

**Improving the oral hEalth of oLder aDults using milk supplEmented with fluoRide and probiotics (*ELDER*): An interventional feasibility study and pilot RCT.**

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**Acknowledgement**

We would like to acknowledge Prof Christina Stecksen-Blicks for her invaluable contributions to the study design and her insightful feedback throughout the project. Her expertise and dedication were crucial to the work. Although Prof Christina Stecksen-Blicks passed away midway through the project, her influence and contributions remain a vital part of this research.

Dental caries, particularly root caries, remains a major global oral health problem among older adults, especially those living in care homes. This pilot feasibility randomised controlled trial (RCT) investigated the feasibility, acceptability and practicality of delivering milk supplemented with fluoride and/or probiotics as a preventive oral health intervention for care home residents. The study also explored preliminary clinical and microbiological outcomes to inform the design of a future definitive RCT.

The primary objectives were to assess participant adherence to and acceptability of the intervention, evaluate the practicality of implementation within the care home environment, and explore potential effects on primary root caries lesions (PRCL). Clinical outcomes were treated as exploratory endpoints, while microbiological measures served as surrogate indicators of caries activity. Ethical approval was obtained from the East of England – Cambridge East Research Ethics Committee and the Health Research Authority (#22/EE/0258).

The study employed a four-arm, parallel-group, double-blind, cluster randomised controlled feasibility design and was conducted in care homes in Northeast England. Care homes were randomly allocated to one of four intervention arms: (1) normal milk (control), (2) milk supplemented with fluoride (5.0 mg F/L), (3) milk supplemented with probiotics ( $10^7$  CFU/mL *Lactobacillus rhamnosus* LB21), or (4) milk supplemented with both fluoride and probiotics.

A total of 63 participants completed the study, representing a retention rate of 47% from initial consent and 62% from those who commenced the intervention. Attrition was largely due to factors common in this population, including death, health deterioration, DoLS restrictions, relocation, and loss of capacity or willingness to continue. Baseline demographic characteristics were broadly comparable across groups, although dentition status differed, with more dentate participants in the control and milk plus probiotic groups.

Adherence to the intervention was below the predefined threshold across all groups. Only 46% of participants consumed milk on more than 50% of intervention days. Despite limited compliance and small sample sizes, exploratory analyses indicated reductions in PRCL across all intervention groups, with the largest relative decrease (40%) observed in the milk supplemented with both fluoride and probiotics. No change was observed in the control group.

Overall, the study demonstrated that delivering supplemented milk in care homes is feasible but highlighted challenges related to retention and adherence. The preliminary findings suggest potential benefits of fluoride and probiotic supplementation, supporting the rationale for a larger, adequately powered definitive RCT.

The study has now concluded, and preparation of a manuscript for submission to a peer-reviewed journal is underway.

Conference presentations:

M Yasin, C Orr, S John, P Ajay, and FV Zohoori. Fluoride and Probiotics: Impact on Oral Microbiome in Older Adults in UK Care Homes. 72 Congress ORCA 2025.

S John, C Orr, M Yasin, C Yare, C Stecken-Blicks, FV Zohoori. Oral microbiome of adults in UK residential care homes: a cross-sectional analysis from an RCT. 71st Congress ORCA 2024