

Assessment of the SmartJournal intervention for improved oral care in nursing homes: an evaluation study

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None

1. Background

Poor oral health is common in frail and care-dependent older adults and includes tooth loss, poor oral hygiene, high prevalence of dental caries and periodontal disease, defective dental prostheses, hyposalivation and various oral lesions caused by misfitting dentures and/or precancerous or cancerous states [1,2]. Alarming, oral health is shown to be the most neglected area in Norwegian nursing homes [3] and oral healthcare is the first task to be downgraded due to lack of resources [4]. A study by Willumsen et al. [5] indicated that more than 40% of Norwegian nursing home residents have unacceptable oral hygiene. Neglect of oral health, resulting in poor oral hygiene, may cause infections and inflammation both locally and systemically. Oral infections have been associated with systemic conditions such as atherosclerosis [6,7], diabetes [8] and aspiration pneumonia [9,10]. Aspiration pneumonia is a highly mortal disease, and a review by Sjøgren et al. [11] estimated that 10% of all deaths from pneumonia in nursing homes could have been prevented with improved oral hygiene. Moreover, chewing difficulties as a result of poor dental status have been associated with altered dietary habits, malnutrition and cognitive decline [2]. Yet, the oral health of care-dependent elderly does not receive the necessary attention [12]. A few decades ago, most older adults were denture wearers. Today, an increasing number of elderly keep their natural teeth – often in combination with complex fixed and/or removable prosthesis [13]. While dentures are easy to manage, the more complex prosthetic devices can represent a challenge with regard to handling and cleaning [14]. Thus, care-dependent elderly have to rely on caregivers to maintain satisfactory oral health [15]. In Norway, nursing home residents (and other care-dependent people) have a statutory right to good oral hygiene and necessary dental treatment [16]. Health personnel are responsible for preserving these rights through daily oral hygiene routines and referral to dental professionals when needed. Research from Sweden and Denmark has shown that about 80% of nursing home residents need assistance with daily oral hygiene practices [15,17]. Thus, it is disturbing that healthcare professionals report numerous barriers when it comes to provision of adequate oral care assistance. The most frequently reported barriers are lack of knowledge and skills [18] and care resistant behaviors (CRB), in particular among patients suffering from dementia [18,19]. A study by Willumsen et al. [5] showed that more than 50% of Norwegian nursing home residents with dementia refuse oral care assistance. In cases of frequent CRB, daily oral care may be postponed repeatedly, resulting in poor oral hygiene and increased risk of oral and systemic infections. Other reported barriers include lack of adequate oral care routines, lack of systems for documentation of issues related to oral health [20,21], a high workload and unclear responsibilities [19].

Various tools have been developed to assist health personnel in providing oral care in frail elderly. One example is ‘oral care cards’ with illustrated instructions about how to carry out daily oral hygiene routines in individual patients. Another example is ‘signature lists’ to document daily oral care. These tools may function well but have some shortcomings. While oral care cards do not allow for documentation of oral health issues, signature lists do not contain information on individual needs. Moreover, text-based diagnostic tools such as the Revised Oral Assessment Guide (ROAG) [22] and the Oral Health Assessment Tool (OHAT) [23], have been developed to assist caregivers in recognizing oral conditions. However, research indicates that these tools may not be well suited for non-dental professionals [24,25].

Other limitations of the above-mentioned tools are that they lack procedures for documentation of deviance related to oral health, and that none of them include strategies for handling CRB.

1.1. SmartJournal

As a response to the shortcomings of existing tools, and to overcome reported barriers for provision of adequate oral care in nursing homes, an intervention tailored at nursing staff has been developed by researchers at the Oral Health Centre of Expertise in Rogaland, Norway, in close collaboration with innovative research- and development institutions, dental- and healthcare professionals. The intervention addresses key behavioural components as postulated by the capability, opportunity, motivation model of behaviour (COM-B model) [26]. According to the COM-B model, there must be sufficient capability (C), opportunity (O), and motivation (M) present for a given behaviour to occur. Hence, this intervention aims to facilitate oral care in nursing homes by providing strategies to improve caregivers' capability, opportunity and motivation for this task. The intervention is constructed as an interactive and easy-to-use mobile application for tablet named SmartJournal. SmartJournal consists of three modules: Module 1, 'registration of oral hygiene routines', offers a system for simple checkbox registration of daily oral hygiene routines (i.e., whether they have been performed or not). It also includes an open text field for additional comments if relevant (e.g., reasons for not performing oral hygiene routines and/or strategies used to reduce CRB in the patient). This straight-forward registration ensures documentation of oral hygiene routines and deviations related to such routines, keeping health personnel informed about potential oral hygiene issues for individual patients. Module 2, 'monthly oral health assessment', offers a system for monitoring the patient's oral health status through monthly check-ups. In this component, the principles of the text-based tool ROAG is transformed into an image-based, interactive learning- and assessment tool. As for ROAG, conditions for six oral sites (lips, mucous membranes, tongue, gingiva, teeth and prosthetic devices¹) are graded as follows: grade 1=healthy/normal condition, no need for measures; grade 2=pathology, need for measures at a 'local level' (i.e., at the nursing home, delivered by nursing home personnel); grade 3=advanced pathology, need for measures delivered by dental professionals (in the nursing home if feasible, at a dental clinic if necessary). SmartJournal contains several validated example pictures for each grade for all six oral sites. This part of the tool is also checkbox-based to limit health personnel's workload related to documentation. Upon completion of the monthly oral health assessment, health personnel receive a summary report with suggestions for tailored preventive and/or curative measures to be initiated, thus reducing the risk of deteriorated oral health in the patients. Module 3, 'e-learning', offers an easily accessible knowledge base which includes information on geriatric oral health, standard equipment and procedures for daily oral hygiene routines in patients with natural teeth and various prosthetic devices, and oral care for patients with special care needs (including patients with swallowing difficulties, bedridden patients and palliative care patients). It also includes detailed information on scientifically documented strategies that may be used to approach patients with dementia refusing oral care assistance. These strategies are adapted

¹ Prosthetic devices include all forms of removable dentures and fixed prosthodontics.

from the interventions ‘Managing Oral Hygiene Using Threat Reduction’ (‘MOUTH’) [27,28] and ‘Mouth Care Without a Battle’ (MCWB) [29]. The content in this part of the tool is illustrated with photos and figures and includes a video with recommendations on how to handle situations where patients refuse oral care assistance. Acceptability of the SmartJournal prototype has been tested in a feasibility study which has already been notified to, and approved by, the Regional Committee for Medical and Health Research Ethics (REK 2020/31294) and the Norwegian Centre for Research Data (NSD). Preliminary results from this study indicates that SmartJournal is well accepted among its users: According to survey data collected from caregivers employed at three nursing homes in Rogaland, Norway (n=86), 72% reported that SmartJournal is a useful tool, 94% reported that it is easy to use and 69% reported that they would like to use a refined version of the tool in the future.

2. Study objectives

Since SmartJournal seems to be well accepted among its potential users, the present study aims to evaluate *effects* of its usage. Thus, the objectives of the current research are to assess 1) the effectiveness of SmartJournal in enhancing nursing home caregivers' capability, opportunity, motivation and routines related to oral care tasks, 2) whether SmartJournal usage may result in improved oral health for nursing home residents and 3) whether SmartJournal usage may result in changes in the documentation of oral health related issues in patient journals.

3. Methods

3.1. Further improvement of the SmartJournal tool

Recently, SmartJournal has been further improved and adapted to the nursing home setting. Since user involvement is a central feature in the development of interventions [33], this improvement was guided by results obtained from the feasibility study (i.e., data acquired from meetings, qualitative interviews and survey questionnaires). Following this, the improved version was subjected to two functionality tests in a controlled laboratory environment. These tests were performed by Norwegian Smart Care Cluster (NSCC)². Insights gained through the functionality tests have been used for additional, minor adjustments of the tool, which is now ready to be tested in the evaluation study described in this protocol.

3.2 Design and recruitment

A pragmatic cluster randomized controlled trial (C-RCT) [34] will be employed to assess effects of SmartJournal usage as specified under study objectives. Public nursing homes located in the southern part of Rogaland county, Norway, will be recruited and randomly assigned to an intervention group and a control group. Institutions housing long-term residents will be included, while institutions with primarily short-term residents, institutions already following a specific protocol for oral care and/or participate in other comprehensive interventions are excluded. Nursing homes in the intervention group will be provided with

² NSCC: National and international collaboration arena for large and small companies, municipalities, hospitals, public organizations, user organizations, academia / R&D institutions and investors. The cluster works to develop sustainable health solutions for the future (<https://www.smartcarecluster.no/english/about-us>).

tablets containing SmartJournal, while nursing homes in the control group will continue with existing oral care routines. The intervention will last for 12 weeks. Measurements will be performed at baseline, 3 months and 9 months.

Strategies used for recruitment of individual participants (caregivers and residents), and procedures for delivery of the intervention, will be similar to those used in the feasibility study since they proved to be successful: resource groups, comprised of heads of wards and selected health personnel, will be established at each of the included nursing homes. Meetings will be scheduled to adapt delivery of the project to each individual institutions' resources and facilities, and members of the resource groups will be assigned the task of recruiting individual participants. Written informed consent will be requested for both residents and caregivers to be enrolled in the study. Nursing home residents constitutes a vulnerable group in which many individuals may have reduced decision-making capacity. For these individuals, deputy consent will be obtained from their next of kin. Residents receiving end-of-life palliative care are excluded. Both full- and parttime nursing staff will be included. Health personnel with purely administrative tasks (i.e., heads of institutions) are excluded. Following recruitment of participants and baseline measurements, nursing homes in the intervention group will be provided with SmartJournal toolboxes and packages with oral hygiene equipment, while nursing homes in the control group will receive oral hygiene equipment packages only. The SmartJournal toolboxes include tablets with SmartJournal installed, antibacterial touchscreen wipes, flashlights for monthly oral inspections, an instruction video, an instruction book and SmartJournal information posters. The oral hygiene equipment packages include toothbrushes for permanent teeth and prosthetic devices, dental floss, interdental brushes, toothpaste and inspection mirrors. Training, follow-up and technical support for SmartJournal users will be provided by project staff employed at the Oral Health Centre of Expertise Rogaland.

3.3 Measurements

The effectiveness of SmartJournal in enhancing nursing home caregivers' capability, opportunity, motivation and routines related to oral care tasks will be measured by a survey questionnaire capturing components of the COM-B model [26]. Caregivers in both the intervention- and the control group will be asked to fill out the survey questionnaire three times: at baseline, 3 months and 9 months.

Effects of SmartJournal usage on nursing home residents' oral health will be assessed using the mucosal-plaque score (MPS) (21) as a primary outcome measure. MPS is comprised of a four-point plaque score (PS) and a four-point mucosal score (MS). PS = 1: no visible plaque, PS = 2: plaque is barely visible, PS = 3: moderate amount of plaque, PS = 4: large amount of plaque almost covering the whole surface of teeth. MS = 1: normal mucosa, MS = 2: mild inflammation, MS = 3: medium inflammation, MS = 4: strong inflammation. For both scores, if in doubt between 1 and 2, dental personnel are instructed to score 1. If in doubt between 3 and 4, they are instructed to score 4. The index is designed to evaluate oral health and oral hygiene in groups of individuals. This makes it a suitable index to be used when conditions

are not optimal to assess the patient's oral health. In a nursing home setting, dental personnel have limited equipment and poor light compared to an ordinary dental clinic setting. Therefore, using an index designed to be applied outside a dental clinic setting is feasible in this context. Residents in both the intervention- and the control group will have MPS assessment at three times: at baseline, 3 months and 9 months. MPS assessments will be performed by dental professionals employed at the Oral Health Center of Expertise Rogaland, Norway. Calibration will be undertaken to ensure reliability of the clinical measurements.

Effects of SmartJournal usage on documentation of oral health related issues in patient journals will be measured both quantitatively (i.e., frequency of documentation) and qualitatively (i.e., qualitative assessment of documentation) at three times throughout the project period: at baseline, 3 months and 9 months. Additional journal data shown to be associated with oral health will also be retrieved and used to describe the study sample and to be included as covariates in statistical analyses. These data include socio-demographics, medical conditions and prescribed medication.

3.4 Power calculations and estimation of sample size for clinical outcomes

Experiences from the feasibility study show that resident participation may comprise a challenge due to high rates of morbidity, mortality and CRB in this part of the population. Estimation of sample size is largely reproduced from Overgaard et al. [32] who also used MPS as a primary outcome variable in their study on oral health in nursing home residents. Overgaard et al. based their power calculations on reductions in $MPS \geq 2$ from 60% to 15% as reported by Hede et al. [17]. Like Overgaard et al. we assume an alpha of 0.5, a power of 80% and a 33% drop-out rate due to the residents' frail condition and a median resident time of two years. Using the programme G*Power 3 [35] for power calculations, Overgaard et al. found that at least 92 residents should be included in each group for oral health assessments. A medical statistician has been consulted to further adapt the calculations to the present study setting (taking into account the number of eligible nursing homes and residents in the southern part of Rogaland), recommending the inclusion of 12 nursing homes each with 30 residents opted for oral health assessments. Thus, a total of 360 residents will be included for oral health assessments, 180 in the intervention and control group, respectively. All eligible caregivers in the 12 included nursing homes will be invited to take part in the survey capturing components of the COM-B model as described in the Measurements section (4.2). Experiences from the feasibility study indicate that this broad inclusion strategy, along with assigning the recruitment task to members of the institutions' resource groups, foster a sense of community regarding project participation. This may, in turn, motivate institutions and individual participants to remain part of the project throughout the study period.

3.5 Data analyses

The statistical software package SPSS (IBM) will be used for analyses of quantitative data (i.e., survey data, MPS data and frequency data from patient journals). These analyses will include descriptive statistics (to describe the samples) and statistical techniques to look for changes and differences in the study variables within and between the intervention- and the control group throughout the project period - e.g., t-tests and analysis of variance (ANOVA)

tests. We hypothesize that SmartJournal usage will lead to favorable changes in variable scores. In caregivers: increased scores on the measured COM-B components (survey data). In residents: improved oral health as measured by MPS. In patient journals: increased reporting of oral health related issues. Additionally, regression analysis may be employed to investigate associations between study variables while adjusting for potential covariates (e.g., age, gender, educational level, medical conditions and prescribed medication). NVivo (Alfasoft) will be used as a tool in content analysis of oral health-related reports in patients journals. These analyses will (qualitatively) describe potential differences and changes in such reports within and between the intervention- and the control group throughout the project period.

4. Ethics and privacy

The SmartJournal intervention aims to assist non-dental care providers with preserving nursing home residents' statutory right to good oral hygiene and necessary dental treatment. Respect for the individual's intrinsic value, self-determination and situation pervades the development and anticipated use of the tool. The project is guided by the intentions of the Declaration of Helsinki and ethical guidelines provided by the Norwegian National Research Ethics Committees. Informed consent will be obtained from nursing home caregivers and residents before data collection. Consent forms are designed in accordance with the templates for information material provided by Sikt – Norwegian Agency for Shared Services in Education and Research, and Regional Committees for Medical and Health Research Ethics. Nursing home residents constitute a vulnerable group in which many individuals may have reduced decision-making capacity, and thereby, difficulties giving free and informed consent to being subjects of research. However, since the overall aim with the SmartJournal intervention is to assist health personnel with preserving oral health in this particular group, it is essential to include them in the research. Therefore, if residents have reduced decision-making capacity, deputy consent will be obtained from their next of kin. Data registered in SmartJournal (i.e., data for residents included in the intervention group) will be transferred to a research database at the University of Stavanger. At the SmartJournal login site, health personnel are asked to enter three codes: one code for the nursing home, one (personal) caregiver code and one (personal) resident code. The codes for caregivers and residents will be listed in an identification key which is only available to authorized project staff. At the end of the project, data will be deidentified and it will not be possible for anyone to link any information to individual participants. Data obtained from questionnaires, clinical assessments (MPS) and patient journals are registered with the same, individual codes as for data registered in SmartJournal, which makes it possible to link data obtained from all sources. Extractions from the UiS database and data from questionnaires will be stored in a highly secured data system at the Oral Health Centre of Expertise Rogaland. Only authorized project staff will have access to the data.

5. Contributions

This study will add to the research on how improved oral care may be obtained in nursing homes. Results from this work can also be used to inform 1) continued development and implementation of SmartJournal in nursing homes and other caring facilities, including in-home care, and 2) development and implementation of other digital tools aiming to enhance

healthcare services offered to care-dependent people. Since research has shown that oral health education and training is inadequate in non-dental healthcare professionals [24,36,37], SmartJournal also has potential as a learning tool in educational programs for nurses and other healthcare professionals.

6. Dissemination

Results from the study will be published in high impact academic journals and other relevant channels of dissemination including academic and practitioners' conferences and various public media.

7. Project group and collaborating partners

The core project group is comprised of researchers at Oral Health Centre of Expertise Rogaland: *Elisabeth Lind Melbye* is principal investigator and senior researcher. Melbye has a MSc in clinical nutrition and a PhD in behavioural nutrition. Her previous experience includes several years of clinical (authorized dietitian) and academic (professorship at the University of Stavanger) work. Melbye has been leading the SmartJournal feasibility study. *Lene Elisabeth Myhren* is research coordinator and researcher. She has a PhD in molecular medicine and is involved in several studies related to oral health in vulnerable groups of the population. *Ann-Kristin Berge* is project coordinator and dentist. She has been involved in all phases of the SmartJournal project. *Enes Karamehmedovic* is PhD student and will do his PhD research within this project.

Collaborating partners from academic institutions: *Anne N. Åstrøm* is professor at Department of Clinical Dentistry, University of Bergen. Åstrøm will assist in statistical analyses and supervise Karamehmedovic's PhD work together with Melbye and Bull. *Björg Oftedal* is professor and vice dean for education at the Faculty of health, University of Stavanger. Oftedal was involved in early phases of the SmartJournal project and will be engaged in future usage of SmartJournal components in health education. *Tonje Holte Stea* is professor at the Faculty of health and sport sciences, University of Agder. Stea is experienced in intervention research and will assist in quality control of the intervention, analyses and dissemination.

Other collaborating partners include: NETTOP-UiS, Centre for development of institutional and home care services (USHT) in Rogaland and Norwegian Smart Care Cluster (NSCC). Additional research environments and collaborators may be included at a later stage if feasible.

8. Funding

The initial phases of the SmartJournal project (i.e., development of the prototype and the feasibility study) were funded by the Norwegian Regional Research Funds Vestland (RFF Vestland) and the Oral Health Centre of Expertise - Rogaland (TkRog) (project ID: 291051/2018). The research described in this protocol (i.e., the evaluation study) has recently received funding from the Norwegian Regional Research Funds Rogaland (RFF Rogaland, project ID: 332666/2022).

9. Time schedule

The study is scheduled between 01.02.2023 and 31.12.2025 (Table 1).

Table 1. Anticipated time schedule and research activities.

Activities	From	Quarter	To	Quarter
Recruitment and baseline measurements (T0)	2023	1	2023	2
Intervention*	2023	3	2023	4
Measurements at 3 months (T1)*	2023	4	2024	1
Measurements at 9 months (T2)*	2024	1	2024	3
Analyses and dissemination	2024	4	2025	4

*The intervention will last for 12 weeks. Since the start date may vary between included nursing homes, a 12 month period is scheduled to perform the intervention and measurements at T0, T1 and T2.

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