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Original article

# An innovative brioche enriched in protein and energy improves the nutritional status of malnourished nursing home residents compared to oral nutritional supplement and usual breakfast: FARINE+ project

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SUMMARY

*Background & aims:* To compare the effects of a 12-week nutritional intervention, in which an innovative protein-and-energy-enriched brioche, an oral nutritional supplement or a usual breakfast were eaten, on food intake and nutritional status in nursing home residents.
*Design:* Three-armed, multicentre, controlled trial.
*Setting:* Eight nursing homes in Burgundy, France.
*Participants:* Sixty-eight malnourished participants aged between 70 and 99 years old.
*Intervention:* Participants were randomly assigned to one of three groups according to the breakfast provided: brioche group, one portion of 65 g brioche enriched in protein and energy (12.8 g and 180 kcal) added to usual breakfast; supplement group, 200-ml of a ready-to-use, energy-dense liquid (14 g protein and 200 kcal) added to usual breakfast or control group, a usual breakfast only.
*Measurements:* Total energy intakes were assessed for three days at different periods of the study (day 0, day 30 and day 90); blood parameters, nutritional status (mini nutritional assessment, weight) and functional capacities (grip strength and activity level) were measured at the beginning and at the end of the nutritional intervention study (day 0 and day 90).
*Results:* The participants of the brioche group had higher total energy intakes at day 30 (p value 0.004) and at day 90 (p value 0.018) compared with the supplement group and the control group. At the end of the interventional study, 72% of the participants in the brioche group had reached the recommended minimum level of protein of 0.8 g/kg/day, compared with 53% in the supplement group and 36% in the control group (*p* value 0.036). In addition, between day 0 and day 90 in the brioche group, blood levels of vitamins $B_9$, $B_2$, D (all *p* value <0.001), $B_6$ (*p* value 0.026) and $B_{12}$ (p value 0.036) had increased and plasma homocysteine had decreased (*p* value 0.024).
*Conclusion:* The protein-and-energy-enriched brioche effectively increased energy and protein intakes and improved the nutritional status of elderly people living in nursing homes. It could be a good alternative to oral liquid nutritional supplements to counteract protein-energy-malnutrition.


## 1. Introduction

An adequate food intake is necessary to maintain good health in ageing, but this objective is sometimes difficult to achieve because of physiological alterations, functional disabilities and diseases [1]. As they get older, people eat less, even though nutritional needs do not decrease. This imbalance predisposes elderly people to weight loss and increases their nutritional risk. These problems are particularly present in dependent older people living in nursing homes, in which the incidence of malnutrition is high, ranging from 17% to 65% [2].

Malnutrition can be defined as: 'A state of nutrition in which a deficiency or excess (or imbalance) of energy, protein and other

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nutrients causes measurable adverse effects on tissue/body form, function and clinical outcome' [3]. In this article, we used the term malnutrition synonymously with undernutrition.

Malnutrition is associated with a decline in functional status, impaired muscle function, delayed recovery from surgery, an increased incidence and severity of various diseases and complications, longer hospital stays, increased readmission rates, increased social isolation, reduced quality of life and increased mortality [4]. It places a considerable burden on community and health services and resources [4].

One of the most important causes of malnutrition is insufficient intake of nutrients because physiological, psychological and social changes associated with ageing [1]. Schroll et al. [5] estimated that 10% of elderly persons consume less than 1300 kcal/day (*i.e.* about 35% less than a normal adult). More recently, Bon et al. [6] noted that food intake only just reached 1500 kcal in hospitals and nursing homes, the threshold below which it is difficult to cover the majority of nutritional requirements [7] and one of the indicators of risk for inadequate micronutrient intake [8]. The recommended daily intake should be 1800 kcal for women and 2200 kcal for men aged more than 60 years old [9]. Current recommendations for protein intake are 0.8−1.0 g per kilogram of body weight a day (g/kg/day) for healthy older adults [9] and as high as 1.2−1.5 g/kg/day for older adults with an acute or chronic disease [10]. When elderly people do not meet their protein requirements, enriched nutritional supplements can be provided to make up the difference. The meta-analysis by Milne et al. [11] showed the positive clinical outcomes of nutritional interventions. There is evidence that supplements can increase survival, reduce complications and increase energy and protein intake in older people. Compliance in elderly people taking supplements is low, because of taste, satiety effects and the extra volume that needs to be consumed [12]. In addition, these products are often regarded as medications and not food.

The aims of the current study were to evaluate the effects of providing elderly nursing home residents (NHR) with enriched brioche as compared with an oral nutritional supplement (ONS) or the usual breakfast over a 12-week nutritional intervention, during breakfast, 1) on the nutritional intake and nutritional status, plasma albumin, and plasma prealbumin, in NHR at risk of malnutrition or undernourished, as the primary outcomes, and then on different secondary outcomes, such as 2) the evolution of other blood criteria, i.e. an increase in vitaminsB1, B2, B6, B9, B12 and D and selenium on the one hand, and a decrease in homocysteine and C-reactive protein (CRP) on the other, 3) the functional status, and finally 4) BMI. These results of two 12-week nutritional interventions, enriched brioche and an oral nutritional supplement (ONS), were compared with a control group. Brioche was chosen because it is a staple food and is commonly consumed in France.

## 2. Materials and methods

The nutritional intervention was a randomized controlled trial. Each participant was enrolled in the study for 12 weeks, which is sufficiently long to report clinical and nutritional outcomes. Each participant consumed one of the three breakfasts every day: enriched-brioche (brioche group), ONS (supplement group), or the usual breakfast (control group).

### 2.1. Participants

The study was conducted in eight nursing homes in the Dijon area. In accordance with the inclusion criteria, residents were first screened by the medical teams of each nursing home in order to select those who were eligible for this study. Then, physicians involved in the nutritional intervention interviewed each person directly to verify the inclusion and non-inclusion criteria. Participants were included if they had the following criteria: a Mini Nutritional Assessment (MNA) score $\leq$23.5 [13] or plasma prealbumin $\leq$0.2 g/L, and aged 70 and older. Participants were excluded if they were allergic or intolerant to any of the foods offered in the study, suffering from an acute episode of disease at the time of the study or were incapable of feeding themselves. The study was approved by the Burgundy Ethics Committee (2010-A01337-32). After receiving information about the study, the participants signed a consent form. For elderly people with a low cognitive status, the study was explained in simple terms, corresponding to their level of understanding. If an elderly person did not manifest refusal to participate in the study, the study was explained to his/her legal guardian or representative, who countersigned the consent form.

### 2.2. Nutritional intervention

All participants consumed their breakfast sitting in their usual place in their nursing home and received the usual food regimen except for the breakfast in the two experimental groups (brioche and supplement groups) in which usual bread at breakfast was replaced by the enriched brioche or an oral nutritional supplement, respectively. The participants in the brioche group were given one brioche roll per day for 12 weeks. The brioche roll weighed 65 g and had one of three randomised flavours, orange, vanilla or honey and contained 12.8 g of protein and 180 kcal. The brioche was supplied by Cerelab® (Dijon, France) and was specially designed to suit the preferences, chewing and sensory abilities of the elderly [14]. It was designed to bring similar levels of energy and macro and micronutrients to those in the ONS, and focused on elements such as group B vitamins, vitamin D and selenium (for the composition of the brioche see Table 1). The participants in the supplement group received one 200-ml carton of a ready-to-use, energy-dense liquid with three randomised flavours, strawberry, coffee or vanilla (Fresenius Kabi, Nestlé S.A., Labége, France). The supplement contained 14 g of protein and 200 kcal (for the composition of the supplement see Table 1). In the brioche and the supplement groups, participants completed their breakfast with a hot drink, juice, butter, jam and ordinary bread or toast if they wanted to. Consumption of the brioche and the supplement was recorded every day by trained nursing-home staff who evaluated the quantity of brioche not consumed as 0, 25, 50, 75 and 100% of the portion served. Participants in the control group received their usual breakfast provided by the nursing homes.

### 2.3. Study parameters

On the day of inclusion, the variables studied included gender, age, cognitive status (Mini Mental State Estimation (MMSE) score) [15], nutritional status (MNA score), Body Mass Index (BMI), functional status (Activities of Daily Living (ADL) score) [16] and level of efficiency in basic and instrumental activities (Instrumental Activity Daily Level (IADL) score) [17], grip strength using a hydraulic dynamometer (JAMAR® plus+) as a measurement of muscle function, plasma albumin and plasma prealbumin values, medication use, prescription of ONS and dental status. Body-weight was measured with participants in light clothing after overnight fasting on a calibrated scale (to the nearest 0.1 kg, SECA, FRANCE). The BMI was calculated by dividing body weight by the square of the height, the latter using the Chumlea equation [18]. The BMI, MNA score, grip strength and ADL and IADL scores were also assessed at the end of the study (day 90).

Food intake was assessed at three time points, before the beginning of the nutritional intervention (day 0), then at one

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month (day 30), and at three months (day 90). For each time point, the mean intake over three days was calculated (day-3, -2 and -1; day 30, 31 and 32; day 90, 91 and 92). To evaluate total energy intake, each food provided during each meal (breakfast, lunch, snack, dinner) was weighed separately (Soehnle balance, FRANCE, precision required: ± 1 g), the weight before the meal and the waste after the meal were recorded by an experienced dietician. Energy intake was evaluated using nutritional information on the packaging of the products or for the different foods eaten using Bilnut software (Bilnut, S.C.D.A. Nutrisoft, Cerelles, France). For each group, the mean of 3-day records was calculated to evaluate total energy intake and energy intake for each meal. The consumption of water was not assessed because water was placed on the table and available to all participants.

At two time points, day 0 and day 90, blood parameters were evaluated. Blood samples were collected to measure plasma concentrations of $B_1$, $B_2$, $B_6$, $B_9$, $B_{12}$ and D (25-hydroxyvitamin D) vitamins, homocysteine, selenium, plasma albumin, plasma prealbumin and CRP. Plasma prealbumin was also evaluated at day 30. For each parameter, 2 mL of serum was collected at 7–8 am after overnight fasting. Blood samples were taken at the nursing home by an independent laboratory.

### 2.4. Safety

No adverse events related to consuming the brioche or the ONS were expected. Food safety was ensured by following the Hazard Analysis and Critical Control Points (HACCP– Management method of food safety) and EC Regulation 852/2004 guidelines [19]. The study had no influence on the medical prescriptions of the physician and/or personal staff of nursing home and/or dietician (for example, prescription of other ONS). Any adverse effects or problems with the subject's health were reported to the management team and personal staff.

### 2.5. Statistical data and analysis

A sample of 23 participants was required in each group to demonstrate a difference of 10% in total intake, with a statistical power of 80% and an alpha-level of 0.10. Subjects eligible for participation were randomly allocated by a generated random number sequence in an excel table with a ratio 5:3:3 into either the brioche arm (n = 50) or the supplement arm (n = 30) or the control arm (n = 30) stratified by age, gender and BMI. Subjects were randomised as they were included at the eight nursing homes. Continuous variables were expressed as means and standard deviations (SD), and categorical variables as percentages. Descriptive statistics were used to describe the baseline characteristics of the study population: gender, age, cognitive and nutritional status, BMI, ADL, IADL, plasma albumin and plasma prealbumin levels, medication use, prescription of ONS and dental status. Baseline characteristics were compared between groups using one-way analysis of variance (ANOVA) or by Pearson's chi-square tests (Fischer's exact test) for categorical variables, such as dental status and the prescription of diary ONS.

Blood parameters and nutritional and functional data were analysed using Student t-tests paired between day 0 and day 90 within groups. For quantitative parameters with normal distribution, ANOVA were used, after a pretest for homogeneity of variances, to test the effects of the period (day 0, day 30 and day 90) between each group. For each significant effect, a multiple comparison of means was done using the Tukey test. In cases of abnormal distribution, a nonparametric test was used (Kruskal–Wallis rank test) followed by a multiple comparison according to Dunn's method.

**Table 1**
Composition of the brioche and the ONS used.

| | | Brioche | Supplement |
|---|---|---|---|
| | | Per portion = 65 g | Per portion = 200 mL |
| Energy | kcal | 180.0 | 200.0 |
| | kJ | 761.0 | 846.0 |
| Proteins | (g) | 12.8 | 14.0 |
| Carbohydrates | (g) | 15.5 | 23.6 |
| Sugar | (g) | 4.0 | 5.6 |
| Lipids | (g) | 7.3 | 5.6 |
| Vitamins B1 | (mg) | 0.4 | 0.3 |
| Vitamins B2 | (mg) | 0.6 | 0.3 |
| Vitamins B6 | (mg) | 1.2 | 0.4 |
| Vitamins B9 | (µg) | 183.0 | 40.0 |
| Vitamins B12 | (µg) | 1.9 | 0.2 |
| Vitamins D | (µg) | 5.0 | 1.0 |
| Selenium | (µg) | 23.0 | 12.0 |

List of ingredients for brioche: Water, wheat flour, wheat gluten, canola oil, eggs, wheat fibre, rice proteins, milk proteins, yeast, sugar, emulsifiers: E471, E472e and E481, hydrolysed wheat gluten, butter, powdered skimmed milk, maltodextrins, vitamins and minerals (magnesium, phosphorus, calcium, iron, zinc, selenium, vitamins D3, B1, B2, B6, B12, folic acid), salt, glucose syrup, lysine hydrochloride, thickener: E412, flavouring, wheat starch, sweetener: E955, flour treatment agent:E300, colorants:E101, E160a.

All variables for food intakes (total energy intake, at breakfast, at lunch, at the snack and at dinner) and for plasma prealbumin levels were analysed using a mixed model with a random effect for subjects, a fixed effect for the factors groups (3 levels: brioche, supplement, control) and periods (3 levels: day 0, day 30, day 90), and a fixed interaction of group*period.

Food intake parameters were analysed using analysis of covariance (ANCOVA) to assess the effect of the intervention during the study, adjusting for baseline measurements as a covariate.

Pearson's correlation test was used for the variables MNA, BMI, and plasma albumin.

The subjects' compliance with the brioche and the oral supplement was evaluated as consumption of more than 75% of each brioche and oral supplement for each participant during the whole study using the independent samples Student t test.

Statistical analyses were conducted using SAS/STAT (SAS/STAT, 1989) or using SigmaStat software (version 3.1, Systat Software Inc., Richmond, CA, USA). The threshold for statistical significance was set at a p value $<0.05$.

## 3. Results

### 3.1. Participants

A total of 111 participants living in nursing homes were screened for the study (Fig. 1). A group of 24 residents were not eligible for the nutritional intervention, because the MNA score was above 23.5 and/or the plasma prealbumin value was higher than 0.2 g/L or because participant did not want to change his breakfast. In addition, after randomisation into groups, 7 participants did not commence the study because they refuse ONS. Because it was difficult to recruit subjects in the supplement group, the distribution of subjects was adjusted in order to balance groups, and as a result, the last nursing home had a larger number of participants in the supplement group. The participants included in this nursing home were older than those in the other groups.

During the follow up, 12 participants were excluded from the data analysis because of hospitalisations, death or withdrawal from the study. Baseline characteristics of the participants are presented in Table 2. There were no significant differences between the participants in the three groups, except that those in the brioche group

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were significantly younger than those in the supplement group ($p$ value 0.038) and that IADL scores in the control group were better than those in the other groups ($p$ value 0.028).

### 3.2. Subjects' compliance with the brioche and the oral supplement

Compliance concerning the consumption of the enriched brioche during breakfast was very good with a mean of 83% of the 29 participants of the brioche group who ate all of the brioche provided. It was a little lower for the supplement group with 74% of the 17 participants of the group consuming the whole ONS ($p$ value 0.001).

### 3.3. Energy intake (EI)

The evolution in energy intake at each meal in each group is reported in Table 3. During the study, changes in total EI were different in the three groups ($p$ value 0.0045) with a greater total EI for the brioche group at day 30 ($p$ value 0.004) and at day 90 ($p$ value 0.018) compared with the supplement group and the control group. EI at breakfast changed differently during the study (period effect, $p$ value 0.0015 and interaction effect, $p$ value $< 0.001$) with a positive evolution for the brioche group and the supplement group but not for the control group at day 30 ($p$ value $<0.001$) and at day 90 ($p$ value $<0.001$). EI at lunch was different in the three groups ($p$ value 0.0092) with a higher EI in the brioche group than the other two groups only at day 90 ($p$ value $= 0.001$). At the snack, there was no difference between groups ($p$ value 0.286). Finally, EI at dinner evolved in the same way in all groups with a group effect ($p$ value 0.0349) and a period effect ($p$ value 0.0104) but with no interaction effect ($p$ value 0.2013).

Concerning total protein intake, at the end of the study (day 90), the ONS and the brioche provided significantly more protein than did the usual breakfast ($p$ value 0.021). At the end of the interventional study, 72% of the participants in the brioche group had reached the recommended minimum level of 0.8 g/kg/day, compared with 53% in the supplement group and 36% in the control group ($p$ value 0.036). At day 90, the calories ingested per kg of body weight ($p$ value 0.038) were significantly greater in the brioche group than in the other groups.

### 3.4. Blood parameters

Table 4 illustrates the evolution of blood parameters.

Plasma albumin was similar in all three groups at the beginning of the study ($p$ value 0.605) and did not change during the nutritional intervention ($p$ value 0.424). Between day 0 and day 90, no change was observed whatever the group (brioche $p$ value 0.815, supplement $p$ value 0.396, control $p$ value 0.266).

For plasma prealbumin values, there was no group effect ($p$ value 0.340) but a period effect ($p$ value $<0.001$) with no interaction effect ($p$ value 0.854). For all groups, the plasma prealbumin values were higher at day 30 than at day 90 ($p$ value 0.001).

No difference was found in CRP values between the three groups at the beginning ($p$ value 0.442) or at the end of the study ($p$ value 0.518). No change was found in any group (brioche $p$ value 0.786, supplement $p$ value 0.305, control $p$ value 0.309).

No difference was observed in homocysteine values between the three groups at the beginning ($p$ value 0.220) or at the end of the study ($p$ value 0.103). However, homocysteine levels in residents receiving brioche or supplement fell between day 0 and day 90 ($p$ value 0.024 for the brioche group, $p$ value 0.046 for the supplement group) while there was no difference for the control group ($p$ value 0.163).

Concerning the vitamin and mineral status, no significant difference was observed between groups at the beginning of the intervention ($B_9$, $p$ value 0.123, $B_{12}$, $p$ value 0.170, $B_1$, $p$ value 0.561, $B_2$, $p$ value 0.135, $B_6$, $p$ value 0.090, D, $p$ value 0.910, and selenium, $p$ value 0.125). At the end of the interventional study, as indicated in Table 4, significant differences were observed between groups for vitamins $B_2$, $B_9$ and $B_6$, and selenium (all $p$ value $<0.001$ except for $B_2$, $p$ value 0.007) with no change for vitamin $B_{12}$ (p value 0.314), for vitamin $B_1$ ($p$ value 0.065) and for vitamin D ($p$ value 0.074). In the brioche group, the values for vitamins $B_9$, $B_2$, D (all $p$ value $<0.001$), $B_6$ ($p$ value 0.026) and $B_{12}$ ($p$ value 0.036) increased during the nutritional intervention. With the supplement, only vitamin $B_6$ levels increased between day 0 and day 90 ($p$ value 0.033), no change occurred for vitamins $B_9$ ($p$ value 0.067), $B_{12}$, ($p$ value 0.158), $B_1$ ($p$ value 0.345), $B_2$ ($p$ value 0.135) and D ($p$ value 0.893) or selenium ($p$ value 0.426). In contrast, in the control group, levels of vitamin $B_{12}$ and selenium fell ($p$ value 0.009 and 0.002, respectively). No change was observed for vitamins $B_9$ (p value 0.666), $B_1$, ($p$ value 0.237), $B_6$ ($p$ value 0.081) or D ($p$ value 0.309), but an increase was found for $B_2$ ($p$ value $<0.001$).

### 3.5. MNA and BMI at the end of study

There was no significant difference between groups for BMI at the end of the nutritional intervention ($p$ value 0.161; Table 4). The one-way ANOVA per group indicated no change in any group (brioche group $p$ value 0.826, supplement group $p$ value 0.443, and control group $p$ value 0.487). In addition, there was no significant difference between groups for the MNA score at the end of the nutritional intervention ($p$ value 0.153; Table 4) and no change was observed in any group (brioche group $p$ value 0.552, supplement group $p$ value 0.644, and control group $p$ value 0.614).

For all participants, there was a fair correlation between participants' nutritional status determined by MNA and participants' BMI. Participants at a high nutritional risk had a lower BMI while participants at a low nutritional risk had a normal BMI ($r = 0.405$, $p$ value 0.001). In contrast, there was no correlation between participants' BMI and plasma albumin values ($r = 0.152$, $p$ value 0.217), or between participants' MNA and plasma albumin values ($r = 0.157$, $p$ value 0.219).

### 3.6. Evolution of functional status

There was no difference between groups for grip strength values at the beginning ($p$ value 0.903) or at the end of the nutritional intervention ($p$ value 0.695; Table 4). The strength measured in the residents of control group had significantly declined at day 90 ($p$ value 0.007), with no change in the other two groups (brioche group, $p$ value 0.051 and supplement group, $p$ value 0.200).

No difference was observed between groups for ADL scores at the beginning ($p$ value 0.161) or at the end ($p$ value 0.107) of the study (Table 4). In addition, no change was detected in any group between day 0 and day 90 (brioche group $p$ value 0.526; supplement group $p$ value 0.262; and control group $p$ value 0.378).

The IADL scores, which were significantly higher in the control group at the beginning of the intervention, stayed higher at the end of the study compared with the two other groups ($p$ value 0.028 and 0.004, respectively). There was no significant change in the IADL scores within groups (brioche group $p$ value 0.136; supplement group $p$ value 0.164; and control group $p$ value 0.328).

## 4. Discussion

Because malnutrition is still undetected and undertreated with immense damage and high costs for the individual and for the

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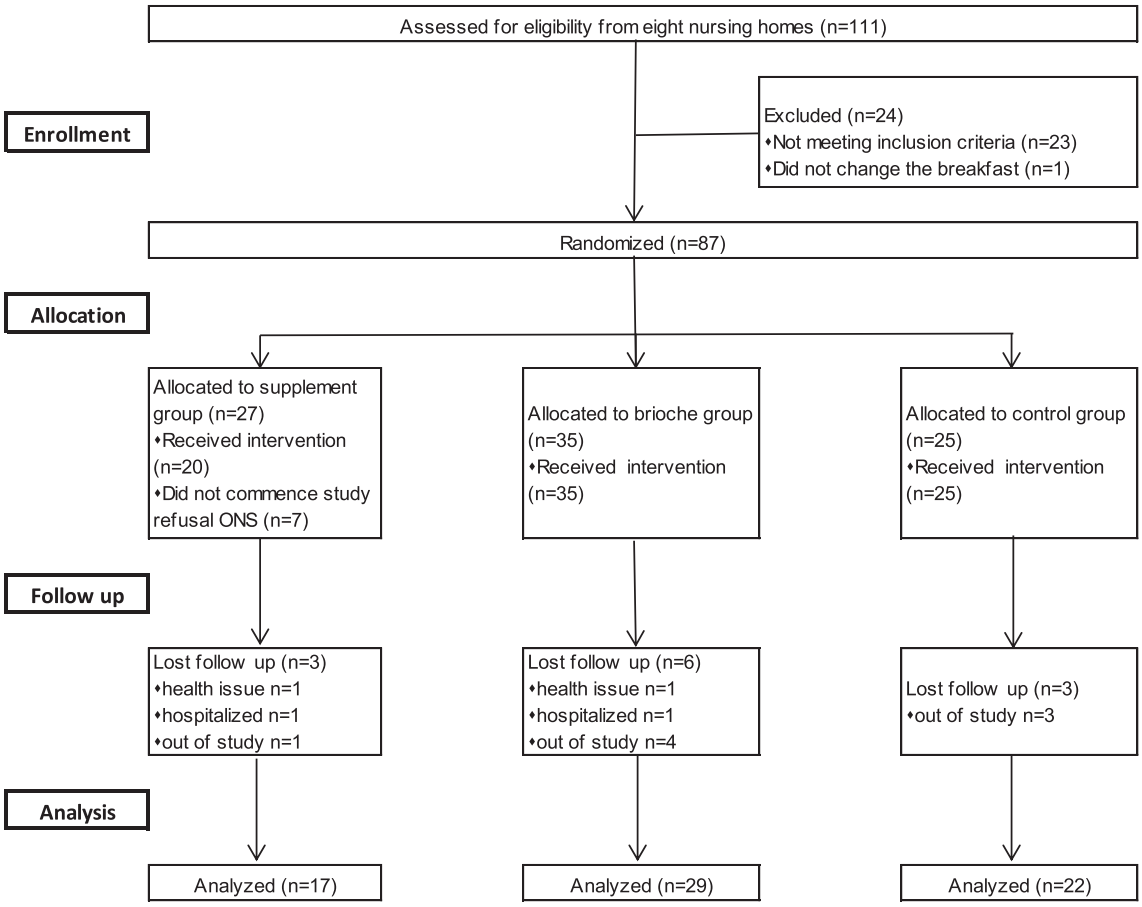


**Fig. 1.** Study design and numbers of patients enrolled and included in the analysis.

**Table 2**
Characteristics of participants in each group (n).

| | Brioche group (n = 29) | Supplement group (n = 17) | Control group (n = 22) | p-value | Test |
|---|---|---|---|---|---|
| Female [% (n)] | 79.3 (23) | 82.3 (14) | 77.3 (17) | 0.930 | ANOVA |
| Age, year [mean, (SD)] | 84.2 (7.9) a | 90.3 (6.5) b | 87.3 (8.0) ab | **0.038** | ANOVA |
| Mini Mental Score [mean, (SD)] | 17.6 (7.2) | 19.7 (4.8) | 18.6 (6.5) | 0.626 | ANOVA |
| Body mass index, kg/m$^2$ [mean, (SD)] | 29.1 (7.3) | 24.9 (6.4) | 28.1 (5.8) | 0.104 | ANOVA |
| Mini Nutritional Assessment® (MNA®) [mean, (SD)] | 21.1 (2.8) | 19.9 (3.5) | 21.8 (2.7) | 0.211 | ANOVA |
| ADL [mean, (SD)] | 3.1 (1.9) | 2.4 (1.6) | 3.6 (1.9) | 0.161 | ANOVA |
| IADL [mean, (SD)] | 1.1 (1.3) a | 1.1 (0.8) a | 1.9 (1.1) b | **0.028** | ANOVA |
| Plasma Albumin, g/L [mean, (SD)] | 38.1 (4.1) | 37.6 (2.4) | 38.7 (2.9) | 0.605 | ANOVA |
| Plasma Prealbumin, mg/L [mean, (SD)] | 246.2 (75.8) | 231.2 (32.2) | 237.7 (48.3) | 0.695 | ANOVA |
| Numbers of pills prescribed/day [mean, (SD)] | 7.6 (3.6) | 6.7 (2.5) | 6.9 (3.4) | 0.612 | ANOVA |
| Prescription of diary ONS [% (n)] | 10.3 (3) | 29.4 (5) | 9.1 (2) | *0.141* | *Chi-square* |
| Total removable denture [% (n)] | 41.4 (12) | 35.3 (6) | 45.4 (10) | *0.900* | *Chi-square* |
| Total natural teeth [% (n)] | 10.3 (3) | 0 (0) | 13.6 (3) | *0.378* | *Chi-square* |
| No natural teeth or removable denture [% (n)] | 6.9 (2) | 11.8 (2) | 4.5 (1) | *0.931* | *Chi-square* |

Means with different letters show significant differences; no letters show there were no significant differences.
The bold p values indicate significant differences; the italic p values result of Chi-square analysis.

healthcare system [20], it is necessary to develop supplements adapted to and accepted by elderly people especially. The results of our study concerning the consumption of enriched brioche are particularly relevant: a) given the high consumption of the enriched brioche throughout the study period, it was obviously much appreciated and compliance was higher than that with ONS, b) the total energy intake had improved at day 30 and at day 90 with enriched brioche and 72% of the participants in the brioche group reached the recommended level of 0.8 g/kg/day of protein, and c) the participants in the brioche group had improved their vitamin $B_9$, $B_2$, $B_6$, $B_{12}$ and D status. To our knowledge, this is one of the rare intervention studies concerning a food included in the usual diet.

The improvements in average daily energy intake in the brioche group are consistent with Donahue's study [21], but greater than those in other studies which used protein-enriched 'regular products'. For example, Pouyssegur et al. [22] found no change in the quantity of food and beverage consumed by elderly people given enriched cookies, and Stelten et al. [23] found no significant difference between a control group and an intervention group given protein-enriched brioche and protein-enriched drinking yoghurt. In addition, in our study, the proportion of participants reaching a

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**Table 3**
Evolution of energy intake at each time point of the nutritional intervention in each group (n).

| | | | Brioche group (n = 29) | Supplement group (n = 17) | Control group (n = 22) |
|---|---|---|---|---|---|
| Energy intake (kcal) | | | | | |
| Total | day 0 | [mean, (SD)] | 1343.76 (294.4) | 1112.85 (417.0) | 1240.13 (292.0) |
| Total[e] | day 30 | [mean, (SD)] | 1414.03 (291.8)a | 1182.92 (318.0)b | 1205.99 (192.2)b |
| Total[b,e] | day 90 | [mean, (SD)] | 1394.08 (312.1)a | 1102.17 (301.5)b | 1135.38 (264.2)b |
| At breakfast | day 0 | [mean, (SD)] | 292.89 (83.3) | 267.88 (144.7) | 316.71 (104.3) |
| At breakfast[e] | day 30 | [mean, (SD)] | 357.6 (77.2)a | 305.66 (142.4)a | 292.99 (92.8)b |
| At breakfast[c,e] | day 90 | [mean, (SD)] | 356.82 (82.7)a | 313.84 (140.5)a | 288.66 (95.6)b |
| At lunch | day 0 | [mean, (SD)] | 580.12 (181.5) | 485.97 (229.9) | 484.16 (145.0) |
| At lunch | day 30 | [mean, (SD)] | 554.05 (141.3) | 471.60 (163.4) | 497.50 (129.7) |
| At lunch[b,e] | day 90 | [mean, (SD)] | 588.31 (177.5)a | 415.47 (144.6)b | 469.46 (149.2)b |
| At the snack | day 0 | [mean, (SD)] | 6.04 (21.2) | 5.14 (21.2) | 15.94 (55.6) |
| At the snack | day 30 | [mean, (SD)] | 32.9 (53.0) | 5.42 (22.4) | 16.27 (44.1) |
| At the snack | day 90 | [mean, (SD)] | 24.76 (38.9) | 4.9 (16.0) | 19.43 (54.2) |
| At dinner | day 0 | [mean, (SD)] | 464.69 (149.2) | 353.85 (171.6) | 423.31 (106.5) |
| At dinner | day 30 | [mean, (SD)] | 469.47 (148.4) | 400.23 (132.2) | 399.23 (82.4) |
| At dinner[d] | day 90 | [mean, (SD)] | 424.18 (123.9)[a] | 367.96 (119.3)[b] | 357.81 (96.4)[b] |
| Protein g/kg | day 0 | [mean, (SD)] | 0.795 (0.240) | 0.799 (0.363) | 0.735 (0.214) |
| Protein g/kg | day 30 | [mean, (SD)] | 0.953 (0.233) | 0.937 (0.348) | 0.779 (0.188) |
| Protein g/kg[e] | day 90 | [mean, (SD)] | 0.893 (0.210)a | 0.875 (0.292)a | 0.711 (0.195)b |
| Protein requirements | | (n = )[a] | 20 | 8 | 8 |
| Energy cal/kg | day 0 | [mean, (SD)] | 20.99 (5.24) | 20.21 (9.10) | 20.49 (6.07) |
| Energy cal/kg | day 30 | [mean, (SD)] | 22.02 (5.01) | 21.39 (7.09) | 19.96 (4.51) |
| Energy cal/kg[e] | day 90 | [mean, (SD)] | 21.65 (4.93)a | 19.71 (5.41)b | 18.72 (4.93)b |

Data are mean ± SD.
[a] Number of participants reaching the minimum protein requirement of 0.8 g/kg/day.
[b] Differences by linear mixed model including group effect.
[c] Differences by linear mixed model including period effect and interaction effect (groupxperiod).
[d] Differences by linear mixed model including group effect and period effect.
[e] ANCOVA with baseline value as covariate used to compare difference between groups; different letters show significant differences; no letters show there were no significant differences.

sufficient intake of protein was significantly higher in the brioche group than in the supplement and control groups. This result was also found in other studies that used enriched food [23] or particular supplements [24]. In the current study, even though the intake of energy and proteins was higher in the brioche group than in the supplement and control groups, intake in the majority of residents in the brioche group was below the recommendations [9,10] with mean intakes of 1394 kcal of energy and 0.89 g/kg/day of protein.

Our results are extremely encouraging and suggest that this enriched brioche could be considered a staple food. The latter is defined by the FAO as foods that are eaten regularly and supply a major proportion of the energy and nutrient needs. Staple foods are generally cereal products that constitute a major part of a diet and are culture-specific, e.g., bread in France. Bouis [25] suggested enriching staple foods with macronutrients in order to combat nutritional deficiencies caused by undernutrition. The present study confirmed that daily consumption of brioche did not induce lassitude for brioche, as compliance was very good. These results substantiate the advantages of brioche as a way to improve the nutritional quality of a diet especially in dependent populations at risk of malnutrition. Its nutritional content, particularly with regard to protein, provides nutritional support to forestall complications in malnourished elderly people as indicated by Drommer et al. [26].

Concerning the positive effect of brioche consumption on plasma vitamins (vitamins $B_2$, $B_6$, $B_9$, $B_{12}$, and D status) and homocysteine status, these results are consistent with the study by Manders et al. [27], who found a statistically significant beneficial effect of a nutrient-enriched drink on plasma vitamin status (vitamins $B_6$, $B_9$, $B_{12}$, and $D_1$, homocysteine status) and the study by Abizanda et al. [28] or Bauer et al. [24], who observed increased levels of vitamin D after the ingestion of ONS.

Thanks to participatory research, the development of brioche suited to the preferences of the elderly fostered very good compliance. Effectively, the significant improvement in intake and nutritional status could be explained by several points. First, the brioche was designed for and by elderly people over 65 years whether they lived at home, in a nursing home or in hospital [14]. Special attention was paid to creating a product that was suitable for old people given the alterations in their senses of smell and taste and their eyesight. We also wished to create a true food rather than a supplement: it has a special long baguette shape, a golden brown colour, with three different flavours and is easy to chew. Several studies, including studies in nursing homes, have reported the interest of adopting flavour-enhancement strategies to compensate for the decline in food intake in elderly people [29,30]. Another point could be linked to the soft texture of brioche. In our study, half of the elderly residents presented a poor dental status and easy mastication possibly contributed to good aroma release; texture and flavour being both significant drivers of food intake [31]. Finally, the amount of fat in the brioche could be a further explanation. Indeed, it has been shown that pleasant-flavoured oral fat, as represented in the brain via neural mechanisms, plays a potentially important role in appetite and eating behaviour [32].

Limitations of the study include the fact that participants consumed the experimental products only at breakfast. In France, breakfast usually has the same composition throughout an adult's life, and even though compliance was good, it was sometimes difficult to change the food habits of our elderly people. It might have been better to give the residents the opportunity to choose when to eat the products. Another limitation was the lack of information about comorbidities among participants. This information could have given indications about factors that influenced food behaviour.

The lack of any improvement in functional capacities in the brioche group was another limitation. The additional protein intake was not compensated for but remained insufficient to increase muscle strength as indicated in major studies with protein-enriched foods [10,11].

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**Table 4**
Evolution of nutritional status at two different time points of the nutritional intervention in each group (n).

| | | Brioche group (n = 29) | | Supplement group (n = 17) | | Control group (n = 22) | | One-way ANOVA P value |
|---|---|---|---|---|---|---|---|---|
| | | | T test P value | | T test P value | | T test P value | |
| Plasma Albumin (g/L) day 0 | [mean, (SD)] | 38.1 (4.1) | | 37.5 (2.4) | | 38.7 (2.9) | | *0.605* |
| Plasma Albumin (g/L) day 90 | [mean, (SD)] | 38.2 (3.3) | 0.815 | 37.0 (1.9) | 0.396 | 38.0 (3.2) | 0.266 | *0.424* |
| Plasma Prealbumin (mg/L) day 0 | [mean, (SD)] | 246.2 (75.8) | | 231.2 (32.2) | | 237.7 (48.3) | | *0.695* |
| Plasma Prealbumin (mg/L) day 30 | [mean, (SD)] | 258.8 (65.9) | | 234.7 (40.1) | | 243.2 (39.9) | | *0.297* |
| Plasma Prealbumin (mg/L) day 90[μ] | [mean, (SD)] | 244.1 (81.5) | | 212.9 (53.2) | | 226.8 (48.3) | | *0.289* |
| CRP (mg/L) day 0 | [mean, (SD)] | 9.1 (12.2) | | 7.6 (6.8) | | 5.7 (5.7) | | *0.442* |
| CRP (mg/L) day 90 | [mean, (SD)] | 8.2 (15.1) | 0.786 | 12,2 (18.8) | 0.305 | 7.0 (7.4) | 0.309 | *0.518* |
| Homocysteine (nmol/mL) day 0 | [mean, (SD)] | 24.6 (17.2) | | 18.6 (5.9) | | 20.4 (5.1) | | *0.220* |
| Homocysteine (nmol/mL) day 90 | [mean, (SD)] | 19.2 (8.5) | **0.024** | 16.7 (5.7) | **0.046** | 21.7 (6.1) | 0.163 | *0.103* |
| Vitamin B9 (ng/mL) day 0 | [mean, (SD)] | 5.4 (2.3) | | 5.9 (3.7) | | 4.3 (1.7) | | *0.123* |
| Vitamin B9 (ng/mL) day 90 | [mean, (SD)] | 9.9 (3.4) ***a*** | **<0.001** | 6.7 (4.7) ***b*** | 0.067 | 4.4 (2.1) ***b*** | 0.666 | ***<0.001*** |
| Vitamin B12 (ng/L) day 0 | [mean, (SD)] | 288.5 (112.7) | | 284.1 (123.4) | | 346.7 (107.2) | | *0.170* |
| Vitamin B12 (ng/L) day 90 | [mean, (SD)] | 329.5 (102.6) | **0.036** | 275.1 (126.8) | 0.158 | 302.6 (97.7) | **0.009** | *0.314* |
| Vitamin B1 (nmol/L) day 0 | [mean, (SD)] | 149.2 (36.9) | | 147.5 (42.8) | | 138.0 (35.2) | | *0.561* |
| Vitamin B1 (nmol/L) day 90 | [mean, (SD)] | 139.1 (30.9) | 0.181 | 157.4 (37.7) | 0.345 | 129.7 (40.6) | 0.237 | *0.065* |
| Vitamin B2 (nmol/L) day 0 | [mean, (SD)] | 321.7 (49.9) | | 339.6 (56.7) | | 303.8 (59.2) | | *0.135* |
| Vitamin B2 (nmol/L) day 90 | [mean, (SD)] | 472.1 (100.2) ***a*** | **<0.001** | 380.4 (95.5) ***b*** | 0.135 | 400.2 (107.5) ***ab*** | **<0.001** | ***0.007*** |
| Vitamin B6 (nmol/L) day 0 | [mean, (SD)] | 84.5 (33.9) | | 75.6 (21.0) | | 67.1 (20.3) | | *0.090* |
| Vitamin B6 (nmol/L) day 90 | [mean, (SD)] | 105.7 (46.7) ***a*** | **0.026** | 86.5 (19.5) ***a*** | **0.033** | 60.7 (18.6) ***b*** | 0.081 | ***<0.001*** |
| Selenium (μg/L) day 0 | [mean, (SD)] | 77.5 (30.3) | | 63.2 (15.8) | | 68.7 (17.4) | | *0.125* |
| Selenium (μg/L) day 90 | [mean, (SD)] | 79.6 (20.8) ***a*** | 0.487 | 61.7 (13.1) ***b*** | 0.426 | 63.5 (16.8) ***b*** | **0.002** | ***<0.001*** |
| Vitamin D1 (ng/mL) day 0 | [mean, (SD)] | 12.4 (9.2) | | 12.2 (8.6) | | 13.7 (14.9) | | *0.910* |
| Vitamin D1 (ng/mL) day 90 | [mean, (SD)] | 18.2 (10.0) | **<0.001** | 12.0 (6.4) | 0.893 | 12.7 (12.5) | 0.309 | *0.074* |
| BMI (kg/m$^2$) day 0 | [mean, (SD)] | 29.11 (7.1) | | 24.82 (6.4) | | 28.06 (5.8) | | *0.104* |
| BMI (kg/m$^2$) day 90 | [mean, (SD)] | 29.06 (7.3) | 0.826 | 25.04 (6.8) | 0.443 | 27.94 (6.2) | 0.487 | *0.161* |
| MNA day 0 | [mean, (SD)] | 21.07 (2.9) | | 19.87 (3.5) | | 21.78 (2.8) | | *0.211* |
| MNA day 90 | [mean, (SD)] | 20.86 (2.5) | 0.552 | 20.20 (3.2) | 0.644 | 22.07 (2.9) | 0.614 | *0.153* |
| Grip strength (kg) day 0 | [mean, (SD)] | 14.69 (7.5) | | 15.66 (11.5) | | 14.31 (6.6) | | *0.903* |
| Grip strength (kg) day 90 | [mean, (SD)] | 13.80 (7.9) | 0.051 | 14.50 (12.1) | 0.200 | 12.88 (5.4) | **0.007** | *0.695* |
| ADL score (/6) day 0 | [mean, (SD)] | 3.10 (1.9) | | 2.40 (1.6) | | 3.59 (1.8) | | *0.161* |
| ADL score (/6) day 90 | [mean, (SD)] | 2.96 (1.8) | 0.526 | 2.13 (1.7) | 0.262 | 3.45 (1.9) | 0.378 | *0.107* |
| IADL score (/8) day 0 | [mean, (SD)] | 1.06 (1.2) ***b*** | | 1.06 (0.7) ***b*** | | 1.86 (1.1) ***a*** | | ***0.028*** |
| IADL score (/8) day 90 | [mean, (SD)] | 0.86 (1.0) ***b*** | 0.136 | 0.93 (0.7) ***b*** | 0.164 | 1.77 (1.1) ***a*** | 0.328 | ***0.004*** |

Data are mean ± SD.
The bold p values indicate significant differences; the italic p values result of One-way ANOVA.
Different letters show significant differences by One-way ANOVA.
[μ] Differences by linear mixed model including period effect.

Finally, our participants did not gain weight. Recently, Pouyssegur et al. [22] presented the results of study showing an increase in weight in the interventional group. In their study, participants consumed enriched cookies for 6 weeks (+244 kcal) and a persistent weight gain at 1 and 3 months after the end of the cookie consumption compared with the control group. The cookies in the Pouyssegur's study [22] provided more calories than our brioche, but the period of consumption was shorter. For us, a 12-week follow-up was necessary to observe differences between the groups in both dietary intake and nutritional status. It is important to note that the participants' intra-individual differences in food intake were high, which could explain the findings concerning the increased energy intake and the stability in body weight.

The effect of the brioche was superior to that of the ONS for food intake and for different blood parameters (B9, B2 and Selenium). Supplementation with brioche produced consistent increase in protein intake in elderly people. There may also be a beneficial effect on complications and mortality, which needs to be studied. Further research is now necessary to determine whether a longer-term use of these products will also result in better clinical outcomes and better quality of life.

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## 5. Conclusion

In conclusion, the enriched brioche is a particular innovation from two points of view: first, it has an energy density of 2.8 kcal/g compared with the majority of oral/creamy supplements, which usually provide only 1 kcal/g or 1 kcal/mL, and rarely more than 2 kcal/g. ONS thus require consumption of a large volume. Secondly, unlike most oral supplements, which are milky, our brioche is one of the rare supplements in the form of a fortified food to be included in the usual diet. These results suggest that the enriched brioche could be considered a staple food and is perfectly able to forestall the onset of malnutrition in institutionalised elderly people. It could be a good alternative to oral liquid nutritional supplements or a good additional supplement in association with oral dietary supplements.

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## Author contributions

**Virginie Van Wymelbeke:** Study concept, study design, study conduction, acquisition of subjects and data, Statistical analysis, interpretation of data, writing the manuscript.

**Laurent Brondel:** data analysis, revising critically for important intellectual content.

**Francis Bon:** acquisition of data, data collection.

**Isabelle Martin-Pfitzenmeyer:** revising critically for important intellectual content.

**Patrick Manckoundia:** Study design, revising critically for important intellectual content.

All authors read and approved the final manuscript.

## Conflict of interest

Authors have no conflict of interest and all have been actively involved in the research project.

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