FIFO protocol

Ref: CHD 052-016

« Nutritional Intake of "Finger-food" on Elderly People in Seniors's Resident (FIFO) »

Protocol for paramedical research in routine care

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Titre : Nutritional Intake of "Finger-food" on Elderly People in Seniors's Resident (FIFO)
Numéro d'enregistrement IRCB : 2016-A00656-45

SIGNATURES

SIGNATURE OF THE INVESTIGATOR

I have read all the pages of the clinical trial protocol sponsored by La Roche sur yon Hospital. I confirm that this protocol contains all the information necessary for the conduct of the trial. I agree to conduct the trial according to the protocol and to abide by all provisions set forth therein. I agree to conduct the trial in compliance with:

- the principles of the "Declaration of Helsinki",
- international (ICH) and French good clinical practice regulations and guidelines (Règles de bonnes pratiques cliniques pour les recherches biomédicales portant sur des médicaments à usage humain (Décision du 24 novembre 2006))
- national laws and regulations relating to clinical trials,
- the current European Clinical Trials Directive

I also agree for the investigators and other qualified members of my staff to have access to the copies of this protocol and documents concerning the conduct of the study so that they abide by all provisions set forth therein.

NAME: Sylvie VERBRUGGHE

Signature : …….. Date :

SIGNATURES

Sponsor :

NAME :

Signature : …… Date :

Principal Investigator:

CENTER : Date :
NAME :

Signature : ……

SUMMARY

Title of the study	Nutritional Intake of "Finger-food" on Elderly People in Seniors's Resident (FIFO)
Keys words	« Finger food », nutrition
Head of research	**Centre Hospitalier Départemental de Vendée – La Roche sur Yon**
Number of centers planned	Monocentric study carried out on elderly people in senior's resident of the CHD VENDEE. <u>- Site de LRSY :</u> Le Marais / La Plaine **Principal Investigator** : Mme Fabienne RABAUD <u>- Site de Luçon</u> : La Roseraie **Principal Investigator** : Mme Nelly AFONSO DE ARAUJO L'Olivier (seniors's residents) **Principal Investigator** : Mme Huguette GUILLON <u>- Site de Montaigu</u> : Augereau **Principal Investigator** : PAVAGEAU Nelly Le Soleil de la Maine **Principal Investigator** : GARNIER Céline
Type of study	*Research evaluating routine care*
Planning of the study	Total duration: 8 months Recruitment period: 1 month Duration of follow-up per resident: 7 months
Study design	❖ Nursing study ❖ Study pilot ❖ Monocentric ❖ Prospective ❖ Randomized in 2 parallel groups o Arms without finger-food o Arms with finger-food ❖ Open
Objectives of the study	**Main objective :** To evaluate the added value of "finger-food" on the nutritional intake on elderly people in seniors's resident **Secondary objective(s) :** Describe the evolution : ❖ Nutritional status ❖ Associated comorbidities ❖ From autonomy ❖ Behavior around the meal ❖ Resident satisfaction / pleasure of eating ❖ The burden of hotel/care on elderly people in seniors's resident
Projected number of cases	All elderly people in seniors's resident who met the inclusion criteria at the beginning of the study will be included. Of the 269 residents institutionalized in these facilities, we estimate that about 60 subjects meet all the criteria.

Schedule of the different visits and examinations	❖ Recruitment period: 1 month ❖ Duration of follow-up per resident: 7 months Collect of : - Nutritional intake - Nutritional indicators - Associated comorbidities - Autonomy - Behavior - Satisfaction / pleasure of eating - Impacts on serniors's resident professionals - Significant events on food intake
Criteria	**Inclusion criteria :** - Residents institutionalized in seniors's resident for 3 months at least - Residents in disability to feed single-handedly because of cognitive and/or physical disorders - Having at least use of a hand - Do not opposing the participation in the study or information and not opposition of the family / close to confidence / legal guardian in case of resident in incapacity to understand (senility, insanity) **Exclusion criteria :** - Confined to bed - Specific diets (without residue, allergen, …) - Enteral nutrition - Absence motricity of 2 hands
Primary endpoint	Quantitative measurement of ingesta (caloric and protein intake), monthly between M-1 (before implementation of the "finger-food") and M6.
Secondary endpoint(s)	**Nutritional indicators:** Weight curve BMI Biological indicators: Albumin / Pre-albumin, CRP MNA Score Screening **Associated Comorbidities:** Number of wounds and pressure sores Number of falls **Autonomy :** Power supply autonomy: EBS Physical or psychological autonomy: GIR **Behavior around the meal:** - Assessment of eating disorders: Blandford scale **Resident satisfaction / enjoyment of food:** VAS **Hospitality/care load of seniors's resident professionals**

Expected results	This study will evaluate each of the defined evaluation criteria, analyze them in order to measure their impact on the following criteria: - Maintain and/or improve the nutritional status of residents - Improvement of autonomy, behavior, quality of life - Reduction of associated comorbidities Then to think about other projects, by formalising hypotheses, with an impact study.

CONTENTS

1. JUSTIFICATION OF THE STUDY

Undernutrition and the prevention of its risk in elderly people in seniors's resident constitute a major public health issue. The diagnosis of undernutrition and its risk are systematically recommended in these structures where the food of the persons is a problem because often unsuited to their capacities of grip and consequently to their nutritional needs. One of the solutions to remedy this could be the food offer proposed by the "finger-food".

The FIFO (Finger-Food) study, with a monocentric and randomized design, aims to verify the hypothesis that "finger-food" would increase food intake in seniors's residents with prehension disorders and/or requiring feeding stimulation and/or assistance with meal preparation.

1.1 GENERAL DESCRIPTION OF THE STUDY

The scientific justification of this study project is organized in two parts. The first part deals with the aging population in France, with a snapshot of the epidemiology, undernutrition (definition, causes, consequences), its link with aging and loss of autonomy. The nutritional strategies that can be used to prevent or treat undernutrition are then presented. The "finger-food" is one of them. After a presentation of this concept, we will highlight the current problem of the lack of proof of its effectiveness, which this study aims to fill.
The second part of this justification will focus on the Vendée department, the population in which this study will be carried out, and more specifically within the seniors's resident of the Centre
Hospitalier Départemental (CHD) of Vendée. Finally, the main objective of the study will be formalized and supported by secondary objectives, which will be developed in the relevant paragraph.

The increase in life expectancy is leading to an aging population in France. Indeed, while there are currently 15 million people over the age of 60, the project on the adaptation of society to ageing carried out by Marisol TOURAINE1 and Pascal BOITARD2, clearly sets the context by estimating that there will be 20 million of them in 2030 and nearly 24 million in 2060. The over 75s represented 5.7 million in 2012, they will be 12 million in 2060. As for the over 85s, their number will increase from 1.4 million to 4.8 million in 2050 [1].

As a consequence of this aging process, the institutionalization of elderly people with a loss of autonomy is on the rise in France. This loss of autonomy impacts the quality of life of seniors's residents, their nutritional status and can progressively lead to a rupture of social ties.

As Claude FISCHLER [2] points out, "eating: nothing more vital, nothing more intimate"; eating is not only a vital physiological need but also an emotional and relational act. For residents who are unable to feed themselves, the psychological impact is strong and leads to a loss of confidence and self-esteem. Meals are no longer experienced as a moment of pleasure but of stress. The assistance of the caregivers in feeding, by giving food with a spoon, can sometimes be invasive and give the image of dependence. The meal, very badly lived, then becomes an anguishing moment, of shame and embarrassment for the residents.
A prospective survey carried out in 67 French seniors's residents on the nutritional status of 1550 residents highlighted the need for assistance with meals for 31% of the subjects [3]. Many of them progressively lose their appetite, with the onset or even worsening of undernutrition, a real public health problem in seniors's residents. A 2011 French study [4], involving 57 seniors's residents and 4520 residents with an average age of 85.8 ± 7.8 years, showed that 45.6% (44.2% - 47.1%) of the residents had undernutrition, including 12.5% with severe undernutrition. In addition, dependence on food was the characteristic that most discriminated between undernourished residents and others (+23.9%). According to P. BROCKER3 , the prevalence of undernutrition in institutions varies between 15 and 38% [5]. M. FERRY4 estimates that the prevalence of undernutrition can reach 70% of elderly patients in hospitals [6].
According to the Agence Nationale d'Accréditation et d'Evaluation en Santé (ANAES), protein-energy undernutrition results from an imbalance between the body's protein-energy intakes and needs [7]. The Haute Autorité de Santé (HAS) [8] defines the diagnosis of undernutrition according to the existence of one or more of the following criteria: weight loss ≥ 5% in 1 month and/or ≥ 10% in 6 months and/or Body Mass Index5 (BMI) < 21 and/or Albuminemia < 35g/l (to be interpreted taking into account the C-reactive Protein (CRP)) and/or overall Mini Nutritional Assesment6 (MNA) < 17. Undernutrition is characterized as severe if weight loss ≥ 10% in 1 month and/or ≥ 15% in 6 months and/or BMI < 18 and/or Albumin < 30g/l.

Undernutrition leads residents into a vicious circle, as described by M. FERRY [9]; a vicious circle that is self-perpetuating between the causes and consequences of undernutrition. The risks of comorbidities and mortality increase [10], with an increased risk of bedsores and falls.

A study carried out on 8428 hospitalized patients, on the relationship between mortality and

BMI, shows a mortality three times higher in subjects aged 70 to 79 years, when the BMI was lower than 18, compared to a BMI between 32 and 40 [11].

In addition, the quality of life of the residents is altered [12] and they become more prone to develop swallowing disorders, food dependency, hunger sensation disorders and modified texture sometimes becomes necessary.

In spite of the respect of nutritional needs, today, the food offered to these patients is rarely effective because it is not very appetizing, always presented in the same way and consequently little consumed [13]. The notion of pleasure is no longer present. Also, as specified by A.RAYNAUD-SIMON7 , "in institutions, the prevalence of undernutrition is linked to the importance of pathologies and dependence, but also to the quality of the food service and the time available to caregivers to help with feeding" [6].

In order to fight against this public health problem, the National Nutrition and Health Program

(PNNS) 3 (2011-2015) [14] has defined, through axis 3, actions to reduce the prevalence of undernutrition. In this respect, a certain number of nutritional strategies can be implemented, such as oral nutritional supplements, "homemade" enriched preparations, dietary advice, pleasure trays" or even "finger-food". Developed in seniors' for about ten years, the "finger-food" approach is not new. It has been implemented in order to meet the specific needs of residents, but without measuring its impact. This concept of "finger-food", also called "finger-food", has been particularly developed by Pr Charles Henri RAPIN8 , in a geriatric unit in the Canton of Geneva (Switzerland) and consists in proposing dishes that can be seized with the fingers and eaten as such. Most often, these are individual bites with a high energy density in a small volume. The objective is to stimulate the appetite and the autonomy of people who need it [15].

There has been little research on this concept. A 2015 review of the practicalities of "finger-food" confirms the "lack of hard evidence of its effectiveness in the scientific literature" [16].

The Nancy University Hospital has evaluated the impact of "finger-food" on the food intake of demented patients [17]. This evaluation showed a significant increase in protein intake, but it seems to be effective only in certain patients (those with the least associated pathologies and who have retained the ability to eat).

The hospital of Gimont (32) has questioned this concept of "finger-food" which would seem to maintain and/or give back autonomy to the residents, thanks to easy finger foods [18]. It would also tend to guarantee the residents sufficient nutritional intake (caloric and protein) to cover their needs, which are often increased due to the high prevalence of undernutrition or its risk in seniors's residents.

In addition, this concept could reduce food waste, which is important in seniors's residents,

due to a service that is not always adapted to the expectations and needs of residents [19].
In this national context, according to the National Institute of Statistics and Economic Studies (INSEE), "the Vendée could see the number of people aged 60 or more double between 2007 and 2040, to reach 310,000 inhabitants: seniors would then represent 36% of the Vendée population" [20]. Moreover, the number of people over 80 years old will increase by 57,000 between 2010 and 2040. The department of Vendée will thus experience, along with Loire-Atlantique, the most significant aging in the Pays de la Loire region [21].
An Evaluation of Professional Practices (EPP) relating to undernutrition carried out at the CHD Vendée highlights a significant prevalence of undernutrition or its risk, regardless of the medical and surgical sectors, and concerns 30 to 50% of patients (source: data communicated by the Dietetics and Nutrition Unit of the CHD Vendée).
As the proportion of elderly people is high in these sectors, the prevalence of undernutrition in seniors's residents can be estimated at one in three or even one in two patients. A survey conducted by the CHD Vendée catering service showed that 30% of long-stay patients have a modified texture diet. In addition, 20% of meals in the Long-Term Care Unit (USLD) are not consumed (source: data provided by the CHD Vendée catering service). To remedy this problem, the CHD catering service has received theoretical and practical training for a new presentation of modified textures. The tests carried out with the patients following this training were well perceived with 3 positive points noted: increase in the quantities eaten, increase in the time spent at the table, socialization of the patients. This multidisciplinary research project proposed at the CHD Vendée is part of a desire to consider food as a care in its own right and supports the institutional work of individualizing the care of the resident, via the personalized life project developed for each of them within these structures.
The main objective of this study is to evaluate the added value of "finger-food" on the nutritional intake of seniors's residents who are unable to eat with cutlery and/or who require stimulation of food intake and/or assistance with meal preparation.
As weight, BMI and albumin levels are subject to multifactorial variations, the main objective of this study will be to target the dietary intakes of these patients and more precisely, the caloric and protein intakes. The other evaluation criteria of the nutritional status specified above will be evaluated as secondary objectives, as will be the impact of eating hands on falls, pressure sores, quality of life, autonomy of eating, behavior around meals, pleasure of eating or the care load of professionals. These criteria will be further documented in the "secondary objectives" section.

The willingness of the CHD management to maintain this "finger-food" service beyond the study for residents who wish and/or need it, is a real opportunity to respond to the essential values of pleasure, conviviality, self-esteem and freedom of choice, as well as to the needs

of the residents, notably autonomy and nutritional status. The act of eating, beyond its primary function of feeding, must remain a source of pleasure. As J-A BRILLAT-SAVARIN [22], a French gastronome, stated, " the pleasure of the table is for all ages, all conditions, all countries and all days; it can be associated with all pleasures and remains the last to console us for their loss ".

1.2 SUMMARY OF BENEFITS, IF ANY, AND FORESEEABLE AND KNOW RISKS TO INDIVIDUALS INVOLVED IN THE STUDY

There are no foreseeable risks associated with participation in the study. Residents will be managed according to standard practice.

In contrast, this study seeks to demonstrate the predictable direct benefits to the residents participating in the study:
- Maintain or improve nutritional status
- Improved autonomy, behavior, and quality of life
- Reduction of associated comorbidities

1.3 STATEMENT THAT THE STUDY WILL BE CONDUCTED IN ACCORDANCE WITH THE PROTOCOL AND WITH GOOD CLINICAL PRACTICE AND THE LEGISLATIVE AND REGULATORY PROVISIONS IN FORCE

The investigator also agrees that this study will be conducted:

- in accordance with the protocol,
- in accordance with the recommendations of the "Declaration of Helsinki
- in accordance with current French and international Good Clinical Practices
- in accordance with the laws and regulations currently in force in France and internationally

The investigator undertakes to comply with all legislative and regulatory provisions that may apply to the study.

2. OBJECTIVE AND ENPOINTS

2.1 PRIMARY OBJECTIVE AND ENDPOINT

2.1.2 Primary objective

To evaluate the added value of "finger-food" on the nutritional intake of residents in seniors's residents.

2.1.3 Primary endpoint

Quantitative measurement of ingesta (caloric and protein intake), monthly between M-1 (before implementation of the "finger-food") and M6.

The assessment of nutritional intakes will be carried out on 3 consecutive days, by a dietician, for lunch and dinner, at a point in time between M-1 and M0 (i.e. before the implementation of the "eat-in" system), and then monthly.

This dietary assessment will be done by means of photos BEFORE/ AFTER the consumption of the meal, by the housekeepers. The photos will target the actual consumption of the meal compared to the proposed service. This tool is preferred to the food monitoring form, usually used in the seniors's residents, but which does not allow for a detailed analysis of the food consumed and the quantities per dish actually ingested by the residents.
Also, the environment of the meal will be photographed in order not to wrongly consider the possible food losses, notably food on the ground, as food contributions. The residents' faces will not be photographed.

Information on the taking of these photographs will be provided to the appropriate people in order to have an image quality that is conducive to analysis and to respect a certain homogeneity of distance in the taking of photographs and in the analysis that will result from them.
The same dietician will ensure the analysis of the photos and intakes to avoid bias.

The photos will be analyzed using a quantitative and qualitative approach:

- Meal consumption: A global evaluation of the meal will be done according to whether the resident ate all of his meal, ¾, half, ¼ of his meal or nothing at all, while taking

into account the environment.

- Type of dish consumed (starter / main course: meat-fish-egg, vegetable-starch / dairy product / dessert).
- The caloric (in kilocalories) and protein (in grams) intakes of the meal trays will be calculated before distribution to the residents.
- The same calculations will be made after the meal has been consumed, taking into account the environment and what the resident has actually eaten. They will be compared to the amount of the proposed meal tray in order to take into account residents with a poor appetite for whom half portions are usually proposed.

2.2 SECONDARY OBJECTIVES AND ENDPOINTS

2.2.1 Secondary objectives

Describe the evolution:

- Nutrional status
- Associated comorbidities
- From autonomy
- Behavior around the meal
- Resident satisfaction/ pleasure of eating
- The burden of hospitality/ care for seniors's residents professionals

2.2.2 Secondary endpoints

All endpoints will be compared between the no "finger-food" period (M-1 - M0) and the resident follow-up period (M0 to M6) depending on the randomization arm.

Nutritional indicators :

- Monthly weight

The same scale will be systematically used on each seniors's residents.

- Monthly BMI

Please note: a height measurement will be taken at inclusion

- Biological indicators (albumin / pre-albumin, CRP) at M-1 and M6

The albumin/pre-albumin and CRP blood tests will be taken into account only in the absence of an inflammatory syndrome. In case of CRP > 15 (HAS recommendations - 2003) [23], it will not be taken into account in the analysis.

- MNA score screening at M-1 and M6

The MNA screening score (*Appendix 5*) will make it possible to measure the number of residents for whom the nutritional status is normal, those at risk of malnutrition and those with proven malnutrition. It will be carried out by the department's nurse.

Associated Comorbidities:

- Number of wounds and pressure sores per month

New pressure ulcers and their severity will be plotted throughout the study.

- Number of falls per month

The number of falls will be plotted throughout the study.

These comorbidities will be extracted from the ennov software by a clinical research IDE.

Autonomy:

Power supply autonomy: EBS at M-1 then at M3 and M6.

Eating autonomy will be assessed using the Eating Behaviour Scale (EBS) (Appendix 6).

The completion of this scale will be done jointly by the caregiver and the housekeeper of the ward. It will identify and monitor the resident's autonomy around the meal, depending on whether the resident is independent, dependent or requires verbal or physical stimulation.

Physical or psychological autonomy: GIR at M-1 then M6.

The GIR grid (Groupes Iso-Ressources) will make it possible to evaluate the degree of loss of autonomy or the degree of physical or psychological dependence of the residents in the accomplishment of daily acts (Appendix 7).

This grid will be carried out by the unit's health executive, in collaboration with the care team. This evaluation identifies the resident according to a GIR group ranging from 1 to 6.

Mealtime behavior: Blandford at M-1 and then at M3 and M6.

The Blandford scale [24] will allow the caregiver to assess and classify eating

disorders (*Appendix 8*), according to:

- Resistance behaviors
- Dyspraxia and agnosia
- Selective behaviors
- Neuromuscular oral incoordination
- Food dependency

The realization of this scale will be done jointly by the IDE and the nursing assistant of the service.

Resident satisfaction / pleasure of eating: EVA at M-1 (on 3 consecutive days) then monthly on " 3 consecutive days until M6. The average of the evaluations over the 3 days will be taken into account.

This evaluation will be performed by the housekeeper or caregiver and will assess the satisfaction and pleasure of eating expressed by the resident (regardless of the randomization arm).

This evaluation will be done through the satisfaction scale presented in figure 1.

Figure 1 – Satisfaction scale

Hospitality/care charge for seniors's residents professionals: at M-1 (on 3 consecutive days) then monthly on 3 consecutive days until M6, by the housekeeper according to:

- Average meal duration
- Hospitality load: Number of interventions by the professional per resident. The average number of interventions over the 3 days will be taken into account.

Significant events on food intake (medical, such as an acute episode; environmental, such as a death in the family,...), which may constitute a bias for the analysis of the results, will be traced throughout the study.

Also, a follow-up of the advance medical prescriptions (AMP), oral nutritional supplements, laxatives will be carried out during the whole study.

In addition, any hospitalization, its duration and reason will be traced during the study.

This information, traced by the professionals of the service (patient file / Medical Object) will be recovered by the clinical research IDE.

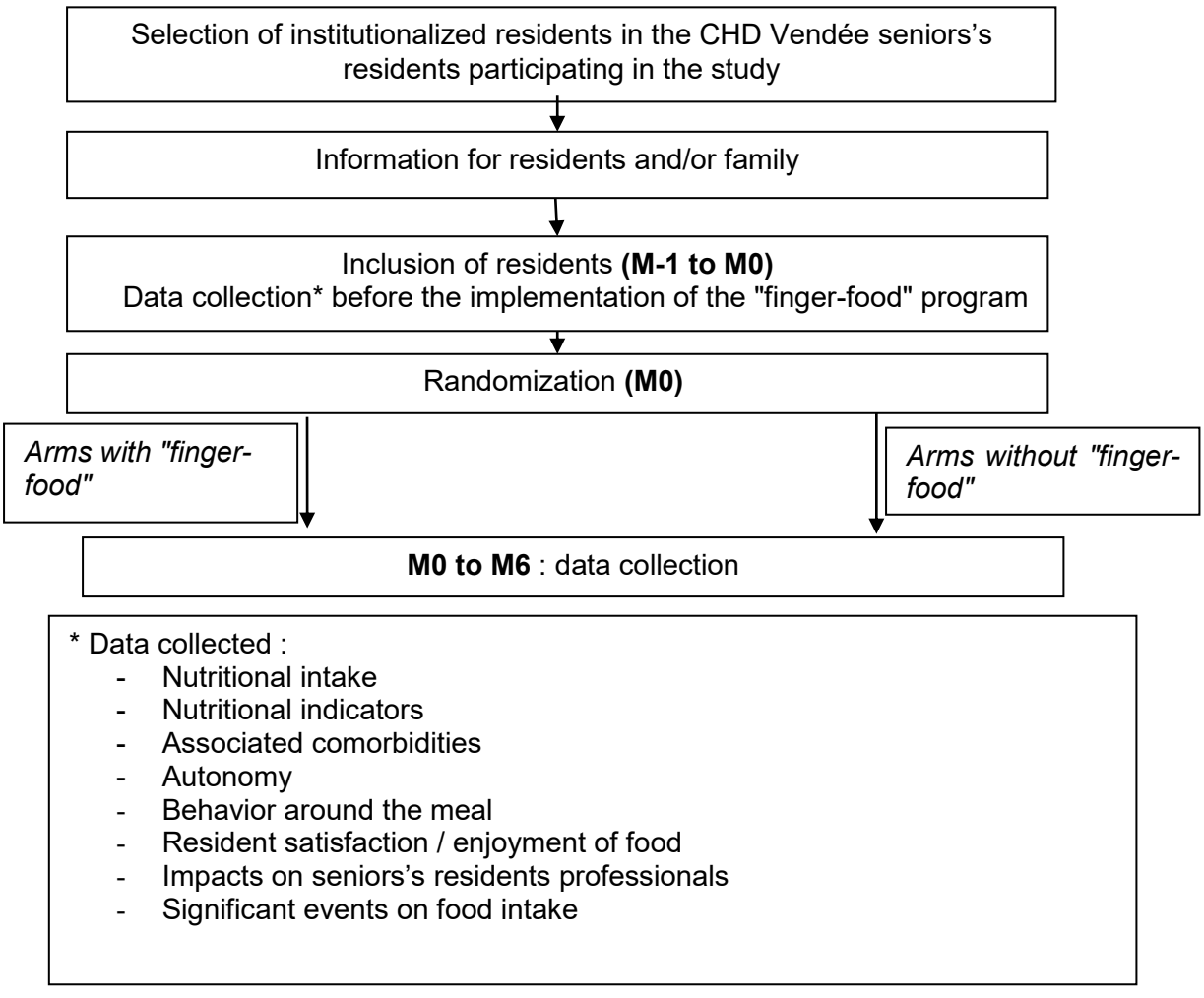
3. STUDY DESIGN

3.1 GENERAL STUDY METHODOLOGY

The study has the following characteristics:

- Nursing project
- Pilot study
- Monocentric
- Prospective
- Randomized in 2 parallel arms
    - Arms without "finger-food"
    - Arms with "finger-food"
- Open

3.2 STUDY DIAGRAM



3.3 RANDOMIZATION

The randomization will be done via the Clinsight software by connecting to the website: https://nantes-lrsy.hugo-online.fr/CSOnline/.
The connection will be done thanks to a login, a password and a study number, delivered by a data-manager of the Research Promotion Department of the CHD of La Roche/Yon.

The following information must be filled in:

- First initial of the name
- First initial of the first name
- Date of birth
- Compliance with inclusion and non-inclusion criteria (yes/no)
- Collection of non-objection (yes/no).

The inclusion number will be assigned automatically during randomization.
An e-mail confirmation will be sent to the person who performed the randomization and to all the persons concerned.

The randomization list will be carried out by a statistician from the Research Promotion Department of the CHD of La Roche/Yon.

A guide to the randomization procedure will be available online under Clinsight.

Randomization will be stratified by center (seniors's residents) and performed in a 1:1 ratio.

4. STUDY POPULATION

4.1 DESCRIPTION OF THE POPULATION

All the residents of the CHD Vendée seniors's residents who meet the inclusion criteria will be able to be included in the "FIFO" trial:

- La Roche-sur-Yon : Le Marais, La Plaine
- Luçon : La Roseraie, L'Olivier
- Montaigu : Augereau, Le soleil de la Maine

Of the 269 residents institutionalized in these facilities, we estimate that about 60 subjects meet all the criteria.

4.2 INCLUSION CRITERIA

- Residents institutionalized in seniors's resident for 3 months at least
- Residents in disability to feed single-handedly because of cognitive and/or physical disorders
- Having at least use of a hand
- Do not opposing the participation in the study or information and not opposition of the family / close to confidence / legal guardian in case of resident in incapacity to understand (senility, insanity)

4.3 NON-INCLUSION CRITERIA

- Condined to bed
- Specific diets (without residue, allergen,…)
- Enteral nutrition
- Absence motricity of 2 hand

4.4 CONTRAINDICATION TO PARTICIPATION IN ANOTHER CLINICAL TRIAL

Residents will be asked not to participate in another clinical trial during the study period. Clinical trials involving oral supplements, anorectic medications, etc., could impact the resident's appetite and nutritional intake.

5. CONDUCT OF THE STUDY

5.1 GENERAL ORGANIZATION

From an ethical point of view, 2 approaches are to be considered.
On the one hand, the place and the look of the "other" in front of the resident who will eat with his fingers. The objective is to preserve conviviality, exchange and pleasure around meals, which play a central role in the regulation of human, emotional and social interrelations [25].
On the other hand, the place and role of the family and friends during mealtime must be thought out and anticipated. In fact, in seniors's residents, the participation of families, anxious to regain a place and a capacity to take charge, results in frequent assistance with meals and is willingly given by professionals, as "this is little connoted with a technicality as other care could be" [26].

An important communication campaign with these different actors is essential to prevent these 2 points.

Communication to Families:

The social life council, user representatives and families will be informed of the research project. A presentation of the study by the project leader is planned during a Social Life Council held regularly on each site of the CHD (La Roche Sur Yon, Luçon and Montaigu), followed by a display in the services for the families.

The global approach of the project and the expected results will be valued in order to limit the possible reticence linked to the Western culture and the education received which could slow down its implementation among some residents, especially the acceptability of eating with the fingers (embarrassment, dirtiness, bad education, synonymous with regression to the childhood stage, ...) [27]

Feedback from a long-term care unit in GIMONT [26] suggests that the resident should be seated in the same way as they are used to and that cutlery should be left available if they wish to use it. This aspect is important in order to preserve the custom of table use.

It is important to take into consideration the place and role of the family and friends in order to allow them to find a place with the resident, reducing the feeling of loneliness and maintaining the social link.

As for hand hygiene, residents will wash their hands before and after eating hand-held meals.

Information and training for professionals:

The seniors's residents and catering professionals will all be informed of the project by the project leader during plenary meetings organized on each site (3 plenary meetings per site). After this information, FIFO referents will be identified in each seniors's residents (1IDE, 2 AS and 2 MM per seniors's residents) and will be trained by the project leader. They will act as an interface between the care team and the professionals of the clinical research unit and will constitute a project resource in each seniors's residents.

STEP 1 : M-1 – M0

This step includes resident selection, resident unopposed, and evaluation before randomization.

- Inclusion of residents

Once the regulatory authorizations have been obtained (CPP, CNIL), the residents of the CHD Vendée's seniors's residents will be selected from all the residents meeting the inclusion and non-inclusion criteria. Then each resident and/or family/guardian will be informed by the principal investigator of each seniors's residents and a note of information and non-objection will be given to them (Appendix 2).

- Initial assessment

The project will evaluate with the residents involved in the project:

Nutritional indicators: Nutritional intake (qualitative measurement of ingesta), weight, BMI, biological indicators, MNA screening score

Associated comorbidities: Number of wounds and pressure sores, number of falls

Autonomy: Autonomy of feeding and physical or psychological autonomy

Behavior around the meal

Resident satisfaction / enjoyment of food

Hospitality/care workload of seniors's residents professionals

Significant events on dietary intake, MAP, NOD, laxatives and any hospitalization will be tracked during this period.

STEP 2 : M0 – M6

- M0 : Implementation of « hand-held » or traditional feeding depending on the randomization arm of the resident.

This step consists in setting up the "finger-food" vs traditional food according to randomization, on the 3 sites of the CHD Vendée, after information/training of the ad-hoc professionals (care services, catering).

The same manufacturing process is planned for all 3 sites.

The distribution of this offer will be ensured by the catering of each site to the services concerned (in individual, nominative trays). The temperature of the food will be adapted to allow consumption with the hands.

At the beginning of this stage (M0), each resident included in the arm with "finger-food" will receive the 2 main meals (lunch and dinner) in the form of finger foods. Those included in the arm without "finger-food" will have the food offer as usually proposed. Breakfast remains the same as usual.

2 types of "finger-food" are planned in the study, depending on the feeding abilities of each resident (normal texture or modified texture) :

- The "classic hand-eater" for residents who are able to eat with a normal texture but have praxis problems and/or physical handicaps.

The proposed food offer will allow to grasp with the fingers, the dishes presented in the form of reduced portions. A diversity of presentation types is planned: food cut into cubes, slices, or sticks (raw vegetables, fruits), meatballs, fish croquettes, surimi, flans, quiches, quenelles, fritters, toasts, terrines, cheese, yoghurt drinks, compote drinks, ice cream sticks, cookies...
The composition in macronutrients and in particular the caloric and protein contributions, will be identical and preserved between the "classic" menu and the "classic eat-in" menu.

- The "smooth mixed feed" for residents who are unable to eat with a normal texture because they are edentulous and/or have oral pathologies and/or swallowing problems.

In this case, it will be the variation of the "mixed" meal in "eat-in" presentation, in the form of bites, whose consistency has been modified with the use of vegetable gelatins. They will be presented in the form of small portions that can be consumed in 1 to 2 bites. The composition in macronutrients and in particular the caloric and protein contributions, will be identical and preserved between the menu "usual mixed smooth" and the menu "eat hands mixed smooth".

In order to maintain the sensory perception of the meals, the bites will be differentiated by their tastes, colors, smells and shapes. A standard presentation of the meal will be proposed (hot/cold and salty/sweet). A thick sauce will be added to the bites to avoid the meal being too dry.

The proposed offer will be identical for all residents, according to texture; the prevalent aversions of this population having been identified beforehand and removed from the food offer.

- Resident follow-up

The project will evaluate with the residents involved in the project:

Nutritional indicators: Nutritional intake (qualitative measurement of ingesta), weight, BMI, biological indicators, MNA screening score.

Associated comorbidities: Number of wounds and pressure sores, Number of falls

Autonomy: Autonomy of feeding and physical or psychological autonomy

Behavior around the meal

Resident satisfaction / enjoyment of food

Hospitality/care workload of seniors's residents professionals

Significant events on food intake, LDCs, laxatives and any hospitalization will be tracked during this period.

5.2 STUDY SCHEDULE

Actions		Inclusion	M-1 to M0	M0 to M1	M1 to M2	M2 to M3	M3 to M4	M4 to M5	M5 to M6
Collection of non-opposition Size measurement		X							
Randomization			X						
Collection of consumption: nutritional intake*.			X	X	X	X	X	X	X
Nutritional Indicators**			X	X	X	X	X	X	X
Nutritional Indicators***			X						X
Associated comorbidities ****			X	X	X	X	X	X	X
Autonomy	Power supply (EBS)		X			X			X
	GIR		X						X
Eating behavior (Blandford scale)			X			X			X
Resident satisfaction (VAS of faces)			X	X	X	X	X	X	X
Impact on professionnals			X	X	X	X	X	X	X
Significant events on food intake *****			X	X	X	X	X	X	X

*3 consecutive days, for lunch and dinner, at a time t between M-1 and M0, then monthly
**Weight, BMI
*** Biological indicators (albumin/ pre-albumine/ CRP), MNA screening score
**** Number of pressure score and severity, number of falls, infectious complications: over the entire study period
***** Medical and environmental events, drug consumption, hospitalization (number, reasons, duration)

5.3 RULES FOR DISCONTINUING SUBJECT PARTICIPATION

5.3.1 Criteria for premature termination of an individual's participation in study

All residents included in the protocol who no longer wish to participate will be removed from the study as soon as this request is made.

5.3.2 Procedures in respect of early withdrawal of a subject from the study

The management of a resident who is prematurely discharged from the study will be identical to the usual management.
In the event that a resident wants to leave the study, he/she will be able to continue to benefit from the "eat-in" if he/she wishes.

5.3.3 Criteria in respect of discontinuation of all or part of the study (excluding biostatistical considerations)

The end of the study is defined as the end of the participation of the last subject.
Reasons for premature, definitive or temporary termination of the study may come from the decision of the sponsor or the coordinating investigators, for example for lack of inclusion.

6. DATA MANAGEMENT AND STATISTICS

6.1 STUDY DATA COLLECTION AND PROCESSING

6.1.1 Data collection

A Case Report Form (CRF/eCRF) will be allocated to each resident. All information required by the protocol will be recorded in the CRF/eCRF. It must include patient's identity, data required for compliance with the protocol, data necessary for statistical analysis, and any major deviations from the protocol.

The data collection will be done on a Clinsight database, developed by the data manager of the CHD Vendée promotion unit.

6.1.2 Data coding

By signing this protocol, the principal investigator and all the co-investigators undertake to keep the identities of the patients taking part in the study confidential.

The transmission of a person's data for research purposes will therefore only be possible if a coding system is applied; the presentation of the research results must exclude any direct or indirect identification.

A code will be set up for each resident. This code will be the only information that will appear on the observation book (CRF) and will allow the CRF to be linked to the resident after the fact.
The research supervisor will also code the resident data on any documents he/she may have in his/her possession (biology reports, etc.) that are attached to the CRF.
Only the first letter of the subject's name and the first letter of the subject's first name will be recorded, along with a coded number specific to the study indicating the center number and the order of inclusion of subjects.
Each investigating center will maintain a file of correspondence between the study code and the identity of the subjects at its own center. None of this direct or indirect identifying information will be available for study analysis and will be kept only at the center concerned.

6.1.3 Data processing

Clinical data collection shall be recorded on a database and creating input templates similar to the CRF in compliance with the protocol and applicable regulations.
The structure of the database and data input screens shall be approved by the trial sponsor.

6.2 STATISTICS

Name and contact information of the person responsible for the analysis:

Aurélie Le Thuaut
Unité de Recherche Clinique
CHD Vendée
Bd Stéphane Moreau – Les Oudairies
85925 La Roche sur Yon
aurelie.le.thuaut@chu-nantes.fr

6.2.1 Description of planned statistical methods, including planned intermediate analysis schedule

The description of quantitative variables will include the minimum, maximum, quartiles, mean and standard deviation. The description of qualitative variables will include the number and percentage of each modality.

Primary endpoint :

The evolution of caloric and protein intakes between inclusion and 6 months will be compared between the 2 groups by a Wilcoxon Mann-Whitney test.

Secondary endpoints :

The evolution of all the parameters collected throughout the monitoring will be described graphically.

Nutritional indicators :

The evolution of all nutritional indicators between inclusion and 6 months will be compared between the 2 groups by a Wilcoxon Mann-Whitney test.

Associated comorbidities:

The number of pressure sores/wounds and the number of falls will be compared between the 2 groups by a Wilcoxon Mann-Whitney test.

Autonomy:

The evolution of the EBS (autonomous eating), GIR and Blandford scale (physical or psychological autonomy) scores between inclusion and 6 months will be compared between the 2 groups by a Wilcoxon Mann-Whitney test.

Resident satisfaction/enjoyment of food:

The evolution of the satisfaction VAS between inclusion and 6 months will be compared between the 2 groups by a Wilcoxon Mann-Whitney test.

Hospitality/care load of seniors's residents professionals:

Changes in meal duration and the number of professional interventions between inclusion and 6 months will be compared between the 2 groups by a Wilcoxon Mann-Whitney test.

6.2.2 Statistical justification of the number of inclusions

To our knowledge, no clinical study has been carried out on the impact of "finger-food" in seniors's residents. Therefore, we have no data available that would allow us to make working hypotheses on its impact on the nutritional status of patients.
The purpose of this pilot study is therefore to collect preliminary data on the nutritional evolution of these patients.
No statistical calculations were performed. All residents of the 6 participating seniors's residents who met the inclusion criteria were included in the study.

6.2.3 Expected level of statistical significance

The significance level is set at 5%.

6.2.4 Statistical criteria for discontinuation of study

NA

6.2.5 Consideration method for missing, unused or invalid data

The main criterion being the comparison of the evolution of the quantity of ingesta between the inclusion and the 6 months of follow-up, a missing value of these data will entail an imputation of this one by the worst value then, by the average of its group.

6.2.6 Management of changes made to the initial analytical strategy

NA

6.2.7 Choice of subjects to be included in analysis

All residents included in the study will be analyzed.

7. SAFETY

The occurrence of an adverse effect related to the care of the resident during the present protocol will give rise to a declaration in the appropriate vigilance system (pharmacovigilance, biovigilance, hemovigilance, materialovigilance, etc.).

8. SOURCE DATA AND DOCUMENTS ACCESS RIGHTS

8.1 ACCESS TO DATA

The medical data of each resident will be transmitted only to the organization of the person in charge of the research or any person duly authorized by this one in the conditions guaranteeing their confidentiality.

8.2 SOURCE DOCUMENT

Le cas échéant, l'organisme de rattachement de la personne responsable pourra demander un accès direct au dossier médical pour vérification des procédures et/ou des données de la recherche, sans violer la confidentialité et dans les limites autorisées par les lois et régulations.

8.3 CONFIDENTIALITY OF DATA

Persons having direct access will take all necessary precautions to ensure the confidentiality of information relating to the persons who have access, particularly with regard to their identity and the results obtained.
These persons, as well as the investigators themselves, are subject to professional secrecy (according to the conditions defined by articles 226-13 and 226-14 of the penal code).
During or at the conclusion of the research, the data collected on the individuals involved in the research and provided by the researchers will be anonymized.
Under no circumstances should the names of the persons concerned or their addresses appear in clear text.
Only the first letter of the subject's name and the first letter of the subject's first name will be recorded, along with a coded number specific to the study indicating the order of inclusion of the subjects.

9. QUALITE ASSURANCE

The research will be conducted according to the standard operating procedures of the management center. The management of the persons in the participating centers will be done in accordance with the ethical and medical recommendations.

10. RATIONALE FOR REQUESTING VALIDATION OF CURRENT CARE STUDY

Based on all of these elements, the principal investigator qualifies this research as primarily **routine care research,** since:

- All procedures are performed as usual (biological samples for assessment, clinical data).

The study does not focus on techniques or strategies that are neither innovative nor obsolete.
Blood samples will be taken as described in the usual check-ups.

An additional assay (albumin/pre-albumin/CRP) will be performed.
This assay involves a blood test to be performed outside of standard practice (albumin/pre-albumin and CRP assay: once a year as part of standard practice).
It will also be coupled, whenever possible, with another blood test.

Apart from this dosage, the overall care of the resident will be identical to the usual practice.

Consequently, the particular modalities of implementation in the research represent negligible constraints for the person who lends himself to the research. (Article R 1121-3 of the public health code (CSP), decree n° 2006-477 of 26 April 2006).

The person in charge of the research will therefore, before any implementation of the research, submit the study protocol to the Comité de Protection des Personnes Ouest V de Rennes for a favourable opinion and confirmation of the qualification of the research, accordance with article L 1121-1 of the public health code (CSP) as they result from the laws n°2004-806 of August 9, 2004 and n° 2006-450 of April 18, 2006 relating to the public health policy.

11. ETHICAL CONSIDERATIONS

11.1 SPECIFIC MONITORING PROCEDURES

As this is a routine care study, no therapeutic modifications will be made within the framework of the protocol. The occurrence of an adverse event during the present protocol will give rise to a report in the appropriate vigilance system (pharmacovigilance, biovigilance, hemovigilance, materialovigilance, etc.).

11.2 ETHICAL CONSIDERATIONS

The person in charge of the research undertakes to submit the study project to a Committee for the Protection of Persons (CPP) in order to obtain an ethical opinion.

Amendments to the protocol

Any substantial modification to the study protocol must be notified to the CPP in order to verify that the proposed modifications do not alter at any time the guarantees provided to the persons undergoing the research.
The modified protocol will have to be the subject of an updated dated version.
The information sheet will need to be amended if necessary.

11.3 RESIDENTS'S INFORMATION

Residents and/or their families will be fully and fairly informed, in understandable terms, of the objectives of the study, their rights to refuse to participate in the study, or the opportunity to withdraw at any time. All of this information will be included on an information and no-objection form given to the resident.
The resident will be able to ask all the questions he or she wants and obtain all the information necessary for a good understanding of the project.

12. DATA PROCESSING

12.1 DATA ENTRY

Residents are informed during their information and non-opposition collection that the results are available to them at the end of the analysis of this study. The computer processing of the data is completely anonymous once the clinical collection and biological analysis have been completed.

12.2 COMPUTERIZED DATA AND SUBMISSION TO THE CNIL

A request for authorization to the “Commission Nationale Informatique et Libertés” (CNIL) for the processing of personal data for the purpose of research in routine care.

12.3 MONITORING

Monitoring is planned for this study.
Monitoring will be carried out by the Clinical Research Unit of the CHD Vendée. A Clinical Research Associate (CRA) will visit each site to perform quality control of the data reported in the observation books.

The monitoring plan is defined in consultation between the research team and the responsible institution according to the objectives of the study.
As the study does not present any risk to the residents, the monitoring is classified as category A (the lowest).
The ARC monitor will visit each center:

- after the inclusion of the first three to five residents whose files will be entered. This monitoring will be complete for this first visit;
- at the end of the inclusions to validate the quality of the data before the baseline freeze. This monitoring visit will focus on compliance with inclusion procedures, selection criteria and data related to the primary endpoint.

12.4 ARCHIVING

The archiving of the study documents will be done in accordance with Good Clinical Practices and the regulations in force.

13. FINANCING AND INSURANCE

13.1 BUDGET OF THE STUDY

Funds allocated by Clinical Unit of CHD.

13.2 INSURANCE

Insofar as the research is qualified as Research in routine care by the CPP requested, which means that there is no additional risk associated with the study, the insurance will be that of the institution responsible for the care (article L. 1142-2).

14. PUBLICATION RULES

The scientific communications and reports corresponding to this study will be carried out under the responsibility of the principal investigator coordinating the study with the agreement of the responsible investigators. The co-authors of the report and publications will be the investigators and clinicians involved, in proportion to their contribution to the study, as well as the biostatistician and associated researchers.

The rules of publication will follow international recommendations (N Engl J Med, 1997; 336:309-315).

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