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FERMENTED CEREAL WITH SPECIFIC BIFIDOBACTERIA NORMALIZES BOWEL MOVEMENTS IN ELDERLY NURSING HOME RESIDENTS. A RANDOMIZED, CONTROLLED TRIAL

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Abstract: *Objective:* To assess how fermented oat drink with two selected Bifidobacterium longum strains influences bowel movements among elderly nursing home residents. *Design:* A randomized, double-blind, placebo-controlled trial. *Setting:* 12 wards in two nursing homes in Finland. *Participants:* 209 residents *Intervention:* Wards were randomized to receive daily a fermented oat drink with 1) 10^9 CFU/day Bifidobacterium longum strains or 2) 10^9 CFU/day Bifidobacterium lactis Bb12 or 3) without viable bacteria (placebo) for 7 months. *Measurements:* Regularity of bowel movements (no movements or functioning) and consistency of stools (normal, soft or diarrhoea) were recorded for each resident on a daily basis. *Results:* The fermented oat drinks were well taken by the subjects, compliance being 85%. The groups receiving active products had more frequent bowel movements than did the placebo group (B. longum group normal functioning 28.5% of follow-up days, B.lactis group 26.9%, and placebo group 20.0%, respectively). The differences between the B. longum and the placebo group (mean 7.1, 95% CI 2.3 – 11.9, p=0.004) and between the B.lactis group and the placebo (mean 6.7, 95% CI 2.5 – 10.9, p = 0.002) were significant even when diarrhoea and constipation in the 3 months prior to the study were used as covariates. *Conclusions:* It is possible to normalize bowel movements in frail nursing home residents with natural food supplies consisting of probiotics (B.longum or *B. lactis*).

Key words: Probiotics, bifidobacteria, bowel movements, constipation, nursing home.

Introduction

Chronic constipation is a common problem among the institutionalised elderly. Constipation has been defined as bowel movements every four days or less frequently (35-36). According to several descriptive studies about half of nursing home residents suffer from constipation (1-3). Several studies have shown that 56-75% of all nursing home residents regularly take laxatives or stool softeners (4-7) despite limited evidence of their effectiveness (8) and their side-effects (6, 9). In addition, non-infectious and infectious diarrhoea often occurring with faecal incontinence is a prevalent symptom among nursing home residents (10, 11). The expenses involved in management of bowel symptoms is significant in nursing homes, staffing costs mainly accounting for them (12).

Significant intestinal microbiota alterations have been reported among the elderly with potentially important clinical consequences related to bowel regularity and intestinal infections (13-14). Culture-based methods assessing the human intestinal microbiota demonstrate changes in microbial composition in old age (15). The defining factors in microbiota composition and fluctuation in old age are largely unknown. Specific species such as bifidobacteria, which are regarded as key members of a healthy and protective intestinal microbiota, have been reported to decline in concentration in old age (16) and some support for the conception is offered by recent studies using molecular methods (17). Bifidobacteria in general have been reported to be important for the gut and gut health during all phases of life (18).

Probiotics are living microorganisms which, when administered orally, are of benefit to human health (19-20). All are non-pathogenic bacteria often normally present in the healthy human intestine, for example lactobacilli, bifidobacteria or enterococci (20). Several studies have yielded promising results concerning the health effects of probiotics. Some are reported to exert favourable effects in alleviating infections (21) or allergy (22). Selected probiotics been shown to promote Helicobacter pylori eradication (23-24).

In addition, specific probiotics are known to have favourable effects in shortening the gut transit time among healthy volunteers (25) and normalizing bowel movements in infectious or antibiotic-associated diarrhoea (14, 26). Therefore, the probiotics may prevent both constipation and diarrhea. By reason of their assumed health-promoting activities bifidobacteria are commonly used as probiotics, and enhancement of bifidobacteria in the intestinal content has been considered beneficial (18). However, few studies have attempted to clarify the impact of bifidobacterial supplementation on the gut health of elderly subjects.

We therefore have selected, isolated and characterized

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bifidobacteria from very old healthy subjects who have remained healthy without any known gastrointestinal diseases. Specific strains were then selected to adhere well to the human intestinal tract and specifically to the mucus isolated from elderly subjects thus facilitating longer contact with the intestinal mucosa. These strains have been further characterized as members of the normal healthy intestinal microbiota. They have also been administered to healthy subjects and have been demonstrated to be well tolerated and safe in human use (27).

This study was based on the finding that a decrease in the number of bifidobacteria in elderly subjects and concomitant changes in the other microbiota potentially predispose the elderly to constipation and gastrointestinal and other infections (13, 15). The aim now was to administer two selected Bifidobacterium longum strains in a fermented oatmeal product to elderly nursing home subjects, the objective being to characterize their impact on bowel movement regularity, use of laxatives and the incidence of diarrhoea in a ward setting.

Subjects and methods

Setting and participants

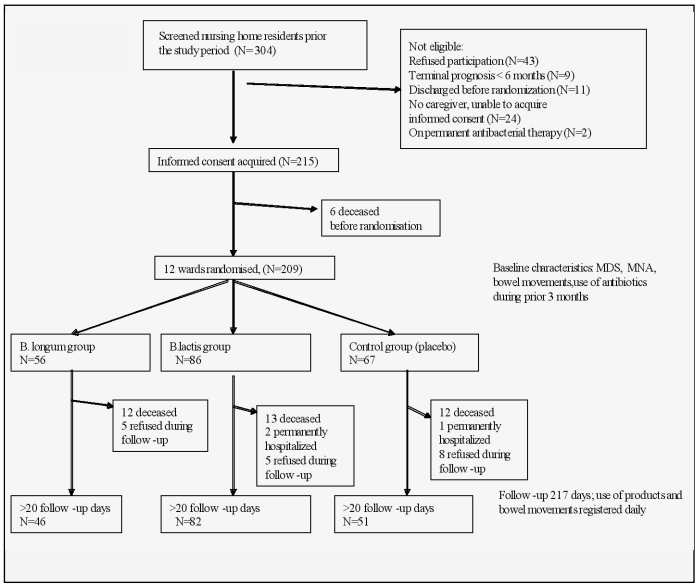
The study was approved by the Helsinki University Hospital Ethical Committee and Helsinki City. The study population was selected from two nursing homes in the Helsinki area. Altogether 209 elderly residents in 12 wards were selected. Written informed consent was required from the subjects or their next of kin, if the resident could not give informed consent by reason of impaired cognition. Impaired cognition was defined as scoring less than 20 in the Minimental State Examination /MMSE) (28) or showing moderate or severe impairment in cognition according to the Minimum Data Set (MDS) (MDS scores > 3) (29-30). The only exclusion criteria for participation were that the participant had an estimated prognosis less than 6 months or he/ she was on long-term antimicrobial therapy. However, those on urinary tract antimicrobial prevention therapy (low-dose trimethoprim or metemamiohippurate) were included.

Design and randomization

The design was a randomized, double-blind, placebo-controlled intervention study, in which the wards were randomly allocated to three groups at baseline. We randomized wards instead of individual subjects to avoid ethical problems and mixing of the treatment between subjects as well as to ensure compliance. These subjects cannot cooperate properly, they may take each other's food and mix up the drinks. In addition, by giving the same drink to the whole ward irrespective whether they participated the trial or not we avoided interference between study subjects and other residents and ethical problems related to inequality.

The wards selected for this study were all familiar with the MDS since 2001; the nurses were trained in the proper use of the MDS and they performed regular semi-annual assessments to complete individual care planning (30). The forms comprise approximately 400 questions and the data provide standardized information, among other things residents' age, gender, dementia stage, health profile including diagnoses, and various symptoms, physical and mental disability. In addition, the internationally well-validated scales constructed from the items in the MDS questionnaire provide a comprehensive description of the case-mix of the wards (31-34). MDS gives the patient profile, often called "case mix". These may be "psychogeriatric", physically disabled" or "cognitively impaired". MDS also gives the mean level of residents' need for assistance etc. After identifying the case-mix in each of the wards, the wards were divided into group of three having approximately the same characteristics. These triplets were further randomized by block randomization techniques into three groups to receive daily one of the three products described below. This randomisation techique was applied to achieve balance of these important characteristics between study groups. Randomization was performed by means of computer-generated random numbers. The study nurse contacted a randomization staff member not familiar with the wards, residents or their records, who assigned the number from the computer and the group assignments to the ward. Owing to the diverse sizes of the wards and the differing proportions of residents consenting to the trial, the randomized groups were somewhat different in size (Figure 1.).

Figure 1
Design and randomization of the study



Intervention

According to the study protocol Group 1 received daily a fermented oat drink (200 mL) with study Bifidobacteria longum (B.longum 46 and 2C) at levels of 10^9 CFU/day, Group 2 daily a commercial Yosa® fermented oat drink (200 mL)

with Bifidobacterium lactis Bb12 at levels of 10^9 CFU/day, and Group 3 daily a pasteurized fermented oat drink (200 mL) without viable bacteria (placebo). The study products were manufactured by Bioferme Ltd, (Kaarina, Finland). All study products were in identical yellow packages with only the group number distinguishing them from each other. The appearance and taste of all three products were identical. The drinks were given to the residents in between the main meals. Otherwise, the residents were given the same food and the diets were kept as before the trial.

Assessments

The baseline characteristics of study participants in respect of bowel movements, constipation, diarrhoea, and other intestinal problems were recorded for the three months prior to randomization. Constipation during the previous three months was defined as bowel movements every four days or less frequently (35-36). Infections, antibiotic treatments and use of probiotics (usually lactobacillus-containing products) during these three months were recorded. Special diets were retrieved from residents' records. All other probiotics were interrupted for the study period.

All participants were interviewed and assessed at baseline and at 6 months. This included assessment of nutrition by Mini-Nutritional Assessment (MNA) (37), of cognition using the Cognitive Performance Scale (29), ADL functioning using the hierarchical ADL scale (38), and depression using the Depression Rating Scale (39) embedded in the MDS. All active diagnoses were retrieved from patients' records as well as their demographic data and use of medications.

The ward nurses followed and recorded the residents' bowel movements and their consumption of the drinks. Before the study began all the ward nurses received a one day training which included the rationale for the study, the follow-up methods, what to do in case of unreliable follow-up, and how to ensure the compliance of drink consumption. The ward nurses filled up two separate lists for each subject: one for the drink comsumption and one for the bowel movements. The study nurse visited each ward once a day to ensure reliable data. She collected the lists once a week and recorded them to the database immidiately.

Participants' compliance in consuming the study product was followed up on a daily basis (consumed completely or almost completely / about half of the product consumed / a little or none consumed). Since each participant was offered one 200ml drink/day, consumed drinks and compliance were counted as follows:

"Consumed drinks during the study period" = "Completely consumed" + 1/2 x "about half of the product consumed"

Compliance (%) = 100 x "consumed drinks during the study period" / reliable follow-up days.

Bowel movements were recorded daily as follows: 1. functioning normally with solid or normal consistency of stools (N), 2. functioning a little with solid or normal consistency of stools (L), 3. not functioning (NO), 4. functioning with soft stools (S) and 5. functioning with diarrhoea (D). Days with more than one defecation were summarized as follows:

D, if diarrhoea at least once during that day,

S, if soft tools at least once but no diarrhoea during that day, and

N, if solid or normal stools at least once, but no soft stools or diarrhoea during that day.

The total number of follow-up days of bowel functioning was counted as = "N" + "L" + "NO" + "S" + "D".

Since many residents were discharged to hospitals or visited their relatives during the follow-up period, the number of follow-up days varied from one participant to another. In addition, some residents with dementia may have used toilets independently and could not always be reliably followed, and some follow-up days were thus missed. We therefore also analyzed the days with verified follow-up and divided both compliance days and bowel function days by the reliable follow-up days.

The study products were administered and follow-up of bowel movements continued for altogether 217 days. A special study nurse devoted solely to the study tasks was a member of the study team to conduct assessments and interviews as well as register and follow consumption of the test products and control the follow-up of the residents' bowel movements.

The regular use of laxatives were recorded during the study. Laxatives were classified as bulk laxatives, osmotic agents, and stimulant laxatives. The following laxatives were used: seeds of plantago ovata (bulk laxatives), senna, bisacodyl, and sodium picosulfate (stimulant laxatives), saline laxatives, polyethylene glycol '3350', lactulose, and lactitol (osmotic agents). A resident was classified as a laxative user if she, according to her medical chart, was regularly receiving laxatives.

Statistics

The sample size was originally defined on the basis of feasibility at about 200 participants. This sample size makes it possible to detect a difference of 25% in proportions of participants having bowel functioning >30% of days (definition for normal functioning) (35-36). According to several studies about 60% of institutionalized aged residents suffer from constipation (1, 3, 7). It was assumed that with bifidobacteria the proportion of subjects with normal bowel functioning may be increased from 40% to 65%. With a type 1 error of 5% and power of 80% to detect this difference, we counted that a sample size of 62 participants /group is needed to detect this clinically significant difference.

Data were coded in the Microsoft Access program and analyzed by the NCSS for Windows statistical program (www.ncss.com) and SPSS for Windows. Participants in the three groups were compared at baseline by Chi-square test for categorical variables and analysis of variance for continuous

variables. The Kruskall-Wallis test was used to test differences between continuous variables which were not normally distributed.

All randomized participants were analyzed in their original groups irrespective of whether they consumed their oat drinks or not (intention-to-treat analysis). The bowel movement analyses included all those participants for whom at least 21 reliable follow-up days were recorded. As colonization with probiotics has been demonstrated within two to three days, 21 days was considered long enough period to show the effect of probiotics on bowel movements and to achieve reliable estimates of the end-point variables. Differences between the groups with respect to the continuous dependent variables were compared by analysis of variance (ANOVA). In addition, due to the minor differences at baseline, the differences between the groups were assessed by means of analysis of covariance (ANCOVA) with baseline constipation and diarrhoea as dichotomous covariates, as baseline constipation and diarrhoea were considered as strong prognostic factors, with minor differences at baseline. Fisher's LSD test was used for paired comparisons, and differences between groups are given with means and 95% confidence intervals. The Chi-square test was used for unadjusted analysis with respect to the dichotomized variables and logistic regression analysis was used to compare B.longum and B.lactis to placebo, respectively. Baseline constipation and diarrhoea were included as dichotomous covariates and the results are given as odds ratios (OR) with 95% confidence intervals.

Results

The groups were well balanced at baseline (Table 1.). The mean age of participants was 84 years (range 61-102) and 82% were females. According to the CPS 45% of the participants suffered from severe dementia and 21% were dependent or totally dependent in the activities of daily living according to the ADL hierarchy scale. About 38% were malnourished according to the MNA; 24 % had suffered from diarrhoea during the three months prior to the study. There were no significant differences between the groups with respect to baseline characteristics.

The follow-up of compliance in consuming the fermented oatmeal drinks shows that fermented oatmeal products were well accepted by the participants. During the reliable follow-up days 85% of the drinks were consumed. However, in compliance there was a significant difference between the study groups (78% in placebo, 84% in B. longum group and 91% in *B. lactis* Bb12 group, p=0.003). The compliance was at least 80% in 64% of subjects in placebo group, in 79% in B.longum and in 88% in B.lactis Bb12 group.

Both the B.longum and the *B. lactis* Bb12 product had a significant effect in normalizing participants' bowel movements (Table 2.) when compared to the placebo with no viable bacteria. The percentage of days with normal bowel movements was higher among subjects in the B.longum group (mean 28.5, SD 13.1) than among the subjects receiving placebo (mean 20.0, SD 10.9). The difference between these

Table 1
Characteristics of the nursing home residents at baseline

Variable	Group on B. longum product (N=56)	Group on *B. lactis* product (N=86)	Group on placebo product (N=67)
Mean age (range), years	84.7 (65-102)	83.9 (65-99)	84.7 (61-99)
Females (%)	88.5	82.6	74.2
Education, ≤primary school (%)	56.4	58.2	52.0
MDS cognition – severe dementia (CPS >3), (%)	50.0	41.6	45.3
MDS – ADL, 5-6 (%)	25.9	16.9	20.3
MDS –depression (%)	33.3	20.8	28.1
Nutrional status according to MNA (%)			
malnutrition, <17p	34.6	36.0	41.9
at risk of malnutrition, 17-23,5 p	59.6	57.0	58.1
well nourished, >23,5p	5.8	7.0	0
Mean BMI (SD), kg/m^2	22.4 (4.4)	23.0 (4.5)	22.7 (4.7)
Diarrhoea during the previous 3 months (%)	20.4	27.7	22.0
Constipation during the previous 3 months (%)	27.5	23.8	20.2
Vomiting during previous two weeks (%)	4.2	0.0	6.6
Proportion using laxatives	77.4	70.9	73.1
Dementia	88.2	90.2	86.9
Ventricular or duodenal ulcer	1.9	3.5	0.0
Chronic bowel disease	3.8	4.7	3.2
Prior cancer	9.8	11.6	8.1

1. The differences between groups were nonsignificant for all variables

Table 2

Bowel movements during the study period. Only those participants having >20 follow-up days were included in the analyses.

		B.longum (n=46)	*B. lactis* (n=82)	Control (n=51)	ANCOVA[1]	Pairwise comparisons	Mean	95% CI	p-value
Defecation	Mean	38.8	36.0	30.6	p=0.042	B.longum vs control	6.7	1.0 to 12.4	0.021
(% of days)	Median	34.3	34.4	29.9		B.lactis vs control	5.2	0.3 to 10.2	0.038
	SD	15.3	13.1	14.4		B.longum vs B.lactis	1.5	-3.7 to 6.6	0.574
	Min-Max	10.3-77.0	7.1-68.5	0.0-64.9					
Normal bowel	Mean	28.5	26.9	20.0	p=0.003	B.longum vs control	7.1	2.3 to 11.9	0.004
movements	Median	27.6	25.4	18.0		B.lactis vs control	6.7	2.5 to 10.9	0.002
(% of days)	SD	13.1	11.1	10.9		B.longum vs B.lactis	0.4	-4.0 to 4.8	0.862
	Min-Max	1.6-62.0	3.6-61.2	0.0-61.4					
Diarrhoea or	Mean	5.4	5.4	6.5	p=0.585	B.longum vs control	-1.0	-3.7 to 1.8	0.480
loose stools	Median	2.9	2.7	4.4		B.lactis vs control	-1.2	-3.6 to 1.2	0.309
(% of days)	SD	7.3	6.7	6.7		B.longum vs B.lactis	0.3	-2.2 to 2.7	0.843
	Min-Max	0.0-34.9	0.0-29.4	0.0-28.6					

1. Analysis of covariance (ANCOVA). The baseline diarrhoea and constipation were used as dichotomous covariates.

Table 3

The effects of B.longum and B.lactis on bowel movements. Results are based on logistic regression analysis, where the baseline diarrhoea and constipation were used as dichotomous covariates. Only those participants having >20 follow-up days were included in the analyses (B.longum n=46 and *B. lactis* n=82 and Control group n=51)

Dependent dichotomous variable	Group	N (%)	OR[1]	95% CI	p-value
Bowel movements	Control	25 (49)	1.00		
at least 30% of days	B.longum	32 (70)	2.51	1.02 to 6.16	0.044
	B.lactis	48 (59)	1.55	0.73 to 3.28	0.253
Normal [2] bowel movements at least 30% of days	Control	7 (14)	1.00		
	B.longum	17 (37)	3.44	1.22 to 9.70	0.020
	B.lactis	25 (30)	2.75	1.07 to 7.07	0.036
Diarrhoea	Control	19 (37)	1.00		
at least 5% of days	B.longum	13 (28)	0.62	0.25 to 1.58	0.319
	B.lactis	22 (27)	0.62	0.28 to 1.37	0.239
Diarrhoea	Control	42 (82)	1.00		
at least once	B.longum	36 (78)	0.76	0.26 to 2.22	0.621
	B.lactis	56 (68)	0.46	0.18 to 1.13	0.090

1. Reference group = Control group; 2. Functioning normally with solid or normal consistency of stools

groups was significant even when baseline diarrhoea and constipation were used as covariates (mean difference 7.1, 95 % CI 2.3 – 11.9, p=0.004). In addition, the bowel movements of subjects receiving *B. lactis* Bb12 were more frequent (mean 26.9, SD 11.1) than those of subjects receiving placebo (mean difference 6.7, 95 % CI 2.5 – 10.9, p=0.002).

There was no significant difference between the groups in respect of diarrhoea or soft stools. Of subjects receiving B. longum, 28.3% had diarrhoea ≥5% of the follow-up days; of those receiving *B. lactis*, 26.8% had diarrhoea, and the corresponding figure for the placebo group was 37.3% (p=0.421). However, in normal bowel movements the groups differed significantly. In the B.longum group 37% of participants had normal bowel movements at least 30% of the days, while in the *B. lactis* and the placebo groups the respective figures were 30.5% and 13.7% (p=0.026). For all these variables the differences between B.longum and B.lactis were non-significant.

Using logistic regression analysis the active treatment groups B.longum and B.lactis were further compared to the control group (Table 3). The treatments with B.longum and B.lactis increased normal bowel functioning. The adjusted odds ratios for normal bowel functioning were 3.44 (95% CI 1.22 to 9.70, p=0.020) in the B.longum group and 2.75 (1.07 to 7.07, p=0.036) in B.lactis.

The regular use of laxatives during the study period did not differ between the groups. Of the group receiving the test product B.longum, 76.8% used laxatives while the respective

figures for the group receiving *B. lactis* Bb12 and the placebo group were 67.4% and 77.6%.

Discussion

The subjects receiving the B.longum product and the *B. lactis* Bb12 product had more frequent bowel movements that did those receiving placebo. Our trial was blinded. Therefore, the results could not be biased by nurses or study personnel. Those receiving the product with either of the bifidobacteria had bowel movements on the average more frequently than every fourth day. No increase in diarrhoea was observed within these groups. Although the use of laxatives did not differ between the groups, this study effect may have favourable implications for the workload of staff in nursing homes as well as for the quality of life of elderly residents.

Our finding that probiotics may normalize bowel movements is in line with those in some previous studies (25-26,40). However, the findings in previous studies are inconsistent (41-42) possibly due to lesser statistical power and the use of different probiotic strains. In any case, our study is the first to investigate the effects of probiotics among frail, insitutionalized elderly residents. Among them constipation is a major problem worsening the quality of life and causing a significant workload for the personnel in these institutions (1-3,12). Thus, means of normalizing bowel movements – with or without laxatives – may have favourable effects on both the quality of life of elderly residents and the workload of the staff.

Our participants represent a typical nursing home population in which high age, multiple comorbidities, dementia, impaired nutritional status and disabilities are common. Symptoms in the gastrointestinal tract are common among aged residents, as shown in previous studies (3). There are several risk factors for constipation, among them drinking too little (3), problems in locomotion (3) and receiving too little fiber and energy (43). In our intervention all participants received additional fiber, since the placebo drink also contained the same amount of oat fiber. However, the groups receiving either bifidobacteria showed more frequent bowel movements, suggesting that the bifidobacteria are responsible for normalizing bowel functioning.

There are several limitations in our study. This is a challenging study population as many participants die during the study, they fall ill and are admitted to hospitals, they visit their relatives in between and are therefore not available for assessments at the ward. In addition, most residents are severely cognitively impaired which limits their cababilities to cooperate and to comply with the study regulations. The compromises related to completeness of the data and randomising the wards instead of individuals are unavoidable when this kind of populations are to be studied. Thus, randomised intervention studies on very frail nursing home patients are still very rare.

Due to the population structure some bowel movements may have escaped our control and registration as some subjects may have used the toilet independently. Suffering from dementia they could not always comply in informing the staff each time their bowel functioned. The follow-up can never be complete in this kind of population. The average number of reliable follow-up days for the bowel movements were: 1. Bifido longum: 176 days (mean 88% of those days subject was in the ward) 2. Bifido lactis: 171 days (mean 87% of those days the subject was in the ward) and 3. Placebo: 152 days (mean 72% of days subject was in the ward). The respective figures for the drink consumption were: 1. Bifido longum: mean 88% of days subject resided in the ward 2. Bifido lactis: mean 89% of those days the subject was in the ward and 3. Placebo: mean 79% of days subject was in the ward. There was a significant difference in the follow up days between the groups. We therefore performed our analyses in a rather conservative manner taking into account only those days for which there were notations on functioning/non-functioning. The placebo group had more days without any recordings of bowel movements. Our estimate that the bowel functions more frequently with a bifidobacteria product than with placebo product is thus rather an underestimate than an overestimate of the true situation. It is much easier to confirm bowel movements when they take place than reliably confirm that they have not occurred.

Compliance in consuming the study drinks was very good considering that many aged residents usually eat only half of the portion offered them (3). These products should thus be easy to administer if they are to be implemented as health-promoting food supplies for this kind of populations.

According to culture-based methods the human intestinal microbiota is altered in composition in old age, with significant decreases in bifidobacteria compared to younger subjects (15). This may be associated with decreased diversity of the microbiota, leading to intestinal infections and altered bowel movements. Our study is the first to approach this phenomenon by supplementation using fermented oat-based products with bifidobacterial strains selected for adherence properties in the intestinal mucus of the elderly. The results demonstrate an impact on bowel movements and regularity. The exact mechanisms involved need to be characterized, but the observed clinical effects certainly warrant further studies to assess the impact on both bowel regularity and quality of life.

Conclusions

Randomized, controlled trials are still rarely perfomed among the frailest elderly patients, particularly among nursing home residents. According to our trial, it is possible to increase the bowel movements of frail elderly nursing home residents without increasing their diarrhea with natural food supplies consisting of specific probiotics (B. longum 2C and 46 or *B. lactis* Bb12). This may have favourable implications for staff workload as well as for the quality of life of elderly residents.

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