Title: Encouraging, Assisting and Time to EAT: Improved nutritional intake for older medical patients receiving Protected Mealtimes and/or additional nursing feeding assistance

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Short title: Improving nutritional intake in older patients

Non-standard abbreviations: PM: Protected Mealtimes, AIN: assistant-in-nursing,

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ABSTRACT

Background & Aims: Inadequate feeding assistance and mealtime interruptions during hospitalisation may contribute to malnutrition and poor nutritional intake in older people. This study aimed to implement and compare three interventions designed to specifically address mealtime barriers and improve energy intakes of medical inpatients aged ≥65 years.

Methods: Pre-post study compared three mealtime assistance interventions: PM: Protected Mealtimes with multidisciplinary education; AIN: additional assistant-in-nursing (AIN) with dedicated meal role; PM+AIN: combined intervention. Dietary intake of 254 patients (pre: n=115, post: n=141; mean age 80±8) was visually estimated on a single day in the first week of hospitalisation and compared with estimated energy requirements. Assistance activities were observed and recorded.

Results: Mealtime assistance levels significantly increased in all interventions (p<0.01). Post-intervention participants were more likely to achieve adequate energy intake (OR=3.4, p=0.01), with no difference noted between interventions (p=0.29). Patients with cognitive impairment or feeding dependency appeared to gain substantial benefit from mealtime assistance interventions.

Conclusions: Protected Mealtimes and additional AIN assistance (implemented alone or in combination) may produce modest improvements in nutritional intake. Targeted feeding assistance for certain patient groups holds promise; however, alternative strategies are required to address the complex problem of malnutrition in this population.

Keywords: malnutrition, aged, hospitalization, mealtimes, feeding, energy intake,

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INTRODUCTION

The prevalence of protein-energy malnutrition in elderly hospital patients is reported to be as high as 60% \textsuperscript{1,2}, and is associated with poor clinical outcomes \textsuperscript{3}. Nutritional intake of older people during hospitalisation is often inadequate \textsuperscript{4-6}, which may lead to further decline in nutritional status during the hospital admission \textsuperscript{7-9}. The reasons for poor nutritional intake in hospital are multi-factorial. They include patient factors such as poor appetite, feeding dependency and cognitive impairment\textsuperscript{5}, staff factors such as competing tasks, lack of role clarity and unclear responsibility for mealtimes \textsuperscript{10-12} and environmental factors such as interruptions and a poor mealtime environment \textsuperscript{13}. These challenges may explain the marginal benefits seen in studies of oral nutritional interventions in this patient group \textsuperscript{14}.

Interventions to improve nutritional intake in the acute hospital setting through explicitly addressing these barriers have not been adequately researched \textsuperscript{14}. Studies using feeding assistance provided by volunteers or health care assistants have shown mixed results \textsuperscript{14-17}, which may be explained by differences in the assistant’s scope of practice, unintentional improvements in care of the control group and/or differences in the ward culture or environment where research was conducted. There has also been limited evaluation of the impact of mealtime environment strategies, such as Protected Mealtimes where mealtimes are protected “from unnecessary and avoidable interruptions, providing an environment conducive to eating” \textsuperscript{18}. Das et al \textsuperscript{19} demonstrated a small increase in energy intake and weight during their pilot of Protected Mealtimes; however other authors report no significant difference in nutritional intake after implementation of Protected Mealtimes \textsuperscript{20-23}. An unexpected reduction in feeding assistance was noted in one study \textsuperscript{22}, highlighting the potential for perverse outcomes in this complex environment and the need for a multi-faceted approach to enhance patient mealtimes. No studies have investigated the impact of mealtime interventions on patients at particular risk of poor intake.
This study aimed to implement and compare three interventions designed to specifically address mealtime barriers in older medical patients, with the primary objective of improving energy and protein intakes of elderly medical inpatients in the first week of their acute hospital admission. This study also aimed to explore the benefit of these interventions in patient sub-groups known to be nutritionally vulnerable during hospitalisation (patients with anorexia, cognitive impairment and functional dependency).
MATERIALS AND METHODS

Study setting and participants: This prospective study was conducted on three Internal Medicine wards in a large metropolitan public teaching hospital in Brisbane, Australia. Participants were consecutive patients aged 65 years or older who had a hospital stay of more than 2 days, and were admitted from the emergency department to the study wards. Patients who were critically or terminally ill, or were not receiving an oral diet at the time of admission were excluded. Informed consent was obtained from all participants; where cognitive impairment was present, consent was obtained from a suitable proxy (close family member or recognised carer). The study was approved by the hospital human research ethics committee.

Intervention design and implementation: Pre-intervention data (November 2007 to March 2008) were collected as part of a multi-methods exploratory study establishing baseline conditions and informing potential interventions. In the pre-intervention context, there were established malnutrition screening and nutrition support policies and procedures in place. However, there were no mealtime procedures, and mealtime assistance was provided by nursing staff in an unstructured manner, with intermittent support from assistant-in-nursing (AIN) staff.

Between July and December 2009, three different feeding assistance models were designed and implemented; all with a focus on “Encouraging, Assisting and Time to EAT” (Table 1). Each intervention was allocated to medical wards based on which intervention the nursing managers felt would be most effective and easily implemented on their ward. An action research approach was used to engage clinicians in the design and implementation of specific strategies in line with their allocated intervention. This involved facilitating sessions with
physicians, nurses and allied health professionals where “look, think, act” cycles were used to reflect, problem solve and negotiate change to mealtime practices as outlined in Table 1. These were reinforced throughout the study period using strategies including point-of-care reminders, modelling by opinion leaders and regular feedback sessions with clinicians to monitor progress and proactively manage emerging issues. The implementation was supported using an enabling facilitation role by the principal author (AY) and an experienced nurse implementer.

Evaluation design: The study was evaluated using a pre-post study design, with participants in the pre-intervention and post-intervention group sampled from the same wards using the same recruitment protocol. Post-intervention data were collected once the proposed interventions were established (January to June 2009). Participants were allocated to one of three interventions based on the ward to which they were admitted (using existing bed allocation system based on day of admission and bed availability). The researchers had no control over allocation. A pre-post design rather than concurrent control design was chosen for this study, as there was a high risk of contamination of care received by a concurrent control group due to required changes in organisational culture associated with the interventions.25,26

Implementation outcomes: Participants were observed on a single day between day 3 and day 7 of the hospital admission. An Accredited Practicing Dietitian (AY) and two trained dietetic assistants observed participants at breakfast, lunch and dinner to determine if assistance was provided by staff (defined as any activity which encouraged or assisted the patient with eating the meal) and if participants were interrupted during the meal (defined as any activity performed by staff which stopped the patient from eating the meal for one minute...
or longer). Activities of nursing staff at each observed mealtime were also recorded and classified as either being a clinical (e.g. medication rounds), patient communication (e.g. writing in medical charts) or non-clinical activity (e.g. cleaning, making beds). While ward staff were aware that data were being collected on the food and drink intake of patients, they were not aware which patients were participants in the study or that data were collected on levels of feeding assistance and interruptions.

**Nutritional outcomes**: The primary outcomes were daily energy and protein intake. Dietary intake was measured on the same day that process outcome data were collected. Measurement was performed by the same dietitian and dietetic assistants using visual estimation of plate waste, which has been shown to closely correlate with measured plate waste \(^{27,28}\). Observation of food intake of hospitalised patients on a single day has been shown to closely correlate with two and three day records \(^5,28\). Each meal was inspected on delivery and on completion, and consumption was estimated (none, 1/8, ¼, ½, ¾, all) for each component of the meal (e.g. soup, meat, potato, green vegetables, bread). Mid-meal intake was estimated by observation and/or patient recall. Each dietary intake observation was converted to energy and protein intake based on known food composition for each specific meal, using FoodWorks Professional nutrient analysis software (version 3.02, Xyris, Brisbane Australia 2004).

**Covariables**: Potential confounding variables were identified from the literature and our previous research into predictors of poor nutritional intake in this patient group \(^5,10\). Demographic and disease variables (age, sex, usual place of residence, discharge destination, primary diagnosis, cognitive impairment, number of co-morbidities and number of
medications) were obtained from the medical record and hospital databases. Weight was measured by the study dietitian using a single Tanita HD351 scale, precise to 0.1 kg; on occasions where seated scales were required, ward scales were used and calibrated to the reference scale. In 21 cases, it was not possible to weigh the patient, and the study dietitian estimated weight to the nearest kilogram. Height was estimated from knee height using age-adjusted equations, and used to derive body mass index (BMI). Nutritional status was assessed using the Subjective Global Assessment, where ratings of B or C indicate malnutrition. Appetite was evaluated using the Simplified Nutritional Appetite Questionnaire, with scores of 14 or less indicating impaired appetite. Functional dependency was assessed based on the number of basic activities of daily living (ADL; including dressing, bathing, toileting, transfers, mobility and feeding) for which assistance from another person was required. This was assessed using Katz ADL index using self-report data confirmed by nursing documentation and/or researcher observation. Feeding dependency was also analysed as a separate variable, including the need for assistance with set-up or supervision of meals.

**Statistical analysis:** Participant characteristics were summarised using means and standard deviations for normally-distributed continuous variable, or categorised according to validated cut-offs and clinical meaning. Due to similarities in the level of pre-intervention mealtime care and nutritional intakes of patients between wards (data not presented), pre-intervention data from the three study wards were combined as a “Pre-intervention” group. Energy and protein intake were analysed in three ways: comparison of group mean intake; comparison of group mean intake adjusted for body weight; and comparison of the proportion of participants meeting estimated requirements. Based on published data from hospitalised
elderly patients, we estimated resting energy expenditure (REE) (89kJ/kg actual body weight for patients with a BMI <21, 77kJ/kg for BMI >21) which was multiplied by an activity factor of 1.42 to calculate estimated energy requirements (EER). Adequate protein intake was defined as daily protein intake equal or greater than 1g/kg body weight.

One-way analysis of variance was used to assess differences in mean energy and protein intakes between groups. Analysis of covariance (ANCOVA) was used to adjust for differences in characteristics between groups. Purposeful selection of covariates was used to fit the ANCOVA model, where variables were selected which differed between groups in bivariate analysis \( p<0.25 \). Non-significant variables (defined as \( p>0.10 \) and <15% change in standard errors when variable removed from the model) were removed using stepwise backward elimination to obtain the most parsimonious model. Fisher’s exact tests were used to assess differences in proportion of patients meeting estimated energy and protein requirements between groups. A purposeful selection approach was also used to fit multiple logistic regression models to confirm effect of the intervention on the outcome of adequate energy intake (intake \( \geq \) EER). Significant associations were defined as \( p<0.05 \) in multivariate models. Due to small sample size, comprehensive sub-group analyses using interaction terms in the multivariate model were not conducted. Instead, descriptive statistics were used to compare energy intakes of participants in each sub-group (presence of anorexia, cognitive impairment and feeding dependency) with estimated EER and REE. Finally, to ensure that weight estimates did not influence the outcome of the study, sensitivity analysis was undertaken whereby these 21 cases were excluded from analysis.

Using data from our previous research, we estimated a minimum sample size of approximately 35 participants in each group to detect a clinically meaningful difference in energy intake of 1500kJ with 90% power and type 1 error of 5% or less (two tailed).
RESULTS

Participants: 254 participants were enrolled in the study, of whom 115 were recruited in the pre-intervention observational study and 139 participants during the post-intervention study (AIN: n=58; PM: n=39; PM+AIN: n=42). This represents a consent rate of 40%, with participants and eligible non-participants being similar in age (mean 80 years vs. 81 years), gender distribution (47% male vs. 42% male) and primary diagnosis. Characteristics of participants differed across intervention groups, with participants in PM group being older, with more admitted from a residential aged care facility, dependent with one or more ADLs and having a primary diagnosis of infection or fall/fracture (see Table 2). More participants in the PM and PM+AIN groups had cognitive impairment, compared with the pre-intervention and AIN groups. Overall, 40% of participants (n=101) were malnourished using SGA, 50% had anorexia (n=108) and 38% required some assistance at mealtimes (n=97).

Implementation evaluation: There was a significant increase in mealtime assistance provided after the introduction of the interventions, with 30% of participants in the pre-intervention group receiving assistance at one or more meals on the study day, compared with 79% (AIN), 80% (PM) and 76% (PM+AIN) (p<0.01). No reduction in the occurrence of mealtime interruptions was observed, despite introduction of Protected Mealtimes concept in PM and PM+AIN (pre: 38% of patients interrupted, AIN: 22%, PM: 33% PM+AIN: 26%; p=0.18). There was a significant reduction in non-clinical nursing tasks at mealtimes in all interventions (pre: 66% of meals where nurses were completing non-clinical tasks, AIN: 31%, PM: 27% PM+AIN: 36%; p<0.01).

Energy intake: There were no differences in mean energy intakes between intervention groups (see Table 3), even when adjusted for differences in patient characteristics between groups (p=0.35). However, when energy intake was compared with energy requirements
(REE and EER), significantly more participants in the intervention groups had adequate energy intake (intake ≥ EER), compared with pre-intervention (p<0.01, see Figure 1). No statistical difference was seen between any of the intervention groups (p=0.29). These findings were confirmed in the multivariate analysis, with participants receiving a mealtime assistance intervention (AIN, PM or PM+AIN) being more likely to have energy intake meeting or exceeding their EER (adjusted OR 3.4 (95% CI 1.3 – 8.7) p=0.01; adjusted for BMI, anorexia, feeding dependency, nutritional status, cognitive impairment, age and diagnosis). When we excluded cases where no measured weight was available (n=21), findings did not differ significantly (data not presented). The data presented in Figure 1 suggests a shift in the proportion of patients with “borderline” intake (i.e. intake between REE and EER) to adequate intake (i.e. intake ≥ than EER), but no change in the proportion of patients with “poor intake” (i.e. intake < REE) between intervention groups.

Energy intake – sub-group analysis: The adequacy of energy intake of participants with anorexia, cognitive impairment and feeding dependency was also explored (see Figure 2). While the intervention appeared to have minimal impact on participants with anorexia (p=0.77), significantly more participants in the post-intervention group with cognitive impairment (p=0.01) or feeding dependency (p=0.03) had an adequate energy intake to meet EER.

Protein intake: There was a trend toward improved protein intakes in AIN and PM+AIN groups (p=0.07; See Table 3). However, when adjusted for differences in participant characteristics between groups, there was no significant difference in total protein intake between groups (p=0.20). Only 50 participants (20%) had adequate protein intake (≥ 1g/kg). Similar to findings for energy intake, significantly more participants in the post-intervention groups had adequate protein intake (Pre-intervention: 12% had adequate protein intake; AIN: 26%; PM: 21%; PM+AIN: 31%; p=0.03); with no significant difference between the three
interventions ($p=0.57$).
DISCUSSION

In this study, we implemented and compared three interventions to improve the mealtime experience for older patients in acute medical wards. All three strategies resulted in greater assistance and fewer non-clinical tasks during mealtimes, although mealtime interruptions were not significantly reduced. While the mean energy or protein intake did not significantly increase in the post-intervention groups, patients who received any of the three interventions were more likely to achieve adequate energy and protein intakes to meet estimated requirements than the pre-intervention group. Improvements in nutritional intake appeared to be in the “borderline” group of patients (i.e. intake between REE and EER), with limited impact on patients with very poor nutritional intake (i.e. intake < REE).

This study is the first to suggest that improving mealtime assistance by enhancing the mealtime involvement of existing staff across disciplines (PM) may be as effective as introducing a dedicated feeding role (AIN). At an annual cost of $AU 45,000-50,000 (€ 35,000) per AIN staff member, this is an important finding in current times where healthcare costs and staffing demands are rising. While widely used in practice, the effectiveness of unpaid feeding assistant programs requires further evaluation. It was anticipated that the combined intervention (PM+AIN) would produce larger improvement in process and outcomes than the other interventions alone. While this study appeared to suggest a higher proportion of participants in the combined intervention (PM+AIN) with adequate energy intake than the other intervention groups, this result was not statistically significant. As this study was powered to detect a substantial increase in mean energy intake, a larger sample size may have detected more subtle differences in nutritional outcomes between groups. Other potential explanations for the absence of an additive effect of the combined intervention include difficulties in integrating the AIN role into the Protected Mealtimes environment or shift in attitudes and behaviours of ward staff with the introduction of the AIN. Further
qualitative evaluation of the interventions is planned to tease out these issues using data collected during staff focus groups and ward observations. Improvements in nutritional intake were observed, despite no decrease in the frequency of mealtime interruptions. This suggests that an emphasis on increasing mealtime assistance may be more important than focusing on mealtime “protection” (reducing mealtime interruptions).

Patients with cognitive impairment and feeding dependency appeared to benefit most from mealtime assistance interventions. Given the nature of the interventions, it is not surprising that these patient sub-groups responded better to enhanced mealtime assistance, as has been shown previously in the residential aged care setting. Patients with delirium and cognitive impairment are at particular risk of poor intake and malnutrition, and more aggressive nutritional therapies such as enteral tube feeding can be difficult to achieve and may not improve patient outcomes. As these patients only accounted for a third of the study sample, the benefits of feeding assistance for the overall heterogeneous group of older medical patients may have been diluted. Therefore, a larger intervention trial to study nutritional and clinical outcomes of targeted feeding assistance for these nutritionally vulnerable groups of patients may be warranted. In contrast, providing enhanced mealtime assistance to anorexic patients appears to have limited benefit. In this study, over 70% of participants had suboptimal nutritional intake despite enhanced feeding assistance and nutrition support protocols based on evidence-based guidelines. This suggests that it is possible that inpatient nutritional support intervention may have limited benefits for this patient group, particularly with the reducing length of hospital stays, and that the focus of nutrition interventions should be on preventing nutritional decline during hospitalisation and nutrition rehabilitation in the post-hospital setting.

There are several limitations of this study which should be acknowledged. The pre-post study design has inherent methodological weaknesses. This approach was selected to ensure
successful implementation of the interventions, which could not have been delivered to randomised participants within the same ward. A larger cluster randomised control trial or stepped wedge design could be used to confirm and strengthen our findings. Blinding research staff to intervention allocation of patients was not attempted, given the action-based research approach taken in this study where the researchers had significant involvement in implementing the interventions. While this has potential to bias study results, use of blinded independent research staff was unlikely to solve this problem given the visible nature of the interventions. As monitoring and auditing have been highlighted as important change management strategies, the presence of the researchers on the ward at mealtimes to collect data may have influenced the outcome of the study by reinforcing positive mealtime behaviours by staff. There was no formal assessment of inter-rater reliability of observers of food intake. Informal assessment conducted prior to the studies found high agreement, as would be expected for trained Accredited Practicing Dietitian and dietetic assistants who observe hospital meals and food intake on a daily basis as part of their clinical role. High inter-rater reliability of observers of food intake (with minimal training) has been reported by previous researchers. A further limitation of the assessment of dietary intake was the estimation of the energy requirements of individual participants, rather than measurement using indirect calorimetry, and the assessment of food intake on only one day of hospital admission. Previous research in this population has shown no difference in energy or protein intakes between Day 3 and Day 7 of hospitalisation. The small sample size of this study limited assessment of more subtle differences in energy intake between intervention groups (with the study powered to detect a difference of 1500kJ), the impact on clinical outcomes, such as length of stay, readmission and mortality rates, and limited our ability to conduct cost-effectiveness analysis. It is not possible to draw conclusions about the generalisability of these results to other acute care settings. These interventions were implemented by motivated
and engaged clinicians in medical wards where quality improvement and holistic care of elderly patients is of a high priority, which may enhance the effect compared to other settings where Protected Mealtimes is implemented as a result of hospital policy.

This study demonstrates that the nutritional intakes of elderly medical patients can be improved when mealtime interventions are successfully implemented by enthusiastic and motivated clinicians using an action research approach. The study findings also suggest that an emphasis on mealtime *assistance* may be a more effective change strategy than emphasizing mealtime *protection* (reduced interruptions). However, increasing levels of mealtime assistance in a non-targeted, ward-level intervention may only produce modest improvements in nutritional intake in a heterogeneous group of older medical patients. It is possible that mealtime assistance interventions may have the greatest effect on elderly inpatients with cognitive impairment or feeding dependency, and future research should examine targeted feeding assistance for these nutritionally vulnerable groups. This would enable clinicians to prioritise and focus enhanced mealtime assistance on those patients who would receive the largest improvement in nutritional outcomes. Despite efforts to improve the nutritional intake of elderly inpatients, the majority of patients continued to eat poorly. With decreasing lengths of hospital stay, clinicians need to carefully review the effectiveness of short-term inpatient nutrition interventions, and consider whether malnutrition interventions in the community and hospital-to-home transition period may produce better health outcomes for this patient group.
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Statement of authorship contributions:

AY conceived and designed the study, implemented interventions, undertook data collection, analysis and interpretation and drafted the manuscript.

AM contributed to conception and design of study, supported implementation of interventions, provided statistical advice and contributed to data interpretation and critical review of the manuscript.

MB and LR contributed to conception and design of study, supported implementation of interventions, contributed to data interpretation and critical review of the manuscript.

LD contributed to data interpretation and critical review of the manuscript.

All authors read and approved the final manuscript.
Conflict of interest statement:

The authors have no conflict of interest to declare. Study sponsors had no role in study design, analysis or manuscript preparation.
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