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Protocol

Effectiveness of online psychological intervention for caregivers on the quality of life of people with Alzheimer disease: a randomized clinical trial protocol

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ABSTRACT

Background: Alzheimer's disease (AD) has a significant impact on the quality of life (QOL) and interventions aimed at their improvement show inconclusive results. Objectives were study protocol to evaluate the effectiveness of a multicomponent caregiver intervention on the QOL of persons with AD.
Methods: The design is a randomized clinical trial with blinded assessment of response variables. Ninety-four dyads of informal caregivers and their relatives with AD will be recruited in the Osona and Ripollès territorial service of geriatrics and palliative care of the Consorci Hospitalari de Vic (Osona, Spain) and randomized into experimental (EG) and control group (CG). An 8-week online multicomponent psychological intervention including psychoeducation and mindfulness will be provided to the EG caregivers. The CG will perform the usual care. Outcome will be the QOL of persons with AD assessed with the QOL-AD.
Conclusions: The multicomponent online caregiver research detailed in this protocol could be incorporated into health and care facilities for persons with AD and their families to improve caregiving and QOL.

Keywords: Alzheimer disease, QOL, Caregivers, Psychological intervention, Mindfulness, Personality

INTRODUCTION

Alzheimer's disease (AD) has a prevalence of 5% in Europe (up to 23% in those over 85 years of age), an incidence of 11 per 1000 person-years and estimated cost of 160 billion euros in 2008.[1,2] Worldwide 47 million people suffer from this disease, and the estimated prevalence by 2050 will be 131 million affected.[3]

AD is a chronic, degenerative condition with no curative treatment, and interventions prioritize the maintenance of well-being and QOL. QOL in persons with AD is a complex construct that is associated with multiple people with AD, caregiver and disease factors. Psychological and behavioral symptoms of dementia, (especially depression), cognitive impairment and dependence in activities of daily living alter the QOL of the person with AD as well as can increase the burden and affect the mood of caregivers. In older people without dementia and people with other pathologies, (psychiatric and oncological) QoL is associated with the certain personality traits, especially neuroticism as well as extraversion.[4] Social participation and a good relationship with the caregiver improve the QOL of the person with AD, but the factor most linked to the QOL of the persons with AD is the QOL of the caregiver, since it promotes higher quality care.[5]

Caregivers provide the support that persons with AD require because of the progressive dependence. Informal caregivers are between 75% to 85% family members, mostly women.[6,7] The maximum responsibility falls on the so-called primary caregiver, who presents more depression, anxiety, burden, diminished cognitive performance and lower QOL than non-caregiver controls and other informal caregivers.[8-10] The most associated factor with caregiver QOL is their physical and mental health, especially depression, anxiety and sleep quality, in fact one of the goals of care for people with dementia is the improvement of caregivers' well-being.[11] In addition to mood, other caregiver characteristics have been described that can modulate their QOL, such as personality and received as well as perceived social support.[12,13]

Nonpharmacological interventions improve caregivers QOL.[6] Multicomponent programs combine different therapeutic strategies (such as psychoeducation, social support, skills training and emotional regulation techniques), formats (individual, group, face-to-face, online) and professionals, allowing impact on various outcomes and needs. Multicomponent interventions present excellent results in efficacy and efficiency in improving caregiver QOL.[14,15] The combination of psychoeducation and psychotherapeutic components is particularly effective in improving caregiver mental health.[16] Psychoeducation consists of providing scientific evidence-based information about the disease, treatment, and behavioral management. Mindfulness is defined as moment-to-moment awareness with an attitude of non-judgment, acceptance, and openness and aims to increase awareness of mental, emotional, and somatic processes through a state of alertness in the present moment that slows and evidences impulses and reactions.[17] Mindfulness practice in caregivers of persons with AD improves depression, burden, QOL, and cognitive abilities.[18,19]

In recent years there has been an increase in online therapeutic proposals for caregivers of persons with the AD that allow improving accessibility and cost-efficiency of interventions, especially since the declaration of pandemic status by COVID-19 in March 2020.[20] A recent meta-analysis[21] indicates that the therapeutic benefit of online interventions on the mood of caregivers of people with the dementia is similar to face-to-face interventions. Furthermore, it concludes that multicomponent online interventions combining psychoeducational elements, behavior change and stress management techniques show the best results on caregivers' well-being.

Nonpharmacological interventions targeting persons with AD include cognitive stimulation, physical exercise and music therapy among others.[22,23] These interventions are focused on slowing cognitive decline, improving psychiatric symptoms and improving general health and QOL. However, the cognitive impairment of AD jeopardizes the implication as active agents of change and favours the emergence of caregiver-mediated nonpharmacological interventions.[24] In the case of caregiver-mediated interventions for persons with AD, improvements in psychological and behavioral symptoms of dementia have been detected but there is no evidence of improvement in persons with AD-QOL.[25]

The main objective of the study is to determine the effectiveness of a multicomponent online intervention delivered to caregivers on the QOL of persons with AD compared to the CG.

Secondary objectives are to determine the impact of the intervention on caregivers' mental health and cognitive performance, the use of health resources of persons with AD and the mediating effect of caregiver’s mood, personality, social support, and healthy habits on the results.

METHODS

Study design

Randomized clinical trial of the two parallel groups to assess the efficacy of a multi-component intervention aimed at the caregivers on the QOL of the persons with the AD.

The trial has been registered in clinicaltrials.gov (https://clinicaltrials.gov/) on February 17, 2020. NCT Number: NCT04280861

Participants and setting

The study will be conducted in Osona (Barcelona, Spain). The Osona region has a population of 164,077 people, 29,000 of whom are >65 years old in 2021.[26] It presents an aging rate of 110.6% and an over aging rate of 18.7% in 2020.[27] Osona and Ripollès territorial service of geriatrics and palliative care provides comprehensive care in geriatrics, palliative care, chronic and complex patients through an integrated model that includes several hospitals and social and health care facilities: Vic university hospital, Manlleu hospital, Campdevànol Hospital and Santa Creu hospital.

Neuropsychologist or physician of the geriatric evaluation service located at the Manlleu hospital will provide information about the study to all people diagnosed with early or moderate stage of the AD

(Global deterioration scale was 4 or 5) as well as their relatives.

Inclusion criteria

Participants will be individuals with diagnosis of AD dementia according to national institute where aging and Alzheimer's association criteria and their informal caregivers living in community.[28] For caregivers include being 18 years of age/older, being primary informal caregiver (person in patient's environment with whom they have significant relationship and to whom they provide care and assistance), having email, smartphone/ tablet with internet connection were included.

Exclusion criteria

Persons with moderate-advanced AD, who lack the ability to respond to a brief video conference interview, or who have severe hearing impairment and medical or personal conditions that significantly compromise cognitive performance (other than dementia). Caregivers with severe/unstable cardiovascular, metabolic, neurological or psychiatric diseases in the last 6 months, substance abuse diagnosis, severe sensory disturbances or any situation that does not allow the completion of the interview. Caregivers with a mini mental state examination (MMSE) score of less than 24 or those undergoing psychotherapy for the purpose of treating caregiver stress will also not be included were excluded.

Candidates who agree to participate and meet inclusion criteria will be recruited and randomly assigned to EG and CG (Figure 1).

We used SPIRIT 2013 statement defining standard protocol items for clinical trials to undertake this study protocol.[29]

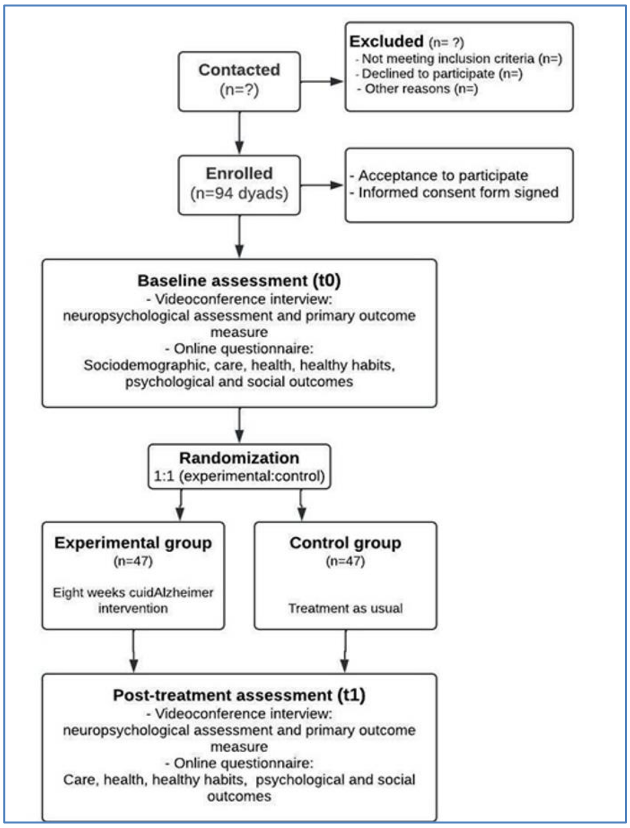

Figure 1: CONSORT diagram of study.

Variables

The caregiver will answer demographic, care, health, habits, psychological, social and resource use variables in an ad hoc online questionnaire (Table 1) baseline questionnaire (Q0) and post-treatment questionnaire (Q1). Participants will receive explanations on how to answer the tests and can communicate with the principal investigator (PI) via telephone or e-mail to resolve any doubts.

Table 1: SPIRIT flow diagram: flowchart of study-schedule of enrollment, interventions, and assessments.

Variables			Enrollment	Base line	Intervention 8 weeks	Post-treatment	
Time point			-t1	t0		t1	
Informed consent			X				
Eligibility screening			X				
Allocation				X			
Intervention							
Outcomes	**Who evaluates**	**Who answers**		**Q t0**	**V t0**	**Q t1**	**V t1**
Principal							
QoL-AD	Person with AD	Person with AD			X		X
Sociodemographic							
Age, gender, marital status, educational level, profession, cohabitation, relationship with the person with AD	Person with AD and caregiver	Caregiver		X			

Continued.

Variables			Enrollment	Base line	Intervention 8 weeks	Post-treatment	
Outcomes	**Who evaluates**	**Who answers**		**Q t0**	**V t0**	**Q t1**	**V t1**
Care							
Daily time spent on caregiving Duration in years	Caregiver	Caregiver		X		X	
Health							
Comorbidities, medication, body mass index (BMI), smoking and alcohol consumption	Caregiver	Caregiver		X			
COVID-19 infection prior to the study.	Person with AD and caregiver	Caregiver		X			
Duration of AD in years	Person with AD	Caregiver		X			
Healthy habits							
Physical activity: type and frequency. Sleep: duration and quality, Adherence to the Mediterranean diet (PREDIMED)	Caregiver	Caregiver		X		X	
Psychological-							
Anxiety and depression (HADS)	Caregiver	Caregiver		X		X	
Happiness (OHQ)	Caregiver			X		X	
Burden (CBI)	Caregiver			X		X	
Personality (NEO-FFI)	Person with AD			X		X	
Personality (NEO-FFI)	Caregiver			X		X	
Previous experience in mindfulness	Caregiver			X		X	
State of mindfulness (MAAS)	Caregiver			X		X	
QOL (QoL-AD)	Caregiver			X			
Social							
Loneliness (UCLA), Perceived social support (DUKE-UNC)	Caregiver	Caregiver		X		X	
Cognitive and behavioural							
Global cognitive performance (MMSE)	Person with AD and caregiver	Person with AD and caregiver			X		X
Memory (RAVLT)	Caregiver	Caregiver			X		X
Information processing speed (Oral-SDMT)	Caregiver	Caregiver			X		X
Fluency-Cognitive flexibility (oral-TMT)	Caregiver	Caregiver			X		X
Psychological and behavioral symptoms of dementia (NPI)	Caregiver person with AD	Caregiver			X		X
Use of health resources							
Visits to hospital emergency rooms	Person with AD	Caregiver				X	
Visits to primary care						X	
Hospital admissions						X	
Prescription of psychotropic drugs						X	

The cognitive and behavioral assessment and the main study variable will be assessed via video-conference by the neuro-psychologist, in the oral format as well as with the modifications proposed by the inter organizational practice committee for the practice of teleneuropsychology (baseline videoconference-VC0 video call as well as post-treatment videoconference-VC1).[30]

Outcome

The primary outcome is the quality of life of people with AD assessed with the Quality Of Life-AD (QoL-AD). This self-administered scale contains 13 items, each of which is rated according to the level of QOL experienced by the person. Scores range from 13 to 52 points, with a higher score indicating better QOL. It shows excellent internal and external reliability and adequate criterion validity in persons with AD even in moderate stages of the disease and has been used in a videoconferencing format.[31,32]

Caregivers' variables

Sociodemographic: age, gender, marital status, educational level, profession, cohabitation, relationship with the person with AD.

Care: daily time spent on caregiving is assessed with the question "on a typical day in the last month, how many hours do you spend helping your family member with activities of daily living?". Duration in years with the question "how many years have you been caring for your family member?"

Health: comorbidities, medication, BMI, smoking and alcohol consumption, COVID-19 infection prior to the study.

Healthy habits: i) The type of physical activity (mild, moderate and vigorous) and its frequency (daily, habitual, occasional or not at all) will be recorded according to the WHO classification and recommendations.[33] ii) The duration of sleep (hours per night) will be recorded by the following question: “how many hours do you sleep each night?”. The quality of sleep is examined by the following question: “how do you rate the quality of your sleep?” iii) Adherence to the Mediterranean diet will be assessed through the PREDIMED (Prevención con dieta mediterránea), one of the dietary patterns with the greatest benefits especially for cardiovascular health.[34]

Psychological: i) The hospital anxiety and depression scale (HADS) is frequently used to assess depression and anxiety and has been used in caregivers of people with MI. It is a self-administered questionnaire that measures anxiety and depression in two independent subscales of 7 items each. Each question has 4 response options that score from 0 to 3 on a Likert scale. Each subscale has a range of scores from 0 to 21, the authors suggest that scores equal to or greater than 11 are considered indicative of morbidity, scores between 8 and 10 imply borderline or probable cases, and scores below 8 indicate absence of pathology.[35] ii) Happiness (defined as the repeated experience of pleasant emotions, the loss of unpleasant feelings, and the overall feeling of life satisfaction is a measure of subjective well-being that is assessed with the 8-item Spanish version of the Oxford happiness questionnaire (OHQ).[36] It has a range of scores from 8 to 54 points, with higher scores corresponding to higher levels of subjective well-being.[37] iii) Caregiver burden in physical, psychological health, social activities and economic resources will be studied with Zarit's caregiver burden interview (CBI).[38] Each of the 22 items is scored on a 5-value Likert scale in a total range from 22 to 110 points, with the following cut-off points for the Spanish version:[39] 22-46 (no burden), 47-55 (burden), 56-110 (intense burden). iv) The NEO five factor inventory (NEO-FFI) assesses the five major factors of normal personality, using the S-form (self-administered) consisting of 60 items with 5 Likert-type response options. The Spanish adaptation edited by TEA is administered. v) The state of mindfulness in daily life is assessed with the mindful attention awareness scale (MAAS). The person responds to the 15 items according to adherence to each statement on a 6-point Likert-type scale, so that higher scores mean greater mindfulness. vi) The QOL of caregiver will be assessed with QOL-AD.

Social: i) Feeling of loneliness will be assessed with University of California at Los Angeles. Ver3 will be used, which consists of 10 questions scored from 1-4, obtaining total score of 10-40 points. Scores of 20-30 indicate a moderate degree of loneliness, scores below 20 may indicate an intense degree of loneliness.[40] ii) DUKE-UNC (University of North Carolina) assesses perceived social support. It is self-administered questionnaire of 11 items that is answered using Likert-type scale, score ranges from 11-55 points (higher score is associated with lower support). Spanish validation presents a cut-off point at 15th percentile that discriminates against people with normal (<32)/low (≥32) perceived support.[41]

Cognitive: Cognitive functioning of caregivers includes measures of memory, processing speed and executive functions. i) Global cognitive performance will be assessed with the telephone version of the Folstein mini mental state examination (MMSE).[42] This is hetero-applied instrument of 16 items that assesses mental state in following domains: orientation, memory, attention and calculation, language, praxis and constructional praxis. Once the direct test score (range 0-26) is obtained, it is converted to MMSE score (usual range 0-30), with higher scores indicating better cognitive status. Cut-off point can range from 23-27 points depending on educational level of subjects. ii) Memory will be assessed with Spanish version of Rey auditory verbal learning test that studies learning, memory recall and recognition of 15 words presented orally in 5 trials.[43] iii) Symbol digit modalities test (SDMT) assesses information processing speed in a task consisting of copying symbols that are paired to numbers from 1 to 9.[44] The oral version is administered. iv) Cognitive flexibility will be studied with oral version of trail making test part B.[45] v) Fluency will be assessed by asking for animal names and words beginning with P/M in 1 min of time. Scales of Neuronorm project will be used to correct test.[46] vi) Alternative models in RAVLT, SDMT and phonetic fluency will be used to avoid learning effect between baseline and post-treatment assessment.

Person with ADs' variables

Sociodemographic: age, gender, marital status, educational level, profession and attendance at cognitive stimulation therapy.

Health: duration of AD in years, medication and COVID-19 infection prior to the study.

Cognitive and behavioral: Personality will be assessed with NEO-FFI administered to caregiver who responds retrospectively about person with AD personality in the 40-50 years decade.[47] Cognitive status will be assessed via telephone MMSE. Psychological and behavioral symptoms of dementia will be assessed through Spanish version of Vilalta of neuropsychiatric inventory (NPI), a hetero-applied interview that collects information on 12 symptoms, with a total score obtained from the product of frequency by severity of each subscale.[48]

Use of health resources: visits to hospital emergency rooms and primary care. Hospital admissions and prescription of psychotropic drugs.

Multicomponent intervention

The CG will perform the usual intervention, which depending on each person with the AD consists of follow-up medical visits, prescription of drugs for dementia and attendance at the day hospital or the day center. EG will perform usual care and the CuidAlzheimer's intervention.

CuidAlzheimer is an eight-week online multicomponent program specifically developed for this study to provide information, support and care strategies. It includes psychoeducation, mindfulness and professional support. Psychoeducation consists of sixteen psychoeducational videos that provide information on AD, impact of the caregiving, psychological and behavioral symptoms of dementia, emotional psychoeducation, management tools, communication improvement, as well as the cross-cutting skills to promote physical and mental health of caregivers and person with AD. Figure 2 shows an example of content of the videos. Training in the basic factors of mindfulness and guided practices are performed with the fifteen audios. Table 2 shows contents of eight sessions.

Table 2: Content of the eight sessions of the CuidAlzheimer program.

Sessions (week)	Psychoeducation (videos)	Mindfulness (components and practice audios)	
AD	Video 1. AD. Symptoms and stages. Video 2. Pharmacological and non-pharmacological treatment	Audio 1. What is mindfulness Audio 2. The 7 factors	Audio 3: Body scan and meditation postures
Behavioral and psychological symptoms of dementia	Video 3. General management guidelines of behavioral and psychological symptoms of dementia Video 4. Aggression, delusions and hallucinations: how to identify and manage Video 5. Driving and economic management: problem-solving and coping strategies	Audio 4. Beginner's mind (factor 1)	Audio 5: raisin meditation
Emotions	Video 6. Basic emotions. Emotion dynamics Video 7. Depression and anxiety Video 8. Depression, anxiety and AD	Audio 6. Trust (factor 2)	Audio 7: safe place meditation
Experience cycle	Video 9. Experience cycle: thoughts, emotions and behavior	Audio 8. Non-judging (factor 3)	Audio 9: breathing meditation
Caregiver stress syndrome	Video 10. Physical and mental health effects of caregiving. Caregiver burden	Audio 10. Acceptance (factor 4)	Audio 11: STOP technique
Communication	Video 11. Assertive communication Video 12. Communication strategies for Alzheimer's caregiving	Audio 12. Patience (factor 5)	Audio 13: music meditation
Healthy habits	Video 13. Physical exercise: benefits and recommendations Video 14. Healthy eating habits and gut microbiota Video 15. Healthy sleep habits	Audio 14. Letting go (factor 6)	Audio 15: paying attention meditation
Social relationships	Video 16. Received and perceived social support. Social network	Audio 16. Non-striving (factor 7)	Audio 17: self-care guided meditation

Each week caregiver will receive videos and audios that he/she has to watch and listen to once, although repeated practice of mindfulness and playing videos many times as necessary for comprehension is recommended.

Participants will be encouraged to make comments, resolve doubts and share the experience, and will be offered professional support tailored to each case by phone or mail.

Adherence to treatment will be monitored with weekly feedback on frequency, usability of videos and audios.

Figure 2: Screenshots from psychoeducational videos.

Participant timeline

We will assess the effect of the CuidAlzheimer's program on care, psychological, social, cognitive and health outcomes. The evaluation will be carried out at two points in time: baseline assessment (t0) and post-treatment assessment (t1), two months later (Table 1).

Sample size

The expected sample will be 94 dyads of caregivers and person with AD randomized into two groups: EG and control group (CG). Calculation performed with G*Power 3.1.9.2 software taking into account an effect size of 0.6[49] of change in QOL-AD score, an α error of 0.05 and a power of 0.80, resulting in a sample of 42 individuals in each group, which is expanded to 47 individuals predicting losses of 10%.

Recruitment

The PI will conduct a telephone or face-to-face contact with all person with AD diagnosed with dementia of the Alzheimer type, global deterioration scale score of 4 or 5 and their primary caregivers of the Consorci hospitalari de Vic-territorial service of geriatrics and palliative care. Recruitment will be carried out at two hospitals belonging to the territorial service: Manlleu Hospital and Vic Santa Creu Hospital.

To facilitate recruitment, a video has been created to explain the objectives, methods of assessment and intervention with the approximate time of involvement of the participants. This video will be sent to all the people contacted who show interest in the study.

Allocation and blinding

Participants will be assigned (1:1) according to a computer-generated random sequence and they will be randomized into EG or CG at the time of the first assessment (t0) and after signing the informed consent.

The nature of the intervention does not allow double-blinding, so we have opted for third-blind assessment: the cognitive assessment of person with AD and caregiver and the assessment of the main study variable (QOL of the person with AD) will be performed by neuropsychologists who are blinded to group assignment, both at baseline and post-intervention assessment.

The research neuropsychologists will conduct training prior to the start of the study to homogenize cognitive assessment, test administration and data collection.

Data management and statistical methods

Participants' personal data will be coded and stored in a password-protected electronic document. The data collection forms to be used by the neuropsychologists for cognitive assessment will be identified with a numerical code and contain no personal information. The neuropsychologists will be blinded about the person with AD and their caregivers and group assigned. The correspondence between the identification code and the participant's name will be stored in a password-protected file with limited access to PI. The PI is responsible for the storage of the data collection questionnaires.

A descriptive analysis of the data will be performed to evaluate the homogeneity between the EG and CG in the different variables studied. To evaluate the main objective (improvement in the QOL of person with AD), a multivariate analysis will be used, with the QOL-AD test score as the dependent variable and the rest of the variables as independent variables. The multivariate analysis will be repeated with the QoL of the caregiver (QOL-AD) and the personality of the caregiver and the person with AD. Crude and adjusted odds ratios (OR) will be calculated. A repeated measure analysis of variance (ANOVA) will be performed to determine the evolution of the dependent variables during trial. Variable differences in the QOL-AD scale score and the other scales with respect to baseline will be calculated. Student's t-test will be used to compare the differences between variables in the two groups. The measure of effect will be estimated using the Standardized effect size

(SUS). The level of statistical significance used for the hypothesis tests performed will be 5%. The analysis will be carried out using SPSS for Windows, version 26 (SPSS Inc., Chicago, IL, USA).

Ethical considerations

The study has been submitted and approved by the ethics and clinical research committee of vic university hospital on January 28, 2020, with code 2020056/ AC278.

An informative document and informed consent will be designed and given to person with AD and their primary caregivers.

Data anonymity will be guaranteed at all times in accordance with national and international standards according to the declaration of Helsinki and Tokyo, on ethical aspects and standards of good clinical practice in clinical research. The confidentiality and anonymity of the data will be guaranteed according to the state laws in force (Organic Law 3/2018, of December 5, on protection of personal data (LOPD) both in execution phase and in presentations or publications arising from study.

DISCUSSION

This randomized control trial will test the effectiveness of online psychological intervention for caregivers on the QOL of person with AD. If the study has positive outcomes, dementia care units and general health care facilities would have a new and efficient intervention to improve caregivers' access to information and provide them with toolbox to cope with challenges of caregiving.

Previous studies have shown the impact of AD and required care on multiple caregiver outcomes but results in person with AD are more limited. For example, the impact of caregiver personality on health, burden, depression and coping style has been studied but it is unknown whether it affects QOL in AD person with AD.[50,51] In this study, we want to contribute to the understanding of the impact on caregivers and person with AD on a personal and social level and on their QOL. We are interested specifically in potentially modifiable caregiver factors. For this, we comprehensively include psychological, social, cognitive, behavioral and health measures of the two members of the dyad. The QOL in person with AD is one of the indicators that allows us to gauge the general and subjective state of this population, taking into account the limitations posed by cognitive impairment. The difference with previous studies is that the intervention will be carried out on caregivers to assess the impact on person with AD.

The literature points out that caregiver-mediated psychoeducational and behavioral management interventions of all types show positive results in care recipients, but this has not been assessed in the case of QOL of person with AD.[24] The multicomponent format acts on several needs of caregiver and person with AD.

Psychoeducation and two current and very promising aspects have been included in this study: mindfulness and the online format.

Mindfulness promotes mindfulness and calm attention, avoiding the feeling of being overwhelmed. It promotes an attitude of compassion towards others and oneself, minimizing feelings of guilt, anger or frustration. Awareness of personal psychological dynamics applied to caregiving aims to improve the caregiver's health and QOL but can also have positive consequences on the well-being of the person with AD.[52]

The online format of the intervention allows optimizing resources (audios, videos) and improves accessibility to the project. In our clinical experience, many caregivers do not have the time to attend face-to-face interventions and in any case, it is difficult for them to have the same time slots. The present intervention is asynchronous and therefore guarantees accessibility to the contents at any time. The expected results of the CuidAlzheimer study will contribute to increase the knowledge of the factors associated with QOL in person with AD and the efficacy of online psychological intervention in its improvement.

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