Longitudinal assessment of the eating pattern of people with dementia and its association with problems for feeding and malnutrition: a prospective follow-up study protocol

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ABSTRACT

Introduction Dementia conditions the patient’s nutrition from the beginning and vice versa. Generating difficulties for feeding (FEDIF) will influence its evolution. There are currently few nutritional longitudinal studies in people with dementia. Most focus on problems already established. The Edinburgh Feeding Evaluation in Dementia (EdFED) Scale identifies FEDIF of patients with dementia by studying their behaviours while eating or being fed. It also indicates areas of potential clinical interventions.

Methods and analysis Prospective multicentre observational study carried out in nursing homes, Alzheimer’s day care centres and primary healthcare centres. The study population will be dyads composed by the patient (diagnosed of dementia, over 65 years of age and who have feeding difficulties) and their family caregiver. Sociodemographic variables and nutritional status (body mass index, Mini Nutritional Assessment, blood test and calf and arm circumference) will be assessed. The Spanish version of the EdFED Scale will be completed and the presence of nursing diagnoses related to feeding behaviours will be collected. Follow-up will take place for 18 months.

Ethics and dissemination All data will be carried out respecting European legislation 2016/679 in data protection, and the Spanish ‘Organic Law 3/2018 of December 5th’. The clinical data will be kept segregated and encrypted. The informed consent has been obtained. The research has been authorised by the Costa del Sol Health Care District on 27 February 2020 and the Ethics Committee on 2 March 2021. It has obtained funding from the Junta de Andalucía on 15 February 2021. Findings of the study will be presented at provincial, national and international conferences and published in peer-reviewed journals.

INTRODUCTION

According to a report by WHO on the global dementia situation, the number of people living with dementia is growing: it is currently >55 million (8.1% of women and 5.4% of men over 65 years of age). This figure will increase to 78 million by 2030 and to 139 million by 2050.1 In Europe in 2019, it was almost 10 million and these figures are expected to double by 2050.2

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Longitudinal follow-up is the most appropriate to demonstrate the predictive capacity of the Edinburgh Feeding Evaluation in Dementia Scale to identify nutritional changes over time, in addition comparing it with already consolidated nutritional parameters (Mini Nutritional Assessment or body mass index) will show us its usefulness to measure the risk of malnutrition or malnutrition.

⇒ May show limitations of the advanced stage of dementia, where the feeding difficulties are very steep, and there is no change in the patient’s condition or level of cognitive or nutritional level for being in the highest level of impairment.

⇒ To minimise the bias that those patients have different caregivers at each meal, the scale will always be answered by the same family caregiver or referring professional of the patient during the entire follow-up.

⇒ To control research quality, it is necessary to ensure that all measurements are carried out at the appropriate time and with standardised techniques, that is why the follow-ups will be carried out every 6 months by the same professionals on the same participants.

⇒ A high mortality is expected in a short period of time; therefore, we will start with the initial sample of the first research of the questionnaire validation (262 participants).
WHO defines dementia as a syndrome in which there is a deterioration of cognitive function beyond what would be expected due to the usual consequences of ageing. The decline of cognition also entails a functional, social and occupational worsening. In dementia, functional impairment is associated with three major types of abilities: basic activities of daily living (ADL), instrumental ADL and advanced ADL. The disability associated with dementia is a key factor in the health costs related to this disease. WHO estimates that the cost of dementia is equivalent to 1.1% of gross domestic product (GDP). Families would assume 85% and the social and health system 15%. Dementia affects nutrition almost from the outset, producing anorexia, weight loss and eating/swallowing difficulties. Feeding difficulties (FEDIF) presented by patients with dementia have a prevalence of around 25%–50%, leading the patient to nutritional problems or putting them at risk of malnutrition. Malnutrition affects physical health and increases morbidity and mortality; consequently, the quality of life decreases and the evolution of dementia becomes more torpid and rapid. It is important to detect and identify the presence of FEDIF as soon as possible; because, over half of the FEDIF that affect elderly persons with dementia are due to factors unrelated to dementia itself, such as poor appetite, fatigue, depression, use of neuroleptics, oesophageal reflux or distraction environmental factors, and could be solved.

FEDIF include eating inadequate amounts, things that are not food, refusing to eat, not recognising or using utensils, not chewing or swallowing well. FEDIF are the result of a combination of intrapersonal, interpersonal and environmental factors. Among the intrapersonal factors we find the presence of comorbidities, increased use of medications, dysphagia, cognitive impairment or physical impairment. The latter two factors being the most important. Interpersonal factors include both maintaining a close relationship with the family and the assistance of caregivers during mealtimes. Environmental factors, although not directly related to dementia, can affect FEDIF such as the type of diet (soft or liquid), long meals or physical environments with a lot of noise or light. These factors are largely modifiable. The best predictors of feeding dependence are, first of all, difficulty for swallowing, followed by physical dependence.

Usually, the factors that contribute to the FEDIF are not correctly identified and are assumed as problems inherent to ageing or dementia, or go unnoticed because it is not evaluated during routine care, hence the importance of having good tools that allow the correct evaluation of these factors. Hospital staff often makes assumptions about the persons’ ability to eat and drink without adequate consultation with family carers. A shared decision-making process is key among all people involved to address holistic needs and personal values of people with dementia and family carers. The detection would enable early and effective interventions that would prevent nutritional deterioration or improve nutritional status, thereby reducing morbidity and mortality.

The Edinburgh Feeding Evaluation in Dementia (EdFED) Scale is an instrument that measures the FEDIF that patients with dementia have or manifest, identifying potential nutritional problems of patients and related factors. It analyses the FEDIF by studying the attitudes or behaviours of these patients while eating or being fed, by observation or verbal feedback by the caregivers. In addition, it also indicates where clinical intervention is necessary. This scale, which was initially used in English for patients in nursing homes and by health professionals, has been validated in multiple languages. In the Spanish version, it has been adapted and validated for its use with patients in the community setting (Alzheimer’s day care centres and nursing homes) and to be completed by healthcare professionals, and by family caregivers.

There are currently very few nutritional follow-up studies in older people and even fewer of people with dementia. Those that exist in the literature focus on the diagnosis and treatment of nutritional problems already established, but preventive approaches to early identify the appearance of new FEDIF or the aggravation of existing ones through longitudinal follow-up in this population are scarce.

### Research hypothesis and aims

The main aim of this study is to explore the capacity of the EdFED Scale to identify changes in FEDIF, at any level, while the condition evolves (responsiveness). As a secondary aim, this study will also evaluate the association of EdFED Scale thresholds with the presence of nursing diagnoses related to feeding behaviours and nutritional status.

The main hypothesis is that the EdFED Scale is responsive to changes in FEDIF over time, detecting worsening as dementia progresses, and consequently, predictive thresholds could be determined to anticipate feeding behaviour deterioration, as well as nutritional and functional decline.

### METHODS AND ANALYSIS

#### Study design

This is a prospective multicentre observational study.

#### Planned start and end dates

Enrolment of the cohort study commenced on March 2020, and follow-up began in June 2021 with an estimated date of end of the study around December 2022. Due to the COVID-19 pandemic, the study has suffered a delay in its execution, so it is expected to be completed by March 2023—date from which the data exploitation will begin.

#### Participants and setting

The study population will be dyads composed by the patient and their family caregiver. Patients over 65
years of age will be included, in nursing homes or in the community (Alzheimer’s day care centres or their homes), who present a diagnosis of dementia (International Classification of Diseases code 294.20) or cognitive impairment (recorded in their clinical records) who give consent to participate through their legal representative or their family caregiver. They will have to present FEDIF at any level or need help to eat even if it is only supervision.

Patients will be excluded if they are in a terminal situation or with added diseases that would hinder or prevent feeding (stroke, amyotrophic lateral sclerosis, motor neuron diseases, Parkinson’s disease, fractures, paralysis, etc), if they have feeding tubes or enteral nutrition, or if their legal representatives of family caregivers do not give their consent to participate.

For this study, family caregivers will be considered as the patients’ relative who have legal authority over the patient or, failing that, who assume their care or who bear the responsibility for their care. Once chosen as the main family caregiver, he/she will always be the same reference person to complete the investigation until the end of the follow-up. They will be considered apart from professional caregivers, participating centres. They will have knowledge about the recruited patients and will have delivered care to them within the centre. Once chosen as the main professional caregiver, he/she will always be the same reference person to complete the investigation until the end of the follow-up.

The study is being conducted in the community setting from four Alzheimer’s day care centres and nursing homes in collaboration with primary healthcare centres of the Costa del Sol Health District (they include the cities of Fuengirola, Mijas, Marbella and Estepona). Additionally, data collection will be held in five nursing homes of the Costa del Sol and one of the Malaga Districts.

**Sample size**

To detect a difference of 0.3 units in the mean of EdFED Scale, with an SD of 1.5 units (obtained in an initial pilot study), with 95% CI, in a repeated measures analysis, a total of 226 subjects is necessary. This sample will be over-estimated up to a 10% to cover potential missing data.

**Data collection**

The data collection will be carried out at the participating centres (Alzheimer’s day care centres or nursing homes) or at the patients’ homes. The current measures in prevention against COVID-19 will be considered at all times, creating safe environments. Face-to-face contacts are limited to data collection that can only be carried out in person. The rest of the data will be collected by telephone through interviews with the caregivers.

The data will be collected (see variables to be collected) at the time of recruitment and at each follow-up (every 3 months) for 18 months.

**Main variables**

Sociodemographic variables: age, date of birth, gender, relationship, origin, educational level, economic level.

Functional status: diseases, medication, functional-level Barthel Index, hospital admissions, falls, oral problems and dental prosthesis, comorbidity (Charlson Comorbidity Index).

Cognitive status: (Pfeiffer Test), (Global Deterioration Scale (GDS)-Fast).

Nutritional status: height, weight, body mass index (BMI), Mini Nutritional Assessment (MNA), forearm and calf circumference.

Blood test: albumin, transferrin, lymphocytes, cholesterol, total proteins.

Difficulty for feeding: EdFED Scale (Spanish) (online supplemental appendix 1), presence of dysphagia, dependency to feed, food supplier, help needed to eat, nursing diagnoses: self-care deficit in food (00102), nutritional imbalance: lower than body needs (00002), swallowing impairment (00103).

For patients recruited from Alzheimer’s day care centres, three participants (nurses, professional caregivers and family caregivers) will apply the EdFED Scale, providing three different measures about the same patient. Data will be collected during three different meals: breakfasts and lunches that are delivered in the centre and dinners that are given at home. In the case of patients at home, the views of the family caregiver and the reference nurse at the healthcare centre of the patient will be collected, of the same meal on the same patient. Thus, two versions of the same patient were obtained on the same meal. In patients at nursing homes, professionals (nurses and care assistants) will assess with the EdFED Scale the eating problems. All participants will be trained in the management of the EdFED Scale. This approach will help in obtaining the inter-rater reliability from different instrument users (figure 1).

Moreover, to estimate the test-retest reliability, the EdFED Scale will be administered twice in a subsample of patients (n=102) in a short interval of time (48 hours). The questionnaire will be answered both times by the same family caregiver of the patient. This interval is optimal to prevent potential changes in the patient’s clinical or functional status. The reliability will be studied in the sample corresponding to the community participants since the same family caregivers are always present with the patient at their meals.

**Data sources and measurements**

**Difficulty feeding**

The EdFED Scale evaluates the problems with eating and feeding in patients with moderate-to-advanced dementia, by observing certain behaviours. The data can be collected by observing the person directly or by asking formal caregivers or relatives, both in person and by telephone. The scale consists of 11 items: 4 items evaluate the assistance required by the person during feeding, 6 items evaluate how cognitive impairment interferes and 1 item
evaluates the intensity of help required by the patient. All items consist of 3 response options that measure the frequency of occurrence (0=never, 1=sometimes, 2=almost always) and item 11 captures the intensity of help required (moderate, mild or total). The maximum score is 22 points. However, there is no cut-off score, but rather it is a measure of position on a continuum to worse. The Spanish version used in this study obtained a good reliability and validity. It has obtained a Cronbach’s alpha 0.88, global interitem correlation 0.43 and homogeneity index ranged from 0.42 to 0.73. Confirmatory Factor Analysis (Analisis Factorial Confirmatorio (AFC)) reproduced the original trifactorial model, with Kaiser-Meyer-Olkin (KMO) 0.86 and a significant Bartlett’s sphericity test (p<0.0001) that explained 62.4% of the total variance, Minimum Discrepancy Function by Degrees of Freedom divided (CMIN/DF) 3.179; Goodness of Fit Index (GFI) 0.92; Normed Fit Index (NFI) 0.92; Comparative Fit Index (CFI) 0.94 and Root Mean Square Error of Approximation (RMSEA) index 0.10 (90% CI 0.084 to 0.121). Criterion validity showed moderate and significant inverse correlation with albumin, total protein and transferrin, and inverse correlation with BMI and good correlation with MNA.

Nutritional status
It will be evaluated through anthropometric measures such as weight, height, BMI, forearm () and calf circumference (), the MNA and the malnutrition criteria of the Global Leadership Initiative on Malnutrition (GLIM).

The MNA Scale is a screening tool that helps to identify malnutrition or the risk of suffering from it in the geriatric population. It consists of 18 items divided into four parts: (1) anthropometric measurements (weight, height and weight loss); (2) global assessment of 6 questions related to lifestyle, medication and mobility; questionnaire dietary (8 questions related to the number of meals, food and fluid intake, and the feeding autonomy); (4) subjective assessment of health and nutrition. The maximum score is 30 points, with a score ≥24 indicating an adequate nutritional status, a score between 23.5 and 17 a state of risk of malnutrition and a score <17 a state of malnutrition.

The GLIM has three phenotypic criteria (non-voluntary weight loss, low BMI and reduced muscle mass) and two aetiological criteria (reduction of food intake or...
assimilation, and inflammation or disease burden). To diagnose malnutrition, at least one phenotypic criterion and one aetiological criterion must be present.

In addition, a blood test will be performed at the beginning of the follow-up and another at the end, in which the levels of albumin, transferrin, lymphocytes and cholesterol and total proteins will be measured.

**Cognitive state**

The Pfeiffer Test in its Spanish validation and the GDS will be administered to determine the cognitive state of each subject. The Pfeiffer Test\(^35\) allows the detection of possible cognitive impairment in people over 65 years of age. If the person commits between three and four errors, a mild cognitive impairment is present, between five and seven a moderate cognitive impairment and more than eight errors a severe cognitive impairment.

The GDS\(^36\) includes seven phases that, from normal (GDS 1) to the most severe stage (GDS 7), defines the continuous progress of the evolution of dementia and cognitive decline.

Furthermore, the following variables will be also measured: sociodemographic variables such as age and sex, place of origin, medication, number of hospital admissions and falls in the previous 3 months, presence of dysphagia, oral problems, use of oral prostheses, comorbidities (Charlson Comorbidity Index)\(^34\) as well as the presence of nursing diagnoses related to self-care for food (deficit of self-care in food (00102), nutritional imbalance: lower than body needs (00002) and impaired swallowing (00103)) (North American Nursing Diagnosis Association (NANDA) 2021–2023).\(^40\)

**Statistical analysis**

Through exploratory analysis, descriptive statistics of the variables will be performed, obtaining measures of central tendency and dispersion or percentages, according to the nature of the same and the normality of the distribution will be evaluated by the Kolmogorov-Smirnov test.

Two approaches will be used to evaluate responsiveness: distribution measures and anchor-based. For the first calculations, the minimum detectable change (MDC), effect size and standardised response mean will be estimated with the values of EdFED obtained across the 18-month follow-up period (difference between follow-up and baseline divided by the SD of the group’s baseline scores). Within-subjects repeated analysis of variance will be used to estimate mean differences, adjusted by Bonferroni’s method for multiple measures. MDC will be estimated based on the SE of measurement: \(\text{SEM}=S\sqrt{1-r}\), where \(r\) is the reliability, which will be measured with the intraclass correlation coefficient (ICC), and \(S\), the SD. MDC will be calculated with the formula: \(\text{MDC}=\text{SEM} \times 1.96 \times \sqrt{2}\). MCD will be evaluated as the smallest difference in EdFED scores. Correlations between different pairs of measures across time will be estimated by using the ICC. For the second approach, EdFED scores will be compared among those participants with MNA, brachial circumference, BMI and serum albumin values suggesting malnutrition, risk of malnutrition or normal nutritional status. First, linear correlation will be calculated to test linearity between both measures. Differences in mean values among these three groups will be gauged using general linear models to detect changes in EdFED scores. Predictive value of baseline EdFED score will be calculated to compare minimally important difference threshold between subjects who develop malnutrition or not at 18 months, as well as the presence of any of the three nursing diagnoses used in the study, obtaining the receiver operating characteristic curves, sensitivity, specificity and positive and negative predictive values.

Generalised linear models will be calculated to estimate EdFED Scale differences among subgroups by nutritional functional status, adjusted by gender, baseline status and comorbidities as initial factor variables.

**Patient and public involvement**

This study has not developed specific patient and caregiver involvement actions during the initial stages of designing the research process. Nevertheless, family caregivers, dementia charities and associations have a key role in developing the recruitment and data acquisition. For this purpose, the research team will closely work with dementia non-profit organisations from the beginning of the study to adapt to the recruitment, access and relation with patients and their family caregivers according to their values and preferences. Additionally, these partners will be involved during the dissemination of the results to expand the results beyond the academic and research space to a wider community of citizens, organisations and families. They will be consulted on which results are more relevant to be shared with general audience and in which format.

**Ethics and dissemination**

The standards of good clinical practice and ethical principles established for human research in the Declaration of Helsinki and its subsequent revisions and in the Belmont and Gracia report shall be maintained at all times. As well as the legislation in force in Spain in accordance with the provisions of ministerial order SAS/3470/2009, relating to the conduct of observational studies.

All data will be carried out respecting data protection (European legislation 2016/679 and Spanish legislation Organic Law 3/2018 of December 2005). The clinical data will be kept segregated from the identification data and the database will be encrypted and kept on a specific computer exclusively intended for the project. The data will be destroyed after 5 years.

The informed consent of all participants has been obtained and the research has been authorised to be carried out by the directorate of the Costa del Sol Health District 27 February 2020 and by the CEI Costa del Sol Biomedical Research Ethics Committee on 2 March 2021. It has obtained funding on 15 February 2021 from the Junta de Andalucía by the Progreso y Salud Foundation,
4.8% were malnourished; 47 a Spanish study found that 38.4% of their sample was at risk of malnutrition, and 11.3% were malnourished. 49 In addition, it should be borne in mind dementia is associated with an increased risk of mortality and lower survival. 51 The reasons for this increase in mortality are unclear. Some of the factors that may be related to the increase in frailty 32 and the disease process itself are the presence of medical comorbidities, 53 the severity of dementia 54, 55 or dependence on ADLs. 56 Therefore, it can be assumed that inadequate nutrition increases the risk of dementia and that the occurrence of dementia exacerbates malnutrition and dependence on ADLs, which leads to mortality. 57 That is why longitudinal studies are needed to evaluate the effects of nutrition on dementia and its possible causes.

Although FEDIF are often the cause that people with dementia have a high risk of malnutrition since they interfere with the adequate consumption of nutrients, 24 many other factors have also been found that contribute to it. Those that we expect to find in our study population are: being a woman, 58, 59 the presence of greater cognitive impairment, polypharmacy, 60 dysphagia, 61 ideatory apraxia, 62 orofacial dysfunctions, 63-64 lack of appetite 17 or the presence of comorbidities. 10 Chewing problems, swallowing difficulties, constipation and eating less than half of the portion of food offered are also expected to be factors that predict FEDIF and malnutrition. 50

Regarding nursing diagnoses, the most prevalent in our target population are the deterioration of the dentition, 64 constipation, diarrhoea and nausea 65 and nutritional imbalance, fluid volume deficit and aspiration risk. 66

There are no studies on the diagnoses being studied in this project.

EDFED Scale helps to promptly visualise the FEDIF in patients with dementia. An early detection of possible eating problems would contribute to develop timely interventions to preserve their feeding capability and nutritional status for as long as possible. As dementia progresses, it is to be expected that attitudes and eating skills deteriorate. If the EDFED Scale shows to be sensitive to changes in these difficulties over time, we will be able to detect these deteriorations in different states of dementia even within the more advanced phases of the condition. Before the signs of malnutrition or dysphagia advance, we must establish early interventions to avoid or reduce the deterioration caused by the altered behaviour that worsens or appears again. When compared with the rest of the tools that evaluate malnutrition, if it proves to be sensitive over time, it will indicate that it is a reliable tool to also measure FEDIF.
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