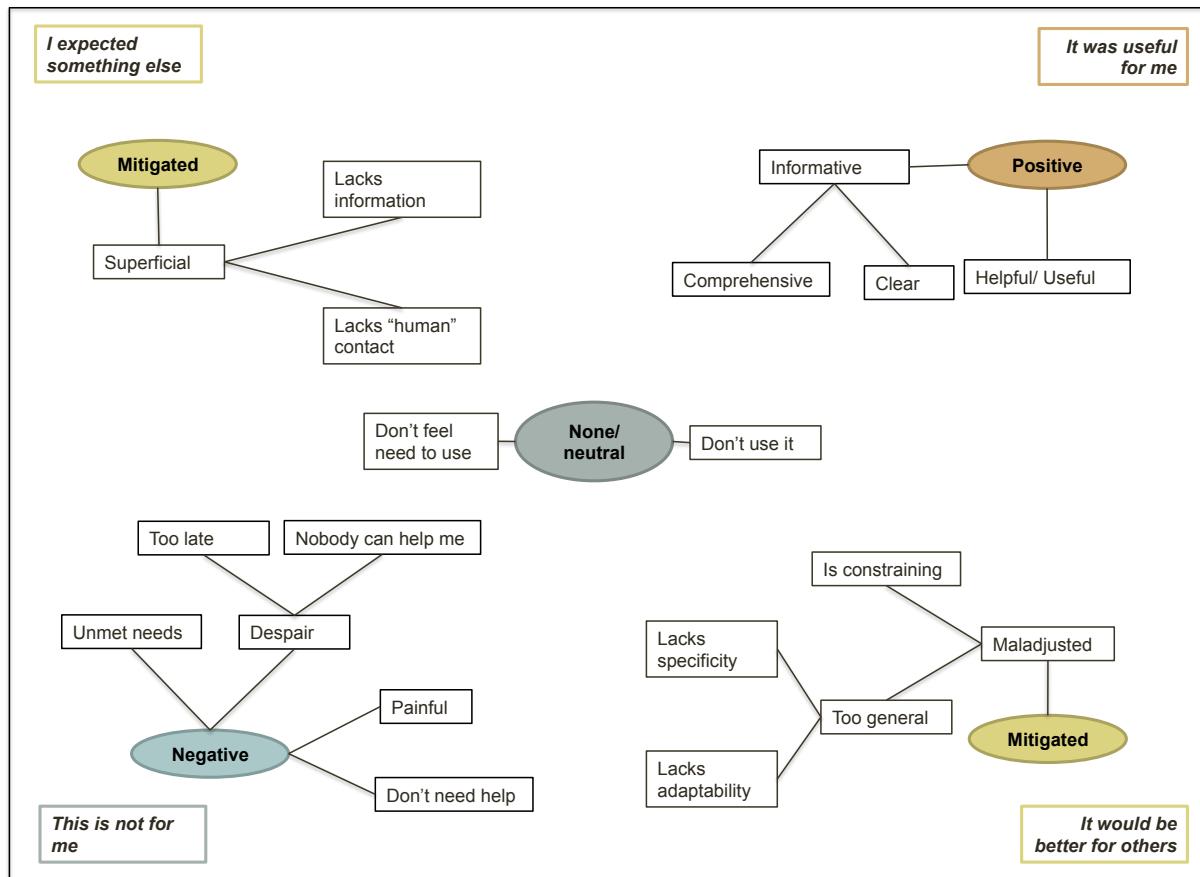
***"It would be better for others"***: Participants considered the program focusing on caregivers with a relative in later stages of the disease or, conversely, in the earliest stages. Most children thought that "message" more adapted for spouses rather than for them. The contrary was not stated.

***"I expected something else"***: Some participants found the content was not comprehensive enough. They would have preferred to receive more specific advice, more adapted to their individual situation, they also expected more "human interaction" with professionals or peers. Other participants would have preferred another kind of intervention (e.g. face-to-face, individual therapy, respite, financial support).

***"This is not for me"***: A few participants reported not feeling need for help, since they did not believe/accept the diagnosis or since they knew enough about caregiving for a PWAD. Others were in despair, and considered that the program had come too late, or did not believe that someone/something could help them. Most of them withdrew from the protocol.

Additionally, many EG and CC participants (from CC information was collected informally during visits M3 and M6) reported having used other resources to better understand the disease and adapt their behavior (reading books, asking for help, or contacting associations).

**Figure 4.** Thematic map of four opinion trends and topics revealed by the thematic analysis.



**Table 5.** Qualitative data. Categories and examples

Topic	Example (Verbatim)
<b>It was useful for me</b>	<p><b>Mr. P, husband, 83 y/o:</b> "The topics were highly interesting and useful for me. Advice is clear and helpful for improving communication with my wife"</p> <p><b>Mr. R, son, 51 y/o:</b> "The more I read the more I found it interesting. Sometimes I came back (to the first sessions) and I found that my perception of the topics had changed (...) I've understood that my mother behaves like this because of the illness, and her reactions are not against me"</p> <p><b>Mr. L, husband, 80 y/o:</b> "At the beginning I did not feel concerned, I was wrong. Maybe I was in denial. Now I find (in the program) a lot of interesting advice"</p>
<b>The program would be better for others</b>	<p><b>Mrs. L., daughter, 55y/o:</b> "I did not feel concerned at all, not yet (...) my mother is in the earliest stages"</p> <p><b>Mrs. R, wife, 75 y/o:</b> "This program is not adapted to the current state of my husband, he was diagnosed 7 years ago, I've already experienced these situations"</p> <p><b>Mrs. FR, daughter, 55 y/o:</b> "(...) some ideas and solutions are more adapted for spouses or for someone living with the person"</p>

<p><b><i>I expected something else</i></b></p>	<p><b>Mrs. L, daughter, 56 y/o:</b> <i>“The content is almost superficial, it lacks more information about books, addresses, events (...).”</i></p> <p><b>Mrs. R, daughter, 55 y/o:</b> <i>“I wished to know how to accurately behave or react when my mother upsets me, when she repeats the same question”</i></p> <p><b>Mr. L, husband, 81 y/o:</b> <i>“(Diapason) is too impersonal and “cold”, I tried to use the forum, but I need to look at the person in front of me (...).”</i></p>
<p><b><i>This is not for me</i></b></p>	<p><b>Mr. C, husband, 71 y/o:</b> <i>“I still don’t understand why the doctor said she had Alzheimer’s. For me she is depressed, that is all, this is normal after retirement (...).”</i></p> <p><b>Mrs. C, daughter, 56 y/o:</b> <i>“I know how to manage my mother, I have acquired some more experience in my professional life (Professor in Economics) The most important is to be organized, I am not stressed (...) the reason why I’ve participated is only to contribute to research”</i></p> <p><b>Mrs. M, daughter, 60 y/o:</b> <i>“I’ve tried to use the Website, but reading how my mother will lose her memory, her abilities is painful for me, (...) I am anxious, I’d preferred a psychotherapy. Finally I am not ready for that (...).”</i></p>

## Discussion

Due to the primary role of caregivers and the consequences of burden and physical weakness, national and international authorities have shown an increased interest in implementing innovative and cost-effective interventions in order to prevent caregivers’ weariness over the past years (Ankri and Van Broeckhoven, 2013; World Health Organization, 2012). In order to allow overburdened caregivers access to a psycho-educational program which complements usual care, we designed and adapted a fully-automated Web-based program based on a user-centered design approach. In this RCT our primary aim was to evaluate the efficacy of the Diapason program on perceived stress by caregivers of PWAD. To our knowledge this is the first RCT based on a mixed method, evaluating an online program for PWAD caregivers, which was adapted from a previously tested face-to-face program.

## Principal findings

Statistical analysis did not show significant differences in self-perceived stress (PSS-14) over time between the two groups. This result is most likely due to low statistical power, as we did not reach the planned sample size. Interestingly, while perceived stress level remained stable over time, VAS stress scores have risen, and AD progressed. Nevertheless, this



stabilization is observed in control groups from similar studies. In these, it seems that caregiving stress rarely increases in a period of three (or even six) months [17]. Moreover, VAS measured caregivers' overall stress, including other sources than caregiving. This has already been described by other authors [33].

After six months, a few participants had heightened stress levels. It may be due to a raised awareness of their loved one's diagnosis. However, awareness of diagnosis may improve their self-efficacy and ability to cope with it (Figure 2, e.g. Mr. L, husband, 80y/o). Understanding, accepting and anticipating the illness of their relative, even when stressful, might be useful and adaptive for caregivers who deploy positive coping strategies (e.g. self-regulation, problem-focused coping, positive emotion) [34], while those using avoidance-escape coping strategies (e.g. denial of diagnosis) may suffer from more negative long-term consequences (e.g. inability to cope with behavioral problems) [35]. The questionnaire used may have restricted stress capturing only negative aspects of stressful situations, and preventing differentiation of different coping styles.

Furthermore, the self-perceived level of knowledge of the disease was significantly improved between M0 and M3 in the EG. This level of knowledge was however equivalent in the two groups at M6. During the first 3 months, the Diapason program may have accelerated the learning process of EG participants, compared to CC participants, but the latter may have reached similar levels thanks to their experience and to information collected from other sources (e.g. websites, books, professionals/institutions, friends, etc.). However, our findings are comparable to those obtained in other studies, in which the intervention also had a major impact on disease knowledge [13].

During the first three months the program was highly used, in contrast with other studies [36], most likely thanks to obligatory weekly topic validation. Nevertheless after M3 almost no participant used the website, probably due to the lack of program content updating. Anyway, no significant correlation was found between frequency or duration of website use and PSS-14 score change from M0 to M3.

## **Qualitative results**

Our qualitative results were very similar to other studies. In fact, caregivers considered the program could be useful for people other than themselves [2] and wished to receive more personalized support, extensive information, specific assistance, and more communication with professionals and peers [37]. They preferred the topics offering strategies to maintain

the PWAD's autonomy and teaching skills for coping with behavioral problems [38] and were less interested in the notion of self-care [9]. Furthermore, specific subgroups of caregivers rather than others benefited from the program [39,40]. Some reported having a better perception of the disease or accepted diagnosis after the program [13]. In contrast with other studies [2] the most interested users were male caregivers. This is probably linked to the fact that our program was informational and centered on skill development. In fact, other studies reported that male caregivers preferred this kind of interventions, rather than emotional-focused ones. Besides, a floor effect in emotional questionnaires was also described in male caregivers, due to their underreport of negative feelings [41], which may explain this trend. In our study, daughters expressed more optimistic opinions of the program, compared with female spouses. In our view, since most of the children were working caregivers, distance-based interventions may constitute interesting and promising alternatives for them. Moreover, since female caregivers living with PWAD (often spouses) face greater caregiving challenges and are less aware of the damage that caregiving is provoking in them [42] they may need for more personalized interventions.

### **Strengths of the study**

A recent literature review [43] on the efficacy of Internet-based interventions for AD caregivers found that multicomponent programs, combining information with interaction between caregivers showed the most promising results. The Diapason program combined these recommended components. Furthermore, our study protocol met almost all the “best practice” criteria for a RCT (i.e., randomization, intention-to-treat analysis, prior sample size calculation, and restriction of analysis to primary outcomes) [44] and controlled intervention's implementation errors [45]. Indeed, we paid particular attention to the control of divergences in the information accessed by users in the Website. For instance, the Web-based program (Diapason) retained a similar structure to that of the on-site psycho-educational program. It proposed a weekly thematic session. In this way, we controlled the information viewed by the caregiver according to a specific schedule. Additionally, the Website content remained static during the study in order to propose the same content to all participants. Finally professionals moderated the forum and did not interact with caregivers in discussion so as to avoid the bias associated with the hypothetical imbalance of number of messages exchanged with the professional at the beginning and at the end of the protocol (e.g. the first participants would not have benefited from discussions published later in the study). Moreover, by adopting a mixed method analysis this program follows current methodological trends [46] advocating pertinence and need of using qualitative data to complement and contextualize RCT results

[19]. For instance, the results of satisfaction surveys showed more optimistic results than thematic analysis, which demonstrated the high relevance of the latter to nuance the opinion surveys.

### **Limits and lessons learned**

Although we used different strategies to facilitate the recruitment, only 37.98% (49/129) of pre-screened caregivers were included in the study. This trend is also observed in other studies evaluating Internet-based interventions (e.g. 26.52% in Chiu & Eysenbach, 2010; 42.37% in Kajiyama and colleagues, 2013). Thus, our recruitment difficulties may be due to negative attitudes towards a Web-based program [47]. However, reluctance of caregivers is also described in face-to-face interventions [48]. Otherwise, it is also possible that more caregivers could have participated if we had planned an online-based protocol for follow-up assessment. In any case, replication with bigger samples is necessary to complement our results. Besides, since caregiving characteristics (e.g. relationship, time of diagnosis, etc.) may affect coping strategies and stress levels, authors advise to limit inclusion criteria. Finally, despite the methodological rigor of the Diapason program, the choice of non-blinded assessments may have contributed to biased outcomes [49].

Nevertheless, the qualitative analysis provided us with valuable information for improving the program and understanding the results. Indeed, for daily use, the program requires warranted modifications such as frequent updating of contents and a greater interaction with professionals. Furthermore, to prevent the negative feelings described by some caregivers when they used the program, we strongly recommend the implementation of individual online support (e.g. chat) to reassure caregivers, and to clarify and contextualize the information offered by the program. Also some contents should be reviewed and nuanced.

### **Conclusions**

The mixed analysis approach in this study provided valuable information for improving content and methods, and has complemented and contextualized statistical results. This addresses optimistic perspectives for Internet-based interventions for incoming caregivers' generations. Indeed, our study highlighted that younger caregivers were more interested in

this kind of intervention. Nevertheless, they also expected more dynamic and exhaustive information, and greater interaction between professionals and caregivers. Finally, we recommend online support in order to clarify and reassure caregivers. We underline the need of an iterative adaptation of this kind of interventions in order to better meet caregivers' needs and expectations, evolving with caregiving and technological progress.

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## **Authors' Contributions**

VCL is the manager of the study, contributed to the design, and implementation the study, the statistical analysis, as well as to results analysis and wrote the paper. JW participated in the data collection and analysis of qualitative data and the edition of the paper. AR supervised statistical analysis, undertook the randomization process, and edited the paper. IG contributed to the data analysis and the edition of the paper. TD contributed to statistical analysis and to the revision of the paper. ASR is the main investigator, supervised the study, oversaw the implementation of the project, and edited the paper. All authors read and approved the final manuscript.

## **Conflict of interest**

None declared

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## ANCILLARY STUDY: CAREGIVERS' NEEDS AND EXPECTATIONS OF AN INTERNET-BASED INTERVENTION. A PRELIMINARY OVERVIEW

In this section we expose a preliminary overview of an ancillary study aiming at the evaluation of caregivers' needs and expectations of an Internet-based program. A part of this study was presented as a poster at the 11<sup>th</sup> International Conference on Alzheimer's and Parkinson's diseases (Florence, Italy – 2013)<sup>7</sup>.

### BACKGROUND

As described in this work, Internet-based programs represent a promising complement to usual care management and reach isolated or overburdened caregivers. Despite the promising results of online interventions (Boots et al., 2013), an important concern in this field of research is to favor the use and adoption of programs, and avoid their attrition (Chiu & Eysenbach, 2010; Christensen & Mackinnon, 2006; Eysenbach, 2005). In the most frequently used model designed to explain and predict health services use (Behavioral Model of Health Service Utilization - BHMSU, Andersen, 1995), the perceived needs of users are one of three main<sup>8</sup> factors determining the use of a service. Indeed, its author underlines the importance of perceived needs as the "*prime determinant of use at the expense of health beliefs and social structure*" (Andersen 1995, p. 3). These assumptions are supported by the findings of various studies in which caregivers have reported that they did not use interventions which do not correspond with their needs (van der Roest et al., 2009).

Therefore, the evaluation of end-users' needs and expectations in conceptual stages of design might ensure the adoption and avoid the attrition of intervention programs (Chiu & Eysenbach, 2010). Although other teams have already studied caregivers' needs (e.g. Amieva et al., 2012; Van der Roest et al., 2007), to our knowledge this is the first study evaluating caregivers' needs and expectations towards an Internet-based intervention. In our view, users' needs and expectations of services or products are closely linked to their

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<sup>7</sup> Cristancho-Lacroix, V. Wrobel, J., Rigaud, AS. (2013). Assessments of needs and requirements of caregivers of patients with Alzheimer's disease, for the design and development of a web-based psycho-educational program. *Neuro-degenerative diseases journal*.

<sup>8</sup> In the BHMSU model the other two components are predisposing factors (social, cultural or individual), and enabling factors that may facilitate the behavior of use but are not sufficient (also community or individual factors). Finally needs of users that could be evaluated (determined by the professional) or perceived (defined by the user).

familiarity in using similar services, and this would mainly be true for those based on technologies, which evolve quickly and constantly. The results obtained in this study might guide the conception of multiple Internet-based interventions for caregivers and constitute a valuable step forward in the iterative design process of the Diapason program. In this section we will describe the methodological design of this study and summarize the results of focus groups. They must be interpreted with caution, since they correspond to a partial analysis, conducted by one of the co-evaluators<sup>9</sup> (VCL).

## METHODS AND PROCEDURE

We conducted a descriptive study based on the methodological triangulation of quantitative and qualitative methods (Guion et al., 2011; Jones & Bugge, 2006). The methodological triangulation involves the use of multiple measuring methods in order to improve the validity of results, by analyzing a research question with different methods, which are qualitative for most but may also be quantitative. Thus, we involved three methods: focus groups, individual semi-structured interviews, and an online closed-ended questionnaire (Table 8). Moreover, we evaluated the perspectives of informal caregivers and healthcare professionals with interviews and focus groups. All participants gave their written consent before participation. An online consent was used for the questionnaires completed on the Internet.

**TABLE 8. OVERALL DESCRIPTION OF PARTICIPANTS PER METHOD**

<b>Method</b>	<b>Caregivers <i>n</i>, gender, relationship</b>	<b>Healthcare Professionals <i>n</i> gender, profession</b>
Focus groups	3 focus groups. 11, 8 female, 3 male 4 spouses, 6 children, 1 son-in-law	2 focus groups. 15 female: 4 geriatrists, 4 psychologists, 2 occupational therapists, 2 speech language pathologists, 1 social worker 15 female
Individual semi-structured interviews	12, 7 female, 5 male 4 spouses, 8 children	4 female 3 psychologists, 1 occupational therapist
Online Questionnaires	83, 59 female, 23 male, 1 non reported	None

<sup>9</sup> The qualitative data is concurrently analyzed by Laëticia Ngatcha-Ribert (Sociologist, Fondation Médéric Alzheimer) and Victoria Cristancho-Lacroix (Psychologist)

	42 children, 26 spouses, 3 friends, 7 others <sup>1</sup>	
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<sup>1</sup> Grandchild (2), niece (1), sister (2), daughter-in-law (1), son-in-law (1).

After their participation in the RCT, caregivers from the experimental and control groups were proposed to be involved in a focus group, or an individual interview. Before their participation all the volunteers had used the Diapason program. We conducted the focus groups and the interviews following a flexible thematic guide, exploring: a) their needs just after the disclosure of the relative's diagnosis, b) their current needs, c) their expectations towards a web-based support/psycho-educational program, and d) their suggestions to improve the Diapason program. In parallel we invited professionals of the Broca hospital having experience in the follow-up or counseling of informal caregivers of PWAD. In addition, we asked four professionals, experienced in counseling and psychotherapy for families of PWAD, if they were willing to be individually interviewed. The topics addressed in focus groups and interviews with professionals were the same as those evoked with caregivers. At the end of each interview and focus group, we noted, paraphrased and confirmed the "main ideas" with the participants, in order to avoid researcher bias when selecting the main topics. Additionally, we transcribed the interviews and focus groups, and used the thematic analysis method as defined by Braun and Clarke (Braun & Clarke, 2006). For that purpose two researchers would concurrently analyze the contents following the following phases: familiarization, coding, analysis, corroboration with initial verbatim, comparison of topics between evaluators, and reformulation (if necessary). Initial paraphrased ideas would be compared with conclusions of thematic analysis.

We designed the questionnaire based on preliminary results, and on the literature review (H Amieva et al., 2012; Oyeboode, 2003; Peeters, van Beek, Meerveld, Spreeuwenberg, & Francke, 2010; Rosa et al., 2010; H. G. van der Roest et al., 2009; Wackerbarth & Johnson, 2002). The questionnaire was reviewed and adapted based on the recommendations of three experts (2 geriatrists and 1 psychologist) with more than 20 years of experience working with caregivers of PWAD. The final version of the questionnaire was computerized and accessible online. The link was regularly published during 6 months (from October 2013 to April 2014) in the social networks (Facebook®, Twitter®) of the Diapason account, and posted in French forums devoted to informal caregivers of persons with dementia. The first questions defined caregivers' profile (relationship, age, diagnosis of relative, time spent in caregiving, etc). The second section evaluated their preferences regarding the contents (information), advice, and skills proposed by the website. The last part examined their

preferences about the delivery setting (e.g. website vs. forum vs. chat-room vs. videoconference) (an extract of the computerized version of the questionnaire is available in Appendix 19).

## PARTIAL FOCUS GROUPS RESULTS

We conducted five focus groups: three with informal caregivers (n=11), and two with health professionals (n=15) until data saturation (Ritchie & Lewis, 2003). The socio-demographics of both group types are summarized in Tables 9 and 10.

Most of the caregivers were female (66.6%, 8/12), aged between 51 and 79, and reported having helped or supported their relatives for 1 to 7 years. Groups were defined depending on the availability of participants.

**TABLE 9. INFORMAL CAREGIVERS' DEMOGRAPHICS BY FOCUS GROUP**

Focus Group	Gender		Age, y/o Mean (Sd)	Relationship	Years of caregiving Mean (Sd)
	Female	Male			
1	4	1	70,2 (5,8)	3 spouses, 2 children	4,4 (2,8)
2	1	1	63,5 (10,6)	1 child, 1 son-in-law	3,5 (2,1)
3	3	1	60 (6,2)	3 children, 1 spouse,	3,3 (2,1)

Professional caregivers were women, having 8 to 10 years of experience in the follow-up of caregivers, in private and in public institutions, and in different units (long term hospitalization, care centers, and memory clinics).

**TABLE 10. HEALTHCARE PROFESSIONALS' DEMOGRAPHICS BY FOCUS GROUP**

Focus Group	Gender		Age Mean (Sd)	Profession	Years of experience Mean (Sd)
	Female	Male			
1	7	0	40,3 (9,3)	4 psychologists, 2 speech therapists, 1 geriatrist	10,5 (6,0)
2	8	0	37,1 (12,0)	3 geriatrists, 2 occupational therapists, 2 psychologists, 1 social worker	8,1 (7,2)

Although caregivers and professionals addressed multiple topics during focus groups, for the purpose of this work, only the data concerning their needs and expectations of an Internet-based program are summarized.

#### NEEDS FOR HELP OR SUPPORT AND CONTENTS EXPECTED BY CAREGIVERS

Concerning the help expected online, children and spousal caregivers converged on their expectation to receive more information about the illness. Nevertheless, they showed some divergences in other areas. We calculated the ratio of comments in each topic per relationship in an attempt to compare them (Table 11). We noted that spouses expressed their interest in skills training with the same frequency as social or psychological support. In contrast, children evoked skills training four times more than psychological or social support. The practical information (e.g. address of institutions providing financial support or respite) was the least evoked field by both children and spouses.

**TABLE 11. CAREGIVERS' VERBALIZED NEEDS BY RELATIONSHIP**

Caregivers' needs	Total of comments	Spouses (n=4) N comments - $c/n^1$	Children (n=7) N comments - $c/n^1$
For skills training	35	7 - 1,75	28 - 4
For more information about illness	34	9 - 2,25	25-3,57
For psychological or social support	17	7 - 1,75	10 - 1,42
For practical information	10	1 - 0,25	9 - 1,28

<sup>1</sup>  $c/n$ : Total of comments per category divided by the number of participants in each category.

Caregivers expected the contents should be proposed not only to them, but also to other members of their family, and a few of them suggested adding the PWAD in the targeted group. Moreover, they wished to receive information not only about Alzheimer's disease but also about related dementias, in order to facilitate the identification and acceptance of diagnosis. In fact, sometimes they mentioned that their relatives did not "exactly" match the regularly described profile of Alzheimer's disease, and said they wanted to receive additional information on other forms of dementia. A few caregivers expected to receive information guiding them to improve the environment and life conditions of their loved-ones (e.g. avoiding administrative issues, ensuring home safety), and legal and administrative information, as well as practical advice (e.g. how and where to find a professional caregiver?).

As regards the comprehensiveness of information we observed contradictions. For instance, some caregivers wanted to know “everything about the illness, even the latest molecular studies”, while others commented, “we are not physicians, I don’t want to become the physician of my husband, I am her spouse”. Similarly, some preferred a website for all caregivers, independently of the disease, while others advocated for the specificity of caregiving for persons with Alzheimer’s disease and related dementias. Not surprisingly, depending on the stage of the disease of care-recipients, the concerns and expectations were different. For instance a female spouse said: “the most difficult for me was to learn how to persuade my husband to use diapers, I spent a lot of time on the Internet looking for advice without any result”. While another caregiver in the same group responded: “(I think) it would be really hard to read about it for people who are still not at this stage. There are other websites for this, for people who are more dependent”.

Health professionals suggested providing information illustrated by examples. Moreover they suggested including information motivating families and patients to go out and participate in cultural and local activities.

**TABLE 12. CONTENTS EXPECTED BY CAREGIVERS**

Caregivers' expectations	Professionals' suggestions
<ul style="list-style-type: none"> <li>• Talking about Alzheimer’s disease and related disorders so they can easily recognize the symptoms of their loved-ones.</li> <li>• Creating a website for the informal caregiver, the patient, and for the rest of the family</li> <li>• Delivering practical solutions such as “How can we find a professional caregiver?” or “How to choose the providers of food and delivery services?”</li> <li>• Giving advice in order to improve the patients’ life conditions (e.g. administrative issues, home security)</li> <li>• Providing more legal and administrative information (e.g. curatorship, tutorship and advisership)</li> <li>• Adding links to specialized websites as a complement</li> </ul>	<ul style="list-style-type: none"> <li>• The program should suggest specific and practical examples to explain the basics of AD (e.g. What kinds of memories are impaired in patients suffering from AD).</li> <li>• The contents should be specific to AD and exhaustive enough for caregivers.</li> <li>• Adding information about local cultural activities for family caregivers and patients.</li> <li>• Providing less theoretical and more practical information</li> <li>• The contents should be regularly updated</li> </ul>



## DELIVERY AND IMPLEMENTATION CHARACTERISTICS

The participants also exposed various opinions on how they expected the program to be delivered (Table 13). Most of the caregivers thought it should be proposed immediately after the disclosure of the diagnosis, in order to recall or reinforce the information, which was forgotten or not understood upon disclosure.

Spouses were more concerned than children about the privacy and protection from intruders: “*some individuals could access the forum just for fun, we need to make sure that there are only “real” caregivers, they must be referred by general practitioners*”. In contrast, children were more flexible about website accessibility, and said “*it should be a website for everyone, it is unnecessary to ask for a code*”. Almost all agreed on the importance of a moderator/animator for the forum who should propose specific topics to capture the interest of caregivers. Various caregivers considered interaction with peers and professionals as a cornerstone of the program arguing: “*otherwise we can read a book or go to another website*”. Some of the caregivers suggested that face-to-face meetings with a professional be organized for the available participants of the online program. Thus, the topics addressed during these meetings could feed into the forum discussion.

**TABLE 13. CAREGIVERS' EXPECTATIONS OF THE PROGRAM'S IMPLEMENTATION AND DELIVERY CHARACTERISTICS**

Caregivers' expectations	Professionals' suggestions
<ul style="list-style-type: none"> <li>• The program should be proposed immediately after disclosure of diagnosis</li> <li>• The program should be freely accessible (at any time, for everyone)</li> <li>• The program should be proposed by a general practitioner to avoid the presence of “non caregivers” in the forum</li> <li>• The access to the forum should be controlled by a code and remain anonymous</li> <li>• The forum should be moderated by a professional or a senior caregiver</li> <li>• The forum has to offer some topics of discussion, in order to target the needs and motivate participation</li> <li>• Organizing meetings with caregivers. The conclusions or topics addressed during the meetings could feed into the forum discussion</li> <li>• Offering a didactic approach</li> </ul>	<ul style="list-style-type: none"> <li>• Giving everyone access to the website, except for the forum, which should be controlled by a code</li> <li>• Although the users should have free access to all the website, it should be mandatory to access some topics (essential information) (i.e. in order to avoid misunderstandings)</li> <li>• The forum should be moderated by a healthcare professional</li> <li>• The forum may offer the discussion on different topics</li> <li>• Organizing (online?) social events for caregivers. Something to help them take their minds off their daily concerns.</li> <li>• Organizing topic-centered meetings and transmitting them by video-conferencing.</li> </ul>

- |   |  |
|---|--|
| <ul style="list-style-type: none"><li>• Vulgarizing the program by advertizing it through general practitioners' offices, medical journals, or television</li></ul> |  |
|---|--|

Interestingly caregivers also evoked the necessity to divulgate the program by advertising it through general practitioners' offices, medical journals, or even TV, the objective being that all caregivers or most of them should have access to this program.

Professionals' opinions of the delivery characteristics of the program were for most of them in agreement with those of caregivers. Moreover, they underlined the individual characteristics and needs of caregivers, and the necessity to help them also from an individual perspective. However, they stressed the necessity for more didactical (videos, graphics, pictures) and less theoretical information. One common complaint of caregivers and professionals was about the multiplicity of disjointed and sometimes incomprehensible resources and services for caregivers in the country. They evoked the idea of centralizing and informing caregivers of all the resources and services in existence for them in a unique space.

## PRELIMINARY CONCLUSION

Given the wealth of data collected in this ancillary study, the results presented in this section only constitute a part of them. Although we cannot come to conclusion about the overall trends of these data based on a partial analysis, we wish to underline the expectations' divergences between subgroups of caregivers, depending on their relationship with the PWAD, as well as the latter's level of dependency, also described in the literature (A. Steffen et al., 2008). These differences support the recommendations for the design of interventions, which suggest to adapt the contents for different subgroups of caregivers, favoring their personalization as much as possible. Some ideas regarding how Internet-based programs could be individualized are described by other authors (Beauchamp et al., 2005; Kajiyama et al., 2013; HG Van der Roest, Meiland, Jonker, & Dröes, 2010). For instance, the definition of different "user-profile system" based on the socio-demographic characteristics and the reported needs might allow the system to adapt the program content. Additional perspectives for this work, supported by the literature, are discussed in the next chapter.

## **Part 3**

### General discussion and perspectives

## CHAPTER SIX

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# GENERAL DISCUSSION AND PERSPECTIVES

*"To succeed, one cannot afford to be a realist"*

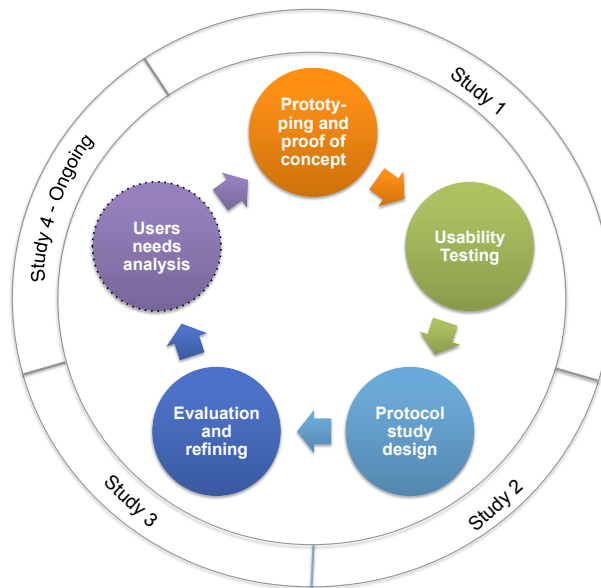
~ Albert Bandura ~

Address before the American Psychological Association, 1998

Despite the growing interest in Internet-based programs for caregivers of PWAD, to our knowledge few studies have investigated them from a cyclical perspective. The aim of this work was to explore the whole process from the development to the evaluation of a Web-based program for caregivers. Throughout this document we overviewed the socio-demographic and economic impact of caregiving, and provided a brief review of stress theories, and of the consequences of stress on caregivers' health and wellbeing (Chapter 1). This was followed by an overview of current trends in non-pharmacological interventions and support programs for caregivers of PWAD as well as the methodological recommendations for their evaluation and implementation. Then, we presented a short review of the user-centered design approach, and offered some examples of web-based programs (Chapter 2). In the empirical and experimental part of this work we presented four studies (Figure 11).

Firstly, we presented the aims and contents of the Diapason program, as well as the iterative user-centered design approach for the development and improvement of the program's usability (Chapter 3, *paper 1*). Secondly, we conceived the study protocol of a randomized clinical trial (RCT) to evaluate the efficacy of the Diapason program (Chapter 4, *paper 2*), and we discussed the methodological and ethical considerations for this study. Thirdly, we displayed the qualitative and quantitative findings of the RCT, the limits, strengths, recommendations, and perspectives for this work (Chapter 5, *paper 3 (submitted)*). Finally, we overviewed the partial and preliminary results of an ongoing study to evaluate the caregivers' needs and expectations towards a web-based program, based on a methodological triangulation (Chapter 5).

**FIGURE 11. STUDIES CONDUCTED DURING THE CYCLICAL PROCESS OF THE DIAPASON PROGRAM'S DEVELOPMENT AND ASSESSMENT**



In the present chapter we summarize and discuss the main results of this thesis, and present its limitations and methodological issues, its scientific implications, along with the recommendations and perspectives of this work.

## MAIN FINDINGS

The studies presented in this thesis illustrate the different stages of the development and evaluation process of the Diapason program (Figure 11). During the course of this work we tried to answer the following research questions:

- 1) *How can a user-centered design approach be applied to the development of a web-based program like Diapason?*
- 2) *How can we design an RCT to evaluate a web-based program like the Diapason program?*
- 3) *Is the Internet-based program Diapason useful and acceptable for caregivers of PWAD?*

### HOW CAN A USER-CENTERED DESIGN APPROACH BE APPLIED TO THE DEVELOPMENT OF DIAPASON PROGRAM?

Based on previous experiences of the team in caring for families of PWAD, we developed an online psycho-educational program for overburdened or isolated caregivers. The strategies

and areas of intervention were identified based on professionals' experience and caregivers' needs, informally collected from an earlier project (de Rotrou et al., 2006; de Rotrou et al., 2010), and a literature review conducted by our team (Wu et al., 2009). Diapason was also developed based on cognitive theories of stress (Chapter 1). It was focused on three main action fields aiming at the improvement of caregivers: a) caregivers' beliefs, about the illness and the role of caregiver, b) caregivers' skills, to manage daily life difficulties, and to improve communication with the relatives, and c) caregivers' social support and help-seeking behavior, giving information that may help caregivers to obtain respite or financial support if necessary, as well as offer an anonymous forum to meet and interact with other caregivers.

The second part of Chapter 3 presented an exploratory-descriptive study, in which forty-nine participants (12 healthcare professionals, 6 caregivers, and 31 healthy older-adults) were involved in a double iterative design based on the user-centered design approach for the development of the Diapason program and its website. This approach fosters the conception of accessible products by the involvement of end-users, evaluating their needs and requirements (Fisk et al., 2009). Principally, the Diapason program was dedicated to spouses, who are statistically the most frequent caregivers of PWAD. The needs and requirements of this population, mainly over 65, differ from younger caregivers, owing to perceptual, sensorial and cognitive changes, which come with aging, and due to their little experience in using the Internet. By applying the user-centered design approach we aimed to prevent older caregivers from having to deal with a maladjusted and imposed website (Cristancho-Lacroix, et al, 2014). The process for the development of the Diapason program included perspectives from three groups: experienced professionals participating in workshops, informal caregivers who evaluated the aims, contents, and design during a proof of concept, and healthy seniors who tested the usability of the latest versions of the website. During each workshop a multidisciplinary team of health professionals formulated the specifications and recommendations for each version based on selected criteria, inspired from usability guidelines (Demiris et al., 2001; Fisk et al., 2009; Morrell, 2005; Nielsen & Landauer, 1993), as well as on the results of the proof of concept and usability tests that we conducted. The development of the program included iterative loops between end-users and professionals' feedback, resulting in the correction and development of the newest versions.

In this manner, we obtained four versions of the website, evaluated by end-users at different stages of the development. During the proof of concept and usability tests, the participants pointed out various usability issues, which had not been noticed by professionals, underlining the valuable role of end-users within this process. The application of the usability guidelines raised the accessibility to older adults, in coherence with other works (Morrell, 2005). The users spent less time and asked for less help in the latest version of the Diapason website.

The statistical significance of these differences was not calculated, and only descriptive analysis of data was conducted (means and percentages), as is usual in this field of work (e.g. Or & Tao, 2012; Riiser, Løndal, Ommundsen, Sundar, & Helseth, 2013). Anyway, owing to the lack of resources or time limitations, some usability issues remained unsolved. This version was retained to be tested in an RCT.

## HOW CAN WE DESIGN A RANDOMIZED CLINICAL TRIAL (RCT) TO EVALUATE THE DIAPASON PROGRAM?

**Chapter 4** described the methodological design of the RCT to evaluate the efficacy of the Diapason program. Since this project was partially funded by the French Ministry of Health, the Département de la Recherche Clinique et du Développement (DRCD) from the Assistance Publique des Hôpitaux de Paris (APHP) sponsored and monitored it. To our knowledge, this is the first trial carried out in France designed to evaluate the efficacy of an Internet-based psycho-educational program for caregivers of persons with dementia. The methodological design of this study tried to integrate and match the demands of the research sponsor, the Diapason team's experiences, and the recommendations provided by the state of the art.

Based on the literature, the sample size was defined at 40 persons per group, to obtain a statistical power of 80% (Cristancho-Lacroix et al., 2013; Pedrelli, Feldman, Vorono, Fava, & Petersen, 2008). We resolved that a single-blinded design was not feasible for this study. Moreover, we planned to conduct the assessments at hospital in order to avoid bias and missing data resulting from the inappropriate filling of questionnaires at home without the help of an evaluator, as described in earlier studies (H. Kerhervé, 2010). In agreement with recent recommendations (Vernooij-Dassen & Moniz-Cook, 2014), we attached great importance to controlling the implementation of the program. For this end, the sessions of program was arranged in a pre-determined order, and was progressively activated after validation (i.e. caregivers had to validate session 1 before visualizing session 2, and so on). Moreover, the role of professionals in the forum was limited to ensuring respect between the participants, but direct discussions with participants in the forum or by e-mail were avoided as much as possible. Furthermore, the website content remained static during the study in order to propose the same content to all participants. The only source of variability as regards content came from caregivers' discussions on the forum, but as it was part of the program's aim, we did not control it.

The constructs selected for this study were supported by the expected effects of the Diapason program on caregivers' stress, burden, self-efficacy, and the bother provoked by the BPSD of PWAD (as described in Chapter 4). We based our hypothesis about the effects

of Diapason on Lazarus and Folkman's model of stress and coping (1984) and on Bandura's model of self-efficacy (Bandura, 2009). Following the recommendations from other studies (Boots et al., 2013), this program provided caregivers with: a) information about the disease, b) coping skills, and c) social support between caregivers, through a forum. Our hypothesis was that caregivers using the program would show decreased stress levels associated with caregiving situations, in comparison with caregivers in control conditions, who would not use the program. In agreement with the cognitive stress and coping model of Lazarus and Folkman (Lazarus & Folkman, 1984) changes in knowledge and coping skills might modify caregivers' appraisals about stressful situations, which may increase their self-efficacy and reduce burden. Besides, this may avoid irrational beliefs, which are predictors of depression and poor health (Gonçalves-Pereira et al., 2010).

To evaluate perceived stress, we selected the Perceived Stress Scale (PSS, 14-item version) one of the most used instrument to measure subjective stress. We also measured self-efficacy with a scale specific to caregivers of patients with dementia (Steffen et al., 2002), burden with the Zarit Burden Inventory (Ankri et al., 2005; Zarit et al., 1986) and the emotional impact of BPSD with the Revised Memory Behavioral Problem Checklist (Teri et al., 1992). We also measured health status and depressive symptoms as possible side effects of decreased stress in caregivers. Indeed, the diminution or prevention of distress may positively affect the health status of caregivers (Van Daele, Hermans, Van Audenhove, & Van den Bergh, 2012) as well as their depressive symptoms (Bartolomucci & Leopardi, 2009) as demonstrated in previous works.

For the implementation of the study protocol, geriatricians and psychologists were trained for pre-screening, recruitment, and assessment of participants. A computer-generated randomization list, including blocking and stratification by gender and relationship, was used to assign the participants to one of two groups. An external agent from the hospital controlled the respect of protocol by monitoring the records every two months. The national authorities for the protection of participants approved the protocol study before the recruitment started. During 6 months, the experimental group (EG) had to have access to the program; in the first three months, they had to validate a weekly session, then they had free access to the website. Controls received usual care during 6 months, and then they received free access to the program. Two research psychologists conducted three evaluations at baseline, M3 and M6. Data were collected via an electronic case-report form.



## IS THE INTERNET-BASED PROGRAM DIAPASON USEFUL AND ACCEPTABLE FOR CAREGIVERS?

**Chapter 5** described the results of a unblinded monocentric RCT carried-out between 2011 and 2014 in the memory center of the Broca hospital. Our aim was to evaluate the effect of the Diapason program on caregivers' perceived stress, self-efficacy, burden, and perceived health. Forty-nine participants were randomly assigned to the EG (n=25) or the control condition (CC) (n=24). All available data at baseline were analyzed by intention-to-treat. Our statistical analysis did not show significant differences in self-perceived stress between the groups. Nevertheless this result was most likely due to low statistical power. Indeed, despite 20 months of inclusions, and different strategies to boost the recruitment (posters, leaflets, weekly e-mails to physicians, systematic reminder in the medical records of AD patients, and phone messages for pre-screened caregivers), only 37.98% (49/129) of pre-screened caregivers were actually recruited in the study. Of 80 persons who were not recruited, a) 29% were unreachable and did not give a clear reason to refusing, b) 21% declined the invitation for unknown reasons, c) 16% reported difficulties to come for three evaluations, d) 11% did not feel need of help, e) 8% did not believe or accept the diagnosis, f) 8% reported the recent or planned institutionalization of their relatives, and g) 3% did not have experience with the Internet.

The EG participants significantly improved their knowledge of the disease between M0 and M3 but were equalized by CC at M6. Thus, the Diapason program may have accelerated their learning in EG in the first three months, and CC participants may have increased their knowledge thanks to their experiences and information collected from other sources. Seemingly because the program contents were static, the rate of use was nearly zero after M3.

Following current methodological trends (Clay, 2010; O'Cathain, Thomas, Drabble, Rudolph, & Hewison, 2013) we implemented mixed research methods in our study. For that, we treated interviews and open-ended questions following the thematic analysis method (Braun & Clarke, 2006b). We identified four topics and four trends in the opinions of caregivers. Interestingly the type of relationship seemed to have affected participants' opinions of the program. While daughters had mitigated feelings, and female spouses expressed negative or neutral opinions, male caregivers had the most positive opinions towards the program. We concluded that if male caregivers had a positive opinion from Diapason, this was possibly due to their demonstrated preference for informational and skills-practice interventions, rather than for emotional-focused ones. Otherwise, their tendency to underreport negative feelings was also described in the literature (J. Gant, Steffen, & Lauderdale, 2007). However,

and as described in other works, caregivers expected something else of this program (Nichols et al., 2011), or thought that it may be better for others (Van der Roest et al., 2010a). A minority considered the program was not for them or did not report a clear opinion. Informally, some participants reported that after having used the Diapason program, they read more books or looked for more information through associations or other websites, which matches the results obtained by other web-based programs (Beauchamp et al., 2005). Finally, we concluded that mixed research methods complement the RCT's results with valuable information. These allowed us to plan the improvement of Diapason, and offer recommendations for other interventions.

## STUDIES' LIMITATIONS AND ISSUES

### EXTERNAL VALIDITY

#### USER-CENTERED DESIGN STUDY

Although our study involved informal caregivers and older adults, the latter were recruited through associations for seniors in Paris. The socio-economic and cultural characteristics of most of them likely do not represent those of older adults or of caregivers living in remote regions. Besides, our study only involved seniors who had some experience using the Internet, limiting the generalizability of our findings to other seniors without a similar background.

#### RANDOMIZED CLINICAL TRIAL

The external validity of results obtained in the RCT of Diapason is limited. In spite of different strategies used to reach the pre-established sample size, this was not possible. Unfortunately, the lack of statistical power did not allow us to obtain conclusive results. Furthermore, owing to the monocentric design, the generalizability of our results is minimized. It is important to note that another factor limiting the external validity of this study is the non-inclusion of caregivers who lived in remote regions, which was at the beginning our targeted population. This is likely because most of them were not available to come back to the hospital for the three evaluations. Another inclusion criterion was that caregivers were experienced using the Internet, which has limited the study recruitment, but also deviated our sample from overall characteristics of caregiver populations (also described by Van der Roest, Meiland, Jonker, & Dröes, 2010). Consequently, in this study caregivers were

younger, were more often children, and most of them did not live with the PWAD, in comparison with general caregiver trends. Nevertheless, this criterion (i.e. having experience in using the Internet) appears relevant, firstly in order to include participants in the control group with similar chances to find information through other websites, and secondly by the evident need to have basic skills to use the Diapason program.

While being aware of the risk of bias associated to unblinded studies (Hróbjartsson et al., 2013), we did not implement a single-blinded design for different reasons. The Diapason project had limited resources, which impeded us from having different staff dedicated to the recruitment and the assessments. Moreover, we thought it likely that participants would evoke their use of the program during evaluations. Indeed, during assessment sessions a few participants actually evoked their opinions of the program, without elicitation from the evaluator, confirming the infeasibility of the blinded design for this study.

Another limitation is that all participants were recruited at a hospital (the Broca hospital). Nevertheless, research has demonstrated a subject selection bias, since caregivers who are willing to go to a hospital for assessments or follow-ups are less depressed and distressed than those who prefer being interviewed at home (Steffen et al., 2008).

## METHODOLOGICAL ISSUES AND LIMITATIONS

### USER-CENTERED DESIGN STUDY

Although we involved end-users in different stages of the development, a greater participation is still possible. For instance, end-users might be involved in the workshops in which professionals make decisions. Moreover, some ergonomic mistakes in the first versions of our website might have been prevented earlier in the development process with the involvement of an expert in ergonomics.

### RANDOMIZED CLINICAL TRIAL

#### INCLUSIONS AND DROPOUTS

The main limitation of this study was the lack of statistical power. The low rate of inclusions and high rate of dropouts may suggest that the program contents and/or the methodological protocol did not meet all the needs of caregivers. Indeed, while geriatricians pre-screened 129 potential participants, only 49 were actually recruited. Caregivers did not report clear

reasons in almost half of cases (i.e. 21% declined their participation, 29% were unreachable by phone or by e-mail). However, interestingly, the practitioners who proposed the onsite program (Entr'aïdants, described in Chapter 2) in parallel to the Diapason protocol reported that caregivers who refused to participate in the Diapason protocol often also refused the onsite program. The third reason that caregivers gave for declining participation in the Diapason study may explain why they rejected both programs: coming back to the hospital three times, once every three months was almost impossible for them. Considering that the program is available online, this kind of study might be conducted in a multi-center design, provided the questionnaires are available online.

### UNDERSTANDING THE REFUSALS OF CAREGIVERS

Little research has been devoted to analyzing caregivers' non-use of support and intervention programs. Multiple conditions must be satisfied before caregivers decide to utilize them. Firstly, the person has to consider him/herself a likely target of the intervention. Nevertheless, recognizing oneself as caregiver is not done without external influence (O'Connor, 2007). Anyway, caregiver interventions are proposed to family members who come with patients, often regardless if they consider themselves as caregivers or not. A part of this issue might be fixed by adding a verification of self-identification (as caregivers) on pre-screening protocols. Nevertheless, caregivers might reject the support or help for them for other reasons. For instance, caregivers may feel guilty when they take care of themselves, (O'Connor, 2007) since it is contradictory with their representations of the caregiver's role (i.e. caregivers are able to give, but not to receive care).

Further, Brodaty and his colleagues (2005) found that caregivers of persons with dementia do not use support services mainly because caregivers do not feel need of help, or due to a lack of awareness of their needs. Moreover, and in line with our experience, caregivers reported do not use the services since they used "managing at moment" strategies, or did not want interference from others (Brodaty, Thomson, Thompson, & Fine, 2005).

Like caregivers, patients with depression and anxiety do not use care services and facilities. Only half of those with depression, and one-third of patients with anxiety seek professional help. Specific models for help seeking are used to analyze and promote it (i.a. Azjen's theory of planned behavior, Andersen's behavioral model). In brief, these models are often based on cognitive constructs such as beliefs, appraisals, and awareness of risks. The pathway towards help-seeking behaviors may vary depending on the model, but overall it is influenced by cognitive (e.g. perceived control) or instrumental (e.g. availability of resources) variables

(Gulliver, Griffiths, Christensen, & Brewer, 2012). We did not find specific models to explain the help-seeking behavior of caregivers. Thus, future research may envisage the study and modeling of help-seeking behaviors in caregivers of persons with dementia. Another interesting approach is the study of factors associated with readiness; understood as the degree or stage in which the person feels “ready” to receive support or help. In a recent study, Gitlin and Rose (2014) found that caregivers more or less used and implemented the program's strategies to manage dementia-related behavioral problems, depending on their level of readiness. They conclude that readiness is a “malleable state” that may evolve for most caregivers. Nevertheless, some characteristics of caregivers may limit this evolution, for instance, caregivers having greater financial difficulties were unable to increase their readiness level, while great initial readiness was associated with better caregiver mood, less financial difficulty, lower patient's cognition status and more behavioral symptoms (Gitlin & Rose, 2014).

#### SELECTING A MORE LIMITED SAMPLE

A considerable issue in this field of work is that caregivers are a quite heterogeneous population (Zarit & Femia, 2008), they have different risk factors, and are involved in diverse situations. In addition, they may use various resources to cope with these situations, a few being more efficacious than others. As underlined by Steffen (2008), given that “one size not fit all”, the type of intervention that must be proposed in a given context and for a particular caregiver will depend on the patient's stage of dementia, on the caregiver's coping strategies, and overall psychological and physical health, as well as on the resources available in the community. For instance, caregivers of patients at earlier stages of the disease had other questions and worries than caregivers of persons at later stages of the disease (Steffen et al., 2008). These variables should be taken into account when defining the targeted population of an intervention and the inclusion criteria to research studies.

Thus, although we faced important difficulties to recruit volunteers, methodologically it would have been necessary to limit the inclusion criteria even more. Indeed, the profiles of caregivers recruited in our study were quite heterogeneous. The consequences of that fact were observed in our qualitative results, in which caregivers' opinions towards the program varied depending on their relationship with the care-recipient. As described by various authors, depending on caregivers' characteristics, their needs and benefits from interventions may diverge (Gant et al., 2010). Besides, some constructs, such as self-efficacy, are highly situation-specific, while in dementia caregiving the situations evolve, among others, with the

progression of the illness (Bandura, 2006). As a consequence, self-efficacy scales and other instruments are sensitive to caregivers' profiles, and usually are not adapted for all of them. For instance, in the RSCS (Steffen et al., 2002), the subscales which evaluate the self-efficacy in obtaining respite and managing difficult behaviors, do not fit the caregivers in early stages, since they are not facing all the situations presented in the questionnaire. In the same way, the RMBPC (Teri et al., 1992) evaluating the behavioral and emotional problems of patients, and emotional reactions of caregivers, could be difficult to fill for caregivers of PWAD at the onset of the disease, since they do not present all the symptoms presented in the questionnaire. Thus, the restriction of inclusion criteria may allow a better definition of research hypothesis, a better selection of questionnaires, and a higher reliability of results.

### SELECTING THE MAIN INSTRUMENT OF MEASURE

To our knowledge, the only stress scale validated in French populations is the Perceived Stress Scale (Bellinghausen et al., 2009). Nevertheless, as described in Paper 3 (Chapter 5), although it is the most widely-used scale to measure the perceived stress, it is not able to differentiate the quality of coping strategies (i.e. positive or negative, adapted or not). It means that caregivers who deny the diagnosis of their relatives may score low stress levels, while they are using a negative coping strategy, which may provoke in the long term worse consequences than those for caregivers with high stress scores, but having accepted the diagnosis and using positive coping strategies (e.g. self-regulation, problem-focused coping, positive emotion) (Folkman, 2008). A second limitation is that we adapted the overall instruction of PSS-14, and focused it on caregiving situations; therefore, its validity and fidelity could have changed. Thus, a study of psychometric qualities of PSS-14 in French caregivers is advisable.

### INTERVENTION LIMITS

Although inspired from Lazarus and Folkman's (1984) coping stress model, and from Bandura's self-efficacy model (2008), the Diapason program was not strictly grounded in a clear theoretical framework, which might make its replication difficult. Indeed, the Medical Research Council as well as other authors, recommend the use of a theory-driven design approach, in order to favor the definition of intervention strategies and a more pertinent selection of constructs and outcome measures for evaluating their efficacy (Craig, Dieppe, & Macintyre, 2008; Steffen et al., 2008; Vernooij-Dassen & Moniz-Cook, 2014).

Even if only two Diapason participants complained about the usability of the website, the usability of the program was not totally ensured. Due to a lack of time or resources, the version tested in the RCT presented usability issues that had not yet been fixed. We simplified the content of the Diapason program, thinking that it would meet the needs of overburdened caregivers, since it then required less time to use than earlier versions. Nevertheless, caregivers had expected to receive more comprehensive and in-depth information than provided by the program. Moreover, they also expected to have more interaction (online) with professionals. Our findings in the proof of concept, the RCT, and the focus groups converged on this point. In fact, caregivers (or even professionals) were not fundamentally against the use of Internet-based interventions, provided that the social support and professional advice would be guaranteed through this. Moreover, caregivers had expected to receive more targeted and individualized contents. Various programs overviewed in Chapter 2 demonstrated the feasibility of this option, which might be implemented in further development stages.

As described earlier in this discussion, we adapted the program's setting to reduce the risk of type III errors, associated to the variations in the implementation of the program. Nevertheless, this could have limited the dynamism and interactivity of the program, affecting its use and attractiveness. This might explain why nearly none of the participants of the experimental group used the program after three months. But we cannot rule out the fact that they may have thought the program was ended since they had already validated the twelve weekly sessions.

## ETHICAL CONSIDERATIONS

Some ethical concerns emerged during the course of the study. During the RCT few participants found that some of the program's content was painful for them. For example, a participant was distressed reading about the progression of the illness; and another found it useless and upsetting to read about the possibility of institutionalization, while it was not an option for her husband. In order to avoid such situations, we strongly suggest complementing the program with individual or face-to-face follow-up (even online) thanks to which professionals could reassure caregivers, as well as clarify and contextualize the information offered by the program.

This question sheds light on a related concern: the reasons why some caregivers decided to participate in the program. Why did caregivers who were not ready for this intervention accept to participate? Is it likely that the "white coat effect" has influenced the enrollment in

the study? In fact, the literature has shown the chances that persons agree to participate in a research study are increased by the “*respect for the authority of the recruiting physician, the trust in the research institution, or peer pressure*” (Mandava & Millum, 2013, p. 38). In this respect, two facts in our study have attracted our attention. Firstly, some caregivers have reported having accepted to participate to the RCT even if the program did not interest them. Secondly, many of the participants that gave a positive answer to the physician (n=129), changed their opinion a short while afterwards, when the research psychologist met with them to confirm their inclusion in the protocol. In our study, we have no reason to suggest that the practitioners involved in the pre-screening stage might have disrespected the participants' autonomy; nevertheless we wish to highlight the necessary vigilance in the enrollment stages to protect the patients and their families.

In a recent paper, Mandava and Millum (2013) discussed different strategies based on manipulation, usually used to favor the enrollment in research studies. Their analysis underlines ethical issues and considerations that have to be taken into account in all human-related research in order to avoid the disrespect of participants' autonomy. Thus, strategies like persuasion (i.e. someone motivates another person by showing rational links between his existent reasons to act and that action), and offering, are considered acceptable by authors, since they respect the autonomy of participants. In contrast, deceptive manipulation (e.g. selling a broken object to someone, saying that it was in good condition), motivational manipulation<sup>10</sup>, coercion and circumstantial manipulation<sup>11</sup> are forms of influence that disrespect the autonomy of persons (Mandava & Millum, 2013).

## SCIENTIFIC IMPACT

The results from the development and assessment process of the Diapason program presented in this thesis have multiple scientific implications. Firstly, this is the first psycho-educational online program for caregivers of PWAD developed and tested in France, to our knowledge. Despite the benefit of the user-centered design approach, to improve the acceptability and usability of web-based programs, few works have reported or described its application to developing programs like Diapason (Chiu et al., 2009; Van der Roest et al.,

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<sup>10</sup> Authors illustrate **motivational manipulation** with the example of an Harish Krishna member who hands a flower to a passerby, and says that is a gift for her. When she accepts the flower, he asks if she can give a donation. The manipulation was based on the predictable susceptibility of the person to social norms of reciprocity.

<sup>11</sup> Mandava & Millum (2013) illustrate **circumstantial manipulation** in the following example: a man who calls a friend and invites him for dinner at a restaurant. When the bill arrives, he says that he forgot his wallet. Without this influence the other friend would not have chosen to pay or to have dinner in the restaurant.



2010). Given the greater number of clinical teams attracted by the use of technologies, but not necessarily trained or experienced in the user-centered design approach, the papers reporting the experiences of other teams, the issues and recommendations may be highly useful for them. Other teams in different health domains have also used user-centered design or testing usability to develop e-health interventions (Voncken-Brewster et al., 2013) and prevention programs (Riiser et al., 2013), demonstrating the interest of this approach to improve the feasibility and acceptability of interventions. In fact, this approach may turn out to be beneficial for all users, regardless of their Internet experience or age (e.g. Windows 8 ®) (Nielsen, 2012).

As regards our second paper, research protocols are rarely published in spite of their utility. Protocol studies enable systematic reviewers, funders, and researchers to have an overview of ongoing studies, reduced the distortion of published evidence and prevent the duplication of research efforts. Furthermore, with this kind of publications patients and caregivers are informed on studies in which they could wish to participate. Additionally, publications on the results of such studies rarely permit an in-depth presentation of methodologies, limiting their replication (Skogvoll & Kramer-Johansen, 2013).

Although some research studies evaluating interventions for caregivers using technologies have already been conducted (for instance Brennan, 1995; Chiu & Eysenbach, 2011; Lewis, Hobday, & Hepburn, 2010), few of them have used an RCT design (Beauchamp et al., 2005; Brennan, 1995; Kajiyama et al., 2013) and to our knowledge none has formally used mixed research methods. While our statistical results were not conclusive due to the lack of statistical power, the qualitative analysis underlined critical considerations about future interventions and research in similar domains. Our findings highlighted the decisive role of needs assessment. With the RCT results we had a preliminary overview of the expectations and needs of caregivers concerning an intervention based on Informatics and Communication Technologies (ICT) that should be complemented and confirmed by further studies. To this end, we designed and conducted a descriptive study to evaluate caregivers' needs and expectations. The findings of this study aim to contribute to the improvement of Diapason and to the development of other Internet-based programs for caregivers, in the perspective of better meeting caregivers' needs.

## PERSPECTIVES AND RECOMMENDATIONS

The development of ICT-based programs is a promising field with multiple applications in healthcare. With the recent emergence of smartphones and tablets, broader possibilities are

opening. The enhanced Internet speed connection and the virtual omnipresence of Wi-Fi networks in many countries amplify this field of action. In addition, the digital gap between generations is progressively reducing (Gombault, 2013), which means that most people could be attracted by the use of such programs. In accordance with this context, our findings showed that younger caregivers of PWAD are optimistic and hopeful towards the utility of Internet-based programs (Cristancho-Lacroix, et al, *submitted*). Conclusions from different teams (Craig, Dieppe, Macintyre, et al., 2008; Steffen et al., 2008; Vernooij-Dassen & Moniz-Cook, 2014; Zarit & Femia, 2008) and our own experience (Cristancho-Lacroix et al., 2014; Cristancho-Lacroix et al., 2013) allow us to propose some perspectives for future works, some of which are discussed in this section.

## EVALUATING CAREGIVERS' NEEDS

The development of interventions for caregivers of PWAD is a complex and challenging mission. In fact, the chronicity and progression of symptoms, the loss of autonomy for the patients and the increasing demands and health weakness of caregivers trigger multiple needs for patients and their families. Following the iterative development and improvement process of the Diapason, we designed and conducted a study to better understand the needs and expectations of caregivers towards the contents and functionalities of an Internet-based program (**Chapter 5**). In our view, users' expectations towards a service (or a product) might be affected by their sets of experience. This might be all the more truth of their expectations towards technologies-based services or products, which are continuously evolving; therefore persons may update their wishes or needs based on the progress of technologies. We based this study on a methodological triangulation design in order to ensure the reliability of results (Guion et al., 2011). To achieve this, unpublished data of semi-structured interviews from the Diapason RCT, experts' interviews, five focus groups and 83 online questionnaires were collected. Their concurrent treatment and analysis by two professionals (VCL, psychologist, and LNR, sociologist) is currently ongoing. All the participants from the focus groups and interviews had used the Diapason program at least once. The questionnaire was designed based on preliminary results of focus groups and interviews, as well as on the literature review and experts' advice.

In focus groups and interviews, the participants reported their expectations about the contents, delivery characteristics, and functionalities of an Internet-based program, as well as the kind of support and help that they expected to receive. Based on partial and preliminary results of focus groups, we highlighted the divergences in the needs and expectations of caregivers depending on their age, their relationship with the PWAD and the degree of

dependency of their relatives. These divergences support the findings of open-ended questionnaires filled out by the participants of the Diapason RCT. Nevertheless, the preliminary results of this ancillary study should be analyzed with caution. The merging process of concurrent analysis from focus groups and other methods (i.e. semi-structured interviews and the online needs and expectations questionnaire) might modify the comprehensiveness and focus of results.

## DESIGNING INTERVENTIONS PROGRAMS

The Diapason program is the first version of our web-based program for caregivers. Various changes need to be implemented, using an iterative user-centered design, involving actively caregivers as early as conception stages, for instance inviting them to participate in decision-making workshops and in the design of mockups or in the assessments of contents. The design of the interface has an important impact on the acceptability of the program. Thus, the participation of expert designers and ergonomists is required at this stage. Moreover, the correct estimation of resources and their optimization are key point for the effective development of programs. For instance, testing paper mockups and conducting pilot studies would be inexpensive and effective methods to evaluate the prototypes.

The results of the ongoing qualitative analysis may support the decisions concerning the topics and modalities to deliver the program. An interesting variant of this program may be the involvement of PWAD in the design, if the aim is to create a program for both caregivers and patients. Besides, the development of an adapted version of this program for professionals' training may be contemplated. However, taking into account the great difficulty for caregivers to accept support interventions it might be necessary to add a preliminary stage targeting the improvement of help-seeking behavior, such as is recommended with depression and anxiety (Gulliver et al., 2012). Anyway, the adoption of a clear theoretical framework is highly recommended to support the development of programs. Moreover, it may facilitate the definition of hypotheses and the future evaluations (Craig, Dieppe, & Macintyre, 2008; Steffen et al., 2008; Vernooij-Dassen & Moniz-Cook, 2014). In any case, we should keep in mind that the process to achieve a successful intervention may take many years of multidisciplinary work (Astell et al., 2008; Meiland et al., 2014). Indeed, we could say that this process is endless, since the expectations and needs of patients and families tend to continuously evolve, and in this line the interventions have to be continuously reviewed.

In agreement with current trends, the program should aim more at the positive affects (e.g. self-efficacy, self-regulation, meaning-focused coping), and focus less on the negative

aspects of caregiving (e.g. stress, burden, behavioral problems of relatives). Moscovitz and her colleagues (2012) have recently published an interesting attempt at this: in a pilot study, they evaluated the efficacy and feasibility of an intervention designed to increase positive affect in people suffering from high stress, newly diagnosed with HIV. The multicomponent intervention was grounded in eight empirically founded techniques (i.a. capitalizing, gratitude, mindfulness, positive reappraisal, among others). Over six months of intervention, researchers found significant changes in positive and negative affects, and good acceptability and practice of techniques. The authors recommended using this kind of interventions with other populations experiencing higher levels of stress (Moscovitz et al., 2012), such as caregivers of persons with dementia.

Another suggested approach is to target a specific domain of intervention instead of caregiving-related consequences, which are a broad and highly variable field. An example of a targeted intervention for caregivers is the work of Gitlin and her colleagues (2010). They developed a training program in non-pharmacological strategies to reduce targeted behavioral symptoms of dementia and caregiver burden (Gitlin, Winter, Dennis, Hodgson, & Hauck, 2010a, 2010b).

Finally, our experience underlines the necessity and priority for developing a program, which favors social interaction with other caregivers, and greater contact with professionals. Indeed, regardless of the type of delivery setting for the program, caregivers always ask for more interaction with health professional (Nichols et al., 2011). Given the positive effects of social support on caregivers (Au et al., 2009; Bass et al., 1998; Colvin, Chenoweth, Bold, & Harding, 2004) and on persons with dementia (Amieva et al., 2010), it must be prioritized. At any rate, the development process is closely related to the evaluation stage.

## EVALUATING THE PROGRAMS

There are effective methods to study the feasibility and acceptability of interventions. For instance, Vernooij-Dassen & Moniz-Cook (2014) suggest that before reaching the evaluation stage, researchers should conduct implementation studies such as single-case studies: *“at the developmental phase (they) are a good example of where the researcher can test the success and failure of an intervention”*. Based on these studies, researchers could identify and address contextual factors, overcome obstacles, and reinforce implementation facilitators. The authors underline the relevance of implementation errors (also called type III error, linked to the control of intervention implementation, and affecting their internal validity) in the assessment of interventions.

After these first stages, they suggest beginning the evaluation phase with the efficacy studies based on explanatory trials, and then evaluate its effectiveness using pragmatic trials (Vernooij-Dassen & Moniz-Cook, 2014). In France, the studies on the efficacy of Internet-based interventions for caregivers have only just started. Indeed, French culture has specificities which may impact the acceptability and adoption of these programs, as well as the participation to research protocols, which must be considered. As highlighted by various authors, quasi-experimental studies may be more adapted to evaluate some psycho-educational interventions, rather than RCTs. Indeed, the randomization in studies like Diapason can be limited by the caregivers' selection. For instance, it is quite conceivable that some of the control participants who withdrew from Diapason protocol study sought out a treatment comparable to that received by experimental group (Zarit & Femia, 2008).

In order to be able to generalize the studies' results, the recruitment of isolated caregivers living in remote regions requires more attention. Anyway, based on our experience, the number of outcome measures would be reduced, and targeted in only two or three domains (e.g. self-efficacy and stress, or burden and depression). The use of disparate measures might render the analysis more complex, leading the researchers to wrong conclusions.

In addition, the use of monetary incentives was recently studied, demonstrating significant effects in reducing the attrition of online trials (Khadjesari et al., 2011). Thus its use might be implemented in studies with caregivers to raise their enrollment and reduce the dropouts. Nevertheless ethical considerations in this respect have to be taken into account (London, Borasky, & Bhan, 2012). Finally, cost-effectiveness analysis could contribute to the integration of these initiatives in usual care management systems, by comparing the program with usual care (Tate, Finkelstein, Khavjou, & Gustafson, 2009). Nevertheless cost-effectiveness analysis is not frequently included in the evaluation of programs like Diapason (Blom, Bosmans, Cuijpers, Zarit, & Pot, 2013).

## IMPLEMENTING THE PROGRAMS

It is advisable for professionals to systematically propose the use of the Diapason program to caregivers, once this program is able to meet the needs of caregivers (and likely the patients), and in complement to additional care management strategies offered by the hospital. Indeed, programs like Diapason may ensure the access for every caregiver, including those living in remote regions, or those who are not willing to participate in in-person support programs. Nevertheless, and given that the lack of skills in informatics remains a great limitation for using Internet-based interventions, and other online services

and products (e.g. smartphone applications, websites used to pay one's taxes or do online shopping), we suggest the development of training programs in technologies to accelerate the reduction of the digital gap. Moreover, in coherence with the issues encountered in this work, and the seemingly limited research carried out in this domain, we highly recommend further studies to investigate the mechanisms and factors that may explain the lack of help-seeking behaviors and self-care in caregivers. We think the understanding of this problematic is a key leverage for the successful implementation of programs.

As regards the viability of interventions in middle and long-term perspectives, Kajiyama and his colleagues draw our attention to the economic resources necessary to maintain and offer these services. In fact, even if they are more accessible and less costly in the long term, the Internet-based programs require human and technical resources for their correct functioning. As underlined in their paper, "*cost factors need further consideration in providing a feasible resource that will (be) maximally effective*" (Kajiyama et al., 2013).

Finally, we suggest that the most important aspect to ensure the quality and relevance of intervention programs is their constant evolution, supported by the active involvement of targeted users and stakeholders. The mission of researchers and funders is to guarantee that technologies adapted to health are designed to optimize services and interventions, making them more accessible, and favoring the interaction between patients, families, and professionals.

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# Appendices

## APPENDIX 1. RÉSUMÉ EXTENSIF EN FRANÇAIS

Les programmes psycho-éducatifs et thérapeutiques en ligne suscitent aujourd'hui un intérêt accru. Cependant, peu de programmes à destination des aidants familiaux de personnes atteintes de la maladie Alzheimer existent de nos jours. Ce travail est d'ailleurs, à notre connaissance, la seule initiative existante en France pour cette population. Le but de ce travail était de contribuer à la connaissance et à la compréhension du processus itératif de développement et d'évaluation des programmes d'intervention en ligne pour les aidants familiaux. Nous résumons dans cette annexe les thématiques générales traitées dans ce travail de thèse.

### Partie théorique

*Dans le **Chapitre 1** de ce document, nous avons présenté un aperçu général du contexte sociodémographique et économique de la maladie d'Alzheimer, les conséquences du stress sur la santé et le bien-être des aidants ainsi que les facteurs protecteurs et prédictifs de celles-ci. Nous évoquons les théories cognitives du stress les plus utilisées pour l'étude et l'analyse des relations entre les facteurs sous-jacents à l'aide informelle et les conséquences provoqués sur la santé et le bien-être des aidants.*

Etant donné la magnitude des conséquences socioéconomiques provoquées par la démence dans les pays industrialisés, l'Organisation Mondiale de la Santé (OMS, 2012) l'a définie comme étant le plus grand défi pour la santé publique du XXIème siècle. La maladie d'Alzheimer est la forme la plus fréquente de démence en Europe (Lobo et al., 2000). Bien que, dans les dernières années, de très importantes études aient permis de mieux comprendre les mécanismes physiopathologiques de la maladie, aucun traitement curatif n'existe à ce jour. En effet, le traitement proposé à ces patients est encore symptomatique.

La maladie d'Alzheimer est une maladie neuro-dégénérative, de début progressif et insidieux (Serrano-Pozo, Frosch, Masliah, & Hyman, 2011), plus fréquemment diagnostiquée chez les personnes de plus de 65 ans. Dans les premiers stades de la maladie, des troubles cognitifs principalement de la mémoire épisodique sont décrits (Belin, Ergis, & Moreaud, 2006). Cependant, les nouveaux critères diagnostiques étendent la définition de la maladie d'Alzheimer aux formes non-mnésiques, par exemple avec une atteinte visuo-spatiale, langagière ou exécutive (Lopez et al., 2011; McKhann et al., 2011). Dans les stades modérés et sévères, d'autres régions cérébrales sont affectées, provoquant un déficit croissant des fonctions cognitives supérieures (langage, fonctions exécutives, gnosies, praxies), des troubles psycho-comportementaux tels que l'apathie, agressivité, parfois

hallucinations) et une perte progressive des capacités fonctionnelles (McLaughlin et al., 2010). Comme conséquence de ces altérations cognitives, comportementales et fonctionnelles, les patients perdent progressivement leur autonomie.

Les familles et proches, appelés aidants «informels», «naturels» ou «familiaux» restent la source la plus commune d'aide pour les personnes âgées souffrant d'une déficience physique ou cognitive (A. Steffen, Gant, & Gallagher-Thompson, 2008). Ils jouent un rôle crucial dans le maintien à domicile des patients, en leur apportant soutien, surveillance ou aide dans les activités instrumentales de la vie quotidienne (IADL) tel que la cuisine, le nettoyage, le transport) et/ou dans les activités de la vie quotidienne (AVQ) telles que prendre le bain ou l'habillement.

Dans la maladie d'Alzheimer, en raison de la progression des troubles, les demandes d'aide en temps et en effort augmentent en permanence. En conséquence, les aidants peuvent avoir des difficultés à prendre soin de leur santé, réaliser des activités de loisirs ou se consacrer du temps libre (Brookmeyer et al., 2002; Vitaliano et al, 2003). Les aidants ne sont pas seulement confrontés à la perte progressive des facultés cognitives et aux troubles psycho-comportementaux de leurs proches, mais également à la forte charge émotionnelle qui l'accompagne (Brodaty et Donkin, 2009).

Un des modèles théoriques le plus fréquemment utilisé pour l'analyse du processus du stress est le modèle cognitif (transactionnel) du stress et du coping de Lazarus et Folkman (1984), revu en 1997 par Susan Folkman. Ce modèle postule qu'une situation critique sera considérée plus ou moins stressante en fonction de ce que la situation représente pour la personne et de la manière dont elle évalue ses propres capacités pour y faire face. De multiples facteurs contextuels (nouveau, prédictibilité) et personnels (croyances, engagements) déterminent la manière dont la situation sera évaluée. Ainsi, la situation peut être perçue comme un danger, comme une menace ou comme un défi, face auxquels les personnes déploient des réponses qui seront plus ou moins adaptées. Ces stratégies peuvent être centrées sur la situation stressante (par exemple. des stratégies pour changer ou remédier la situation), centrées sur l'émotion (par exemple. gérer ses émotions avec la relaxation, mais aussi éviter la situation) ou centrées sur la signification (par exemple. en donnant un sens aux situations vécues) (Folkman, 2008).

Les études mettent en évidence une prévalence plus importante de la dépression, du stress chronique, du fardeau et de l'anxiété chez ces aidants que chez d'autres conjoints ou proches de personnes non-dépendantes. Les niveaux de stress semblent être plus élevés chez les épouses, habitant avec la personne malade et confrontées à des problèmes financiers. L'état d'avancement de la maladie, les troubles du comportement et la relation

entre l'aidant et le malade sont également associés aux niveaux du stress des aidants. Des variables intrapsychiques comme les stratégies de coping, la personnalité ou le sentiment d'efficacité personnelle de l'aidant sont également des facteurs protecteurs ou prédicteurs du stress, de dépression et du fardeau.

*Dans le **Chapitre 2**, nous avons décrit les tendances des dernières années dans la prise en charge non-pharmacologique des aidants, qu'elles soient proposées en face-à-face ou en ligne. Nous avons présenté également quelques recommandations méthodologiques pour l'évaluation et la mise en place de ces programmes en tenant compte des particularités des aidants. D'autres recommandations propres à la création et au développement de programmes en ligne sont aussi décrites, en nous basant sur une approche de design centrée sur l'utilisateur.*

L'Organisation Mondiale de la Santé (World Health Organization, 2014) et la Haute Autorité de Santé (Haute Autorité de Santé, 2008) recommandent le développement et la mise en place de programmes psycho-éducatifs pour les aidants. Ces interventions ont pour but de les informer sur la maladie, de les former à des compétences pour prendre en charge les soins quotidiens, et de mettre à leur disposition des consultations ou des interventions comportementales et cognitives pour soulager leur détresse psychologique.

Gallagher-Thompson et Coon (2007) ont classifié les programmes selon le type d'intervention: les programmes psychoéducatifs et d'entraînement aux compétences, les interventions psychothérapeutiques, et les programmes multi-composants, qui incluent au minimum deux types différents d'interventions. De manière générale, les programmes inclus dans leur revue de la littérature ont démontré avoir une efficacité modérée dans la diminution des niveaux de stress et du fardeau chez les aidants.

Bien que la plupart des programmes pour les aidants soient proposés sous un format présentiel dans les centres médicaux, les Technologies de l'Information et de la Communication (TIC, tels que le téléphone, le mail ou le DVD) sont utilisées dans ce domaine depuis la fin des années 90. Ces initiatives répondent aux besoins des aidants qui ne peuvent ou ne souhaitent pas participer aux interventions présentiels. Il est à noter que seulement quatre programmes en ligne à destination des aidants de personnes atteintes de démences ont été jusqu'à maintenant évalués avec un essai clinique randomisé. La plupart de ces programmes étaient axés sur trois domaines d'action: les connaissances, l'entraînement aux compétences et le soutien social. Dans l'ensemble, un (petit) effet significatif a été constaté en utilisant les échelles de dépression, de stress, du sentiment de compétence, d'auto-efficacité, et du fardeau, ainsi qu'une plus grande intentionnalité dans la recherche de soutien.

Les « petits » effets significatifs dans les études précédemment citées seraient dus à des problèmes méthodologiques dans l'évaluation (Zarit et Femia, 2008), ou dans l'implémentation des interventions pour les aidants (Vernooij-Dassen & Moniz-Cook, 2014). Ainsi, les auteurs mettent en garde les chercheurs sur les erreurs fréquemment commises dans les études d'efficacité des interventions pour les aidants lorsqu'elles sont basées sur des standards de recherche clinique ou pharmacologique. Une des erreurs les plus fréquemment observées est de considérer la situation d'aide comme critère principal, en incluant tous les aidants sans définir la variable ciblée par l'intervention. Par exemple lorsqu'un programme ciblant la diminution des symptômes dépressifs inclut tous les aidants indépendamment de leur niveau de dépression. Les auteurs soulignent également l'hétérogénéité des aidants, et par conséquent le besoin de limiter les critères d'inclusion. Ils rappellent également que les critères d'évaluation doivent correspondre aux objectifs de l'intervention. En cohérence avec Vernooij-Dassen & Moniz-Cook (2014), ils soulignent l'importance du contrôle des conditions de mise en place des interventions. En effet, les chercheurs doivent s'assurer du contrôle des variables lors de l'implémentation des interventions, notamment des sources de variabilité provenant des professionnels proposant les interventions.

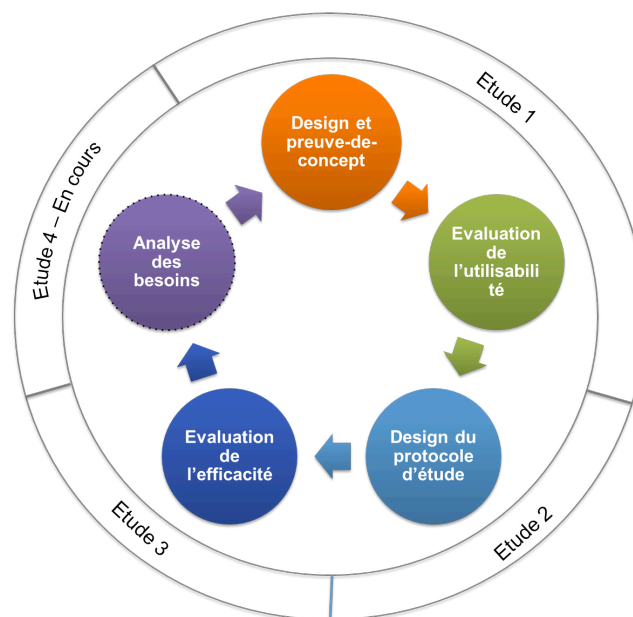
Le développement de programmes psycho-éducatifs en ligne doit également tenir compte de la facilité d'utilisation des interfaces et des outils technologiques. Au cours des dernières années, le design centré sur les besoins et les exigences des utilisateurs a pris une importante place dans le développement de tout type de services et produits (technologiques ou pas) (Gibbons, 2013). Cette approche est d'une grande utilité lorsque les programmes ou services sont à destination de populations ayant des besoins particuliers, telles que les personnes âgées ayant une faible expérience des technologies, et des déficits cognitifs et sensoriels dus au vieillissement normal (Fisk et al., 2009).

Le but principal de cette approche est d'améliorer l'utilisabilité des outils, en facilitant son apprentissage (*learnability*) et sa mémorisation (*memorability*), tout en répondant aux attentes des utilisateurs dans un temps adapté, et en minimisant la possibilité de commettre des erreurs, pour procurer de la satisfaction pendant son utilisation. Le design centré sur l'utilisateur se sert des méthodes inspirées par la recherche en psychologie et en ergonomie. L'utilisation de cette approche dès les premiers stades de développement a montré un impact positif dans l'acceptabilité et une meilleure utilisation des produits et services. (Fisk et al., 2009; Chiu et al., 2009).

## Partie empirique et expérimentale

Dans les **Chapitres 3 à 5**, nous avons présenté quatre études (Figure 1) correspondant aux différents stades de développement du projet Diapason. Tout d'abord, dans le Chapitre 3 (Article 1), nous présentons les objectifs et contenus du programme Diapason, ainsi que son processus de développement et d'adaptation en suivant un design itératif centré sur l'utilisateur. Dans le Chapitre 4, nous décrivons le protocole d'étude d'un essai clinique randomisé (ECR) pour évaluer l'efficacité du programme Diapason (Article 2), et nous en discutons les considérations méthodologiques et éthiques. Enfin, dans le Chapitre 5, nous analysons les résultats quantitatifs et qualitatifs de cet ECR, nous discutons les limites, les points forts, les recommandations et les perspectives de ce travail (Article 3, soumis). Dans la deuxième partie du Chapitre 5, nous résumons les résultats préliminaires d'une étude en cours sur l'évaluation des besoins et des attentes des aidants à l'égard d'un programme en ligne.

**Figure 1.** Etudes menées au cours du processus cyclique de développement et d'évaluation du programme Diapason



Au cours de ce travail, nous avons tenté de répondre aux questions de recherche suivantes:

- 1) Comment un design centré sur l'utilisateur peut-il être appliqué dans l'élaboration d'un programme psycho-éducatif en ligne tel que Diapason?
- 2) Comment concevoir un ECR pour évaluer l'efficacité du programme Diapason?
- 3) Diapason est-il un programme en ligne efficace pour les aidants des personnes atteintes de la maladie d'Alzheimer?



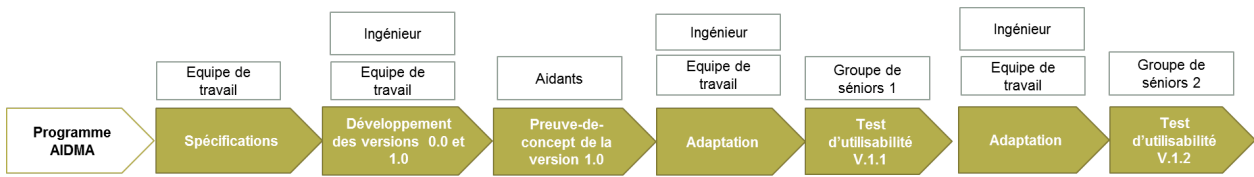
*1) Comment un design centré sur l'utilisateur peut-il être appliqué dans l'élaboration d'un programme psycho-éducatif en ligne tel que Diapason?*

En nous basant sur les expériences de l'équipe dans la prise en charge des familles de personnes avec maladie d'Alzheimer, nous avons développé un programme psycho-éducatif en ligne, ciblant particulièrement les aidants surchargés ou isolés. Les stratégies et les domaines d'intervention ont été identifiés sur la base de l'expérience professionnelle et les besoins des aidants recueillis de manière informelle dans une étude précédente (de Rotrou et al, 2006; De Rotrou et al, 2010), ainsi que d'une revue de la littérature réalisée par notre équipe (Wu et al, 2009). Le programme Diapason cible trois principaux domaines d'action visant l'amélioration: a) des croyances des aidants, sur la maladie et le rôle des aidants, b) des compétences des aidants, pour gérer les difficultés de la vie quotidienne, et mieux communiquer avec leurs proches, et c) du soutien social des aidants ainsi que de la recherche d'aide, avec des informations pratiques pour trouver du répit et l'accès anonyme à un forum pour échanger avec d'autres aidants.

Dans la deuxième partie du Chapitre 3, nous présentons une étude exploratoire-descriptive, dans laquelle quarante-neuf participants (12 professionnels de santé, 6 aidants familiaux, et 31 séniors) ont participé dans le processus itératif de design centré sur l'utilisateur pour le développement du programme Diapason et son site web. Le programme Diapason a été principalement destiné aux conjoints, qui sont statistiquement les aidants les plus fréquents des personnes souffrant d'une maladie d'Alzheimer. En raison des changements perceptivo-sensoriels et cognitifs qui accompagnent le vieillissement normal, et de leur faible expérience de l'utilisation d'Internet, les besoins des conjoints de plus de 65 ans diffèrent de ceux des aidants plus jeunes. En utilisant le design centré sur l'utilisateur, nous avons cherché à éviter que les aidants les plus âgés soient confrontés à un site inadapté à leurs capacités et à leurs ressources (Cristancho-Lacroix, et al, 2014).

Le processus de développement du programme Diapason est basé sur les résultats de réunions de travail (workshops), des preuves-de-concept et des tests d'utilisabilité des deux dernières versions du site (Figure 2). Au cours des réunions, l'équipe de professionnels a formulé les spécifications pour chaque version basée sur des critères inspirés de recommandations d'utilisabilité (Demiris et al, 2001; Fisk et al, 2009; Morrell, 2005; Nielsen & Landauer, 1993). L'ensemble du processus de développement s'est basé dans des boucles itératives entre les observations et les attentes des utilisateurs finaux, les suggestions des professionnels, et les améliorations faites par les ingénieurs.

**Figure 2.** Processus de développement du programme Diapason



Les quatre versions du site (Figure 3), ont été évaluées par les utilisateurs finaux à différents stades du développement. Au cours de la preuve-de-concept et d'utilisabilité, les participants ont souligné divers problèmes d'utilisabilité, qui n'avaient pas été remarqués par les professionnels. L'application des recommandations d'utilisabilité a amélioré l'accessibilité pour les personnes âgées, en cohérence avec d'autres travaux (Morrell, 2005).

**Figure 3.** Aperçu sur des quatre versions du programme Diapason



En effet, les utilisateurs ont eu besoin de moins de temps et ont demandé moins d'aide dans la dernière version du site Diapason, pour exécuter les mêmes tâches. Une analyse descriptive des données a été réalisée (moyennes et pourcentages), comme il est habituellement recommandé dans ce domaine de travail (voir par exemple Ou & Tao, 2012; Riiser, Løndal, Ommundsen, Sundar, et Helseth, 2013). La dernière version de ce travail a été retenue pour être testée dans un ECR.

## *2) Comment concevoir un ECR pour évaluer l'efficacité du programme Diapason?*

Dans le Chapitre 4, nous avons décrit et discuté les décisions prises autour des caractéristiques méthodologiques d'un ECR pour évaluer l'efficacité du programme Diapason. Le Département de la Recherche Clinique et du Développement (DRCD) et l'Unité de Recherche Clinique (URC) de l'Assistance Publique des Hôpitaux de Paris (APHP) ont soutenu et monitoré ce travail en tant que promoteurs. Dans la conception méthodologique de cette étude nous avons tenu compte des demandes du promoteur de la recherche, de l'expérience de l'équipe Diapason, et des recommandations issues de la littérature.

Basée sur la littérature, la taille de l'échantillon a été fixée à 40 personnes par groupe, pour obtenir une puissance statistique de 80% (Cristancho-Lacroix et al., 2013; Pedrelli, Feldman, Vorono, Fava et Petersen, 2008). Deux raisons majeures nous ont conduits à éviter de mettre en place un essai en aveugle. Tout d'abord, en raison de l'insuffisance des ressources humaines, les professionnels impliqués dans la phase de recrutement auraient dû mener aussi les évaluations. Dans tous les cas, même si les ressources humaines avaient été suffisantes, nous n'aurions pas pu contrôler les commentaires des participants au cours des évaluations. Selon Zarit et Femia (2008), l'utilisation d'études en aveugle a été promue par les porteurs d'études pharmacologiques, dans lesquelles le groupe de contrôle reçoit un placebo d'apparence semblable à celle du traitement (c.à.d. le participant peut croire qu'il reçoit le vrai traitement). Comme eux, nous considérons que la méthode en double aveugle est rarement adaptable aux études d'évaluation des programmes d'intervention, et que la méthode en simple aveugle est soumise aux risques de biais car il est presque impossible de dissimuler la véritable nature du traitement aux participants, et dans certains cas, aux évaluateurs.

Les trois visites d'évaluation ont été réalisées sur place, à l'hôpital, afin d'éviter les biais dans le recueil des informations et les données manquantes lorsque les questionnaires étaient remplis à domicile sans la présence d'un évaluateur (comme il est décrit dans certaines études, H. Kerhervé, 2010),

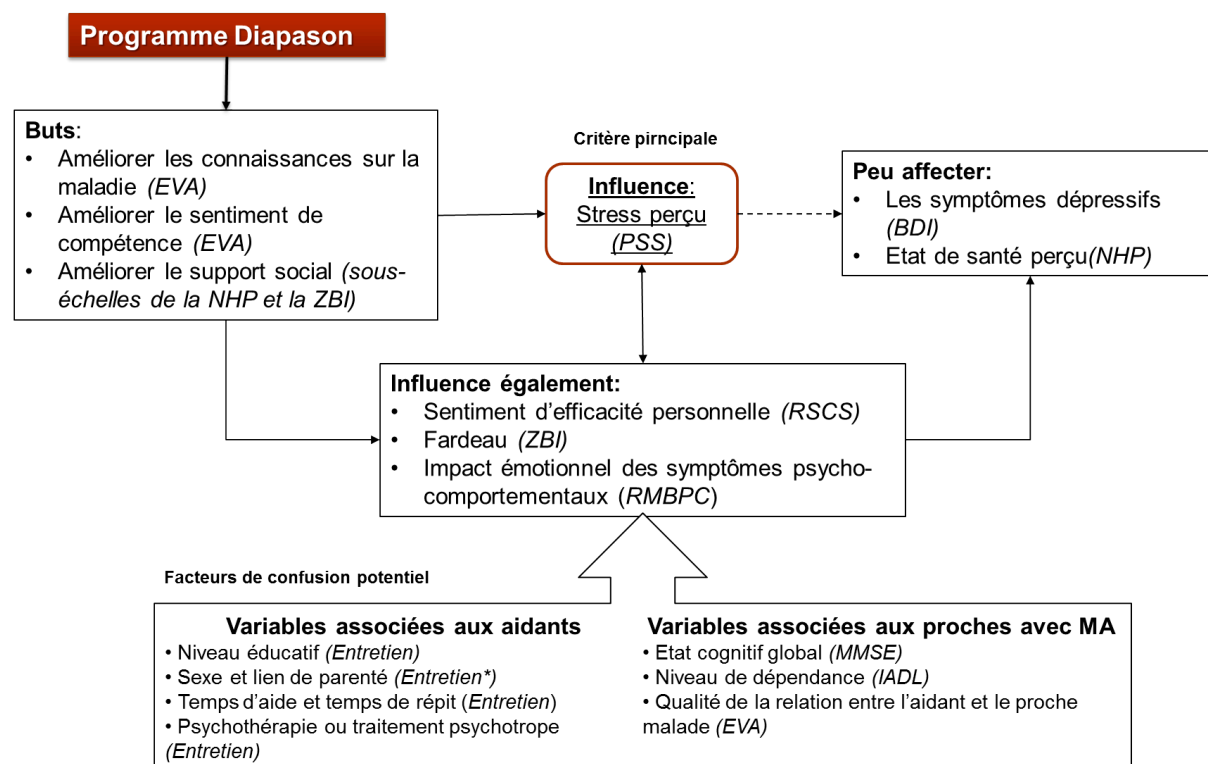
En accord avec les recommandations de Vernooij-Dassen et Moniz-Cook (2014), nous avons attaché un grand intérêt au contrôle de la mise en place du programme. Pour cela, les séances ont été proposées dans un ordre prédéterminé, et ont été progressivement activées de manière hebdomadaire après validation (c.-à-d. les aidants devaient valider la session 1 afin d'accéder à la séance 2). Par ailleurs, la participation des professionnels dans le forum de discussion se limitait à garantir le respect entre les aidants. Ainsi, les discussions entre professionnels et aidants dans le forum ou par e-mail ont été limitées autant que possible.

En outre, le contenu du site est resté stable au cours de l'étude afin de proposer exactement les mêmes informations à tous les participants. La seule source de variabilité dans le contenu du site provenait des discussions des aidants sur le forum, mais étant donné que cette fonctionnalité faisait partie des objectifs du programme, nous avons décidé de ne pas la contrôler.

Conformément aux recommandations d'autres auteurs, ce programme a proposé aux aidants (Bottes et al, 2013): a) des informations sur la maladie, b) un entraînement en compétences pour mieux gérer le quotidien, et c) des informations pour faciliter la recherche de répit et le lien social entre les aidants, à travers un forum. Notre hypothèse était que le programme entraînerait la diminution ou la prévention du stress lié aux situations d'aide, chez les aidants du groupe expérimental en comparaison avec ceux du groupe de contrôle. Nous supposons que le programme Diapason favoriserait également la diminution du fardeau et la gêne occasionnée par les troubles psycho-comportementaux de leurs proches malades, et l'amélioration du sentiment d'efficacité personnelle des aidants. Nous nous demandons si les effets indirects de l'intervention pouvaient entraîner l'amélioration ou le maintien de l'état de santé physique perçue et des symptômes dépressifs (Figure 4). Nous avons basé nos hypothèses sur le modèle de stress et coping de Lazarus et Folkman (1984) ainsi que sur le modèle d'auto-efficacité de Bandura (2009), et des plus récents travaux de la littérature. En accord avec le modèle de stress et coping (Lazarus & Folkman, 1984) l'acquisition des connaissances et des habiletés d'adaptation (coping) sont susceptibles d'altérer la manière dont les aidants évaluent les situations potentiellement stressantes, ce qui peut accroître leur sentiment d'efficacité personnelle et réduire leur fardeau. En outre, cela peut limiter l'apparition de croyances irrationnelles, qui sont des prédicteurs de symptômes dépressifs et d'un état de santé affaibli (Gonçalves Pereira et al, 2010).

Pour évaluer le critère principal, nous avons choisi l'échelle de stress perçue de Cohen (PSS, la version 14-item) un des instruments les plus utilisés pour mesurer le niveau de stress subjectif. Nous avons mesuré également l'auto-efficacité avec une échelle spécifique aux aidants naturels de patients atteints de démence, (Steffen et al, 2002.) et le fardeau avec l'Inventaire de Zarit (Ankri et al, 2005; Zarit et al, 1986). L'impact émotionnel des troubles psycho-comportementaux a été mesuré avec le RMBPC (Teri et al., 1992). Enfin, nous avons mesuré les symptômes dépressifs avec la BDI-2 (Beck et al., 1996) et l'état de santé perçue avec la NHP (Bucquet D, et al., 1990).

**Figure 4.** Effets attendus du programme Diapason



\* Variable contrôlée par stratification dans la randomisation. Entre parenthèses les instruments de mesure.

Le Comité de Protection des Personnes (CPP) local a approuvé le protocole d'étude avant le début du recrutement. Pour la mise en place du protocole de l'étude, les gériatres et les psychologues ont été formés aux processus de pré-sélection, de recrutement et d'évaluation des participants. Les participants étaient affectés au groupe de contrôle ou expérimental grâce à une liste de randomisation générée par ordinateur, et sur la base de la stratification de l'échantillon selon le sexe et les liens de parenté. Le groupe expérimental (GE) avait accès au programme Diapason pendant six mois; dans les trois premiers mois, les participants devaient valider une séance hebdomadaire en ligne, et dans les trois mois suivants ils avaient libre accès au site. Le groupe contrôle (GC) a bénéficié du suivi habituel au centre de mémoire tous les 6 mois, puis ils ont pu accéder librement au programme. Un psychologue a effectué trois évaluations : à la ligne de base, à M3 (à la fin du programme) et à M6 (suivi). Les données ont été stockées au moyen d'un formulaire de recueil électronique (eCRF : electronic Case Report Form). Un assistant de recherche clinique a contrôlé le respect du protocole en faisant un monitoring des dossiers tous les deux mois. Aucun amendement au protocole n'a été pratiqué durant l'étude. Une demande de prolongation de six mois de la période de recrutement a été acceptée par le promoteur et par le CPP.

3) *Diapason est-il un programme en ligne efficace pour les aidants des personnes atteintes de la maladie d'Alzheimer?*

Dans le **Chapitre 5**, nous décrivons les résultats d'un ECR monocentrique mené entre 2011 et 2014 dans le centre de mémoire de l'hôpital Broca. Notre objectif était d'évaluer l'effet du programme Diapason sur le stress perçu des aidants, leur sentiment d'efficacité, le fardeau, et l'état de santé perçu. Quarante-neuf participants ont été randomisés au GE (n = 25) ou au GC (n = 24). Toutes les données disponibles en ligne de base ont été analysées conformément à la méthode en intention de traiter. Les résultats des ANOVA, en contrôlant les variables de confusion, n'ont pas montré de différences significatives du stress perçu entre les deux groupes dans le temps. Ce résultat est sans doute attribuable à la faible puissance statistique de cette étude. Malgré une prolongation de 6 mois dans le temps de recrutement, soit une durée totale de 20 mois, et la mise en œuvre de différentes stratégies pour accroître le recrutement (affiches, dépliants, envoi d'e-mails hebdomadaires à des médecins, rappels systématiques dans les dossiers médicaux des patients atteints de MA), la taille de l'échantillon n'a pas pu atteindre les 80 inclusions prévues au début de l'étude. Selon le report des médecins, parmi les aidants sollicités par eux durant la phase de pré-sélection, environ la moitié ont refusé l'aide proposée. Puis, seulement 37,98% (49/129) des aidants présélectionnés ont finalement accepté de participer à l'étude. Parmi les 80 personnes qui ont refusé de participer, nous avons constaté que a) 29% n'étaient pas joignables ni par mail ni par téléphone, b) 21% ont retiré leur accord initial pour des raisons inconnues, c) 16% ne pouvaient pas se rendre aux trois évaluations à l'hôpital, d) 11 % ne sentaient pas le besoin de suivre un tel programme, e) 8% ne croyaient pas au diagnostic ou ne l'acceptaient pas, f) dans 8% des cas, le proche avait été institutionnalisé (ou les démarches avaient été initiées), et g) 3% n'avaient pas accès à Internet (ou d'expérience de son utilisation).

Les participants du GE ont significativement amélioré leur connaissance de la maladie entre M0 et M3 ( $p=0.008$ ,  $d=0.79$ ), mais leurs niveaux de connaissances perçus ont été comparables à ceux du GC à M6. Ainsi, le programme Diapason aurait accéléré l'apprentissage du GE dans les trois premiers mois, mais les participants du GC auraient pu augmenter leurs connaissances (ou le sentiment de connaître mieux la maladie) grâce à leurs propres expériences et aux informations provenant d'autres sources (avec de livres, émission télévisés, internet). Aucune autre variable de l'étude n'a montré de différence significative entre les groupes dans le temps.

Limités par la taille de l'échantillon, nous n'avons pas réalisé d'analyses statistiques de différences entre les sous-groupes (i.e. pour comparer les effets entre les conjoints vs les enfants, entre aidants jeunes, vs. âgés). Cependant, et en accord avec les tendances méthodologiques actuelles (Clay, 2010; O'Cathain, Thomas, Drabble, Rudolph, et Hewison 2013), nous avons réalisé des analyses qualitatives pour compléter les résultats de cet ECR. Pour cela, nous avons analysés des interviews et des réponses à des questions ouvertes, en suivant la méthode de l'analyse thématique (Braun & Clarke, 2006). Nous avons identifié quatre thèmes et quatre tendances parmi les opinions des aidants, qui de manière générale semblaient varier en fonction du sexe et du lien de parenté avec la personne malade. Ainsi, tandis que les filles de personnes malades avaient des opinions mitigées sur le programme, et que les épouses exprimaient des opinions négatives ou neutres sur cette intervention, les aidants de sexe masculin (époux ou fils) ont rapporté des opinions plus positives à l'égard de celle-ci. En nous basant sur des résultats similaires dans la littérature, nous attribuons cette tendance au fait que les aidants de sexe masculin ont une préférence pour les interventions centrées sur l'information et les compétences pratiques, plutôt que pour celles centrées sur les émotions. Par ailleurs, leur tendance à sous-estimer leurs sentiments négatifs a également été décrite dans la littérature (Gant, Steffen, & Lauderdale, 2007).

Ainsi qu'il est décrit dans d'autres travaux, les aidants de notre étude avaient d'autres attentes par rapport au programme (Nichols et al., 2011), ou pensaient qu'il serait mieux pour d'autres aidants (Van der Roest et al., 2010). Seule une minorité a considéré que le programme n'était pas pour eux ou n'a pas donné une opinion claire sur celui-ci. De façon informelle, certains participants ont indiqué qu'après avoir utilisé le programme Diapason, ils lisaient plus de livres ou cherchaient davantage d'informations par le biais d'associations ou d'autres sites web, ce qui corrobore les résultats obtenus dans d'autres études de programmes en ligne (Beauchamp et al., 2005).

Nous concluons à la nécessité d'une révision des contenus et du format du programme afin de mieux répondre aux besoins des aidants. De plus, l'utilisation d'une méthodologie de recherche plus souple, avec des évaluations en ligne ou par téléphone devrait favoriser le recrutement et permettre l'inclusion des aidants isolés ou très « débordés ». L'utilisation des méthodes quasi-expérimentales ou d'une étude pilote avec une version révisée du programme est hautement recommandée. Pour les équipes préparant un ECR, nous recommandons l'utilisation de méthodes mixtes de recherche afin de compléter les résultats statistiques.

## **Discussion et perspectives de ce travail**

### ***A) Impact Scientifique***

Les résultats de ce travail ont différentes implications scientifiques. Tout d'abord, Diapason est à notre connaissance, le premier programme psycho-éducatif en ligne pour les aidants des personnes souffrant de maladie d'Alzheimer ayant été développé et testé en France. De plus, malgré l'intérêt qui représente l'utilisation du design centré sur l'utilisateur, peu de travaux ont décrit son utilisation pour le développement des programmes similaires à Diapason (p.ex. Chiu et al., 2009; Van der Roest et al. , 2010). De plus en plus, des équipes cliniques sont attirées par l'utilisation de technologies dans un but psycho-éducatif et thérapeutique, sans avoir nécessairement l'expérience dans ce domaine. Pour ces professionnels, les publications empiriques d'autres équipes, rapportant les difficultés rencontrées et les recommandations pour les éviter peuvent être de grande utilité.

En ce qui concerne notre deuxième article, les protocoles de recherche sont rarement publiés, en dépit de leur utilité. En effet, les protocoles d'étude donnent un aperçu des recherches en cours, ce qui évite les distorsions pour les équipes qui réalisent des revues de la littérature ou des méta-analyses, et offre des éléments de jugement plus objectifs sur l'originalité des travaux aux financeurs. En outre, grâce à cette catégorie de publications, les patients et les aidants sont informés des études dans lesquelles ils pourraient souhaiter participer. De plus, les publications sur les résultats de ces études permettent rarement une présentation approfondie des méthodes, limitant ainsi leur réplique (Skogvoll & Kramer-Johansen, 2013).

Enfin, et bien que certaines études d'évaluation des interventions en ligne destinées aux aidants aient été menées auparavant (par exemple Brennan, 1995; Chiu & Eysenbach, 2011; Lewis, Hobday, et Hepburn, 2010), peu d'entre elles ont fait l'objet d'un ECR (Beauchamp et al., 2005; Brennan, 1995; Kajiyama et al., 2013) et à notre connaissance, aucune n'a formellement utilisé des méthodes de recherche mixtes. Bien que les résultats statistiques de notre ECR n'aient pas été concluants en raison du manque de puissance statistique, les résultats qualitatifs ont permis de mettre en relief des considérations importantes pour ce type d'interventions, applicables également à d'autres recherches dans des domaines similaires. Nos résultats ont permis de confirmer le rôle déterminant de l'évaluation des besoins des utilisateurs, non seulement pour le développement du programme mais aussi comme première étape de l'intervention, afin de personnaliser le contenu de celle-ci. Avec les résultats de l'ECR, nous avons obtenu un premier aperçu des attentes et des besoins des aidants informels concernant une intervention en ligne. Ces résultats devraient être complétés et confirmés par d'autres études. Dans ce but, nous avons



conçu et réalisé une étude descriptive pour évaluer les besoins et les attentes des aidants à l'égard d'un programme accessible en ligne, dont les résultats préliminaires sont décrits plus bas (voir section Evaluer les besoins des aidants).

### ***B) Limites de ce travail et les leçons apprises***

Malgré nos efforts, ce travail présente de multiples limites du cadre méthodologique, logistique et interventionnel qui doivent être considérées dans des futurs travaux.

#### *Validité externe de l'étude d'utilisabilité.*

Compte-tenu du fait que les seniors de l'étude d'utilisabilité ont été recrutés par le biais des associations parisiennes des personnes âgées, il est fort probable que leurs caractéristiques ne correspondent pas avec celles du reste de la population âgée. En outre, dans cette étude, les participants devaient avoir une certaine expérience de l'utilisation de l'Internet, ce qui limite la possibilité de généraliser nos résultats à d'autres personnes âgées.

#### *Validité externe de l'essai clinique randomisé.*

La validité externe des résultats obtenus dans l'ECR de Diapason est limitée. Malheureusement, le manque de puissance statistique ne nous a pas permis d'obtenir des résultats significatifs. En outre, en raison d'un recrutement monocentrique, la généralisation de nos résultats serait tout de même limitée. Il est à noter également que du fait des contraintes du protocole (trois visites sur place), la plupart des personnes vivant dans des régions éloignées n'ont pas accepté de participer à l'étude, alors qu'elles avaient les critères d'inclusion de notre population cible.

Par ailleurs, un de nos critères d'inclusion était que les aidants devaient savoir utiliser Internet. Par conséquent, les caractéristiques des aidants recrutés pour cette étude ne correspondaient pas à ce qui est décrit dans la population générale des aidants (également décrits par Van der Roest, Meiland, Jonker, et Droes, 2010). Par exemple, ils étaient plus souvent des enfants que des conjoints, ils vivaient moins souvent avec les personnes malades, et étaient plus jeunes que la moyenne des aidants.

Une autre limitation concernant la validité externe de cette étude est le recrutement en milieu hospitalier. En effet, d'autres études ont démontré que ce type de recrutement peut biaiser le

recrutement des participants, car les aidants qui sont capables de se rendre aux hôpitaux pour des évaluations ou des suivis sont moins déprimés et en détresse que ceux qui préfèrent être évalués à la maison (Steffen et al., 2008).

#### *Difficultés et limites méthodologiques de l'étude d'utilisabilité.*

Bien que nous ayons inclus les utilisateurs finaux aux différentes étapes du développement du programme Diapason, une plus grande participation est toujours possible. Par exemple, ils pourraient être impliqués dans les réunions de travail pour participer aux prises de décisions. En outre, certaines erreurs ergonomiques commises dans les premières versions de notre site auraient pu être évitées plus tôt dans le processus de développement, avec la participation d'un expert en ergonomie.

#### *Difficultés et limites méthodologiques de l'essai clinique randomisé.*

*Inclusions et sorties d'étude.* La principale limite de cette étude a été le manque de puissance statistique. Le faible taux d'inclusions et le taux élevé d'abandons nous permettent de suggérer que le contenu et/ou le protocole méthodologique du programme ne répondaient pas à tous les besoins des aidants. D'ailleurs, bien que les gériatres aient présélectionnés 129 participants potentiels, seulement 49 ont été finalement inclus dans l'étude. Dans près de la moitié des cas (soit 21% ont refusé leur participation, 29% étaient inaccessible par téléphone ou par e-mail) les aidants n'ont pas reporté clairement les raisons du refus. Toutefois, notre attention a été attiré sur le fait que les aidants refusaient également de participer au programme d'éducation thérapeutique proposé sur place (Entr'aidants, décrite dans le Chapitre 2). Il est possible que les aidants qui ne pouvaient pas se rendre à l'hôpital trois fois pour le protocole Diapason, aient également été indisponibles pour venir aux séances groupales hebdomadaires du programme présentiel.

*Le refus des aidants.* A notre connaissance, peu de recherches ont été consacrées à l'analyse de la non-utilisation des services et d'interventions pour les aidants. De multiples barrières semblent expliquer leur refus. Tout d'abord, il semble nécessaire qu'ils s'identifient eux-mêmes comme cible de l'intervention. Cependant, les programmes sont généralement proposés aux accompagnants des malades, indépendamment de leur propre reconnaissance en tant qu'aidants. Deuxièmement, les aidants peuvent se sentir coupables quand ils prennent soin d'eux-mêmes, (O'Connor, 2007). Pour certains d'entre eux, cela serait en contradiction avec leurs représentations du rôle d'aidant. D'autres peuvent ne pas

ressentir le besoin d'aide et/ou ne pas être conscients de leurs besoins (Brodaty, Thomson, Thompson, et Fine, 2005). Enfin, et en cohérence avec notre expérience, les aidants peuvent ne pas souhaiter l'ingérence des autres dans la gestion du soin de leur proches (Brodaty et al., 2005).

Ce refus pour les services de santé n'est pas exclusivement décrit chez les aidants, il est également retrouvé chez les patients souffrant de dépression ou d'anxiété. En effet, seulement la moitié des personnes souffrant de dépression, et un tiers des patients souffrant d'anxiété demandent de l'aide professionnelle. Ils existent des modèles théoriques pour mieux comprendre le refus et la demande d'aide de ces patients (Gulliver, Griffiths, Christensen, et Brewer, 2012). Cependant, et malgré la spécificité de la situation des aidants, aucun modèle n'existe à notre connaissance pour analyser ou expliquer le refus et la demande de cette population.

Une autre approche intéressante est l'étude des facteurs associés au fait d' «être disposé» (*readiness*) à recevoir du soutien ou de l'aide. Gitlin et Rose (2014) ont constaté que les aidants mettaient plus ou moins en pratique les stratégies d'un programme d'entraînement pour gérer les problèmes de comportements de leurs proches, en fonction de leur disposition à recevoir de l'aide. Ils concluent que cet état est «malléable» et peut évoluer chez la plupart des aidants, à condition qu'ils ne soient pas confrontés à des situations financières très difficiles (Gitlin & Rose, 2014).

*Sélectionner un échantillon plus réduit.* En dépit des difficultés de recrutement, il aurait été nécessaire de limiter d'avantage les critères d'inclusion de notre ECR. En effet, les aidants sont une population très hétérogène (Zarit & Femia, 2008), qui se comporte de manière assez variable selon de multiples facteurs individuels et contextuels. Ainsi, une intervention aura un effet différent d'un aidant à un autre, selon les conditions de sa situation d'aide (tel que le stade de dépendance du patient) et de ses caractéristiques individuelles (par exemple, des stratégies de coping utilisées par l'aidant, de son état de santé psychologique et physique et des ressources disponibles) (Steffen, 2008). De plus, certains facteurs tels que le sentiment d'efficacité personnelle, sont sensibles au contexte, et peuvent évoluer, entre autres, avec la progression de la maladie (Bandura, 2006). Ainsi, la restriction des critères d'inclusion peut permettre une meilleure définition des hypothèses de recherche, une meilleure sélection des questionnaires, et une fiabilité des résultats plus importante.

*Sélectionner les critères d'évaluation.* L'inclusion de multiples échelles dans le protocole d'évaluation peut complexifier l'analyse, et peut fausser les interprétations finales. Nous recommandons de limiter le nombre de variables mesurées et de se centrer sur deux ou trois domaines seulement (par exemple l'auto-efficacité et le stress, ou le fardeau et la

dépression), toujours appuyés sur le cadre théorique qui a servi de base pour la conception du programme.

À notre connaissance, la seule échelle de stress validée en France est l'échelle de stress perçu de Cohen (Bellinghausen et al., 2009). Néanmoins, malgré son utilisation fréquente dans le domaine de la santé, elle n'offre pas d'informations sur le type et la qualité des stratégies d'adaptation utilisées par l'aidant. Par conséquent, les aidants qui déniaient le diagnostic de leurs proches, pouvaient rapporter des niveaux de stress assez bas, alors que leur stratégie d'adaptation était négative (fuite et évitement). Celles-ci pourraient provoquer à long terme des conséquences plus importantes chez eux que chez les aidants ayant accepté le diagnostic, présentant des scores plus élevés de stress, mais en utilisant des stratégies plus adaptées à la situation (Folkman, 2008).

### ***Limites de l'intervention***

Bien qu'inspiré par une approche cognitive, le programme Diapason n'a pas été strictement développé selon un cadre théorique strict, ce qui pourrait rendre difficile sa réplique. De plus, alors que les participants durant le développement du programme avaient évoqué le besoin d'un contact en ligne avec des professionnels, nous n'avons pas été en mesure de le mettre en place, du fait du manque de ressources. Comme décrit précédemment, nous avons adapté le cadre du programme pour réduire le risque d'erreur de type III, associé aux variations dans la mise en place des interventions. Néanmoins, celles-ci pourraient avoir limité le dynamisme du programme, et son attractivité pour les aidants. Cela pourrait expliquer pourquoi le programme a été beaucoup moins utilisé par les participants après M3. Enfin, d'après les résultats qualitatifs du ECR, les aidants auraient souhaité recevoir des contenus plus ciblés et personnalisés. Quelques programmes décrits au Chapitre 2 ont démontré la faisabilité de ces options pour les programmes en ligne.

### ***Considérations éthiques***

Certaines préoccupations éthiques sont apparues au cours de l'ECR. Une minorité des participants (2 aidants) ont décrit des affects négatifs tels que de la tristesse et/ou de l'inquiétude en utilisant le programme. Ils ont arrêté leur participation au programme, une personne (Mme M, fille, 60 ans) a préféré avoir une intervention thérapeutique individuelle, alors que la deuxième ne souhaitait recevoir aucun type d'aide (Mme M, épouse, 85 ans). Pour cette raison nous recommandons fortement la participation d'un professionnel

disponible pour les utilisateurs du programme afin de les rassurer, mais aussi pour clarifier et contextualiser les informations du site.

Par ailleurs, ces deux cas mettent en relief la question des motivations des aidants à participer au programme, notamment lorsqu'ils ne souhaitent pas d'aide, ou qu'ils souhaitent un autre type d'aide. De plus, certains aidants ont déclaré à la fin de l'étude avoir accepté de participer à l'ECR même si le programme en lui-même ne les intéressait pas : « j'ai accepté pour aider à la recherche, mais je n'ai pas vraiment besoin de ça ». Enfin, la plupart des participants qui ont donné une réponse positive au médecin (n = 129) ont changé leur avis peu de temps après (n=80), lorsque le psychologue les a rencontrés pour confirmer leur inclusion dans l'étude. Cela pourrait être dû simplement au fait que le psychologue a donné des informations plus approfondies sur les conditions de l'étude (évaluations sur place, questionnaires à remplir, programme en ligne, etc.), ou au non-respect des critères d'inclusion (que le praticien parfois n'a pas eu le temps de valider). Nous n'avons aucune raison de penser que les praticiens impliqués dans la phase de pré-sélection de cette étude ont influencé les participants au-delà de leur volonté, mais nous tenons à souligner le besoin de vigilance dans les étapes de recrutement afin de protéger les patients et leurs familles.

### ***Perspectives et recommandations.***

Les programmes d'intervention basés sur les TIC sont un champ prometteur avec de multiples applications dans le domaine de la santé. Avec la récente émergence des smartphones et des tablettes, les possibilités de ces programmes sont encore plus larges, car ces dispositifs semblent être de plus simple utilisation, et plus accessibles en termes de prix et de transportabilité. En outre, les réseaux WI-FI disponibles deviennent de plus en plus performants et quasi omniprésents dans de nombreux pays. De plus, en France la brèche numérique entre les générations est progressivement réduite (Gombault, 2013), et dans les années à venir, nous pouvons estimer que la plupart des personnes âgées auront autant d'accès et intérêt par l'Internet que les plus jeunes. Ainsi, continuer à travailler dans ce domaine semble assez cohérent avec les tendances culturelles, et pourraient répondre aux besoins individuels et socio-économiques actuels. Dans cette section, nous apportons quelques recommandations pour les travaux futurs dans ce domaine.

#### ***Evaluer les besoins des aidants***

Le développement des interventions pour les aidants des personnes atteintes de démence est une mission complexe. En effet, la progression des troubles et la perte d'autonomie des patients ainsi que les exigences accrues vis-à-vis des aidants, en lien avec la détérioration

de leur état de santé, font que leurs besoins soient constamment en évolution. Afin de poursuivre le processus cyclique de développement et l'amélioration itérative du programme Diapason, nous avons réalisé une étude descriptive pour évaluer les besoins et les attentes des aidants concernant les objectifs et les contenus d'un programme en ligne (Chapitre 5). Nous avons basé cette étude sur une approche de triangulation méthodologique afin d'apporter plus de rigueur et de fiabilité aux résultats d'ordre qualitatif (Guion et al., 2011). Pour ce faire, nous avons réalisé 16 entretiens semi-structurés individuels et 5 focus groupes avec onze aidants et quinze professionnels de santé. Tous les participants avaient utilisé le programme Diapason au moins une fois. Sur la base d'une analyse préliminaire, d'une révision de la bibliographie et de l'avis de trois experts, nous avons conçu un questionnaire en ligne, qui a été rempli par 83 aidants, contacté par le biais de site internet divers (Facebook®, Twitter®, et de forums pour les aidants). Les analyses qualitatives sont actuellement réalisées de manière parallèle par deux professionnels (VCL, psychologue, et LNR, sociologue), en utilisant la méthode d'analyse thématique (Braun et Clarke, 2006).

Dans les groupes de discussion et les entrevues, les participants ont exprimé leurs attentes sur le contenu, sur les caractéristiques d'accès (avec ou sans code, forum avec ou sans modérateur, etc.), et les fonctionnalités d'un programme en ligne, ainsi que le type de soutien et d'aide qu'ils souhaiteraient recevoir. Sur la base des résultats préliminaires des focus groupes, nous avons identifié des divergences dans les besoins et les attentes des aidants en fonction de leur âge, de leur lien de parenté avec la personne malade et du degré de dépendance de leurs parents. Ces divergences sont congruentes avec les résultats des analyses de questions ouvertes remplis par les participants du Diapason ECR (résultats présentés dans l'Article 3). Néanmoins, ces résultats sont préliminaires et doivent être traités avec précaution.

### *Design et développement du programme d'intervention*

Le programme Diapason est la première version de notre programme en ligne. De multiples changements doivent être mis en œuvre, en utilisant un design itératif centré sur l'utilisateur, impliquant activement les aidants dès les premières étapes de conception, par exemple dans les réunions de travail, dans les comités de pilotage et dans la conception de maquettes ou dans les évaluations de contenus. Etant donné que la conception de l'interface a un impact important sur l'acceptabilité du programme, la participation d'ergonomes est fortement conseillée à ce stade.

La définition d'un cadre théorique clair est fortement recommandée pour le développement de programmes. Il peut faciliter la définition des hypothèses et des critères d'évaluations (Craig, Dieppe, et Macintyre, 2008; Steffen et al., 2008; Vernooij-Dassen & Moniz-Cook, 2014). En outre, l'estimation correcte des ressources et de leur optimisation est un facteur clé pour le développement efficace des programmes. Par exemple, utiliser des maquettes papier (*paper mockups*) pour les évaluations d'utilisabilité et les études pilotes visant l'évaluation de la faisabilité d'un protocole seraient des méthodes peu coûteuses mais efficaces.

Les résultats de l'analyse des besoins (en cours) devraient apporter des éléments aux décisions concernant les thématiques et les modalités de mise à disposition du programme. Une variante intéressante de celui-ci pourrait être la création d'un programme à destination des aidants et des patients, pour lequel il serait nécessaire d'impliquer les personnes souffrant de maladie d'Alzheimer ou de démence dans les phases de conception. Par ailleurs, le développement d'une version adaptée de ce programme pour la formation des professionnels pourrait être également envisagé. Cependant, et tenant compte de la grande difficulté pour les aidants à accepter les interventions de soutien, il pourrait être nécessaire d'ajouter une étape préliminaire, visant l'étude des comportements d'acceptation et adoption des thérapeutiques et de recherche d'aide, comme il a été recommandé pour la dépression et l'anxiété (Gulliver et al., 2012 ; Gitlin & Rose, 2014).

Les programmes devraient viser d'avantage les émotions positives (par exemple, l'auto-efficacité, l'autorégulation, ce qui signifie adaptation axée sur), et se concentrer moins sur les aspects négatifs de la situation d'aide (par exemple, le stress, la charge, les problèmes de comportement de proches), en accord avec les tendances actuelles. Moskowitz et ses collègues (2012) ont récemment publié une tentative intéressante. Dans une étude pilote, ils ont évalué l'efficacité et la faisabilité d'une intervention visant à augmenter les affects positifs chez des personnes souffrant de stress élevé, récemment diagnostiqués avec le VIH. Après six mois d'intervention, les chercheurs ont constaté des changements significatifs des émotions positives et négatives, une bonne acceptabilité de l'intervention et la mise en pratique des techniques apprises (Moskowitz et al., 2012). Les auteurs recommandent l'utilisation de cette approche avec des populations soumises à des situations de stress tels que les aidants des personnes atteintes de démence.

Notre expérience confirme la nécessité et l'importance de proposer un programme qui favorise l'interaction sociale avec d'autres aidants, et avec les professionnels. En effet, quel que soit le type du programme (présentiel ou en ligne), les aidants demandent toujours plus d'interactions avec les professionnels de santé (par exemple : Nichols et al., 2011). De plus,

et compte tenu des effets positifs de l'aide sociale sur les aidants naturels (Au et al., 2009; Bass et al., 1998; Colvin, Chenoweth, Bold, & Harding, 2004) et sur les personnes atteintes de démence (Amieva et al, 2010), l'interaction sociale devrait figurer dans les priorités des programmes à destination des aidants et de patients.

Enfin, nous rappelons, sur la base des conclusions d'autres auteurs, que le processus pour obtenir une intervention réussie peut prendre de nombreuses années de travail multidisciplinaire (Astell et al., 2008; Meiland et al., 2014). D'ailleurs, ce processus pourrait être sans fin, étant donnée l'évolutivité des attentes et des besoins des patients et leurs familles, ainsi que la nécessité d'adapter les interventions pour mieux répondre à celles-ci.

### *L'évaluation des programmes*

Vernooij-Dassen & Moniz-Cook (2014) suggèrent qu'en amont du stade d'évaluation, les chercheurs devraient mener des études sur la faisabilité de la mise en place d'études de cas unique: "*dans la phase de développement (ils) sont un bon exemple où le chercheur peut tester le succès et l'échec d'une intervention*". A partir de ces études, les chercheurs pourraient identifier et résoudre les problèmes, et renforcer les facteurs facilitateurs de la mise en exécution des interventions. Ensuite, ils suggèrent de commencer la phase d'évaluation avec des études d'efficacité en utilisant des essais cliniques explicatifs (i.e. en condition contrôlée), puis d'évaluer son efficacité par des essais cliniques de type pragmatique (i.e. en condition réel, dans la pratique médicale) (Vernooij-Dassen & Moniz-Cook, 2014). Par ailleurs, et comme indiqué par divers auteurs, les études quasi expérimentales pourraient être plus adaptées que les ECR pour évaluer des interventions psycho-éducatives. En effet, la randomisation dans les études comme Diapason pourraient être limitée (voir biaisée) par le choix fait par les aidants (Zarit & Femia, 2008). Par exemple, il est tout à fait concevable que certains participants du groupe de contrôle aient abandonné le protocole Diapason pour obtenir ailleurs un traitement comparable à celui reçu par le groupe expérimental.

En France, les études sur l'efficacité des interventions en ligne pour les aidants naturels sont assez novatrices. Leur intérêt par rapport aux travaux réalisés dans d'autres pays est liées aux spécificités culturelles qui pourraient avoir une incidence sur l'acceptabilité et l'adoption de ces programmes.

Une tout autre considération dans l'évaluation de l'efficacité des programmes pourrait être l'utilisation d'incitations financières. Ce domaine a été récemment étudié dans les essais cliniques en ligne, démontrant des effets significatifs dans la réduction des taux d'abandon



(Khadjesari et al., 2011). Cependant, des considérations éthiques dans ce domaine doivent être prises en compte (Londres, Borasky, et Bhan, 2012).

Enfin, l'analyse coût-efficacité est un facteur clé pour déterminer la faisabilité et l'impact économique des interventions. L'intégration de ce volet d'évaluation dans les études d'efficacité pourrait contribuer à l'intégration de ces interventions dans les systèmes de soins courants, lorsque les résultats sont positifs (Tate, Finkelstein, Khavjou, et Gustafson, 2009).

### *Mise en place des programmes*

Une fois que le programme Diapason sera en mesure de répondre aux besoins des aidants (et probablement des patients), il pourrait être proposé systématiquement par les professionnels, en complément d'autres stratégies de suivi et d'éducation proposées par l'hôpital. Des programmes comme Diapason peuvent favoriser l'accès à tous les aidants, y compris les personnes vivant dans de régions isolées, ou n'étant pas disposés à participer aux programmes de soutien en présentiel. Néanmoins, et compte-tenu du fait que le manque de compétences en informatique reste une grande limitation de l'utilisation de services en ligne (tels que les sites web utilisés pour payer ses impôts ou faire du shopping en ligne), nous recommandons le développement de programmes de formation dans les technologies, qui pourraient accélérer la réduction de la fracture numérique. En ce qui concerne la viabilité des interventions à moyen et long terme, Kajiyama et ses collègues (2013) attirent notre attention sur les ressources économiques nécessaires pour le maintien des programmes en ligne. En effet, même s'ils sont plus accessibles et moins coûteux dans le long terme que les programmes en présentiel, ils requièrent des ressources humaines et techniques adaptées afin de garantir leur bon fonctionnement (Kajiyama et al., 2013).

Pour conclure, la mission des chercheurs et des financeurs devrait être de garantir que les programmes d'e-Santé soient créés sous un regard pluridisciplinaire pour le respect des utilisateurs, et pour optimiser la qualité et accessibilité aux services, en facilitant la communication avec leurs pairs et les professionnels de santé, et en veillant de près à la protection de l'isolement des utilisateurs de ces produits.

\*\*\*\*\*

**APPENDIX 2. DIAPASON DELIVERY CHARACTERISTICS BASED ON SCHULZ ET AL, 2010**

<b>Dimension</b>	<b>Definition</b>	<b>Options Checklist</b>	<b>Diapason program</b>
Mode	Method of contact between interventionist and participant	<ul style="list-style-type: none"> <li>Face to face (individual or group)</li> <li>• Telephone (individual or group)</li> <li>• Internet (individual or group)</li> <li>• Video/CD instruction</li> <li>• Telephone contact with computer</li> <li>• Mailing of written material</li> <li>• Personal digital assistant (PDA), cell phone</li> </ul>	Individual in Internet
Materials	Materials used in the delivery of the intervention	<ul style="list-style-type: none"> <li>• Manuals/workbooks</li> <li>• Information sheets/checklists</li> <li>• Pamphlets</li> <li>• Videotapes</li> <li>• Audiotapes</li> <li>• CDs/DVDs</li> <li>• Assistive devices</li> <li>• Internet</li> </ul>	Internet
Location	Where the intervention is delivered	<ul style="list-style-type: none"> <li>• Participant's home</li> <li>• Classroom</li> <li>• Health care provider's office</li> <li>• Hospital, clinic, operating room</li> <li>• Work site</li> <li>• Community center</li> <li>• Nursing home</li> <li>• Group residence facility</li> <li>• Research facility</li> </ul>	Participant's home
Schedule	Duration and intensity of intervention	<ul style="list-style-type: none"> <li>• Overall duration of the intervention</li> <li>• Number of sessions</li> <li>• Minutes of contact per session</li> <li>• Distribution of sessions over</li> </ul>	<p>Duration 3 months</p> <p>Twelve weekly sessions</p> <p>In average 15 and 30 minutes per session – free access to forum and other materials</p> <p>One session per week, during</p>

		time	twelve weeks
Scripting	Level of detail guiding interaction between the interventionist and the participant	<ul style="list-style-type: none"> <li>• Exact script/protocol provided</li> <li>• Specific language provided with elaboration allowed/not allowed</li> <li>• Goals/tasks specified but no further scripting</li> <li>• General guidelines provided</li> </ul>	<p>Exact script/protocol provided for research</p> <p>General guidelines provided for the interaction with participants</p>
Sensitivity to participant characteristics	Extent to which participant background, experience and abilities are incorporated in the delivery of intervention	<ul style="list-style-type: none"> <li>• Intervention materials and delivery in language preferred by participant</li> <li>• Materials written for specific reading or health literacy level</li> <li>• Visual supplements, augmentative communication devices for hearing impaired</li> <li>• Oral supplements and visual enhancements for vision impaired</li> </ul>	None
Interventionist characteristic	Qualifications and training, concordance with participant characteristics	<ul style="list-style-type: none"> <li>• Required disciplinary/professional expertise for interventionists</li> <li>• Licensing/certification requirements</li> <li>• Type and quantity of training provided</li> <li>• Proficiency tests passed</li> </ul>	None. Professionals were trained in for recruitment and assessments
		<ul style="list-style-type: none"> <li>• Race/ethnicity/age/gender matching of interventionist to participant</li> <li>• Intervention staff recruited from participant community</li> <li>• Interventionist knowledgeable of cultural views and values of participants</li> </ul>	No
Adaptability	<ul style="list-style-type: none"> <li>• Extent to which intervention can be modified.</li> <li>• What can be modified</li> <li>• On what basis modifications are made</li> <li>• When in the course</li> </ul>	<p>What:</p> <ul style="list-style-type: none"> <li>• Number/schedule/duration of sessions</li> <li>• Location</li> <li>• Mode of delivery</li> <li>• Content/target</li> <li>• Dosage</li> </ul>	<p>The program is fully automated.</p> <p>Only forum contents are updated depending on topics addressed by participants.</p> <p>A higher participation of professionals in forum would be easily implemented</p> <p>The modifications would be implemented before beginning</p>

	<p>of the study</p> <p>modifications can be made</p>	<p>On what basis:</p> <ul style="list-style-type: none"> <li>• Participant assessment</li> <li>• Participant progress</li> <li>• Spontaneous request</li> <li>• Secular event</li> <li>• Clinical judgment</li> <li>• Checklist/lab test results, performance outcomes</li> </ul> <p>When:</p> <ul style="list-style-type: none"> <li>• Intake</li> <li>• Baseline</li> <li>• Specified intervals during intervention</li> </ul>	<p>the study</p>
<p>Treatment implementation</p>	<p><b>Treatment Delivery:</b></p> <p>Documentation of interventionist compliance to intended treatment and modifications</p> <p><b>Treatment Receipt:</b></p> <p>Extent to which processes are implemented by participant and/or goals are met</p> <p><b>Treatment Enactment:</b></p> <p>Extent to which knowledge and skills acquired during treatment are applied in real world settings outside of treatment</p>	<ul style="list-style-type: none"> <li>• Number and duration of sessions</li> <li>• Content delivered</li> <li>• Knowledge, skills, motivation, self-efficacy, social support/integration, changes in pathophysiology assessed in participant</li> <li>• Direct observation, self-report, observer report of participant</li> </ul>	<p>The website was coded to calculate the time and rate of program's utilization</p> <p>Participants filled a qualitative questionnaire of satisfaction, applicability and emotional benefit.</p>

**APPENDIX 3. DIAPASON CONTENTS AND GOALS, BASED ON SCHULZ ET AL, 2010**

<b>Dimension</b>	<b>Definition</b>	<b>Options Checklist</b>	<b>Diapason program</b>
Treatment content strategies	Specific strategies aimed at improving outcomes	<ul style="list-style-type: none"> <li>• Provision of feedback to participant through tracking and monitoring</li> <li>• Provision of information</li> <li>• Behavioral incentives/reinforcements</li> <li>• Didactic instruction</li> <li>• Skill-Building techniques</li> <li>• Problem-Solving techniques</li> <li>• Stress-Management techniques</li> <li>• Facilitation of social support</li> <li>• Biologic interventions (surgery, medications, radiation)</li> <li>• Structure /process modifications (eg, staffing, scheduling, communications)</li> </ul>	<ul style="list-style-type: none"> <li>• Provision of information</li> <li>• Skill-Building techniques</li> <li>• Stress-Management techniques</li> <li>• Facilitation of social support</li> </ul>
Mechanisms of action	Key processes, goals, or mediators of desired treatment outcomes	<ul style="list-style-type: none"> <li>• Ability to assess risks/goals</li> <li>• Knowledge</li> <li>• Behavioral skills</li> <li>• Problem-Solving skills</li> <li>• Motivation</li> <li>• Self-efficacy</li> <li>• Social support</li> <li>• Social engagement</li> <li>• Environmental motivation</li> <li>• Change in policies/regulations</li> <li>• Biologic pathways</li> </ul>	<ul style="list-style-type: none"> <li>• Ability to assess risks/goals</li> <li>• Knowledge</li> <li>• Behavioral skills</li> <li>• Problem-Solving skills</li> <li>• Self-efficacy</li> <li>• Social support</li> </ul>

**APPENDIX 2. STEP ONE OF USABILITY TESTS - GENERAL INFORMATION**

**INFORMATIONS GENERALES**

1. Genre :       homme       femme
  
2. Date de naissance \_\_\_\_\_
  
3. Depuis quand utilisez vous internet ? \_\_\_\_\_
  
4. A quelle fréquence utilisez-vous internet (Nb de connexions par mois) ?  
\_\_\_\_\_
  
5. Quelle est ou était votre profession/occupation ? \_\_\_\_\_

**APPENDIX 3. STEP TWO OF USABILITY TESTS - GUIDE FOR EVALUATORS DURING THE USER'S UTILIZATION OF THE WEBSITE**

<b>TACHE</b>	<b>NOTES</b>
1. Accéder au site DIAPASON	
2. Accéder à la séance «Le Stress » :	
Visionner les vidéos	
Agrandir la vidéo (mode plein écran)	
3. Chercher le glossaire :	
Trouver le mot « hippocampe »	
4. Chercher les histoires vécues :	
Lire l'histoire « Jeanne semble morose et indifférente à tout ».	
5. Entrer dans le forum :	
Ajouter un nouveau sujet	
6. Entrer dans le carnet de bord :	
Ecrire et enregistrer la phrase « Aujourd'hui j'ai testé le site Diapason »	

**QUESTIONNAIRE DE SATISFACTION SUR LE SITE DIAPASON**

Pour chaque question, entourez la réponse qui reflète le mieux **votre point de vue**

**1) Evaluation globale du site**

Dans l'ensemble votre impression sur le site Diapason est...

Très négative	Plutôt négative	Neutre	Plutôt positive	Très positive
---------------	-----------------	--------	-----------------	---------------

Pourquoi ?.....  
.....  
.....  
.....

**2) Difficulté ou facilité d'utilisation**

De votre point de vue l'utilisation du site internet Diapason est...

Très facile	Plutôt facile	Ni facile, ni difficile	Plutôt difficile	Très difficile
-------------	---------------	-------------------------	------------------	----------------

Pourquoi ?.....  
.....  
.....  
.....

**3) Satisfaction d'utilisation**

La navigation sur le site internet Diapason vous a semblé...

Très agréable	Plutôt agréable	Ni agréable, ni désagréable	Plutôt désagréable	Très désagréable
---------------	-----------------	-----------------------------	--------------------	------------------

Pourquoi ?.....  
.....  
.....  
.....



#### 4) L'organisation du site

Dans l'ensemble vous avez trouvé que le site Diapason était...

Bien organisé	Plutôt bien organisé	Moyennement organisé	Plutôt mal organisé	Mal organisé
---------------	----------------------	----------------------	---------------------	--------------

Pourquoi ?.....  
.....  
.....

#### 5) Design du site

Globalement vous trouvez le design du site...

Très insatisfaisant	Plutôt insatisfaisant	Moyennement satisfaisant	Plutôt satisfaisant	Très satisfaisant
---------------------	-----------------------	--------------------------	---------------------	-------------------

La taille des caractères vous semble-t-elle adaptée ?

Pas du tout	Plutôt non	Moyennement	Plutôt oui	Tout à fait
-------------	------------	-------------	------------	-------------

Trouvez-vous que les couleurs utilisées perturbent la lecture du site ?

Pas du tout	Plutôt non	Moyennement	Plutôt oui	Tout à fait
-------------	------------	-------------	------------	-------------

#### 6) Avez-vous des remarques complémentaires ?

.....  
.....  
.....  
.....  
.....  
.....

## Entretien Semi-structuré

Par rapport à vos réponses au questionnaire avez-vous des remarques supplémentaires ?

Pourriez-vous préciser ... (reprendre les questions, points forts / points faibles du site) :

a) Les points négatifs et positifs du site (selon vous) ?

---

---

---

---

b) En quoi est-ce difficile d'utiliser le site (pour vous) ?

---

---

---

---

c) En quoi est-ce désagréable de naviguer sur le site (selon vous) ?

---

---

---

---

d) En quoi le site pourrait être mieux organisé (selon vous) ?

---

---

---

---

e) Quels points du design devraient être améliorés (selon vous) ?

---

---

---

---

## APPENDIX 6. WEEKLY SATISFACTION QUESTIONNAIRE FOR THE EXPERIMENTAL GROUP IN THE RCT

### Séance n°1 : Le Stress

#### I. Comment avez-vous trouvé les informations contenues dans la séance de la semaine ?

1) Utilité :

0. Pas du tout utiles     1. Peu utiles     2. Plutôt utiles     3. Très utiles

2) Clarté :

0. Pas du tout claires     1. Pas très claires     2. Plutôt claires     3. Très claires

3) Exhaustivité :

0. Très insuffisantes     1. Plutôt insuffisantes     2. Plutôt suffisantes     3. Très suffisantes

#### II. Rubriques

Parmi les autres rubriques que vous avez consultées, notez dans quelle mesure chacune d'entre elles vous a servi cette semaine.

	0. Pas du tout utiles	1. Peu utiles	2. Plutôt utiles	3. Très utiles	9. Non consulté
<b>Documents :</b>					
Histoires vécues	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relaxation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Glossaire	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stimulation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vidéos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Liens utiles	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Forum</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Commentaires :** .....

.....

.....

.....

.....

#### III. Utilité

- Mise en pratique : Dans quelle mesure cette séance vous semble-t-elle applicable dans la vie de tous les jours ? *Mettez une croix là où vous pensez vous situer sur la ligne ci-dessous.*



- Impact émotionnel : Dans quelle mesure cette séance vous a-t-elle aidée à vous sentir mieux ? *Mettez une croix là où vous pensez vous situer sur la ligne ci-dessous.*



# DIAPASON

## *Votre Carnet de Bord*



*Dans ce carnet, vous pourrez mettre à l'écrit votre vécu au quotidien, les situations partagées avec votre proche et les émotions, les pensées et les comportements qui en ont découlé. Son contenu vous appartient et vous êtes le seul à décider avec qui le partager.*

*Il est fréquent que l'écriture et la relecture de ce type de notes aident les personnes à prendre de la distance vis-à-vis de leur situation et à mieux comprendre leurs réactions et l'évolution de la relation avec leur proche.*

*Par ailleurs, écrire sur soi est souvent utilisé comme une manière d'évacuer le « trop plein émotionnel » qui découle fréquemment de situations difficiles.*

*Afin de mieux situer vos expériences dans le temps un emplacement à gauche de chaque page vous permettra d'écrire la date de vos notes. Si vous arrivez à la fin de ce carnet n'hésitez pas à continuer votre écriture dans d'autres supports.*

*Bonne écriture !!*

## APPENDIX 8. EXTRACT USER'S MANUAL FOR THE DIAPASON WEBSITE

### MODE D'EMPLOI DU SITE DIAPASON

Bonjour,

Le site DIAPASON a été créé par une équipe pluridisciplinaire de l'Hôpital Broca et son laboratoire de recherche LUSAGE. Ce site est destiné à informer et à aider les proches de personnes diagnostiqués avec la maladie d'Alzheimer.

Dans ce mode d'emploi vous trouverez les informations nécessaires à la bonne utilisation du site. Toutefois si vous considérez que cette information n'est pas suffisante, ou si vous avez des questions dans l'utilisation du site, n'hésitez pas à nous les communiquer à l'adresse mail suivante:

[diapason.broca@brc.aphp.fr](mailto:diapason.broca@brc.aphp.fr)

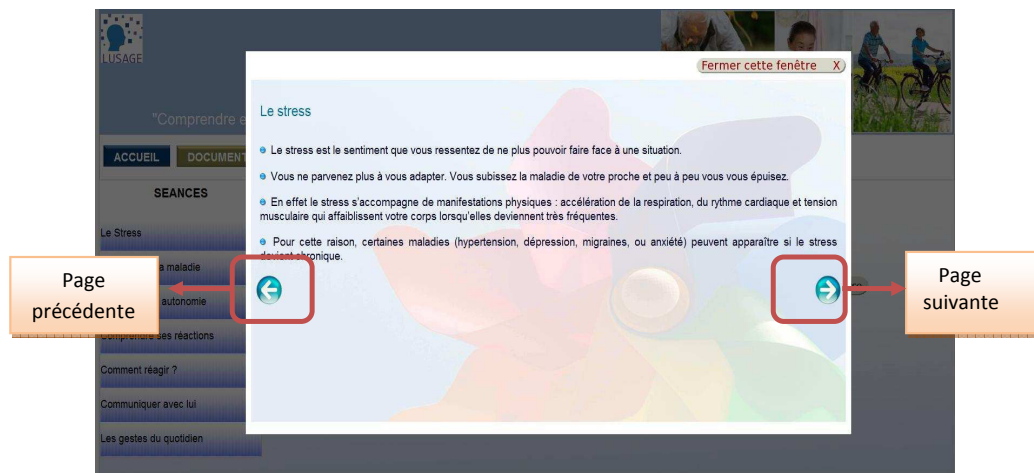


Figure 5

### 3.1 LES VIDEOS DANS LES SEANCES

Dans certaines séances, vous pouvez trouver des vidéos : pour les visionner, cliquez sur le triangle blanc au milieu du cadre (voir figure ci-dessous).

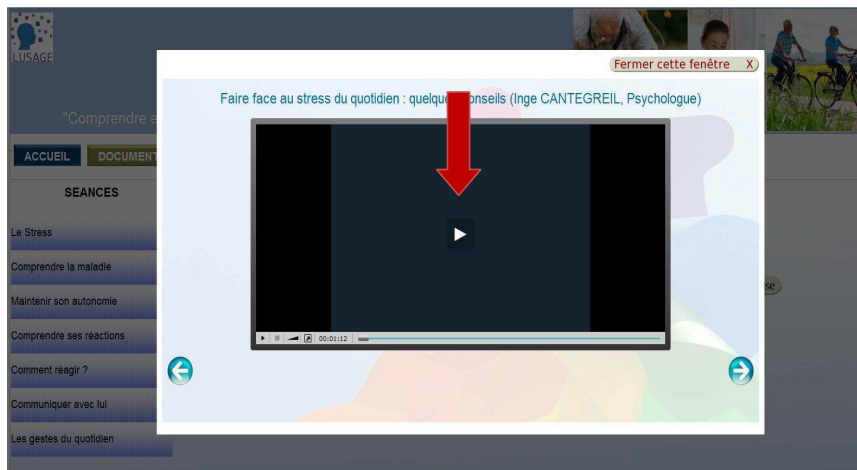



Figure 6

Dans la partie inférieure gauche de la vidéo vous trouverez plusieurs icônes (voir image ci-dessous). Le premier icône est le bouton **pause**, le deuxième correspond au bouton **stop**, le troisième permet **d'ajuster le son** et le dernier sert à **agrandir la vidéo** (ou activer le mode plein écran).



A la fin de la vidéo, pour quitter le mode plein écran, vous devez appuyer sur la touche ECHAP située dans la partie supérieure gauche de votre clavier ou appuyez à nouveau sur ce symbole : 

Pour revenir à l'accueil, cliquez sur l'onglet gris en haut à droite « Fermer cette fenêtre ».

Après avoir cliqué sur l'une ou l'autre de ces histoires, différentes situations vous apparaissent, certaines traitant de difficultés rencontrées par les personnes malades et d'autres par les aidants. Vous n'êtes pas obligé de tout lire ni de suivre un ordre déterminé. Vous pouvez accéder à chaque situation autant de fois que vous le désirez.

Si vous choisissez par exemple l'histoire de Paul et Nicole, vous verrez apparaître l'écran ci-dessous. Vous pouvez alors accéder à l'histoire de votre choix, comme par exemple « Paul est agité, que se passe-t-il ? » en cliquant une fois sur la phrase.

Si vous souhaitez lire l'histoire de l'autre couple, cliquez une fois sur l'onglet gris à droite de l'écran « Revenir aux histoires vécues ».



Figure 10

Après avoir cliqué sur l'histoire « Paul est agité, que se passe-t-il ? », un écran comprenant la description de la situation apparaîtra. Si vous souhaitez accéder aux autres histoires vécues par Paul, il vous suffira de cliquer sur les flèches bleues en bas à gauche. Après avoir pris connaissance des histoires qui vous intéressaient, il vous suffira de cliquer sur l'onglet en haut à droite « Fermer cette fenêtre » pour revenir aux histoires du couple.

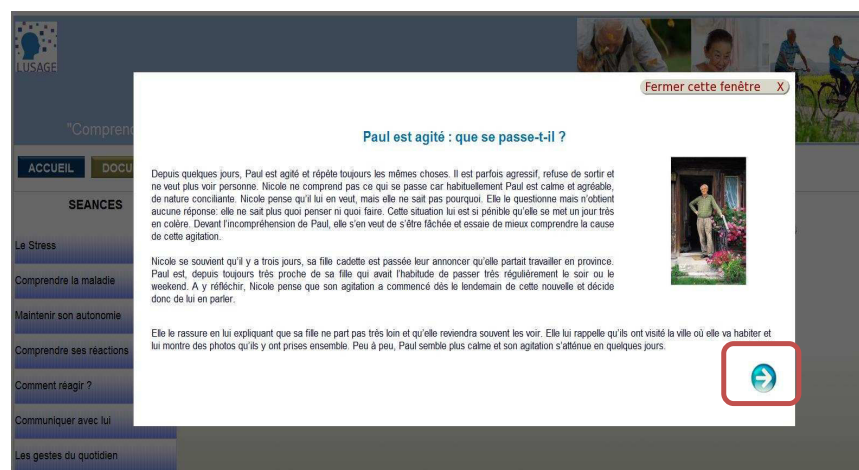


Figure 11



## APPENDIX 9. FUNDING OF DIRECTION DE L'HOSPITALISATION ET DE L'ORGANISATION DE SOINS



MINISTÈRE DE LA SANTÉ ET DES SPORTS

DIRECTION DE L'HOSPITALISATION  
ET DE L'ORGANISATION DES SOINS

Mission de l'observation, de la prospective  
et de la recherche clinique

Affaire suivie par le Dr Patrick GARDEUR  
Tél. : 01 40 56 56 09

Sous-Direction de la qualité  
et du fonctionnement des établissements de santé  
Bureau qualité et sécurité des soins  
en établissement de santé

Affaire suivie par le Dr Jean-Marc NADAL  
Tél. : 01 40 56 46 55

Paris, le 28 AVR. 2009

La Directrice de l'hospitalisation et  
de l'organisation des soins

à

Monsieur le Directeur Général  
de l'Assistance Publique-Hôpitaux de PARIS

A l'attention  
de M. le Directeur du Département de la  
Recherche Clinique et du Développement

1705

**Objet :** Programme de recherche en qualité hospitalière pour l'année 2009

**Réf. :** Circulaire N°DHOS/OPRC/E2/2008/324 du 28 octobre 2008 relative au programme de recherche en qualité hospitalière pour 2009.

**P.J. :** - Annexe 1 : tableau des montants des crédits attribués ;  
- Annexe 2 : avis du comité de sélection et des experts.

**Copie :** - Agence régionale de l'hospitalisation d'Ile de France.  
- DRASS Ile de France  
- Directeur Economique et Financier, AP-HP  
- Directeur du Département de la Recherche Clinique et du Développement, AP-HP  
- Directeur de l'Hôpital Broca  
- Pr Anne-Sophie RIGAUD, Hôpital Broca  
- Dr Marie-Laure PIBAROT, Direction de la Politique Médicale, AP-HP.

Dans le cadre du programme de recherche en qualité hospitalière pour l'année 2009, lancé par circulaire citée en référence, vous avez bien voulu m'adresser un projet intitulé :

" Contribution d'un programme psycho-éducatif en ligne d'aide aux aidants dans la prise en charge globale de la maladie d'Alzheimer et syndromes apparentés".

J'ai le plaisir de vous informer que ce projet a été retenu et que vous bénéficiez d'un soutien financier pour le mener à bien sur une durée de 3 ans. Son montant figure en annexe 1. La première tranche de ces crédits, déléguée en 2009, viendra majorer votre dotation des missions d'intérêt général et sera prise en compte dans le prochain arrêté fixant les dotations.

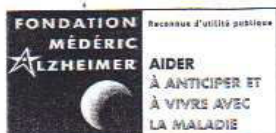
Pendant la durée prévisionnelle de 3 ans indiquée pour le projet, les crédits seront accordés à titre non reconductible pour chacun des exercices.

Vous trouverez en annexe 2 l'avis du ou des membres du comité de sélection exposant leurs observations susceptibles de vous aider à mettre en œuvre le projet.

lettreDHOS/OPRC/E2/2008/324/2009.doc

14, avenue Duquesne 75350 PARIS 07 SP - 01 40 56 60 00

## APPENDIX 10. FONDATION MEDERIC ALZHEIMER FUNDING



Professeur Anne-Sophie RIGAUD  
Service de gériatrie 2 - CMRR Paris Sud  
Hôpital Broca  
54-56 rue Pascal  
75013 Paris

Paris, le 07 juillet 2011

Madame le Professeur,

Dans le cadre de notre appel à projets d'études et de recherche, vous avez soumis un projet intitulé « Contribution d'un programme psycho-éducatif en ligne d'aide aux aidants dans la prise en charge globale de la maladie d'Alzheimer ».

Nous avons le plaisir de vous informer que ce projet a retenu l'attention du jury de présélection et que le conseil d'administration de la Fondation Médéric Alzheimer qui s'est réuni le 6 juillet 2011 a décidé de vous attribuer pour cette recherche une subvention d'un montant de 24 690 € TTC.

Nous attirons votre attention sur le fait que, pour pouvoir établir une convention entre nos deux institutions, nous aurons impérativement besoin du calendrier et du plan de financement que vous avez finalement retenu.

Nous réjouissant de cette collaboration,  
Nous vous prions d'agréer, Madame le Professeur, nos salutations les plus cordiales.

Michèle FREMONTIER  
Directrice

Fabrice GZIL  
Responsable du Pôle Etudes et Recherche

## APPENDIX 11. PERSONS PROTECTION COMMITTEE APPROVAL OF DIAPASON RCT PROTOCOL STUDY

### COMITE DE PROTECTION DES PERSONNES CPP ILE DE FRANCE III

Hôpital Tarnier-Cochin, 89 rue d'Assas 75006 Paris-Tél. : 01.46.33.68.67-Fax : 01.46.33.70.46-  
E-mail : [cpp.iledefrance3@orange.fr](mailto:cpp.iledefrance3@orange.fr)

**Composition du Bureau** : Président : Pr. Boyan CHRISTOFOROV, Vice-Président : Françoise KLELTZ-DRAPEAU, Secrétaire : Olivier SIGMAN, Secrétaire Adjoint : Denis BERNARD, Trésorier : Catherine HOLZMANN, Trésorier Adjoint : Paulette MORIN.

A Paris, le 15 juillet 2011

BC/LG/CC 2011-280

**REF : A rappeler dans toute correspondance :**

Dossier n°: 2011-A00690-41  
Réf. CPP : 2899

Le Comité a été saisi le 10 juin 2011

par le Promoteur : **AP-HP**  
d'une demande d'avis pour le projet de recherche :

N°: **P081002** : « **Contribution d'un programme psycho-éducatif en ligne d'aide aux aidants dans la prise en charge globale de la maladie d'Alzheimer** ».

Dont l'investigateur coordonnateur est le Pr. Anne-Sophie RIGAUD

Le Comité a examiné le protocole -version n°1.0 du 27/05/2011-, les notes d'information et de consentement (patient, aidant, tuteur) - version 1.0 du 27/05/2011- et tous les autres documents constituant le dossier.

Lors de sa séance du **05 JUILLET 2011**

Conformément aux dispositions de l'article R 1123-11 du Code de la Santé Publique, ont participé à la délibération :

Collège n°1 : Personnes qualifiées en matière de recherche biomédicale :

Dr. Bernard ASSELAIN titulaire (compétent en matière biostatistiques) – Dr Alice BEREZNE suppléant - Pr. Michel DETILLEUX suppléant - Dr. Denis BERNARD titulaire - Dr. Thierry BIGOT (psychiatre) (compétent en matière biostatistiques), suppléant

Pharmacien hospitalier : Dr. Marie-Lucie BRUNET suppléant

Collège n°2 : Personnes qualifiées sur les questions éthiques : Françoise KLELTZ-DRAPEAU titulaire, Marie BONNET suppléant

Représentant des travailleurs sociaux : Marie Claude FONTAN suppléant

Personnes compétentes en matière juridique : Olivier SIGMAN titulaire, David SIMHON titulaire

Représentant des associations agréées de malades et d'usagers du système de santé : Paulette MORIN titulaire - Laurence CARTON suppléant

Le Comité rend un **AVIS FAVORABLE** à la mise en œuvre de la recherche biomédicale aux motifs suivants : conditions satisfaisantes de validité / pertinence scientifique / intérêt de la recherche / conclusions de l'évaluation de la balance risque/bénéfice / intelligibilité de la note d'information et la conformité des modalités de recueil du consentement.

Commentaire : la réponse à la demande du comité, datée du 15/07/2011, incluant le protocole modifié -version 1.1 du 12/07/2011-, et les 4 notes d'information et de consentement modifiées (patient, aidant, tuteur, curateur) -version 1.1 du 12/07/2011-, a été prise en compte pour cet avis favorable.

Signé : Le Président

Boyan CHRISTOFOROV



APPENDIX 12. APPROVAL FROM THE FRENCH OFFICE FOR THE SAFETY OF HEALTH PRODUCTS

fax emis par : 33155873642

AFSSAPS U.E.U.

09-06-11 17:59 Pg: 1/1



Agence française de sécurité sanitaire  
des produits de santé

33155873642

**AUTORISATION D'ESSAI CLINIQUE NE PORTANT  
PAS SUR UN PRODUIT DE SANTE (ESSAI-HPS)**

**Nombre de pages : 1**

(Incluant la page de garde)

**Envoi par Télécopie**

**Date : 09 JUIN 2011**

<b>Identifiants de l'essai clinique</b>			
Titre		Contribution d'un programme psycho-éducatif en ligne d'aide aux aidants dans la prise en charge globale de la maladie d'Alzheimer (DIAPASON)	
Promoteur		Assistance Publique - Hôpitaux de Paris (AP-HP)	Réf. CPP Non disponible
Réf. Promoteur	P081002	N° ID RCB	2011-A00690-41
		Réf. Afssaps	<b>B110693-90</b>
<b>Expéditeur</b>		<b>Destinataire (demandeur : nom / société / tél.)</b>	
AFSSAPS / DEMEB / Département de l'évaluation des essais cliniques et des médicaments à statut particulier		Christophe Misse	
Unité essais cliniques médicaments et hors produits de santé		AP HP	
Dossier suivi par : Perrine ROBIN		01 44 84 17 70	
Tél : 33 (0) 1 55 87 36 41 / Fax : 33 (0) 1 55 87 36 42		Fax <b>01 44 84 17 01</b>	
<b>CPP destinataire en copie</b>		Ile-de-France III (Paris-Cochin)	Fax <b>01.46.33.70.46</b> Code <b>27</b>

Vu le code de la santé publique et notamment ses articles L. 1123-8, R. 1123-32 et vu le dossier de demande d'autorisation d'essai clinique adressé à l'Agence française de sécurité sanitaire des produits de santé (Afssaps) ;

L'autorisation mentionnée à l'article L. 1123-8 du code de la santé publique est accordée pour l'essai clinique cité en objet. Cette autorisation est valable pour toute la durée de l'essai à compter de la date de la présente décision.

Toutefois, conformément à l'article R. 1123-33 du code de la santé publique, la présente autorisation devient caduque si la recherche n'a pas débuté dans un délai d'un an.

Pour le Directeur Général et par délégation  
Dr Philippe VELLA  
Chef de l'unité essais cliniques médicaments  
et hors produits de santé

**09 JUIN 2011**

Pour toute demande d'informations complémentaires concernant cette autorisation, je vous recommande de solliciter un rendez-vous téléphonique en adressant à cet effet un courriel uniquement sur la boîte **contact-essaiscliniques@afssaps.sante.fr**.

Je vous demande alors de veiller à reporter dans l'objet du message uniquement les mentions suivantes : **AEC/B110693-90**.

Par ailleurs, afin d'optimiser la gestion des dossiers de modifications substantielles (MS) que vous pourriez être amené(e) à déposer pour l'essai sus-cité, je vous recommande de les transmettre par courriel adressé uniquement sur la boîte **ams-essaiscliniques@afssaps.sante.fr**. Je vous précise qu'il vous est possible d'utiliser à cet effet le système de messagerie électronique sécurisée Eudralink. Lors de l'envoi de ces dossiers, je vous demande de veiller à reporter dans l'objet du message les mentions suivantes :

- pour les MS transmises à l'Afssaps pour information : **MSI/B110693-90**
- pour les MS soumises pour autorisation ou pour les dossiers mixtes (comportant des modifications soumises pour autorisation et d'autres pour information) : **MSA/B110693-90**

**Si vous ne recevez pas toutes les pages de cette télécopie, veuillez contacter le secrétariat de l'Unité essais cliniques médicaments et hors produits de santé au : 33 (0) 1 55 87 36 41.**

**Confidentialité**

Cette transmission est à l'attention exclusive du(des) destinataire(s) ci-dessus mentionné(s) et peut contenir des informations privilégiées et/ou confidentielles. Si vous n'êtes pas le destinataire voulu ou une personne mandatée pour lui remettre cette transmission, vous avez reçu ce document par erreur et toute utilisation, révélation, copie ou communication de son contenu est interdite. Si vous avez reçu cette transmission par erreur, veuillez nous en informer par téléphone immédiatement et nous retourner le message original par courrier. Merci.

**Confidentiality**

This transmission is intended to the addressee(s) listed above only and may contain preferential or/and confidential information. If you are not the intended recipient, you are hereby notified that you have received the document by mistake and any use, disclosure, copying or communication of the content of this transmission is prohibited. If you have received this transmission by mistake, please call us immediately and return the original message by mail. Thank you.

143/147, bd Anatole France - F-93285 Saint-Denis cedex - tél. +33 (0)1 55 87 30 00 - [www.afssaps.sante.fr](http://www.afssaps.sante.fr)

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## APPENDIX 13. DECLARATION MADE TO THE FRENCH DATA PROTECTION AGENCY



### RÉCÉPISSÉ DE DÉCLARATION NORMALE

Numéro de déclaration

**1532816 v 0**

du 19-09-2011

Madame RIGAUD Anne-sophie  
HOPITAL BROCA - ASSISTANCE PUBLIQUE  
HOPITAUX DE PARIS  
54-56 RUE PASCAL  
75013 PARIS

### Organisme déclarant

**Nom :** HOPITAL BROCA - ASSISTANCE PUBLIQUE HOPITAUX DE PARIS

**Service :** SERVICE GERONTOLOGIE 2

**Adresse :** 54-56 RUE PASCAL

**Code postal :** 75013

**Ville :** PARIS

**N° SIREN ou SIRET :**  
267500452 00698

**Code NAF ou APE :**  
8610Z

**Tél. :** 0144083503

**Fax. :**

### Traitement déclaré

**Finalité :** LE TRAITEMENT DES DONNEES S'EFFECTUE DANS LE CADRE DE LA MISE A DISPOSITION D'UN SITE INTERNET POUR INFORMER LES FAMILLES DES PATIENTS ATTEINTS DE MALADIE D'ALZHEIMER ET SUIVIS EN CONSULTATION MEMOIRE A L'HOPITAL BROCA. L'ACCES AU SITE EST PERSONNALISE ET NECESSITE UN LOGIN. NOUS TRAITERONS LES DONNEES DE CONNEXION : TEMPS DE CONNEXION, NOMBRE DE VISITES POUR CHAQUE RUBRIQUE DU SITE, AFIN DE...

La délivrance de ce récépissé atteste que vous avez effectué une déclaration de votre traitement à la CNIL et que votre dossier est formellement complet. Vous pouvez mettre en œuvre votre traitement. Cependant, la CNIL peut à tout moment vérifier, par courrier ou par la voie d'un contrôle sur place, que ce traitement respecte l'ensemble des dispositions de la loi du 6 janvier 1978 modifiée en 2004. En tout état de cause, vous êtes tenu de respecter les obligations prévues par la loi et notamment :

- 1) La définition et le respect de la finalité du traitement,
- 2) La pertinence des données traitées,
- 3) La conservation pendant une durée limitée des données,
- 4) La sécurité et la confidentialité des données,
- 5) Le respect des droits des intéressés : information sur leur droit d'accès, de rectification et d'opposition.

Pour plus de détails sur les obligations prévues par la loi « informatique et libertés », consultez le site internet de la CNIL : « [www.cnil.fr](http://www.cnil.fr) »

Fait à Paris, le 21 septembre 2011  
Par délégation de la commission

Alex TÜRK  
Président

**APPENDIX 14. RESEARCH INFORMATION FORM AND CONSENT FOR THE INCLUSION OF PARTICIPANTS TO THE RCT DIAPASON**

**Titre complet de recherche :**

**Contribution d'un programme psycho-éducatif en ligne d'aide aux aidants dans la prise en charge globale de la maladie d'Alzheimer**

**DIAPASON**

**Cette recherche est organisée par l'Assistance Publique - Hôpitaux de Paris**

**Département de la Recherche Clinique et du Développement**

**1 avenue Claude Vellefaux**

**75010 Paris**

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**NOTE D'INFORMATION**

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**Madame, Monsieur,**

Le Docteur..... (nom, prénom), exerçant à l'hôpital ....., vous propose de participer à une recherche intitulée « Contribution d'un programme psycho-éducatif en ligne d'aide aux aidants dans la prise en charge globale de la maladie d'Alzheimer ».

Il est important de lire attentivement cette note avant de prendre votre décision ; n'hésitez pas à lui demander des explications.

Si vous décidez de participer à cette recherche, un consentement écrit vous sera demandé.

**1) Quel est le but de cette recherche?**

Cette recherche porte sur l'évaluation de l'effet d'un programme psycho-éducatif via internet à destination des aidants de patients ayant une maladie d'Alzheimer, sur leur état de stress et sur une meilleure prise en charge de leur proche.

Pour répondre à la question posée dans la recherche, il est prévu d'inclure environ 150 personnes aidants familiaux, des deux sexes. Ces derniers devront vivre quotidiennement au contact de personnes âgées suivies en consultations et pour lesquelles un diagnostic de maladie d'Alzheimer à un stade mineur ou modéré a été posé par l'équipe médicale du centre mémoire de l'Hôpital Broca.

**2) En quoi consiste la recherche ?**

Dans la recherche proposée, nous allons évaluer l'efficacité d'un programme psycho-éducatif sur l'état psychoaffectif. Si vous êtes affecté au groupe interventionnel, vous bénéficierez du programme psycho-éducatif en ligne en plus de l'accompagnement habituel. Si vous êtes affecté au groupe témoin, vous bénéficierez de la

prise en charge habituelle (consultation semestrielle avec votre médecin à l'hôpital de jour dans le cadre du suivi de votre proche). Un tirage au sort sera réalisé afin de vous répartir dans l'un ou l'autre groupe.

Ce programme psycho-éducatif consiste à vous connecter sur un site internet une fois par semaine pour bénéficier d'une séance qui comprend différents modules : comprendre la maladie et ses termes spécifiques, connaître les réactions possibles face aux difficultés, améliorer la communication entre l'aidant et son proche, réduire le stress, échanger ses expériences avec des personnes vivant la même situation. Ce programme comporte douze séances. A l'issue de ces douze séances, vous pourrez vous connecter librement pour consulter les séances existantes et continuer à accéder au forum des aidants.

### **3) Quel est le calendrier de la recherche ?**

La durée prévisionnelle de la recherche sera de 2 ans et votre participation sera de 6 mois.

L'étude vous sera présentée par un médecin de l'hôpital de jour qui vous remettra pour lecture et réflexion le formulaire d'information et de consentement. Si vous donnez votre accord, l'équipe de recherche vous contactera afin de vous fournir davantage d'informations et le cas échéant vous proposer un rendez-vous. à l'hôpital. Vous pourrez alors poser des questions pour obtenir des éclaircissements si besoin. Le jour de la première visite, si vous acceptez de participer à l'étude, nous vous proposerons de signer le consentement puis de remplir un questionnaire évaluant votre niveau de stress. En fonction de votre score à cette échelle, nous confirmerons avec vous la possibilité de votre participation à cette étude. Si votre participation est confirmée, une prise en charge vous sera attribuée par tirage au sort (suivi habituel ou programme d'information et de soutien en ligne). Lors de cette première visite à l'hôpital, durant une heure et demie à deux heures, vous remplirez également des questionnaires d'évaluation de la situation d'aide et de votre état de santé.

1- Si le tirage au sort vous a désigné dans le groupe bénéficiant du programme d'information et de soutien en ligne, nous vous présenterons le fonctionnement du site internet et vous fournirons son mode d'emploi. Nous vous remettons également un livret d'évaluation du programme, à remplir de façon hebdomadaire. Ensuite vous vous connecterez au site de chez vous, au rythme d'une fois par semaine pour suivre les séances. Chaque séance durera entre vingt et trente minutes. Vous pouvez également accéder librement aux autres rubriques proposées dans le site (documents, forum).

A la fin de la première partie du programme (12 séances), au bout de trois mois, vous viendrez à l'hôpital avec le livret complété. Vous remplirez les questionnaires d'évaluation sur votre situation et celle de votre proche. Cette deuxième visite dure une heure à une heure et demie. A l'issue de cette première partie du programme, vous aurez alors un accès libre au site pendant trois mois.

A la fin de ces trois mois, vous viendrez à l'hôpital et remplirez les mêmes questionnaires d'évaluation.

2- Si le tirage au sort vous a désigné dans le groupe bénéficiant du suivi habituel, vous viendrez à l'hôpital trois mois puis six mois après avoir signé ce consentement pour remplir des questionnaires évaluant la situation d'aide et votre état de santé. Vous rencontrerez le médecin lors des visites prévues dans la prise en charge habituelle de votre proche pour sa maladie (tous les 6 mois). Vous aurez accès au site internet après la fin de l'étude si vous le désirez.

### **4) Quels sont les bénéfices et les contraintes liés à votre participation ?**

Pour ceux qui suivront le programme en ligne, les bénéfices attendus seraient une meilleure compréhension du stress, des difficultés liées à la maladie de votre proche et de la façon d'y faire face. Les seules contraintes engendrées par l'étude seront de vous connecter à un rythme régulier (1 fois par semaine pendant 3 mois) sur le site internet DIAPASON et de vous rendre aux visites d'évaluation à l'hôpital pour remplir les questionnaires.

Pour ceux qui ne suivront pas le programme en ligne, vous pourrez, si vous le désirez, accéder au site DIAPASON, à l'issue de la recherche.



Les seules contraintes engendrées par l'étude seront de vous rendre aux visites d'évaluation à l'hôpital pour remplir les questionnaires.

Si vous acceptez de participer, vous devrez respecter les points suivants :

- Venir aux rendez-vous. En cas d'impossibilité, nous vous remercions de contacter l'équipe de recherche le plus rapidement possible.
- Informer le médecin responsable de la recherche de tout événement inhabituel (ex : hospitalisation, problème de santé) survenant pendant la recherche.
- Ne pas prendre part à un autre projet de recherche comprenant l'évaluation d'un autre programme d'aide aux aidants pendant la durée de la recherche.
- Etre affilié(e) à un régime de sécurité sociale ou être bénéficiaire d'un tel régime.

#### **5) Quels sont les risques prévisibles de la recherche?**

Il n'existe pas de risque prévisible ou attendu dans cette recherche.

#### **6) Si vous participez, que vont devenir les données recueillies pour la recherche ?**

Dans le cadre de la recherche biomédicale à laquelle l'AP-HP vous propose de participer, un traitement de vos données personnelles va être mis en oeuvre pour permettre d'analyser les résultats de la recherche au regard des objectifs qui vous ont été présentés.

A cette fin, les données personnelles vous concernant et les données relatives à vos habitudes de vie, seront transmises au Promoteur de la recherche ou aux personnes ou sociétés agissant pour son compte, en France. Ces données seront identifiées par un numéro de code et vos initiales. Ces données pourront également, dans des conditions assurant leur confidentialité, être transmises aux autorités de santé françaises ou à d'autres entités de l'AP-HP.

Pour tout arrêt de participation sans retrait de consentement, les données recueillies précédemment à cet arrêt seront utilisées sauf si vous ne le souhaitez pas.

#### **7) Comment cette recherche est-elle encadrée ?**

Conformément à l'article L 1121-10 du Code de la Santé Publique, l'AP-HP a souscrit une assurance (N° d'adhésion 904932010106) garantissant sa responsabilité civile et celle de tout intervenant, auprès de la compagnie HGI-GERLING, par l'intermédiaire de BIOMEDICINSURE dont l'adresse est Parc d'Innovation Bretagne Sud C.P.142 56038 Vannes Cedex.

De même et selon les articles L 1121-1 et suivants, l'AP-HP a pris toutes les dispositions prévues par la loi relative à la protection des personnes se prêtant à des recherches biomédicales.

L'AP-HP a également obtenu l'avis favorable du Comité de Protection des Personnes IDF III pour cette recherche le ./.. /....] et une autorisation de l'Agence Française de Sécurité Sanitaires des Produits de Santé (Afssaps).

#### **8) Quels sont vos droits ?**

Votre participation à cette recherche est entièrement libre et volontaire. Vous pouvez vous retirer à tout moment sans justification. Votre suivi, la qualité des soins de votre proche, la relation avec votre médecin, n'en seront pas affectés. A l'issue de ce retrait, votre proche et vous-même pourrez être suivis par la même équipe médicale.



Vous pourrez tout au long de la recherche demander des explications sur son déroulement aux médecins et psychologues qui vous suivent.

Conformément aux dispositions de la CNIL (loi relative à l'informatique, aux fichiers et aux libertés), vous disposez d'un droit d'accès et de rectification. Vous disposez également d'un droit d'opposition à la transmission des données couvertes par le secret professionnel susceptibles d'être utilisées dans le cadre de cette recherche et d'être traitées. Ces droits s'exercent auprès du médecin en charge de la recherche qui seul connaît votre identité. Vous pouvez également accéder directement ou par l'intermédiaire d'un médecin de votre choix à l'ensemble de vos données médicales en application des dispositions de l'article L 1111-7 du Code de la Santé Publique.

Les informations vous concernant et recueillies au cours de cette étude resteront confidentielles et ne pourront être consultées que sous la responsabilité du médecin s'occupant de votre suivi ainsi que par les autorités de santé et par des personnes dûment mandatées par l'AP-HP pour la recherche et soumises au secret professionnel. Vos données seront conservées jusqu'à la publication des résultats de la recherche sauf refus/opposition de votre part.

Des données du dossier médical de votre proche, concernant son état de santé, suivi à l'Hôpital Broca pour un diagnostic de maladie d'Alzheimer seront recueillies pour cette recherche. Votre proche, ou son représentant légal le cas échéant, en seront informés par la remise d'une note d'information.

A l'issue de la recherche et après analyse des données, vous serez informé(e) des résultats globaux, si vous le souhaitez, par l'intermédiaire du médecin responsable ou des investigateurs qui vous suivent dans le cadre de cette recherche.

Si vous acceptez de participer à la recherche après avoir lu toutes ces informations et discuté tous les aspects avec le médecin et les investigateurs, vous devrez signer et dater le formulaire de consentement éclairé se trouvant à la fin de ce document.



## FORMULAIRE DE CONSENTEMENT

Je soussigné(e), M<sup>me</sup>, M. [rayer les mentions inutiles] (nom, prénom).....

**accepte librement de participer à la recherche intitulée**

**« Etude DIAPASON : Contribution d'un programme psycho-éducatif en ligne d'aide aux aidants dans la prise en charge globale de la maladie d'Alzheimer ou maladies apparentées »**

organisée par l'Assistance Publique - Hôpitaux de Paris et qui m'est proposée par le Docteur (nom, prénom, téléphone)....., médecin dans cette recherche.

- J'ai pris connaissance de la note d'information version 1.1 du 12/07/2011 (3 pages) m'expliquant l'objectif de cette recherche, la façon dont elle va être réalisée et les implications de ma participation,
- je conserverai un exemplaire de la note d'information et du consentement,
- j'ai reçu des réponses adaptées à toutes mes questions,
- j'ai disposé d'un temps suffisant pour prendre ma décision,
- j'ai compris que ma participation est libre et que je pourrai l'interrompre à tout moment, sans remettre en cause la qualité des soins et du suivi qui me seront prodigués ainsi qu'à mon proche. J'indiquerai alors au médecin qui me suit, si je souhaite ou non que les données recueillies, jusqu'au moment de ma décision, soient utilisées,
- je suis conscient(e) que ma participation pourra aussi être interrompue par le médecin si besoin était,
- avant de participer à cette recherche, j'ai rencontré le médecin de l'hôpital de jour pour un entretien clinique
- j'ai compris que pour pouvoir participer à cette recherche je dois être affilié(e) à un régime de sécurité sociale ou bénéficiaire d'un tel régime. Je confirme que c'est le cas,
- j'ai bien été informé(e) que ma participation à cette recherche durera 6 mois et que cela implique que je ne pourrai pas envisager de participer à une autre recherche avec un programme de type psycho-éducatif pendant la durée de celle-ci, sans en informer le médecin qui me suit,
- mon consentement ne décharge en rien le médecin qui me suit dans le cadre de la recherche ni l'AP-HP de l'ensemble de leurs responsabilités et je conserve tous mes droits garantis par la loi.

- J'ai été informé(e) que les informations me concernant et recueillies au cours de cette étude resteront confidentielles et ne pourront être consultées que par l'équipe de recherche sous la responsabilité du médecin s'occupant de mon suivi ainsi que par les autorités de santé et par des personnes dûment mandatées par l'AP-HP pour la recherche et soumises au secret professionnel.

**Signature de la personne participant à la recherche**

**Signature du médecin**

Nom Prénom :

Nom Prénom :

Date :

Signature :

Date :

Signature :

**Ce document est à réaliser en 3 exemplaires, dont l'original doit être conservé 15 ans par l'investigateur, le deuxième remis à la personne donnant son consentement et le troisième transmis à l'AP-HP sous enveloppe scellée à la fin de la recherche.**

## APPENDIX 15. LEAFLETS FOR THE RECRUITMENT OF DIAPASON PARTICIPANTS

### QUI SOMMES NOUS?

Nous sommes une équipe pluridisciplinaire comprenant des psychologues, des médecins gériatres, des chercheurs et des praticiens hospitaliers. Suite à plusieurs années d'expérience auprès des malades et leurs familles, nous avons constaté le besoin d'informer plus et d'informer mieux, aussi bien l'équipe médicale que les membres de la famille du patient.

Ce site internet est l'une des multiples initiatives du service du Pr Rigaud et de son laboratoire de recherche « Lusage » (EA 4468 Université Paris Descartes). Ce dernier est spécialisé dans la prise en charge des personnes atteintes de la maladie d'Alzheimer et de leurs proches. Le laboratoire Lusage porte également un intérêt particulier au rôle des nouvelles technologies dans la prévention de l'isolement, le maintien du patient à domicile et la mise en place des techniques facilitant l'accès aux services de santé.



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### Site Diapason



Programme **psycho-éducatif en ligne**  
**à destination des aidants de personnes**  
**atteintes de maladie d'Alzheimer**

Un projet de l'équipe EA 4468 – Laboratoire LUSAGE et le service de Gériatrie de l'Hôpital Broca

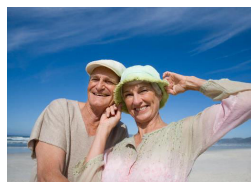


### LA MALADIE DE VOTRE PROCHE ENGENDRE BEAUCOUP DE CHANGEMENTS

Accompagner un proche avec la **maladie d'Alzheimer** n'est pas une tâche facile et peut s'accompagner de fatigue et de stress. Les aidants familiaux sont amenés à mettre en place de nombreux changements dans leur quotidien.

Des informations concernant la maladie, son proche, son entourage et ses réactions dans le cadre de cette maladie pourraient faciliter la vie de tous les jours et celle de la personne malade.

Afin de répondre à ce besoin, les professionnels de santé du pôle de gériatrie et le laboratoire Lusage de l'Hôpital Broca, ont développé un programme psycho-éducatif en ligne **destiné aux familles**.



#### DANS CE SITE ILS TROUVERONT

- DES EXPLICATIONS CLAIRES SUR LA MALADIE
- UN FORUM DE DISCUSSION
- DES INFORMATIONS PRATIQUES SUR LES AIDES HUMAINES ET FINANCIÈRES.
- DES LIENS VERS D'AUTRES SITES
- DES VIDEOS INFORMATIVES
- DES VIDEOS D'ENTRAÎNEMENT A LA RELAXATION

### ET POURQUOI UN SITE INTERNET ?

Les séances d'éducation thérapeutique ayant lieu dans les hôpitaux et centres de santé ne sont **pas toujours faciles d'accès pour les familles**. Les personnes ayant peu de temps ou de ressources financières arrivent rarement à suivre les programmes proposés dans leur intégralité.

Dans ce contexte, ce programme informatisé apparaît comme **une alternative**, permettant la mise à disposition d'informations pertinentes et utiles. Par ce moyen, les aidants pourront également rencontrer et échanger avec d'autres personnes vivant des situations similaires.

#### ÉVALUER LE SITE ET SON EFFICACITÉ

Bien qu'en France il existe déjà des sites internet proposant des informations aux familles, il y a peu d'études portant sur l'efficacité et l'utilité de ceux-ci.



Le programme Diapason a été objet d'une recherche clinique randomisée\* (2011 – 2013) afin d'évaluer ses bénéfices chez les personnes accompagnant un proche atteint de la maladie d'Alzheimer. Les résultats seront publiés en 2014.

\* Etude partiellement financée par la Fondation Médéric Alzheimer et le Ministère de la Santé (PREQHO3)



#### COMMENT ACCÉDER AU SITE?

Un identifiant et un mot de passe pour accéder au site vous sont fournis par l'équipe chargée du projet Diapason.



#### QUI A PARTICIPÉ A L'ÉTUDE

Les familles des personnes atteintes de la maladie d'Alzheimer, suivies à l'hôpital Broca.



#### NOUS CONTACTER

Pour obtenir plus d'informations:

Projet **DIAPASON**  
Tél. 01 44 08 33 51

Victoria CRISTANCHO-LACROIX  
Responsable scientifique

**APPENDIX 16. TRAINING FOR THE EXPERIMENTAL GROUP DELIVERED AT THE BASELINE VISIT  
FORMATION UTILISATION SITE INTERNET**

Les objectifs de cette formation sont, d'expliquer les particularités du site, donner un aperçu des fonctions du site, donner des conseils pour une utilisation pratique et en répondre aux questions de l'utilisateur. La précision des explications dépendra du niveau « d'expertise » du participant.

<b>LES PARTICULARITES DU SITE</b>	« Fait » (marquer avec une X)
<ul style="list-style-type: none"> <li>• <b>Un accès contrôlé</b> : un identifiant et un mot de passe sont nécessaires pour y accéder. Ceux – ci sont obtenus uniquement par l'intermédiaire de l'équipe de recherche.</li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Certaines parties du site sont activées et consultables à fur et à mesure</b> : Ce principe s'applique pour les séances et les vidéos (rubrique documents).</li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Un forum accessible seulement aux inscrits</b> : A part les autres participants à l'étude et l'équipe d'évaluateurs, personne d'autre ne pourra lire les commentaires du forum.</li> </ul>	

<b>ACCUEIL</b>	
Informations importantes (séances en retard ou disponibles)	
Utilisation de la <b>barre de défilement</b> verticale.	
Changement de mot de passe	
<b>SEANCES</b>	
<p><b>Cliquer seulement une fois</b> pour accéder aux séances, documents et tout autre lien dans le site : Il est important de le préciser car si la personne double-clique le lien s'ouvre et se referme immédiatement.</p> <p>Montrer avec un exemple sur le site. (i.e. Séances)</p>	
Apparition d'une fenêtre au sein de l'écran du site pour plusieurs parties (i.e. séances, histoires vécues, glossaire...).	

Quand cette fenêtre s'affiche des <b>flèches</b> apparaissent dans la partie inférieure pour avancer ou reculer dans le document.	
Il faut aller jusqu'à la fin de la séance (ce qui correspond à la dernière « diapo ») pour la valider.	
A chaque fois qu'une fenêtre s'ouvre et qu'on veut revenir à l'écran du site, cliquer « FERMER CETTE FENETRE» ou sur le cadran gris autour.	
<b>HISTOIRES VECUES</b>	
Aller en bas de la page pour montrer les histoires qu'on peut choisir. Rappeler de ne cliquer qu'une fois seulement.	
<b>RELAXATION</b>	
Aller en bas de la page pour montrer les options qu'on peut choisir. Rappeler de ne cliquer qu'une fois seulement.	
<b>STIMULATION</b>	
Aller en bas de la page pour montrer les options qu'on peut choisir. Rappeler de ne cliquer qu'une fois seulement.	
<b>GLOSSAIRE</b>	
Mots organisés par ordre alphabétique	
Cliquer une fois pour accéder à la définition du mot	
<b>VIDEOS</b>	
Montrer comment agrandir et réduire une vidéo et préciser la fonctionnalité de chaque bouton au bas des vidéos. Faire un lien avec le mode d'emploi où cas où la personne oublierait comment procéder une fois seule à la maison.	
<b>LIENS UTILES</b>	
Un nouvel onglet ou une nouvelle fenêtre du navigateur s'ouvre. La page du site reste accessible.	

<b>FORUM</b>	
Demander à la personne si elle a déjà utilisé un forum auparavant. Expliquer ou rappeler les points suivants : « échange de messages entre les personnes inscrites au site », « anonyme, car seul le pseudo (inventé) apparaîtra comme auteur du message », « possibilité de recevoir les réponses à ses messages par mail ».	
Montrer comment créer un nouveau message et vérifier qu'il a bien été publié.	
Montrer comment répondre au message de quelqu'un d'autre ou au sien.	
<b>MODE D'EMPLOI</b>	
Juste montrer la page correspondante.	
<b>QUITTER LE SITE</b> : Rappeler importance d'appuyer sur ce bouton à chaque fois que la personne arrête d'utiliser le site.	

## APPENDIX 17. EXTRACT OF THE QUESTIONNAIRE FOR CAREGIVERS' NEEDS AND EXPECTATIONS ABOUT AN INTERNET-BASED SUPPORT

### QUESTIONNAIRE AIDANTS: Vos attentes sur un site d'information sur la maladie de votre proche

Nous souhaiterions proposer un site d'information et/ou de soutien adapté aux besoins des familles de patients atteints troubles cognitifs . Pour cela, nous voudrions connaître vos attentes à ce sujet.

\*Obligatoire

#### Objectif de l'étude

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Cette étude s'intéresse aux besoins et attentes en termes d'accompagnement et de soutien à distance des familles des proches atteints de la maladie d'Alzheimer (ou maladies apparentées). Les résultats de cette étude nous guideront vers la création de programmes plus adaptés aux attentes des familles.

#### Procédure

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Il vous sera demandé de répondre à un questionnaire de dix minutes concernant vos besoins et attentes en termes d'accompagnement et de soutien à distance.

#### Risques et inconvénients

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Il n'y a pas de risques liés à cette étude.

#### Avantages et progrès escomptés

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Vous ne retirerez pas d'avantage direct en participant à cette étude. L'information que vous partagerez avec nous sera utilisée pour établir des lignes directrices qui permettront de créer des technologies plus adaptées aux aidants des patients atteints de troubles cognitifs.

#### Respect de l'intimité et de la confidentialité

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Les données recueillies sont anonymes et confidentielles. Les informations traitées lors de l'analyse de données apparaîtront dans les rapports sans qu'aucune identification de personnes ne soit possible. Les résultats de cette recherche pourront être publiés dans des revues scientifiques et présentés dans des réunions d'information clinique. Votre accord pour l'utilisation de ces informations est valable jusqu'à la fin du projet, sauf si vous y mettez fin avant. Conformément à la loi "Informatique et libertés" du 6 Janvier 1978, vous bénéficiez d'un droit d'accès et de rectification aux informations qui vous concernent.



## Il n'y a ni bonne, ni mauvaise réponse, il s'agit de votre opinion.

### 15. Je voudrais un site qui traite

*Une seule réponse possible.*

- uniquement de la maladie de mon proche
- de la maladie de mon proche et des maladies apparentées
- Autre : .....

### 16. Je voudrais un site dédié

Plusieurs réponses possibles

*Plusieurs réponses possibles.*

- à l'aidant
- au patient
- à l'entourage du patient

### 17. A quel moment souhaiteriez-vous que l'on vous propose l'accès au site internet?

*Une seule réponse possible.*

- Tout de suite après le diagnostic
- Autre : .....

### 18. Quelles informations souhaiteriez-vous trouver sur un site internet dédié aux aidants? \*

Veillez cocher les phrases qui correspondent à votre attente

*Une seule réponse possible par ligne.*

	Pas du tout d'accord	Pas d'accord	Ni en désaccord ni d'accord	D'accord	Tout à fait d'accord
Je voudrais un site qui m'explique comment le diagnostic est posé.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Je voudrais mieux connaître les causes de la maladie.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Je voudrais avoir des informations sur l'évolution de la maladie.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Je voudrais avoir des informations sur les avancées scientifiques autour de la maladie.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Je voudrais comprendre les changements de comportement et/ou de personnalité de mon proche	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Caractéristiques souhaitées du site

### 23. Je voudrais que l'on me propose un site: \*

*Une seule réponse possible par ligne.*

	Pas du tout d'accord	Plutôt pas d'accord	Ni en désaccord ni d'accord	Plutôt d'accord	Tout à fait d'accord
en libre accès (sans mot de passe)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
qui propose un parcours pédagogique	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
qui adapte les contenus selon mon profil (enfant, conjoint, autre)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
qui offre moins de texte et plus de graphiques, dessins et schémas	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
avec des thématiques traitées en détail.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
qui propose des réunions pour les aidants par visioconférence avec un professionnel.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

### 24. Je souhaiterais que le site me propose un forum (salle de discussion virtuelle) : \*

*Une seule réponse possible par ligne.*

	Pas du tout d'accord	Plutôt pas d'accord	Ni en désaccord ni d'accord	Plutôt d'accord	Tout à fait d'accord
avec un accès libre, où tous les internautes puissent y accéder.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
modéré par un professionnel de la santé	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
modéré par un aidant formé	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
qui soit anonyme	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
qui organise en complément des "cafés-aidants" (rencontres dans un cadre décontracté avec d'autres aidants modérés par un psychologue ou un aidant expérimenté).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
qui propose des salles de discussion par thématique (rubriques).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
qui propose un "tchat" (salle de discussion instantanée).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
qui me prévient par mail des nouveaux messages	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Merci de votre participation!**

25. Si vous souhaitez avoir accès au site Diapason, veuillez noter vos coordonnées ci-dessous - Notre équipe vous contactera. Dans le cas contraire, appuyez sur le bouton en bas "Envoyer", pour enregistrer en envoyant vos réponses. Merci!!

Nom

.....

26. Téléphone

.....

27. Adresse mail

.....

*Arrêtez de remplir ce formulaire.*

28. **Pour quelle(s) raison(s) n'êtes-vous pas intéressé(e)?**

*Plusieurs réponses possibles.*

- Je n'ai pas le temps
- Je n'en ai pas besoin
- Je suis assez informé sur la maladie
- Je n'en ai pas envie
- Autre : .....

**Merci de votre participation!**

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