

## References: Mealtime Difficulties

AJ, T., V, A., C, R., & VH, C. (2003). Restricting fluid intake during a single meal did not affect food intake in older adults. *Appetite* (pp. 79-86)

### **REF ID: 4695**

**Algase, D. L., Son, G. R., Beattie, E., Song, J. A., Leitsch, S., & Yao, L. (2004). The interrelatedness of wandering and wayfinding in a community sample of persons with dementia. *Dementia and Geriatric Cognitive Disorders*, 17(3), 231-239.**

#### **Journal Article; IM**

The aim of this study was to evaluate the relationship of wandering and wayfinding and validate the Revised Algase Wandering Scale - Community Version (RAWS-CV) using a community sample of persons with dementia. Adult caregivers (n = 266) completed the RAWS-CV and the Wayfinding Effectiveness Scale (WES). Four aspects of wandering were confirmed (persistent walking, repetitive walking, spatial disorientation, eloping behavior), and two new aspects were also validated (negative outcomes, mealtime impulsivity). The spatial disorientation subscale of the RAWS-CV had significant ( $p < 0.01$ ) negative correlations with all WES subscales. The global strategies and simple wayfinding goals subscales of the WES correlated significantly with all RAWS-CV subscales except repetitive walking and mealtime impulsivity. ANOVAs comparing wayfinding at 4 levels of wandering revealed differences only for the simple wayfinding goals subscale. Studies examining the relationship of wandering and wayfinding at various levels of cognitive impairment are suggested to further understand these phenomena.

### **REF ID: 4700**

**Altuntas, Y., Ozen, B., Ozturk, B., Sengul, A., Ucak, S., & Ersoy, O. et al. (2003). Comparison of additional metformin or NPH insulin to mealtime insulin lispro therapy with mealtime human insulin therapy in secondary OAD failure. *Diabetes, Obesity & Metabolism*, 5(6), 371-378.**

#### **Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

**AIM:** It has been found that non-fasting plasma glucose is a better marker of diabetic control than fasting plasma glucose in type 2 diabetes. The main aim of treatment of type 2 diabetic patients is to control plasma glucose and HbA1c levels. In this study, we aimed to assess the effects of three different insulin regimens (group I: lispro insulin + NPH insulin, group II: lispro insulin + metformin and group III: regular insulin + NPH insulin) on overall glycaemic control and metabolic parameters in type 2 diabetic patients with secondary oral anti-diabetic drug failure. **METHODS:** Sixty type 2 diabetic patients with secondary OAD failure were randomly allocated into three different treatment groups equally. There were no significant differences between groups concerning age, body mass index, diabetes duration, HbA1c and serum lipid levels at the beginning of the study. During the 6-month treatment period, blood glucose levels were determined 10 times during 24 h at pre-meal, post-prandial 1 and 2 h and at bedtime. **RESULTS:** Group I was found to be the most effective treatment regimen in controlling HbA1c levels (group I vs. group II,  $p = 0.013$ ; group I vs. group III,  $p = 0.001$ ; group II vs. group III,  $p > 0.05$ ). When the comparison was made in each group, change in HbA1c was statistically significant for all groups (-3.18%,  $p = 0.001$ ; -2.02%,  $p = 0.043$  and -2.66%,  $p = 0.008$  respectively). Group I was found to be more effective in controlling fasting and post-prandial plasma glucose levels measured at all times during the day when compared with group II and group III. In group II triglyceride levels were found to be significantly reduced, whereas other groups had no effect on lipids. No serious hypoglycaemic episodes were observed in any of the cases, whereas in group I hypoglycaemic episode rates were increased ( $\chi^2 = 8.843$ ,  $p = 0.012$ ). **CONCLUSIONS:** Lispro insulin plus NPH insulin regimen is more effective in controlling both pre- and post-prandial glucose levels and HbA1c when compared to regular insulin plus NPH insulin combination. Mealtime lispro insulin plus metformin combination therapy should also be seriously considered as an effective and alternative treatment regimen. It is worthy of attention that insulin lispro plus metformin lowered triglyceride levels.

### **REF ID: 5172**

**Altus, D. E., Engelman, K. K., & Mathews, R. M. (2002). Using family-style meals to increase participation and communication in persons with dementia. *Journal of Gerontological Nursing*, 28(9), 47-53.**

**Journal Article, Research, Tables/Charts**

Although researchers stress the importance of encouraging independent behavior in persons with dementia, institutional practices often foster dependence. This study took place in a six-resident locked dementia care unit that followed the common institutional practice of serving meals on prepared plates. The purpose of this study was to examine if changing the mode of meal delivery to "family-style," where residents were presented with serving bowls and empty plates, would increase resident communication and participation in mealtime tasks. An ABAB' reversal design revealed very low rates of appropriate communication (5% of intervals) and mealtime participation (10% of tasks) during baseline, when residents received prepared plates (A). Communication and participation doubled when family-style meal delivery was introduced (B) and dropped back to baseline levels when it was withdrawn (A). Because the levels of communication and participation during family-style meals were still low, the nursing assistant was provided with instruction on prompting and praising appropriate mealtime behaviors (B'). After instruction was provided and family-style meals were reintroduced, resident participation rose to 65% of tasks and appropriate communication increased to 18% of observations. This study suggests family-style meals may result in modest increases in mealtime participation and communication of residents with dementia, but staff training in prompting and praising may be necessary to see large changes in these behaviors.

**REF ID: 4660**

**Anwar, A., Azmi, K. N., Hamidon, B. B., & Khalid, B. A. (2006). An open label comparative study of glimepiride versus repaglinide in type 2 diabetes mellitus muslim subjects during the month of ramadan. *The Medical Journal of Malaysia*, 61(1), 28-35.**

**Clinical Trial; Journal Article; IM**

This study was conducted to compare the treatment efficacy between a prandial glucose regulator, repaglinide and a new sulphonylurea, glimepiride in Muslim Type 2 diabetic patients who practice Ramadan fasting. Forty-one patients, previously treated with a sulphonylurea or metformin, were divided to receive either repaglinide (n=20, preprandially three-times daily) or glimepiride (n=21, preprandially once daily) 3 months before the month of Ramadan. During Ramadan, patients modified their eating pattern to two meals daily, and the triple doses of repaglinide were redistributed to two preprandial doses. Four point blood glucose monitoring were performed weekly during the month of Ramadan and the subsequent month. Measurements of the 4-point blood glucose were significantly lower in the glimepiride group compared to the repaglinide group both during and after Ramadan. The glycaemic excursion was better in the morning for the repaglinide group and better in the afternoon and evening for the glimepiride group during the Ramadan period. There was no statistically significant difference in the incidence of hypoglycaemia between the two groups during and after Ramadan. There was no difference in the glycaemic excursion post-Ramadan. The longer duration of action of glimepiride may offer an advantage over repaglinide during the 13.5 hours of fast in Ramadan for diabetic patients.

**REF ID: 4667**

**Ashwell, S. G., Gebbie, J., & Home, P. D. (2006). Optimal timing of injection of once-daily insulin glargine in people with type 1 diabetes using insulin lispro at meal-times. *Diabetic Medicine : A Journal of the British Diabetic Association*, 23(1), 46-52.**

**Journal Article; Randomized Controlled Trial; IM**

AIMS: To compare blood glucose control when insulin glargine is given at lunch-time, dinner-time, and bed-time in people with Type 1 diabetes using insulin lispro at meal-times. METHODS: In this 16-week, three-way, cross-over study, 23 people with Type 1 diabetes were randomized to insulin glargine injection at lunch-time (L) [mean 12.37 +/- 0.34 (+/- sd) h], dinner-time (D) (18.12 +/- 0.40 h), or

bed-time (B) (22.29 +/- 00.40 h), each plus meal-time insulin lispro. Each 4-week treatment period concluded with a 24-h inpatient metabolic profile. RESULTS: Insulin doses, HbA(1c), and fructosamine concentration did not differ between treatment periods. Pre-breakfast self-monitored blood glucose (SMBG) concentration was higher with injection of glargine at lunch-time than at other times [L: 9.2 +/- 0.3 (+/- se) vs. D: 8.2 +/- 0.3 or B: 8.0 +/- 0.3 mmol/l, P = 0.016], as probably was pre-lunch SMBG (L: 8.6 +/- 0.7 vs. D: 6.4 +/- 0.7 or B: 6.4 +/- 0.8 mmol/l, P = 0.051). Pre-dinner SMBG level was higher with dinner-time glargine than other injection times (D: 9.4 +/- 0.9 vs. L: 4.9 +/- 0.9 or B: 7.4 +/- 1.1 mmol/l, P = 0.007). For 22.00 to 02.00 h, mean inpatient plasma glucose concentration was higher with injection of glargine at bed-time than other times (B: 9.1 +/- 0.6 vs. L: 7.8 +/- 0.6 or D: 6.7 +/- 0.6 mmol/l, P = 0.023). Plasma free insulin concentration was lower at the end of the afternoon with dinner-time glargine than other injection times (D: 11.5 +/- 1.4 vs. L: 20.2 +/- 1.3 or B: 16.5 +/- 1.3 mU/l, P < 0.001). Frequency of hypoglycaemia was not different, but timing of hypoglycaemia differed between treatment periods. CONCLUSIONS: Blood glucose levels rise around the time of injection of insulin glargine whether given at lunch-time, dinner-time or bed-time. Bed-time injection leads to hyperglycaemia in the early part of the night which is improved by giving insulin glargine at lunch-time or dinner-time.

**REF ID: 4710**

**Barkeling, B., Elfhag, K., Rooth, P., & Rossner, S. (2003). Short-term effects of sibutramine (reductil) on appetite and eating behaviour and the long-term therapeutic outcome. *International Journal of Obesity and Related Metabolic Disorders : Journal of the International Association for the Study of Obesity*, 27(6), 693-700.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

OBJECTIVE: To evaluate the short-term effects of sibutramine on appetite and eating behaviour and whether these effects are related to the long-term therapeutic outcome. STUDY DESIGN: Short-term: randomised, double-blind, placebo-controlled, within-subject design. Long-term: prospective open clinical trial. SUBJECTS: A total of 36 obese (nine men/27 women) with a body mass index of 39.3+/- 4.3 (mean+/-s.d.) (range 30.2 - 45.2) kg/m(2) and age 44.4+/-12.1 y. PROCEDURE AND METHODS:: First phase-short-term effects: At baseline, the subjects were treated for 14 days with 15 mg sibutramine/placebo (period 1) followed by a 2 weeks single-blind placebo washout period, the subjects received the alternative therapy for another 14 days (period 2). At baseline, and at day 14 in each treatment period the subjects arrived fasting to the laboratory for a standardised breakfast and an ad libitum standardised lunch using the VIKTOR set-up (a universal eating monitor) to evaluate the microstructure of the eating behaviour (ie amount of food consumed and eating rate). Visual Analogue Scales were applied before and after the meals as well as every hour between the meals to monitor the appetite. During this first phase, subjects were encouraged to keep their habitual eating habits. Second phase-long-term effects: All subjects received 10 months open treatment with 15 mg sibutramine and dietary advice in monthly group sessions with a dietitian. On the last day of this treatment period, the subjects returned to repeat the measurements of appetite and eating behaviour using the same test procedure as during the first phase of the study. RESULTS: First phase: Sibutramine influenced appetite and eating behaviour that could be registered after only 14 days of treatment. The amount of food consumed at lunch on VIKTOR was reduced by 16% by sibutramine compared to placebo, 335+/-123 g vs 399+/-126 g (P<0.0001). Second phase: Responders and nonresponders were defined as those who ate less vs more food on VIKTOR when treated with sibutramine compared to the baseline food intake in the first phase of the study. The weight reduction was greater for responders 11.8+/-6.2 (mean+/-s.d.) kg compared to nonresponders 6.8+/-2.7 (mean+/-s.d.) kg (P<0.05). CONCLUSION: Short-term effects of sibutramine on appetite and eating behaviour were identified such as a reduction in food intake and in ratings of subjective motivation to eat. Short-term sibutramine effects on eating behaviour are to some extent related to the long-term therapeutic outcome in obese subjects.

**REF ID: 5157**

**Evidence Level IV: Nonexperimental Study**

**BatesJensen, B. M., Schnelle, J. F., Alessi, C. A., AlSamarrai, N. R., & LevyStorms, L. (2004). The**

effects of staffing on in-bed times of nursing home residents. *Journal of the American Geriatrics Society*, 52(6), 931-938.

**Journal Article, Research, Tables/Charts**

**OBJECTIVES:** To examine the effect of staffing level on time observed in bed during the daytime in nursing home (NH) residents. **DESIGN:** Descriptive, cross-sectional study. **SETTING:** Thirty-four southern California NHs. **PARTICIPANTS:** A total of 882 NH residents: 837 had hourly observation data, 777 had mealtime observations, 837 completed interviews, and 817 completed a physical performance test. **MEASUREMENTS:** Cross-sectional data collected from participants at each NH site included direct observations (hourly and mealtime), resident interviews, medical record review, and physical performance tests. **RESULTS:** In multivariate analyses, staffing level remained the strongest predictor of time observed in bed after controlling for resident functional measures (odds ratio=4.89;  $P=.042$ ). Residents observed in bed during the daytime in more than 50% of hourly observations were observed also to experience increased daytime sleeping ( $P<.001$ ) and less social engagement ( $P=.026$ ) and consumed less food and fluids during mealtimes than those observed in bed in less than 50% of observations, after adjusting for resident function ( $P<.001$ ). **CONCLUSION:** In this sample of NHs, resident functional measures and NH staffing level predicted observed time in bed according to hourly observations, with staffing level the most powerful predictor. Neither of these predictors justifies the excessive in-bed times observed in this study. Staff care practices relevant to encouraging residents to be out of bed and resident preferences for being in bed should be examined and improved. Practice recommendations regarding in-bed time should be considered, and further research should seek to inform the development of such recommendations.

**REF ID: 5161**

**Evidence Level IV: Nonexperimental Study**

**Beck, A. M., & Ovesen, L. (2003). Influence of social engagement and dining location on nutritional intake and body mass index of old nursing home residents. *Journal of Nutrition for the Elderly*, 22(4), 1-11.**

**Journal Article, Research, Tables/Charts**

The influence of social engagement and dining location on nutritional intake and body mass index was evaluated for 40 nursing home residents aged 80-85 years. Four-days' dietary records were used to assess the intake of energy and micronutrients. A higher prevalence of underweight (BMI < 20) was found among residents with low level of social engagement (67% vs. 11%,  $p < 0.05$ ) or dining in their own room (62% vs. 19%,  $p < 0.05$ ) compared to the others. No differences in prevalence of insufficient intakes of energy and micronutrients were observed between groups. In general the intake of energy and micronutrients was low. Hence, more attention should be given to what is served and consumed by nursing home residents rather than to where they eat or their level of social engagement.

**REF ID: 4737**

**Evidence Level III : Quasi-experimental Study**

**Berrut, G., Favreau, A. M., Dizo, E., Tharreau, B., Poupin, C., & Gueringuili, M. et al. (2002). Estimation of calorie and protein intake in aged patients: Validation of a method based on meal portions consumed. *The Journals of Gerontology. Series A, Biological Sciences and Medical Sciences*, 57(1), M52-6.**

**Journal Article; Validation Studies; AIM; IM**

**BACKGROUND:** Malnutrition is highly prevalent in hospital, mainly in geriatric, wards. Weight loss results from a negative energy balance, a situation where energy intake does not match energy requirements. Estimates of patient calorie consumption are not performed routinely because of technical difficulties. We performed three studies to investigate the meal-portion (MP) method as a tool for estimating calorie and protein intakes in clinical situations. **METHODS:** The MP method was designed to estimate calorie and protein consumption from the portion of the food items actually eaten by the patient, which is evaluated at the time plates and dishes are cleared away. Study 1 tested accuracy of the MP method in 50 meals by comparison to food weighing. Study 2 evaluated the validity of estimates obtained by a physician, a member of nursing staff, and a dietician in 30 elderly patients. Study 3

evaluated the robustness and feasibility of the method by comparing estimates obtained by nursing staff (after 1 year of practice with no additional training) and that of a dietician. RESULTS: Comparison of estimates and true values (obtained by weighing) showed a mean difference of -2 kcal/-0.8 g of protein from evaluations of one-half portions of food (50 meals) and -7 kcal/-1.0 g of protein from one-quarter portions of food; the difference was only significant for protein and one-quarter portions ( $p = .03$ ). When evaluations were performed by observers of different professional categories (nursing staff, physicians, and dieticians) on actual meals consumed by 30 elderly people afflicted with disease, no statistical differences were shown. This interobserver agreement remained, regardless of the cognitive or physical status of the patient. A third study, performed after 1 year of no additional training, showed that the MP method is robust, but prone to clerical errors. CONCLUSIONS: Valid estimates of calorie and protein consumption can be obtained with the MP method, quoting in one-half portions. Quality controls are required both at the food production site (to avoid propagation of errors arising from food composition) and in data collection (to eliminate clerical mistakes). These results suggest that the MP method could be a tool for estimating calorie and protein intakes in many clinical situations.

**REF ID: 4682**

**Blondheim, D. S., Yosef, A., & Marmor, A. T. (2004). Effect of nutritional composition of meals on exercise tests in patients with ischaemic heart disease. *Eur.J.Cardiovasc.Prev.Rehabil.*, 11(6), 503-510.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

BACKGROUND: Patients with ischaemic heart disease have to perform exercise tests repeatedly. It is not clear if a small meal eaten before the test might influence it and if the meal's composition is important. DESIGN AND METHOD: We performed a double blind, randomised, crossover study on 20 volunteers with documented ischaemic heart disease known to have positive exercise tests. Each had three symptom limited exercise tests done one hour after a 200 ml meal, rich in either fat, carbohydrate or protein. Each postprandial test was compared to a fasting exercise test performed just before the meal. RESULTS: Postprandial blood pressure, time to angina and to peak exercise and double product at onset of ST-depression were not significantly altered by any of the meals. Heart rate was slightly increased only after the fat meal. CONCLUSIONS: The nutritional composition of a small meal eaten an hour before an exercise test has no clinically important impact on the results of the test in patients with stable angina pectoris.

**REF ID: 4696**

**Bosley, B. N., Weiner, D. K., Rudy, T. E., & Granieri, E. (2004). Is chronic nonmalignant pain associated with decreased appetite in older adults? preliminary evidence. *Journal of the American Geriatrics Society*, 52(2), 247-251.**

**Journal Article; IM**

OBJECTIVES: To examine the association between self-reported appetite impairment and pain intensity in community-dwelling older adults with chronic nonmalignant pain. DESIGN: Cross-sectional survey. SETTING: An outpatient pain clinic at the University of Pittsburgh. PARTICIPANTS: A convenience sample of 65 older adults with chronic nonmalignant pain. MEASUREMENTS: Demographics, pain intensity (short-form McGill Pain Questionnaire), self-reported appetite impairment using a newly developed instrument, mood (30-item Geriatric Depression Scale, (GDS)), cognitive status (Folstein Mini-Mental State Examination), dependence in feeding, dependence in grocery shopping and meal preparation, and comorbidities (Cumulative Illness Rating Scale). Medication information was classified as total number of medications, number of analgesics, number of opioids, and number of potential appetite-impairing side effects. RESULTS: Univariate analyses revealed that those who reported pain-related appetite impairment had higher pain intensity than those who reported no appetite impairment ( $P < .001$ ). Comparison of subjects with and without pain-related appetite impairment revealed a significant difference in GDS scores ( $P = .027$ ), number of analgesics ( $P = .015$ ), and number of opioids ( $P = .014$ ). None of the other variables was statistically significant. The relationship between pain intensity and perceived pain-related appetite impairment was maintained in an analysis of covariance that controlled for GDS score, number of analgesics, and presence of opioids ( $P = .004$ ). CONCLUSION:

Chronic pain is associated with self-reported appetite impairment in older adults, but examination of the influence of reduction in pain intensity on appetite improvement is needed to establish a causal relationship between chronic pain and diminished appetite.

**REF ID: 4683**

**Calvo, E., Tolcher, A. W., Hammond, L. A., Patnaik, A., de Bono, J. S., & Eiseman, I. A. et al. (2004). Administration of CI-1033, an irreversible pan-erbB tyrosine kinase inhibitor, is feasible on a 7-day on, 7-day off schedule: A phase I pharmacokinetic and food effect study. *Clinical Cancer Research : An Official Journal of the American Association for Cancer Research*, 10(21), 7112-7120.**

**Clinical Trial; Clinical Trial, Phase I; Journal Article; IM**

**PURPOSE:** To determine the maximum tolerated dose of administering CI-1033, an oral 4-anilinoquinazoline that irreversibly inhibits the tyrosine kinase domain of all erbB subfamilies, on an intermittent schedule, and assess the interaction of CI-1033 with food on the pharmacokinetic behavior. **EXPERIMENTAL DESIGN:** Escalating doses of CI-1033 from a dose level of 300 mg/day for 7 days every other week were administered to patients with advanced solid malignancies. Plasma concentration-time data sets from all evaluable patients were used to develop a population pharmacokinetic model. Noncompartmental methods were used to independently assess the effect of a high-fat meal on CI-1033 absorption and bioavailability. **RESULTS:** Twenty-four patients were treated with 69 twenty-eight day courses. The incidence of unacceptable toxicity, principally diarrhea and skin rash, was observed at the 300 mg/day dose level. At the 250 mg/day level, toxicity was manageable, and protracted administration was feasible. A one-compartment linear model with first-order absorption and elimination adequately described the pharmacokinetic disposition. CL/F, apparent volume of distribution (Vd/F), and  $k_a$  (mean +/- relative SD) were 280 L/hour +/- 33%, 684 L +/- 20%, and 0.35 hour<sup>(-1)</sup> +/- 69%, respectively.  $C_{max}$  values were achieved in 2 to 4 hours. Systemic CI-1033 exposure was largely unaffected by administration of a high-fat meal. At 250 mg, concentration values exceeded IC50 values required for prolonged pan-erbB tyrosine kinase inhibition in preclinical assays. **CONCLUSIONS:** The recommended dose on this schedule is 250 mg/day. Its tolerability and the biological relevance of concentrations achieved at the maximal tolerated dose warrant consideration of disease-directed evaluations. This intermittent treatment schedule can be used without regard to meals.

**REF ID: 4686**

**Carlsson, E., Ehrenberg, A., & Ehnfors, M. (2004). Stroke and eating difficulties: Long-term experiences. *Journal of Clinical Nursing*, 13(7), 825-834.**

**Journal Article; N**

**BACKGROUND:** Previous studies have shown that eating difficulties after stroke are common and often associated with communication problems. These difficulties, however, have mainly been studied from a professional perspective. Although numerous aspects of dysfunction have been identified, little knowledge exists about the experiences of living with eating difficulties. **AIM:** To explore how people affected by stroke experience living with eating difficulties, during a prolonged period. **DESIGN:** Explorative, qualitative case study. **METHODS:** Repeated interviews and participant observations with three persons 1.5-2 years after their last stroke. Data were analysed using qualitative analysis. **RESULTS:** Eating difficulties after stroke were experienced as Striving to live a normal life, with the subthemes Abandoned to learn on one's own, Experiences of losses and Feeling dependent. The process of getting back to a life that resembled life before the stroke was experienced as long-lasting and hard work. The informants felt that they were abandoned to manage eating training on their own. The informants experienced a loss of functional eating ability and the ability to perform activities related to food and meals. Feelings of dependence were experienced in mealtime situations. **CONCLUSION:** Living with eating difficulties after stroke is a complex phenomenon. The informants felt abandoned because of lack of support from the nursing staff. They were left on their own to deal with the difficult process of adjusting to a new way of eating and losses regarding mealtime activities. The combination of repeated interviews and participant observations seemed to be an approach that should be tested in larger studies. **RELEVANCE TO CLINICAL PRACTICE:** This case study indicates a need for nurses

to develop and use evidence-based guidelines for eating training during the continuum of care. Nurses need to assess patient's habits and desires related to eating, and to adjust environment according to patient preferences.

**REF ID: 5156**

**Carlsson, E., Ehrenberg, A., & Ehnfors, M. (2004). Stroke and eating difficulties: Long-term experiences. *Journal of Clinical Nursing*, 13(7), 825-834.**

**Journal Article, Research, Tables/Charts**

**BACKGROUND:** Previous studies have shown that eating difficulties after stroke are common and often associated with communication problems. These difficulties, however, have mainly been studied from a professional perspective. Although numerous aspects of dysfunction have been identified, little knowledge exists about the experiences of living with eating difficulties. **AIM:** To explore how people affected by stroke experience living with eating difficulties, during a prolonged period. **DESIGN:** Explorative, qualitative case study. **METHODS:** Repeated interviews and participant observations with three persons 1.5-2 years after their last stroke. Data were analysed using qualitative analysis. **RESULTS:** Eating difficulties after stroke were experienced as Striving to live a normal life, with the subthemes Abandoned to learn on one's own, Experiences of losses and Feeling dependent. The process of getting back to a life that resembled life before the stroke was experienced as long-lasting and hard work. The informants felt that they were abandoned to manage eating training on their own. The informants experienced a loss of functional eating ability and the ability to perform activities related to food and meals. Feelings of dependence were experienced in mealtime situations. **CONCLUSION:** Living with eating difficulties after stroke is a complex phenomenon. The informants felt abandoned because of lack of support from the nursing staff. They were left on their own to deal with the difficult process of adjusting to a new way of eating and losses regarding mealtime activities. The combination of repeated interviews and participant observations seemed to be an approach that should be tested in larger studies. **RELEVANCE TO CLINICAL PRACTICE:** This case study indicates a need for nurses to develop and use evidence-based guidelines for eating training during the continuum of care. Nurses need to assess patient's habits and desires related to eating, and to adjust environment according to patient preferences. Copyright 2004 Blackwell Publishing Ltd

**REF ID: 4701**

**Carroll, M. F., Gutierrez, A., Castro, M., Tsewang, D., & Schade, D. S. (2003). Targeting postprandial hyperglycemia: A comparative study of insulinotropic agents in type 2 diabetes. *The Journal of Clinical Endocrinology and Metabolism*, 88(11), 5248-5254.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; AIM; IM**

This study was designed to compare the efficacy of three insulinotropic agents in the control of postprandial hyperglycemia in type 2 diabetes. Fifteen subjects with noninsulin-requiring type 2 diabetes were admitted to the General Clinical Research Center on four separate occasions. During the control study and following 7-10 d on each study medication, daylong glucose profiles were performed to investigate the effects of the assigned medication on postprandial hyperglycemia. During each admission, placebo or study medications were administered before three isocaloric meals as follows: immediate-release glipizide 30 min before breakfast and 30 min before supper, glipizide gastrointestinal therapeutic system (GITS) 30 min before breakfast, or nateglinide 120 mg 10 min before breakfast, before lunch, and before supper. Blood was drawn for analysis of glucose, insulin, and C-peptide at -0.05, 0, 0.25, 0.5, 1, 2, 3, and 4 h relative to each test meal. Immediate-release glipizide, nateglinide, or glipizide GITS administration resulted in significantly lower integrated daylong (glucose area under the curve) and peak glucose levels, compared with placebo. There were no significant differences in the daylong integrated glucose levels among the three study medications. The peak postbreakfast glucose level (but not glucose area under the curve) was lower with nateglinide, compared with either immediate-release glipizide or glipizide GITS. Postlunch and postdinner integrated glucose levels were significantly lower with immediate-release glipizide or glipizide GITS, compared with nateglinide. C-peptide levels were significantly higher with immediate-release glipizide, compared with glipizide GITS. Insulin levels did not differ among the three study medications. Once-daily glipizide GITS,

twice-daily immediate-release glipizide, or three-times-a-day administration of nateglinide results in equivalent control of postmeal hyperglycemia in type 2 diabetes. The decision to prescribe one of these three insulinotropic agents should be based on factors such as the patient's ability to comply with complex dosing regimens, the need to control fasting hyperglycemia, the risk of interprandial hypoglycemia, and pharmacoeconomic considerations, rather than postprandial glucose-lowering efficacy.

**REF ID: 4718**

**Chadwick, D. D., Jolliffe, J., & Goldbart, J. (2003). Adherence to eating and drinking guidelines for adults with intellectual disabilities and dysphagia. *American Journal of Mental Retardation : AJMR*, 108(3), 202-211.**

**Journal Article; IM**

The extent to which 40 individuals with intellectual disabilities and dysphagia and their caregivers adhered to speech and language pathology dysphagia guidelines was evaluated. These individuals were observed having a meal across four settings. In addition to monitoring overall adherence, guidelines were split into separate sections corresponding to consistency modification of food and drinks, physical positioning, use of equipment and utensils, and support and prompting recommendations. Adherence to speech and language pathology recommendations was generally high, particularly regarding consistency modification that can help reduce the risks of aspiration and asphyxiation. Significant differences in adherence were found across settings, across type of guidelines, and between people who were fed by caregivers and those who fed themselves.

**REF ID: 5148**

**Chang, C., & Lin, L. (2005). Effects of a feeding skills training programme on nursing assistants and dementia patients. *Journal of Clinical Nursing*, 14(10), 1185-1192.**

**Journal Article, Research, Tables/Charts**

**AIMS AND OBJECTIVES:** The purposes of this study were to develop a comprehensive feeding skills training programme for nursing assistants and to test the effects of this training programme on their knowledge, attitude and behaviour and the outcome of dementia patients including total eating time, food intake and feeding difficulty. **BACKGROUND:** Dementia patients have a high probability of feeding problems that result in a substantial risk of malnutrition. Assisting residents with eating is a major task for nursing assistants and they require better training to provide adequate quality of nutritional care. **DESIGN METHODS:** A quasi-experimental study was conducted. Two convenience-chosen dementia-specialized long-term care facilities in North Taiwan were randomly assigned into either a control or a treatment group. Sixty-seven nursing assistants were enrolled (treatment: 31; control: 36). Twenty nursing assistants and the same number of dementia patients were observed during mealtime. The treatment group participated in a feeding skills training programme including three hours of in-service classes and one hour of hands-on training, whereas the control group did not receive any training. **RESULTS:** The treatment group had significantly more knowledge ( $F = 47.7, P < 0.001$ ), more positive attitude ( $F = 15.75, P = 0.001$ ) and better behaviours ( $t = 6.0, P < 0.001$ ) than the control group after the intervention. Dementia patients in the treatment group had significantly longer total eating time ( $t = 2.7, P < 0.05$ ) and higher Edinburgh Feeding Evaluation in Dementia scores (more feeding difficulty) ( $t = 2.1, P < 0.05$ ) than the control group. There was no significant difference on food intake between the two groups ( $t = 0.8, P = 0.49$ ). **CONCLUSION:** This feeding skills training programme has been found to change nursing assistants' knowledge, attitude, and behaviour as well as increasing the eating time for the dementia patients. **RELEVANCE TO CLINICAL PRACTICE:** This study raises attention regarding on-the-job training for nursing assistants. Furthermore, the feeding problems among dementia patients should be further explored as well as the nutritional care.

**REF ID: 4677**

**Charest, A., Vanstone, C., St-Onge, M. P., Parson, W., Jones, P. J., & Lamarche, B. (2005). Phytosterols in nonfat and low-fat beverages have no impact on the LDL size phenotype. *European Journal of Clinical Nutrition*, 59(6), 801-804.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

**OBJECTIVE:** To examine the impact of nonfat and low-fat phytosterol-enriched beverages on low-density lipoprotein (LDL) electrophoretic characteristics. **DESIGN:** Double-blind, randomized, crossover, placebo-controlled dietary trial. **SETTING:** Diets were prepared and consumed at the Mary Emily Clinical Nutrition Research Unit of McGill University. Analyses were performed at the Institute on Nutraceuticals and Functional Foods of Laval University. **SUBJECTS AND INTERVENTION:** In total, 15 moderately hypercholesterolemic persons consumed each of three experimental diets that each comprised a different beverage: nonfat placebo (NF control), nonfat with phytosterols (NFPS) or low-fat with phytosterols (LFPS). Participants consumed three beverages daily at meal time for a total of 1.8 g of phytosterols per day. Nondenaturing 2-16% polyacrylamide gradient gel electrophoreses were used to characterize LDL size characteristics. **RESULTS:** The NFPS and LFPS beverage induced no significant changes in several features of the LDL size phenotype compared to the control diet. **CONCLUSION:** The consumption of phytosterol-supplemented nonfat and low-fat beverages is not associated with clinically meaningful changes in the LDL particle size phenotype.

**REF ID: 4702**

**Chew, C. G., Bartholomeusz, F. D., Bellon, M., & Chatterton, B. E. (2003). Simultaneous 13C/14C dual isotope breath test measurement of gastric emptying of solid and liquid in normal subjects and patients: Comparison with scintigraphy. *Nucl.Med.Rev.Cent.East.Eur.*, 6(1), 29-33.**

**Clinical Trial; Controlled Clinical Trial; Journal Article; IM**

**BACKGROUND:** To develop a simple method for simultaneous solid and liquid gastric emptying assessment using a dual isotope labelled breath test. **MATERIAL AND METHODS:** 13 patients were given 100 g ground beef labelled with 25 MBq (99m)Tc sulphur colloid and 74 KBq (14)C octanoic acid, and 150 ml 10% glucose drink labelled with 8 MBq (67)Ga citrate and 150 mg (13)C acetate. 10 normal volunteers were given the same test meals but labelled with (14)C and (13)C only. Breath was collected at baseline and regularly for 4 hours. The (14)CO(2) and (13)CO(2) activity was measured with liquid scintillation counting and mass spectroscopy. The times to maximum (14)CO(2) and (13)CO(2), were determined. Comparison was made between times to maximum (14)CO(2) with scintigraphic retention of (99m)Tc at 100 minutes and times to maximum (13)CO(2) with the scintigraphic half-clearance time of (67)Ga. **RESULTS:** For the solid meal, the times to maximum (14)CO(2) were: 60-120 minutes in the 8 patients with normal gastric emptying of (99m)Tc; 75-145 minutes for the 10 healthy volunteers; 75-180 minutes for the remaining 5 patients with abnormal gastric emptying of (99m)Tc. There was a weak but significant correlation ( $r = 0.56$ ,  $p < 0.025$ ) between the time to maximum (14)CO(2) and gastric retention of (99m)Tc at 100 minutes. For the liquid meal, times to maximum (13)CO(2) were: 20-35 minutes for the 4 with normal gastric emptying of (67)Ga; 15-40 minutes for the 10 healthy volunteers; 20-75 minutes for the remaining 9 patients with abnormal gastric emptying of (67)Ga. There was a strong and significant correlation ( $r = 0.88$ ,  $p < 0.005$ ) between times to maximum (13)CO(2) and gastric half-clearance time of (67)Ga. **CONCLUSIONS:** Breath tests utilising test meals labelled with \*C isotopes are valid alternatives to scintigraphic studies using (99m)Tc and (67)Ga for the simultaneous assessment of gastric emptying of solids and liquids.

**REF ID: 4676**

**Ciraj, O., Markovic, S., & Kosutic, D. (2005). Patient doses for barium meal examination in serbia and montenegro and potentials for dose reduction through changes in equipment settings. *Radiat.Prot.Dosimetry*, 114(1-3), 158-163.**

**Journal Article; Multicenter Study; IM**

Patient doses for barium meal examination performed at three general hospitals in Serbia and Montenegro were measured using a kerma-area product (KAP) meter. The results were analysed in order to obtain dose-related parameters. Although the observed doses were within the range reported in other studies, intra-hospital and inter-hospital dose variations were significant. Mean KAP values for total examination in three hospitals were 8.4, 24.4 and 13.9 Gy cm<sup>2</sup>, respectively. Contribution from fluoroscopy was greater than from radiography. Factors contributing to the increased dose delivery were determined and the recommendations on radiographic techniques were made. Changes in radiography settings allowed dose reduction up to 48% in the radiographic part of examination, that is, up to 12% in

total dose without loss of image quality. In addition, fluoroscopy time was noted as the second major contributor to the dose variations. The results demonstrated the need for standardisation of practice for barium meal examination in the country.

**REF ID: 5151**

**Cramer, J. A., Okikawa, J., Bellaire, S., & Clauson, P. (2004). Compliance with inhaled insulin treatment using the AERx iDMS insulin diabetes management system. *Diabetes Technology & Therapeutics*, 6(6), 800-807.**

**Journal Article, Clinical Trial, Research, Tables/Charts**

**OBJECTIVE:** The AERx Insulin Diabetes Management System [AERx iDMS, jointly developed by Novo Nordisk (Bagsvaerd, Denmark) and Aradigm Corp. (Hayward, CA)] provides insulin by pulmonary administration. This investigation was designed as a pilot trial to demonstrate the ability of patients to use the electronic device to deliver mealtime inhaled insulin doses and explore the impact on compliance. **METHODS:** AERx iDMS was evaluated in a substudy of a 12-week, multicenter open trial by adult patients with type 2 diabetes previously on any insulin regimen. The device was used for dosing fast-acting human insulin immediately before main meals, in combination with bedtime NPH insulin. The AERx iDMS device recorded the date and time of each insulin inhalation, insulin units used, and inhalation technique during aerosol delivery. Compliance was defined as the percentage of prescribed doses taken during the treatment period, dose timing, and the efficiency of dosing technique. **RESULTS:** Insulin dosing for 49 patients (age 59.1 +/- 7.7 years) using AERx iDMS was monitored for 78.9 +/- 10 days (range, 41-94 days) with 226 +/- 35 doses (range, 122-272 doses). Patients inhaled on average 2.9 +/- 0.3 doses of insulin daily, taking an average of 11.8 +/- 5.6 units per dose. Compliance with the prescribed regimen was 94.3 +/- 9.1% (range, 45-100%). Overall, 4.2 +/- 9.5% of prescribed doses were omitted. Hemoglobin A1c decreased 0.77 +/- 0.96% from baseline to the end of the study. Inhalation technique was excellent, with 97% of patients experiencing fewer than five inadequate doses. **CONCLUSIONS:** Excellent compliance with AERx iDMS dosing, timing, and inhalation technique showed that the device was well accepted by patients. The electronic monitoring feature could be used as an educational tool to help patients and clinicians manage insulin dosing.

**REF ID: 4733**

**Croghan, N. L., Shultz, J. A., Adams, C. E., & Massey, L. K. (2001). Barriers to nutrition care for nursing home residents. *Journal of Gerontological Nursing*, 27(12), 25-31.**

**Journal Article; Multicenter Study; N**

The prevalence of protein-calorie malnutrition (PCM) in nursing home residents has reached 85% in some nursing homes and is linked to increased mortality among residents. Separate survey questionnaires were developed and administered to 99 nursing assistants and 44 nurses (35 RNs, 9 LPNs) from five eastern Washington nursing homes. The purpose was to assess nurse (RN, LPN) and nursing assistant perceived beliefs and views related to nutritional needs of nursing home residents that have a potential impact on PCM of residents. Experienced nursing assistants did not view the nurse as an active participant during mealtime. Specific barriers such as a lack of time and training, too many residents, working short staffed, poor food quality, and a lack of nurse-nursing-assistant teamwork may contribute to residents not getting enough food to eat. An education program addressing staff relationships and nutrition training of nursing assistants could improve the ability of nursing staff to ensure residents' food intake and improve the quality of life for residents in nursing homes.

**REF ID: 5174**

**Evidence Level IV: Nonexperimental Study**

**Croghan, N. L., Shultz, J. A., Adams, C. E., & Massey, L. K. (2001). Barriers to nutrition care for nursing home residents. *Journal of Gerontological Nursing*, 27(12), 25-31.**

**Journal Article, Research, Tables/Charts**

The prevalence of protein-calorie malnutrition (PCM) in nursing home residents has reached 85% in some nursing homes and is linked to increased mortality among residents. Separate survey questionnaires were developed and administered to 99 nursing assistants and 44 nurses (35 RNs, 9 LPNs) from five eastern Washington nursing homes. The purpose was to assess nurse (RN, LPN) and

nursing assistant perceived beliefs and views related to nutritional needs of nursing home residents that have a potential impact on PCM of residents. Experienced nursing assistants did not view the nurse as an active participant during mealtime. Specific barriers such as a lack of time and training, too many residents, working short staffed, poor food quality, and a lack of nurse-nursing-assistant teamwork may contribute to residents not getting enough food to eat. An education program addressing staff relationships and nutrition training of nursing assistants could improve the ability of nursing staff to ensure residents' food intake and improve the quality of life for residents in nursing homes.

**REF ID: 4670**

**Dalla Man, C., Campioni, M., Polonsky, K. S., Basu, R., Rizza, R. A., & Toffolo, G. et al. (2005). Two-hour seven-sample oral glucose tolerance test and meal protocol: Minimal model assessment of beta-cell responsiveness and insulin sensitivity in nondiabetic individuals. *Diabetes*, 54(11), 3265-3273.**

**Clinical Trial; Journal Article; AIM; IM**

Highly informative yet simple protocols to assess insulin secretion and action would considerably enhance the quality of epidemiological and large-scale clinical trials. In an effort to develop such protocols, a 5-h, 11-sample oral glucose tolerance test (OGTT) was performed in 100 individuals and a 7-h, 21-sample meal in another 100. Plasma glucose, insulin, and C-peptide concentrations were measured. We show that virtually the same minimal model assessment of beta-cell responsiveness (dynamic  $[\Phi(d)]$  and static  $[\Phi(s)]$ ), insulin sensitivity ( $S_i$ ), and disposition index (DI) can be obtained with a reduced seven-sample 2-h protocol:  $\Phi(d)$ , reduced versus full: 871.50 vs. 873.32,  $r = 0.98$  in OGTT and 494.88 vs. 477.99  $10(-9)$ ,  $r = 0.91$  in meal;  $\Phi(s)$ : 42.36 vs. 44.35,  $r = 0.88$  in OGTT and 35.31 vs. 35.37  $10(-9) \text{ min}(-1)$ ,  $r = 0.90$  in meal;  $S_i$ : 24.33 vs. 22.77  $10(-5) \text{ dl} \times \text{kg}(-1) \times \text{min}(-1) \text{ per pmol/l}$ ,  $r = 0.89$  in OGTT and 19.03 vs. 19.77  $10(-5) \text{ dl} \times \text{kg}(-1) \times \text{min}(-1) \text{ per pmol/l}$ ,  $r = 0.85$  in meal; and DI: 1,282.26 vs. 1,273.23,  $r = 0.84$  in OGTT and 726.92 vs. 776.97  $10(-14) \text{ dl} \cdot \text{kg}(-1) \times \text{min}(-2) \text{ per pmol/l}$ ,  $r = 0.84$  in meal. This reduced protocol will facilitate the study of insulin secretion and action under physiological conditions in nondiabetic humans.

**REF ID: 4725**

**Daly, J. M., Buckwalter, K., & Maas, M. (2002). Written and computerized care plans. organizational processes and effect on patient outcomes. *Journal of Gerontological Nursing*, 28(9), 14-23.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; N**

The purpose of this study was to determine how use of a standardized nomenclature for nursing diagnosis and intervention statements on the computerized nursing care plan in a long-term care (LTC) facility would affect patient outcomes, as well as organizational processes and outcomes. An experimental design was used to compare the effects of two methods of documentation: Computer care plan and paper care plan. Twenty participants (10 in each group) were randomly assigned to either group. No statistically significant differences were found by group for demographic data. Repeated measures ANOVA was computed for each of the study variables with type of care plan, written or computerized, as the independent variable. There were no statistically significant differences between participants, group (care plan), within subjects (across time), or interaction (group and time) effects for the dependent variables: Level of care, activities of daily living, perception of pain, cognitive abilities, number of medications, number of bowel medications, number of constipation episodes, weight, percent of meals eaten, and incidence of alteration in skin integrity. There were significantly more nursing interventions and activities on the computerized care plan, although this care plan took longer to develop at each of the three time periods. Results from this study suggest that use of a computerized plan of care increases the number of documented nursing activities and interventions, but further research is warranted to determine if this potential advantage can be translated into improved patient and organizational outcomes in the long-term care setting.

**REF ID: 5163**

**De Bellis, A., Willick, C., Mitchell, P., & RoderAllen, G. (2003). Food for thought: Residents with dementia who require assistance with eating and drinking. *Geriatrics*, 21(3), 5-10.**

### **Journal Article, Research**

There is presently limited understanding of the ways in which the delivery of food and fluids impacts on residents with a diagnosis of dementia who reside in aged care facilities and require assistance with eating and drinking. This article presents one facet of a qualitative study involving 24 residents with dementia who required assistance with the oral intake of food and fluids. This article focusses on the non-participant observation of mealtimes involving the residents participating in the study and the relatives and staff who assisted. Themes were identified from the analysis that provided evidence of problems in everyday practices involved in assisting the residents with dementia to eat and drink. The themes centred around the involvement of relatives, the importance of education, a task orientation focus and the role of the Registered Nurse. As a result of the study changes that were deemed necessary by nursing and personal care staff and management were implemented to improve practices.

#### **REF ID: 4722**

**Delahanty, L. M., Hayden, D., Ammerman, A., & Nathan, D. M. (2002). Medical nutrition therapy for hypercholesterolemia positively affects patient satisfaction and quality of life outcomes. *Annals of Behavioral Medicine : A Publication of the Society of Behavioral Medicine*, 24(4), 269-278.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

Following a heart-healthy diet to lower cholesterol levels is often assumed to be difficult, to be burdensome, and to have a negative impact on quality of life (QOL). The purpose of this study was to evaluate the impact of medical nutrition therapy (MNT) versus usual care (UC) for hypercholesterolemia on patient satisfaction and QOL. Ninety ambulatory care patients (60 men and 30 women), age 28 to 66, were randomly assigned to receive either MNT from dietitians using a National Cholesterol Education Program-based protocol or UC from their physicians. Patients who received MNT reported no difference in QOL related to the taste or enjoyment of food compared with UC patients. However, the MNT group reported initial improvements in QOL related to the convenience and cost of following a low-fat diet when compared with the UC group. The MNT group also reported significant and lasting improvements in perceived QOL related to self-care compared with the UC group. MNT patients were more satisfied with the interaction at visits, knowledge and ability to manage their cholesterol, eating habits, appearance, time spent exercising, and life in general. Moreover, MNT patients did not report any negative impact related to following a low-fat diet in regard to feeling restricted by diet; interference with lifestyle activities; or difficulty planning, purchasing, or preparing meals or eating away from home. Contrary to popular belief there is no apparent reduction but rather an improvement in some measures of QOL and patient satisfaction with MNT for hypercholesterolemia.

#### **REF ID: 4719**

**Devineni, D., Walter, Y. H., Smith, H. T., Lee, J. S., Prasad, P., & McLeod, J. F. (2003). Pharmacokinetics of nateglinide in renally impaired diabetic patients. *Journal of Clinical Pharmacology*, 43(2), 163-170.**

**Clinical Trial; Journal Article; IM**

Treatment of hyperglycemia in patients with diabetes mellitus and renal insufficiency is complicated by altered pharmacokinetics of hypoglycemic agents. This study evaluated the pharmacokinetic profile and safety of nateglinide, an amino acid derivative that improves early phase insulin secretion and reduces mealtime glucose excursions. This open-label, single-dose, two-center study included patients (mean age = 57 +/- 10 years) with type 1 or 2 diabetes with impaired renal function (IRF) (n = 10) or with renal failure undergoing hemodialysis (n = 10). Both groups were compared with age-, sex-, height-, and weight-matched healthy controls (n = 20). All participants received a single 120-mg dose of nateglinide immediately before breakfast. Pharmacokinetic and safety evaluations were undertaken up to 48 hours postdose. All 40 subjects completed the study. Plasma nateglinide concentrations increased rapidly in patients undergoing dialysis and matched healthy subjects (t<sub>max</sub> = 0.95 vs. 0.78 h, respectively) and was comparable with patients with IRF and matched healthy subjects (t<sub>max</sub> = 0.80 vs. 0.65 h, respectively). There were no statistically significant differences for C<sub>max</sub> or AUC<sub>0-t</sub> between the groups. Nateglinide was eliminated rapidly in all groups (t<sub>1/2</sub> = 1.9-2.8 h). There was no correlation between the level of renal function and systemic exposure. There was a low extent of renal excretion of nateglinide in

healthy subjects (11%) and diabetic patients with IRF (3%). Nateglinide was well tolerated. These data suggest that nateglinide is suitable for use in diabetic patients with IRF or with renal failure undergoing dialysis. Given the comparable absorption and elimination profiles of nateglinide in renally impaired and healthy subjects, no dose adjustment appears necessary in the renally impaired.

**REF ID: 4693**

**Dimopoulos, M. A., Hamilos, G., Zomas, A., Gika, D., Efstathiou, E., & Grigoraki, V. et al. (2004). Pulsed cyclophosphamide, thalidomide and dexamethasone: An oral regimen for previously treated patients with multiple myeloma. *Hematol.J.*, 5(2), 112-117.**

**Clinical Trial; Clinical Trial, Phase II; Journal Article; IM**

**INTRODUCTION:** Thalidomide is an oral agent with significant activity in one-third of patients with refractory myeloma. However, long-term continuous administration of thalidomide can be associated with significant side effects such as deep-vein thrombosis and peripheral neuropathy. Furthermore, it is not clear whether continuous administration of thalidomide is necessary for its antimyeloma effect. We performed a phase II study with a combination that was based on the intermittent administration of thalidomide. **MATERIALS AND METHODS:** A total of 53 patients with previously treated myeloma received cyclophosphamide 150 mg/m<sup>2</sup> p.o. every 12 h before meals on days 1-5, thalidomide 400 mg p.o. in the evening on days 1-5 and 14-18 and dexamethasone 20 mg/m<sup>2</sup> in the morning after breakfast on days 1-5 and 14-18 (CTD). The CTD combination was repeated every 28 days for three courses. Subsequently, responding patients were scheduled to receive maintenance treatment with monthly courses of CTD administered only for the first five days of each month. **RESULTS:** On an intention-to-treat basis, 32 patients (60%) achieved a partial response with a median time to response of 1.5 months. Among the 43 thalidomide-naïve patients, 67% responded. Toxicities were mild or moderate and the cumulative incidence of deep-vein thrombosis and peripheral neuropathy was 4 and 2%, respectively. The median time to progression for responding patients was 12 months and the median overall survival for all patients was 17.5 months. **CONCLUSION:** The oral, outpatient pulsed CTD regimen is associated with significant activity in patients with previously treated multiple myeloma. The incidence of deep-vein thrombosis and peripheral neuropathy appears to be lower than expected when thalidomide is being administered on a continuous basis.

**REF ID: 4721**

**Donahue, S. R., Turner, K. C., & Patel, S. (2002). Pharmacokinetics and pharmacodynamics of glyburide/metformin tablets (glucovance) versus equivalent doses of glyburide and metformin in patients with type 2 diabetes. *Clinical Pharmacokinetics*, 41(15), 1301-1309.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

**OBJECTIVE:** To compare the effects of two different formulations of glibenclamide (glyburide) combined with metformin on postprandial glucose excursions, and to assess their pharmacokinetics. The formulations were a combination glibenclamide/metformin tablet (Glucovance; controlled-particle-size glibenclamide and metformin) versus glibenclamide (Micronase) and metformin (Glucophage) coadministered separately. **DESIGN:** A randomised, double-blind, two-way crossover study in which patients with type 2 diabetes received either glibenclamide/metformin 2.5/500mg tablets or glibenclamide 2.5mg with metformin 500mg twice daily for 14 days. After a 2-week washout, patients were crossed over to the other treatment for 14 days. Patients consumed standardised meals on the days when pharmacokinetic and pharmacodynamic evaluations were performed. **PARTICIPANTS:** Forty patients with type 2 diabetes were enrolled; 37 were randomised (18 men, 19 women) and 35 completed the study. Mean age was 58 years; mean body mass index was 31 kg/m<sup>2</sup>. The baseline glycated haemoglobin (HbA<sub>1c</sub>) was 9.3% for both treatment groups. **MAIN OUTCOME MEASURE:** Two-hour postprandial glucose excursion (PPGE) was used to assess postprandial glucose dynamics. **RESULTS:** Treatment with glibenclamide/metformin resulted in a significantly smaller mean PPGE than was attained by treatment with glibenclamide plus metformin, according to measurements taken after the day 14 afternoon standardised meal (89.5 vs 117.4 mg/dl, p = 0.011). The mean glibenclamide peak concentration (C<sub>max</sub>) was significantly greater (approximately 16%) after glibenclamide/metformin treatment on both days 1 and 14. Glibenclamide/metformin treatment was

associated with a 2-fold greater area under the concentration-time curve to 3 hours for glibenclamide (AUC(3)) [ $p < 0.001$ ], although the AUC over the administration interval was equivalent for both formulations. CONCLUSION: In patients with type 2 diabetes, glibenclamide/metformin resulted in lower PPGE, suggesting that the higher glibenclamide AUC(3) observed with this formulation may contribute to better postprandial glycaemic control than is attained by glibenclamide plus metformin separately.

**REF ID: 4688**

**Dutta, D., Bannerjee, M., & Chambers, T. (2004). Is tube feeding associated with altered arterial oxygen saturation in stroke patients? *Age and Ageing*, 33(5), 493-496.**

**Clinical Trial; Controlled Clinical Trial; Journal Article; IM**

**BACKGROUND:** Reduced arterial oxygen saturation (SaO<sub>2</sub>) during swallowing, oral feeding and feeding tube placement has been demonstrated in stroke patients. It is not known if tube feeding causes similar episodes of arterial desaturation and whether there is a case for routine pulse oximetry during tube feeding. **OBJECTIVE:** To determine if tube feeding in stroke patients is associated with hypoxia. **METHODS:** We compared ischaemic or haemorrhagic stroke patients who were NG or PEG fed with a control group of age matched non-dysphagic stroke patients who were orally fed. We excluded people already on supplemental oxygen. Pulse oximetry was performed before, during a meal (for 20 min) and for 10 min after and changes from baseline readings determined. **RESULTS:** Data were collected for 20 controls and 18 tube-fed patients. Mean age was 75 years and median time to assessment 14.5 days. The two groups were reasonably matched for age, sex, type of stroke and time to assessment, but differed significantly in the Oxfordshire Community Stroke Project (OCSP) classification and Rankin score. The mean baseline SaO<sub>2</sub> of controls was 96.5% (SD 1.47) and that of the tube-fed group 96.0% (SD 1.46). Reduction in SaO<sub>2</sub> from baseline during and after feeding ranged from 0.35% to 0.78% with no statistically or clinically significant differences between the two groups. **CONCLUSIONS:** No clinically significant reduction in SaO<sub>2</sub> was found in our tube-fed patients as compared to controls. Our study suggests that routine pulse oximetry during tube feeding is not necessary.

**REF ID: 4723**

**Edwards, C., Stewart, R. A., Ramanathan, K., West, T. M., French, J. K., & White, H. D. (2002). Increased myocardial ischemia after food is not explained by endothelial dysfunction. *American Heart Journal*, 144(5), E8.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; AIM; IM**

**BACKGROUND:** Recent studies suggest that a high-fat meal can impair endothelial function. The aim of this study was to determine whether greater myocardial ischemia after either a low-fat or a high-fat meal is associated with an increase in brachial artery endothelial dysfunction. **METHODS:** Twenty subjects with coronary artery disease and  $\geq 1$ -mm ST-segment depression during exercise were studied. In a randomized, double-blind, crossover design, ST-segment changes during treadmill exercise and brachial artery diameter and flow-mediated dilation were measured before and 3 hours after a low-fat milkshake meal or the same meal supplemented with 64 grams of cooked fat. **RESULTS:** After the low-fat but not the high-fat meal, resting brachial artery diameter decreased (before meal 4.72  $\pm$  0.50 mm, after low fat meal 4.62  $\pm$  0.49 mm,  $P = .001$ ; after high fat meal 4.70  $\pm$  0.51 mm, not significant). High-flow brachial artery diameter was similar before (4.81  $\pm$  0.48 mm) and after the low-fat (4.82  $\pm$  0.48 mm) and high-fat (4.84  $\pm$  0.48 mm) meals ( $P > .05$  for all). Brachial artery flow-mediated dilation was not impaired after either meal. Exercise duration decreased more after the low-fat meal (mean change 39 seconds, 95% CI -14 to -63 seconds,  $P = .004$ ) than after the high-fat meal (-7 seconds, 95% CI +19 to -34 seconds, not significant). ST-segment depression during equivalent exercise was greater after compared with before both meals (before meals 1.03  $\pm$  0.69 mm, after low fat 1.27  $\pm$  0.80 mm,  $P = .03$ ; after high fat 1.24  $\pm$  0.74 mm,  $P = .04$ ). **CONCLUSIONS:** Increased myocardial ischemia after food is caused by mechanisms other than endothelial dysfunction and by meal components other than cooked fat.

**REF ID: 5149**

**Ekberg, O., Hamdy, S., Woisard, V., WuttgeHannig, A., & Ortega, P. (2002). Social and**

**psychological burden of dysphagia: Its impact on diagnosis and treatment. *Dysphagia*, 17(2), 139-146.**

**Journal Article, Forms, Research, Tables/Charts**

The social and psychological impact of dysphagia has not been routinely reported in large studies. We sought to determine the effects of dysphagia on broad measures of the quality of life of patients and to explore the relationship between the psychological handicaps of the condition and the frequency of diagnosis and treatment. A total of 360 patients selected on the basis of known subjective dysphagia complaints, regardless of origin, in nursing homes and clinics in Germany, France, Spain, and the United Kingdom were interviewed using an established questionnaire. Qualitative interviews with a total of 28 health professionals were conducted to improve understanding of the patient data in the context of each country. Over 50% of patients claimed that they were "eating less" with 44% reporting weight loss during the preceding 12 months. Thirty-six percent of patients acknowledged receiving a confirmed diagnosis of dysphagia; only 32% acknowledged receiving professional treatment for it. Most people with dysphagia believe their condition to be untreatable; only 39% of the sufferers believed that their swallowing difficulties could be treated. Eighty-four percent of patients felt that eating should be an enjoyable experience but only 45% actually found it so. Moreover, 41% of patients stated that they experienced anxiety or panic during mealtimes. Over one-third (36%) of patients reported that they avoided eating with others because of their dysphagia. In a largely elderly population that might accept dysphagia as an untreatable part of the aging process, clinicians need to be aware of the adverse effects of dysphagia on self-esteem, socialization, and enjoyment of life. Careful questioning should assess the impact of the condition on each patient's life, and patients should be educated on their choices for treatment in the context of any coexisting illness. Awareness of the condition, diagnostic procedures, and treatment options must be increased in society and among the medical profession.

**REF ID: 5150**

**Evidence Level IV: Nonexperimental Study**

**Evans, B. C., Crogan, N. L., & Shultz, J. A. (2005). Innovations in long-term care. the meaning of mealtimes: Connection to the social world of the nursing home. *Journal of Gerontological Nursing*, 31(2), 11-17.**

**Journal Article, Pictorial, Research, Tables/Charts**

Food that reflects our family backgrounds is a source of comfort that can play an important part in recovery from illness or adaptation to the nursing home, especially for older individuals. However, no studies could be found that explored residents' perspectives on how their food and food service preferences are, or are not, met in nursing homes. This exploratory qualitative study examined dietary preferences acquired during the course of a lifetime, and the meaning of mealtimes to 20 nursing home residents, and attempted to connect that meaning with their social world. Exploring the meaning of food and food service to nursing home residents could furnish insights for improving nutritional status, adaptation to the nursing home, and quality of life through promotion of individualized nutritional care.

**REF ID: 5165**

**Evans, B. C., Crogan, N. L., & Shultz, J. A. (2003). Quality dining in the nursing home: The residents' perspectives. *Journal of Nutrition for the Elderly*, 22(3), 1-17.**

**Journal Article, Research, Tables/Charts**

Quality food and food service are integral to quality of life for older adults in nursing homes. The purposes of this article are to examine residents' perspectives about quality dining in nursing homes and to describe implications for practice. Tape-recorded interviews were completed with 20 nursing home residents who told stories about their food and food service and described a "perfect" mealtime. The pattern, "Fostering a Quality Dining Experience" containing five themes derived from residents' perspectives, is discussed in this article. The quality of nursing home food and food service was examined using Rantz et al.'s (1999) multidimensional theoretical model integrating consumer and provider perspectives. Empirical support for the model was provided by the themes and pattern generated from these interviews.

**REF ID: 4731**

**Fackler, W. K., Ours, T. M., Vaezi, M. F., & Richter, J. E. (2002). Long-term effect of H2RA therapy on nocturnal gastric acid breakthrough. *Gastroenterology*, 122(3), 625-632.**

**Clinical Trial; Controlled Clinical Trial; Journal Article; AIM; IM**

**BACKGROUND & AIMS:** Adding histamine 2 receptor antagonists (H2RAs) to proton pump inhibitor (PPI) therapy is a common practice to block nocturnal acid breakthrough (NAB). Controversy exists over its efficacy because of H2RA intolerance. No prospective study has addressed this issue.

**METHODS:** Twenty-three healthy volunteers and 20 gastroesophageal reflux disease (GERD) patients were studied. Ambulatory pH monitoring was performed with one electrode in the gastric fundus and the other 5 cm above the lower esophageal sphincter. Baseline pH testing was performed and repeated after 2 weeks on PPI twice daily before meals (omeprazole 20 mg). All subjects then received 28 days of PPI plus H2RA Qhs (ranitidine 300 mg) with repeat pH testing on days 1, 7, and 28. **RESULTS:**

Eighteen controls and 16 GERD patients completed all 5 studies. Compared with baseline, all 4 medication regimens decreased supine % time pH < 4 (P = 0.001). The administration of PPI + 1 day of H2RA was the only therapy that significantly decreased % time gastric pH < 4 for the supine period compared with PPI twice daily alone (P < 0.001). There was no difference in % time supine gastric pH < 4 between 2 weeks of PPI twice daily alone and either 1 week or 1 month of PPI + bedtime H2RA.

**CONCLUSIONS:** The combination of H2RA and PPI therapy reduced NAB only with the introduction of therapy. Because of H2RA tolerance, there is no difference in acid suppression between PPI twice daily and PPI twice daily + H2RA after 1 week of combination therapy.

**REF ID: 5176**

**Faulkner, M. (2001). The onset and alleviation of learned helplessness in older hospitalized people. *Ageing & Mental Health*, 5(4), 379-386.**

**Journal Article, Research, Tables/Charts**

The objective of this study was to investigate the relevance of learned helplessness (LH) and learned mastery (LM) theories in the respective development of dependence and independence in older hospitalized people. A two-staged experiment was performed. In stage I, meal-related responses of patient participants (n = 84) were automatically completed by a researcher during two consecutive mealtime events (LH induction). LH effects were then assessed by evaluating participant performance during a controllable meal-task and a non-meal-related psychomotor task. In stage II, "helpless" participants (n = 35) were then given an expectation of future control over the mealtime event followed by two further meals during which the researcher provided no active assistance (LM induction). LM effects were assessed as in stage I. Participants exposed to the LH inducing strategy demonstrated LH effects within both the meal and psychomotor tasks. These effects were alleviated through exposing participants to the LM inducing intervention. Exposing older hospitalized people to uncontrollable or disempowering circumstances may potentially lead them to develop a LH induced dependence. This may be alleviated by increasing patient's expectation of control leading to the development of LM.

**REF ID: 4681**

**Fichten, C. S., Libman, E., Creti, L., Bailes, S., & Sabourin, S. (2004). Long sleepers sleep more and short sleepers sleep less: A comparison of older adults who sleep well. *Behav.Sleep Med.*, 2(1), 2-23.**

**Journal Article; IM**

To determine some of the risks and benefits of being a long or short sleeper, psychological adjustment, lifestyle, and sleep parameters were investigated in 239 older adults. Responses of people who slept well and who were either long or short sleepers were studied on 48 variables investigating sleep parameters and sleep-related affect and beliefs; daytime fatigue and sleepiness; demographic factors, including age, sex, and income satisfaction; sleep lifestyle factors, including naps, bedtimes, arising times, and the regularity of these; general lifestyle factors, including regularity of mealtimes, overall daytime pleasantness, perceived busyness, diversity and valence of daily activities, and potentially stressful major life events. In addition, 14 variables evaluated aspects of psychological adjustment, including cognitive and somatic arousal, nocturnal tension, anxious, negative, unpleasant and worrying self-talk,

depression, anxiety, overall psychopathology, neuroticism, and life satisfaction. Overall, the results indicate that short sleepers get up earlier, spend less time in bed, and have lower sleep efficiencies than their long sleeper counterparts. They eat breakfast earlier, and of course, they sleep less. Only one of the 14 psychological adjustment variables was significant. In view of the many differences between short and long sleepers described in prior research, the lack of differences observed between long and short sleepers is noteworthy.

Fitzgerald, D. C. (2001). A descriptive study of the social interactions of older adults diagnosed with dementia. (Doctoral dissertation, The Catholic University of America). , 202. (UMI Order #AAI3004163.)

**REF ID: 4659**

**Fragasso, G., Montano, C., Perseghin, G., Palloshi, A., Calori, G., & Lattuada, G. et al. (2006). The anti-ischemic effect of trimetazidine in patients with postprandial myocardial ischemia is unrelated to meal composition. *American Heart Journal*, 151(6), 1238.e1-1238.e8.**

**Journal Article; Randomized Controlled Trial; AIM; IM**

**BACKGROUND:** Previous studies provide evidence for a significant reduction of coronary flow reserve after ingestion of meals of different compositions. A possible role of hyperinsulinemia and increased free fatty acid levels, which are deleterious during acute myocardial ischemia and reperfusion, has been hypothesized. We assessed in patients with stable coronary disease the effects of high-fat meals (HFMs) and high-carbohydrate meals (HCMs) on ischemic threshold and stress left ventricular function on placebo and after partial fatty acid inhibition by trimetazidine (TMZ). **METHODS:** Ten patients (9 men, age 68 +/- 7 years) were allocated to placebo and TMZ (40 mg TID), both administered in the 24 hours preceding testing, according to a randomized double-blind study design. All patients underwent stress (treadmill exercise testing according to the Bruce protocol) echocardiography after fasting (8 hours) and after an HFM and HCM (2 hours) either on placebo or on TMZ. Time to 1-mm ST-segment depression (time to 1 mm) and stress wall motion score index (WMSI) were evaluated. **RESULTS:** An HFM did not affect exercise variables compared with fasting, whereas an HCM resulted in a reduction of the ischemic threshold (time to 1 mm from 402 +/- 141 to 292 +/- 123 seconds,  $P = .025$ ). Compared with placebo, TMZ improved time to 1 mm after fasting, HFM, and HCM (432 +/- 153 vs 402 +/- 141, 439 +/- 118 vs 380 +/- 107, 377 +/- 123 vs 292 +/- 123,  $F(1,9) = 26.91$ ,  $P = .0006$ ). Compared with placebo, on TMZ, stress WMSI decreased from 1.55 +/- 0.25 to 1.29 +/- 0.14 after fasting, from 1.57 +/- 0.10 to 1.39 +/- 0.28 after HFM, and from 1.64 +/- 0.21 to 1.39 +/- 0.21 after HCM ( $F(1,9) = 37.04$ ,  $P = .0002$ ). Interestingly, stress WMSI on TMZ was never different from rest WMSI on placebo. **CONCLUSIONS:** In patients with coronary disease, exercise testing after an HCM results in more severe myocardial ischemia compared with that after an HFM. The observed beneficial effects of the partial fatty acid inhibitor TMZ seem to be unrelated to meal composition and are possibly caused by the better glucose use induced by the drug.

**REF ID: 4707**

**Gao, Y., Zhou, S., Jiang, W., Huang, M., & Dai, X. (2003). Effects of ganopoly (a ganoderma lucidum polysaccharide extract) on the immune functions in advanced-stage cancer patients. *Immunological Investigations*, 32(3), 201-215.**

**Clinical Trial; Journal Article; IM**

Preclinical studies have established that the *Ganoderma lucidum* polysaccharide (GLPS) fractions have potent anti-tumor activity, which has been associated with the immuno-stimulating effects of GLPS. However, it is unclear whether GLPS has immuno-modulating effects in humans in vivo. This study aimed to investigate the effects of Ganopoly, the polysaccharides fractions extracted from *G. lucidum*, on the immune function of advanced-stage cancer patients. Thirty-four advanced-stage cancer patients were entered onto this study, and treated with 1800 mg Ganopoly, three times daily orally before meals for 12 weeks. Immune parameters (cytokines, T cell subsets, mitotic response to phytohemagglutinin (PHA) and natural killer activity) were compared between baseline and after 12-week treatment. Thirty patients are assessable for their immune functions. Treatment of Ganopoly for 12 weeks resulted in a significant ( $P < 0.05$ ) increase in the mean plasma concentrations of interleukin (IL-2), IL-6, and

interferon (IFN)-gamma, whereas the levels of IL-1 and tumor necrosis factor (TNF-alpha) were significantly ( $P < 0.05$ ) decreased. A marked variability among patients with advanced-stage cancer was observed in the numbers of each lymphocyte subset at baseline. The mean absolute number of CD56+ cells was significantly ( $P < 0.05$ ) increased after 12-week treatment of Ganopoly, whereas the numbers of CD3+, CD4+, and CD8+ were just marginally increased compared to baseline levels, with the CD4:CD8 T cell ratios unchanged. PHA responses after 12-week treatment with Ganopoly were enhanced in most patients, when compared to pretreatment baselines ( $P < 0.05$ ). In addition, Ganopoly treatment resulted in a significant increase ( $P < 0.05$ ) in the mean NK activity compared to baselines (34.5 +/- 11.8% vs 26.6 +/- 8.3%). The present study indicates that Ganopoly enhanced the immune responses in patients with advanced-stage cancer. Clinical evaluations of response and toxicity are ongoing.

**REF ID: 5152**

**Evidence Level IV: Nonexperimental Study**

**GibbsWard, A. J., & Keller, H. H. (2005). Mealtimes as active processes in long-term care facilities. *Canadian Journal of Dietetic Practice and Research*, 66(1), 5-11.**

**Journal Article, Research, Tables/Charts**

Mealtimes are central to the nutritional care of residents in long-term care facilities. There has been little Canadian research to guide interdisciplinary practice around mealtimes. This study included a grounded theory approach to explore mealtime experiences of 20 people with dementia living in two long-term care facilities, and the meal-related care they received from registered nurses, health care aides, and dietitians. Theoretical sampling directed the collection and analysis of data from mealtime observations in special care units and key informant interviews with care providers. The constant comparison method was used to analyze and conceptualize the data. A substantive theory emerged with three key themes: 1. Each mealtime is a unique process embedded within a long-term care facility's environment. 2. Residents are central to the process through their actions (i.e., arriving, eating, waiting, socializing, leaving, and miscellaneous distracted activities). 3. Internal (i.e., residents' characteristics) and external (i.e., co-resident, direct caregiving, indirect caregiving, administrative, and government activities) influences affect residents' actions at mealtimes. The theory suggests that optimal mealtime experiences for residents require individualized care that reflects interdisciplinary, multi-level interventions.

**REF ID: 4666**

**Giovannetti, T., Schmidt, K. S., Gallo, J. L., Sestito, N., & Libon, D. J. (2006). Everyday action in dementia: Evidence for differential deficits in alzheimer's disease versus subcortical vascular dementia. *Journal of the International Neuropsychological Society : JINS*, 12(1), 45-53.**

**Clinical Trial; Journal Article; IM**

The relationship between dementia diagnosis and everyday action (e.g., meal preparation, grooming) is not well understood. This study examines differences between individuals diagnosed with vascular dementia (VaD;  $n = 25$ ) versus Alzheimer's disease (AD;  $n = 23$ ) on the Naturalistic Action Test (NAT; Schwartz et al., 2003), a performance-based measure that includes three tasks of increasing complexity. The percentage of task steps accomplished, number of errors, and performance times were recorded for each task. While the groups did not differ in dementia severity or overall impairment on the NAT, the VaD group committed more errors (3.3 vs. 1.6,  $p = .02$ ). The VaD group also accomplished significantly fewer steps when salient distractor objects were present (74.0% vs. 91.3%,  $p < .01$ ). Correlations between NAT variables and neuropsychological tests suggest the executive control deficits associated with VaD may contribute to specific action difficulties, such as distractor interference and inefficient, error-prone action on complex tasks. In AD, everyday action may be negatively influenced by episodic memory failures. Thus, dementia diagnosis has relevance to everyday function.

**REF ID: 4680**

**Haak, T., Tiengo, A., Draeger, E., Suntum, M., & Waldhausl, W. (2005). Lower within-subject variability of fasting blood glucose and reduced weight gain with insulin detemir compared to NPH insulin in patients with type 2 diabetes. *Diabetes, Obesity & Metabolism*, 7(1), 56-64.**

**Clinical Trial; Journal Article; Multicenter Study; Randomized Controlled Trial; IM**

**AIM:** The aim of this study was to compare the efficacy and safety of a basal-bolus insulin regimen comprising either insulin detemir or neutral protamine hagedorn (NPH) insulin in combination with mealtime insulin aspart in patients with type 2 diabetes. **METHODS:** This was a 26-week, multinational, open-label, parallel group trial with 505 patients with type 2 diabetes (mean age, 60.4 +/- 8.6 years; mean BMI, 30.4 +/- 5.3 kg/m<sup>2</sup>); mean HbA(1c), 7.9 +/- 1.3%). Patients, randomized 2:1 to insulin detemir or NPH insulin, received basal insulin either once or twice daily according to their pretrial insulin treatment and insulin aspart at mealtimes. **RESULTS:** After 26 weeks of treatment, significant reductions in HbA(1c) were observed for insulin detemir (0.2%-points, p = 0.004) and NPH insulin (0.4%-points; p = 0.0001); HbA(1c) levels were comparable at study end (insulin detemir, 7.6%; NPH insulin, 7.5%). The number of basal insulin injections administered per day had no effect on HbA(1c) levels (p = 0.50). Nine-point self-measured blood glucose (SMBG) profiles were similar for the two treatment groups (p = 0.58), as were reductions in fasting plasma glucose (FPG) (insulin detemir, 0.5 mmol/l; NPH insulin, 0.6 mmol/l). At study end, FPG concentrations were similar for the two treatment groups (p = 0.66). By contrast, within-subject day-to-day variation in fasting SMBG was significantly lower with insulin detemir (p = 0.021). Moreover, patients receiving insulin detemir gained significantly less body weight than those who were administered NPH insulin (1.0 and 1.8 kg, respectively, p = 0.017). The frequency of adverse events and the risk of hypoglycaemia were comparable for the two treatment groups. **CONCLUSIONS:** Patients with type 2 diabetes, treated for 26 weeks with insulin detemir plus insulin aspart at mealtimes, experienced comparable glycaemic control but significantly lower within-subject variability and less weight gain compared to patients treated with NPH insulin and insulin aspart. Insulin detemir was well tolerated and had a similar safety profile to NPH insulin.

**REF ID: 4724**

**Hebden, J. M., Blackshaw, E., D'Amato, M., Perkins, A. C., & Spiller, R. C. (2002). Abnormalities of GI transit in bloated irritable bowel syndrome: Effect of bran on transit and symptoms. *The American Journal of Gastroenterology*, 97(9), 2315-2320.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

**OBJECTIVES:** Bloating is an important but poorly understood symptom in irritable bowel syndrome (IBS) that is often aggravated by bran. The aim of our study was to determine whether IBS patients with bloating responded to bran differently from healthy controls. **METHODS:** A total of 12 patients with IBS (according to Rome I criteria), all with moderate to severe bloating, and 12 healthy controls participated in a two way, double blind, randomized, cross-over trial of bran versus placebo (crushed biscuits) 15 g b.i.d. An average daily pain index and bloating score were derived from daily symptom diaries. On day 14, gastric emptying, small bowel transit, percent remaining in ascending colon, and geometric center of a meal marker at 24 h were calculated from scintigraphic images obtained after ingesting a Tc99m-labeled rice pudding meal with 15 g of either placebo or coarse bran. **RESULTS:** Results are given as median (range). Bran significantly increased the pain index and bloating (p < 0.02) in IBS patients but not controls. The most striking finding was that the small bowel transit time of the meal without bran was markedly faster in IBS patients than in controls, being 203 min (range 109-313) versus 367 min (219-543), p < 0.001. Although in controls bran accelerated small bowel transit time to 262 min (180-380), p = 0.03, and significantly reduced % remaining in the ascending colon from 22% (0-46) to 3% (0-25), p = 0.03, this was not seen in the IBS patients. Bran accelerated whole gut transit as assessed by geometric center at 24 h in both IBS patients and controls. **CONCLUSIONS:** Bran accelerates small bowel transit and ascending colon clearance without causing symptoms in controls. Small bowel transit is rapid in IBS patients with bloating and, unlike in healthy control subjects, cannot be further accelerated by bran, which nevertheless aggravates symptoms of pain and bloating. We speculate that bran-induced bloating may originate in the colon rather than the small bowel.

**REF ID: 4717**

**Heymsfield, S. B., van Mierlo, C. A., van der Knaap, H. C., Heo, M., & Frier, H. I. (2003). Weight management using a meal replacement strategy: Meta and pooling analysis from six studies. *International Journal of Obesity and Related Metabolic Disorders : Journal of the International Association for the Study of Obesity*, 27(5), 537-549.**

### **Journal Article; Meta-Analysis; IM**

**OBJECTIVE:** Although used by millions of overweight and obese consumers, there has not been a systematic assessment on the safety and effectiveness of a meal replacement strategy for weight management. The aim of this study was to review, by use of a meta- and pooling analysis, the existing literature on the safety and effectiveness of a partial meal replacement (PMR) plan using one or two vitamin/mineral fortified meal replacements as well as regular foods for long-term weight management. **DESIGN:** A PMR plan was defined as a program that prescribes a low calorie (>800 or =25 kg/m<sup>2</sup>), were evaluated. Studies with self-reported weight and height were excluded. Searches in Medline, Embase, and the Cochrane Clinical Trials Register from 1960 to January 2001 and from reference lists identified 30 potential studies for analysis. Of these, six met all of the inclusion criteria and used liquid meal replacement products with the associated plan. Overweight and obese subjects were randomized to the PMR plan or a conventional reduced calorie diet (RCD) plan. The prescribed calorie intake was the same for both groups. Authors of the six publications were contacted and asked to supply primary data for analysis. Primary data from the six studies were used for both meta- and pooling analyses. **RESULTS:** Subjects prescribed either the PMR or RCD treatment plans lost significant amounts of weight at both the 3-month and 1-year evaluation time points. All methods of analysis indicated a significantly greater weight loss in subjects receiving the PMR plan compared to the RCD group. Depending on the analysis and follow-up duration, the PMR group lost approximately 7-8% body weight and the RCD group lost approximately 3-7% body weight. A random effects meta-analysis estimate indicated a 2.54 kg (P<0.01) and 2.43 kg (P=0.14) greater weight loss in the PMR group for the 3-month and 1-y periods, respectively. A pooling analysis of completers showed a greater weight loss in the PMR group of 2.54 kg (P<0.01) and 2.63 kg (P<0.01) during the same time period. Risk factors of disease associated with excess weight improved with weight loss in both groups at the two time points. The degree of improvement was also dependent on baseline risk factor levels. The dropout rate for PMR and RCD groups was equivalent at 3 months and significantly less in the PMR group at 1 y. No reported adverse events were attributable to either weight loss regimen. **CONCLUSION:** This first systematic evaluation of randomized controlled trials utilizing PMR plans for weight management suggests that these types of interventions can safely and effectively produce significant sustainable weight loss and improve weight-related risk factors of disease.

#### **REF ID: 5171**

**Hicks, S. (2002). Research corner: Relaxing music: What effect does it have on agitation at mealtime among nursing home patients with dementia? *Info Nursing*, 33(3), 17.**

**Journal Article, Research**

#### **REF ID: 5147**

#### **Evidence Level III: Quasi-experimental Study**

**HicksMoore, S. L. (2005). Relaxing music at mealtime in nursing homes: Effect on agitated patients with dementia. *Journal of Gerontological Nursing*, 31(12), 26-32.**

**Journal Article, Pictorial, Research, Tables/Charts**

Agitation in individuals with severe cognitive impairment is a significant problem that affects care and overall quality of life. Building on research conducted by Goddaer and Abraham (1994), this quasi-experimental study proposed that relaxing music played during meals would exert a calming effect and decrease agitated behaviors among nursing home residents with dementia. Thirty residents residing in a Special Care Unit participated in the 4-week study. The Cohen-Mansfield Agitation Inventory (Cohen-Mansfield, Marx, & Rosenthal, 1989) was used to gather data. Baseline data was obtained in Week 1 (no music). Music was introduced in Week 2, removed in Week 3, and reintroduced in Week 4. At the end of the 4-week study, overall reductions in the cumulative incidence of total agitated behaviors were observed. Reductions in absolute numbers of agitated behaviors were achieved during the weeks with music and a distinct pattern was observed.

#### **REF ID: 4736**

**Ho, Y. H., Yu, S., Ang, E. S., Seow-Choen, F., & Sundram, F. (2002). Small colonic J-pouch improves colonic retention of liquids--randomized, controlled trial with scintigraphy. *Diseases of***

*the Colon and Rectum, 45(1), 76-82.*

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

**PURPOSE:** A small 6-cm colonic J-pouch improves stool frequency and continence, without stool evacuation problems. However, the reservoir function is not improved on physiologic studies. Hence, a scintigraphy technique was devised to study the transit of solid and liquid colonic contents in these patients. **METHODS:** Patients were randomly assigned to straight or colonic J-pouch anal anastomoses after ultralow anterior resection. At 1 year after surgery, they were studied by bowel questionnaire, anorectal manometry, and technetium TC 99m tin-colloid liquid test meal/I-131 microcapsule scintigraphy. In the latter, technetium TC 99m tin-colloid was ingested orally to image the colonic liquids. I-131 microcapsules taken simultaneously imaged the solid stools. After ingestion of the radioisotopes, imaging was performed at intervals of 7 to 8, 24, and 56 hours later. Two independent observers noted the presence of technetium TC 99m tin-colloid liquid and I-131 microcapsules in various areas of interest drawn over the colon. **RESULTS:** There were six patients (5 males, mean age, 61.5 (SE mean, 1.9) years) in the straight, and six patients (5 males, mean age, 63.2 (4.5) years) in the colonic J-pouch group. Stool frequency was more in the straight group (4.8 (0.4) vs. 3 (0.2) stools/day;  $P < .001$ ). Continence, evacuation problems, and anorectal physiologic findings were not different. Technetium TC 99m tin-colloid (imaging liquids) transited significantly faster than I-131 microcapsules (imaging solids), at various areas of interest in the colon. In the colonic J-pouch patients, technetium TC 99m tin-colloid liquid was retained significantly longer in the descending colon at 24 hours ( $P < .05$ ). Stool frequency was higher when technetium TC 99m tin-colloid was not retained in the descending colon at 56 hours (3.3 (0.5) vs. 4.3 (0.4) stools/day) but this did not reach statistical significance. There were no significant differences in the distribution of the ingested I-131 microcapsules between colonic J-pouch and straight groups. **CONCLUSIONS:** Reduced stool frequency after colonic J-pouch may be related to factors causing better retention of liquid stools in the distal colon. No difference in solid stool transit could possibly account for minimal evacuation problems in small pouches.

**REF ID: 4679**

**Hodgson, J. M., Burke, V., & Puddey, I. B. (2005). Acute effects of tea on fasting and postprandial vascular function and blood pressure in humans. *Journal of Hypertension, 23(1), 47-54.***

**Clinical Trial; Journal Article; IM**

**BACKGROUND:** Effects of regular exposure to polyphenolic compounds found in tea, leading to improved endothelial function and blood pressure, may reduce cardiovascular disease risk. Controlled trials in humans have found that ingestion of tea can improve endothelial function, but also cause a rapid onset acute increase in blood pressure. **OBJECTIVE:** To examine the acute effects of tea consumption on fasting and postprandial vascular function and blood pressure. **METHODS:** Endothelium-dependent dilatation of the brachial artery, assessed using ultrasound and blood pressure were measured in 20 participants with a history of coronary artery disease. Measurements were performed at baseline and at 3.5 h (blood pressure) and 4 h (endothelial function) after drinking three cups of black tea or hot water (consumed at time = 0, 1.5 and 3 h) with and without a high-fat (50 g) meal: a total of four treatments administered in random order. **RESULTS:** The high-fat meal did not impair endothelial function. In comparison to water alone, endothelium-dependent dilatation was increased by the meal with tea (1.7 (0.4, 3.0)%,  $P = 0.02$ ), but was not significantly altered by the tea alone (0.7 (-0.6, 2.0)%,  $P = 0.32$ ). Systolic blood pressure was significantly increased by tea alone in comparison to each of the other three groups: water alone (9.3 (4.5, 14.1) mmHg,  $P = 0.0003$ ), meal with water (9.8 (5.0, 14.6) mmHg,  $P = 0.0001$ ) and meal with tea (7.2 (2.4, 12.0) mmHg,  $P = 0.004$ ). Consumption of a meal negated the acute increase in systolic blood pressure found with tea in the fasting state. **CONCLUSION:** Consumption of food may alter the acute effects of tea on vascular function and blood pressure.

**REF ID: 5162**

**Horodynski, M. A. O., Hoerr, S., & Coleman, G. (2004). Nutrition education aimed at toddlers: A pilot program for rural, low-income families. *Family & Community Health, 27(2), 103-113.***

**Journal Article, Research, Tables/Charts**

Childhood obesity is a major health problem. Effective strategies are necessary to promote healthy

eating in toddlers. The Nutrition Education Aimed at Toddlers project examined rural, low-income caregivers' knowledge, attitudes, mealtime practices, and dietary intake before and after a nutrition program. A convenience sample of 38 families participated in the study; 19 attended classes, and 19 did not. Six months after the lessons, no significant differences were found between groups; however, the resultant dietary, feeding knowledge, attitudinal, and behavioral data provide a valuable description regarding a hard to reach, high-risk population. However, caregivers' perceptions about feeding their toddlers differed from their reported dietary intakes of dairy, fruits, and vegetables. It appears that knowledge is insufficient to change eating habits. Identification of the issues that prevent caregivers in providing proper feeding is needed for a lasting change of eating habits.

**REF ID: 4703**

**Houwing, N. S., Maris, F., Schnabel, P. G., & Bagchus, W. M. (2003). Pharmacokinetic study in women of three different doses of a new formulation of oral testosterone undecanoate, andriol testocaps. *Pharmacotherapy*, 23(10), 1257-1265.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

**STUDY OBJECTIVE:** To assess the pharmacokinetic parameters of testosterone undecanoate after administration of a new oral formulation, Andriol Testocaps. **DESIGN:** Randomized, open-label, group-comparative, parallel-design, dose-proportionality study. **SETTING:** Clinical pharmacology unit. **SUBJECTS:** Forty-five healthy women without childbearing potential. **INTERVENTION:** Two oral doses each of testosterone undecanoate 20, 40, or 80 mg were administered with meals, separated by a 12-hour dosing interval. **MEASUREMENTS AND MAIN RESULTS:** Serum concentrations of testosterone undecanoate were assayed by liquid chromatography with mass spectrometric detection, and of testosterone and 5alpha-dihydrotestosterone (DHT) by gas chromatography with mass spectrometric detection. Pharmacokinetic parameters were calculated using standard methods. Statistical analysis of dose proportionality was performed on the log(e)-transforms of dose-normalized area under the serum concentration-time curve from 0-12 hours (AUC(0-12)) and from zero to the sampling time of the last measurable concentration after administration of the second dose (AUC(0-t(last))), and maximum serum concentration after the first dose (C(max)I). For testosterone undecanoate, testosterone, and DHT, dose-related increases in plasma concentrations were found with increasing doses of testosterone undecanoate; maximum concentrations were found 5-7 hours after administration. Using baseline-corrected testosterone values, dose proportionality for testosterone was found for AUC(0-12), AUC(0-t(last)), and C(max)I. After higher doses, plasma levels of testosterone undecanoate were higher and plasma levels of DHT lower than could be expected assuming dose proportionality. **CONCLUSION:** Serum testosterone levels are dose proportional after oral administration of two doses of a new formulation of testosterone undecanoate 20, 40, and 80 mg, Andriol Testocaps.

**REF ID: 4708**

**Inoue, Y., Komatsu, Y., Yoshikawa, K., Akahane, M., Isayama, H., & Ohtomo, K. et al. (2003). Biliary motor function in gallstone patients evaluated by fatty-meal MR cholangiography. *Journal of Magnetic Resonance Imaging : JMRI*, 18(2), 196-203.**

**Clinical Trial; Controlled Clinical Trial; Journal Article; IM**

**PURPOSE:** To investigate the possibility of evaluating biliary motor function with magnetic resonance cholangiography (MRC). **MATERIALS AND METHODS:** Twenty patients with gallstones and 30 control subjects were studied using fatty-meal MRC. After baseline MRC, they were encouraged to drink 250 mL of milk and underwent postprandial MRC every 10 minutes for 60 minutes. Postprandial changes in gallbladder volume and the diameter of the common duct were assessed as indicators of gallbladder contractility and biliary obstruction, respectively. Postprandial dilatation at 60 minutes was considered indicative of persistent biliary obstruction. **RESULTS:** Gallbladder ejection fraction was calculated at 66.0% +/- 12.2% (range, 40.3%-88.6%) in the controls. Gallbladder volume expressed as a percentage of the baseline value was significantly larger at 20-60 minutes in the gallstone patients than in the controls. Gallbladder ejection fraction varied widely (mean, 46.4% +/- 24.4%; range, 2.8%-81.5%) and was significantly reduced in comparison with that of the controls (P < 0.01). In two gallstone patients with co-existing ductal stones, transient postprandial dilatation associated with

ampullary impaction was observed. Persistent biliary obstruction was not indicated in any subjects.  
CONCLUSION: The results of this study suggest the feasibility of fatty-meal MRC, as well as its potential for evaluating biliary motor function.

**REF ID: 5168**

**Jensen, J., LundinOlsson, L., Nyberg, L., & Gustafson, Y. (2002). Falls among frail older people in residential care. *Scandinavian Journal of Public Health, 30(1), 54-61.***

**Journal Article, Research, Tables/Charts**

AIMS: A prospective study was carried out to investigate the incidence, circumstances, and injuries from falls among frail older people living in three different types of Swedish residential care settings. METHODS: The settings were senior citizens' apartments, an old people's home, and a group dwelling for people with dementia. The falls were registered during the three-year study period on a semi-structured fall report, and injurious falls were categorized according to severity. RESULTS: In total 428 falls occurred among 121 residents. The incidence rate of falls at the group dwelling was twice the rates of the old people's home and senior citizens' apartments (4282 compared with 1709 and 2114 falls per 1000 person-years respectively). Some 27% of the falls occurred during the night (2100h to 0600h) and 28% were related to a visit to the lavatory. The presence of acute disease at the time of a fall was diagnosed in 23% of the falls. Some type of injury occurred in 118 falls (28%) and 36 of these (8%) led to moderate or serious injuries. In total 48 fractures were diagnosed. CONCLUSIONS: In a preventive programme for falls and injuries in residential care settings, areas of particular interest should include falls after mealtimes and falls at night, conditions of acute diseases, rising up from sitting, walking, and activities in progress, especially visits to the lavatory.

**REF ID: 5164**

**Jordan, S., Snow, D., Hayes, C., & Williams, A. (2003). Introducing a nutrition screening tool: An exploratory study in a district general hospital. *Journal of Advanced Nursing, 44(1), 12-23.***

**Journal Article, Research, Tables/Charts**

BACKGROUND: Concerns have been raised that patients' nutrition is a neglected aspect of care. Accordingly, 'nutrition screening tools' have been devised to ensure that all patients are assessed by nurses and, where appropriate, referred to dieticians. The tool adopted in our hospital was the 'Nursing Nutritional Screening Tool'. AIM: To investigate the impact of this screening tool on: nutrition-related nursing documentation; patient care at mealtimes; dietician referral. METHODS: This study was conducted on two similar general medical wards in a United Kingdom (UK) district general hospital, with the help of staff and patients (n = 175) admitted during two study periods, May 1999 and January 2000. Data were collected over 28 days before and after introduction of the screening tool on one of the wards. For both wards, in each stage of the study, data were collected b: review of patients' notes, non-participant observations of mealtimes. Frequencies of dietician referral and documentation of weight were compared by cross-tabulations and chi2 tests. Nine months later, the findings were discussed with ward sisters in a group interview. FINDINGS: Introduction of the screening tool impacted on the process but not the outcomes of screening. Use of the screening tool increased the frequency of nutrition-related documentation: the proportion of patients with weights recorded increased on the intervention ward (P < 0.001), and decreased on the comparator ward. Frequency of dietician referral decreased on both wards, but differences were statistically insignificant. There was no observable change in patient care at mealtimes. The nurses in charge of the wards felt that introduction of the screening tool had raised awareness of nutrition-related care. CONCLUSIONS: Meeting patients' nutritional needs is a complex aspect of care which may benefit from introduction of structured guidelines. However, the potential of screening tools to improve care is limited by diverse factors, which warrant further exploration.

**REF ID: 4734**

**Juhl, C. B., Hollingdal, M., Sturis, J., Jakobsen, G., Agerso, H., & Veldhuis, J. et al. (2002). Bedtime administration of NN2211, a long-acting GLP-1 derivative, substantially reduces fasting and postprandial glycemia in type 2 diabetes. *Diabetes, 51(2), 424-429.***

**Clinical Trial; Journal Article; Randomized Controlled Trial; AIM; IM**

Glucagon-like peptide 1 (GLP-1) is a potent glucose-lowering agent of potential interest for the treatment of type 2 diabetes. To evaluate actions of NN2211, a long-acting GLP-1 derivative, we examined 11 patients with type 2 diabetes, age 59 +/- 7 years (mean +/- SD), BMI 28.9 +/- 3.0 kg/m(2), HbA(1c) 6.5 +/- 0.6%, in a double-blind, placebo-controlled, crossover design. A single injection (10 microg/kg) of NN2211 was administered at 2300 h, and profiles of circulating insulin, C-peptide, glucose, and glucagon were monitored during the next 16.5 h. A standardized mixed meal was served at 1130 h. Efficacy analyses were performed for the fasting (7-8 h) and mealtime (1130-1530 h) periods. Insulin secretory rates (ISR) were estimated by C-peptide deconvolution analysis. Glucose pulse entrainment (6 mg x kg(-1) x min(-1) every 10 min) was evaluated by 1-min sampled measurements of insulin concentrations from 0930 to 1030 h and subsequent time series analysis of the insulin concentration profiles. All results are given as NN2211 versus placebo; statistical analyses were performed by analysis of variance. In the fasting state, plasma glucose was significantly reduced (6.9 +/- 1.0 vs. 8.1 +/- 1.0 mmol/l; P = 0.004), ISR was increased (179 +/- 70 vs. 163 +/- 66 pmol/min; P = 0.03), and plasma glucagon was unaltered (19 +/- 4 vs. 20 +/- 4 pg/ml; P = 0.17) by NN2211. Meal-related area under the curve (AUC)(1130-1530 h) for glucose was markedly reduced (30.6 +/- 2.4 vs. 39.9 +/- 7.3 mmol x l(-1) x h(-1); P < 0.001), ISR AUC(1130-1530 h) was unchanged (118 +/- 32 vs. 106 +/- 27 nmol; P = 0.13), but the increment (relative to premeal values) was increased (65 +/- 22 vs. 45 +/- 11 nmol; P = 0.04). Glucagon AUC(1130-1530 h) was suppressed (77 +/- 18 vs. 82 +/- 17 pmol x l(-1) x h(-1); P = 0.04). Gastric emptying was significantly delayed as assessed by AUC(1130-1530 h) of 3-ortho-methylglucose (400 +/- 84 vs. 440 +/- 70 mg x l(-1) x h(-1); P = 0.02). During pulse entrainment, there was a tendency to increased high frequency regularity of insulin release as measured by a greater spectral power and autocorrelation coefficient (0.05 < P < 0.10). The pharmacokinetic profile of NN2211, as assessed by blood samplings for up to 63 h postdosing, was as follows: T(1/2) = 10.0 +/- 3.5 h and T(max) = 12.4 +/- 1.7 h. Two patients experienced gastrointestinal side effects on the day of active treatment. In conclusion, the long-acting GLP-1 derivative NN2211 effectively reduces fasting as well as meal-related (approximately 12 h postadministration) glycemia by modifying insulin secretion, delaying gastric emptying, and suppressing prandial glucagon secretion.

**REF ID: 4658**

**Evidence Level IV: Nonexperimental Study**

**Keller, H. H. (2006). Meal programs improve nutritional risk: A longitudinal analysis of community-living seniors. *Journal of the American Dietetic Association, 106(7), 1042-1048.***

**Journal Article; AIM; IM**

**OBJECTIVE:** To determine the independent association of meal programs (eg, Meals On Wheels and other meal programs with a social component) and shopping help on seniors' nutritional risk. **DESIGN:** Cohort design. Baseline data were collected with an in-person interview and subjects were followed up for 18 months via telephone interview. **SUBJECTS/SETTING:** Cognitively well, vulnerable (ie, required informal or formal supports for activities of daily living) seniors were recruited through community service agencies in southwestern Ontario, Canada. Three hundred sixty-seven seniors participated in baseline interviews and 263 completed data collection at 18-month follow-up; 70% participated in meal programs at baseline. **MAIN OUTCOME MEASURES:** The 15-item Seniors in the Community: Risk Evaluation for Eating and Nutrition (SCREEN) questionnaire identified nutritional risk at 18 months. **STATISTICAL ANALYSES PERFORMED:** Descriptive and bivariate analyses were performed and significant associations (P<0.05) used to build the full multiple linear regression model. Meal and shopping variables were forced into the model as predictors of follow-up SCREEN questionnaire scores. **RESULTS:** Meals On Wheels use was independently associated with higher SCREEN questionnaire scores (ie, less risk), as was higher income. Baseline SCREEN questionnaire scores also strongly and positively predicted follow-up scores. Self-reported depression at baseline was associated with lower scores at follow-up. Although use of programs at baseline was associated with decreased risk, if participants experienced increased use of the program (eg, more meals) during the follow-up period this was associated with lower scores, or increased risk. **CONCLUSIONS:** Meal programs can improve or maintain nutritional risk for vulnerable seniors. Increased use of these

programs over time may indicate a senior's declining status. Seniors who are in need of informal or formal supports for food shopping or preparation should be encouraged to participate in meal programs as a means of maintaining or improving their nutrition.

**REF ID: 4668**

**Kempe, K. C., Budd, D., Stern, M., Ellison, J. M., Saari, L. A., & Adiletto, C. A. et al. (2005). Palm glucose readings compared with fingertip readings under steady and dynamic glycemic conditions, using the OneTouch ultra blood glucose monitoring system. *Diabetes Technol. Ther.*, 7(6), 916-926.**

**Journal Article; Multicenter Study; Randomized Controlled Trial; IM**

**OBJECTIVES:** Past studies have suggested the absence of lag between palm glucose and fingertip glucose, even when glucose levels are changing rapidly. However, at any given time point, there may be differences between palm and fingertip glucose values because of glycemic instability and/or test methodology. The objectives of this study included assessing the variability in fingertip blood glucose test results between two fingers, and establishing whether the variability in blood glucose test results obtained from the palm was clinically equivalent to that observed in fingertip-to-fingertip comparisons. **METHODS:** This multicenter trial was conducted on patients under both steady-state glycemic conditions and after meal and exercise challenges (to promote rapidly changing glucose). Sequential capillary glucose testing, performed with the One Touch Ultra Blood Glucose Monitoring System (LifeScan, Inc., Milpitas, CA), was allocated to two of four fingertip sites and one of two palm sites in each subject using a randomized, balanced, incomplete block design. One of the fingertips was designated the reference site. Fingertip-to-fingertip variability and fingertip-to-palm variability were assessed under these steady-state and dynamic testing conditions using error grid analysis and by comparing the proportion of clinically acceptable blood glucose tests at the palm site versus the fingertip site. Clinically acceptable agreement was defined as pairs of values (fingertip to reference, or palm to reference) within 15 mg/dL when reference glucose was 75 mg/dL. **RESULTS:** One hundred eighty-one subjects with type 1 [n = 74 (40.9%)] or type 2 [n = 107 (59.1%)] diabetes at eight clinical sites completed the study. Overall, the proportion of clinically acceptable agreement was high for both palm (95.1%) and fingertip (97.5%) testing. The mean difference between palm and fingertip clinically acceptable agreement when done by healthcare professionals was -1.3% and -4.4%, under steady-state and dynamic glycemic conditions, respectively. Error grid analysis showed >97% of all palm and fingertip measurements fell in Zone A. **CONCLUSION:** This study demonstrated that variability between fingertip-to-fingertip and palm-to-fingertip measurements was in the clinically acceptable range during steady-state conditions and when glucose was rapidly changing.

**REF ID: 4727**

**Kennedy, J. S., Gwirtsman, H. E., Schmidt, D. E., Johnson, B. W., Fielstein, E., & Salomon, R. M. et al. (2002). Serial cerebrospinal fluid tryptophan and 5-hydroxy indoleacetic acid concentrations in healthy human subjects. *Life Sciences*, 71(14), 1703-1715.**

**Clinical Trial; Journal Article; IM**

The role of the serotonergic system in the pathogenesis of behavioral disorders such as depression, alcoholism, obsessive-compulsive disorder, and violence is not completely understood. Measurement of the concentration of neurotransmitters and their metabolites in cerebrospinal fluid (CSF) is considered among the most valid, albeit indirect, methods of assessing central nervous system function in man. However, most studies in humans have measured lumbar CSF concentrations only at single time points, thus not taking into account rhythmic or episodic variations in levels of neurotransmitters, precursors, or metabolites. We have continuously sampled lumbar CSF via subarachnoid catheter in 12 healthy volunteers, aged 20-65 years. One ml (every 10 min) CSF samples were collected at a rate of 0.1ml/min for 24-hour (h), and the levels of tryptophan (TRP) and 5-hydroxy indoleacetic acid (5-HIAA) were measured. Variability across all 12 subjects was significantly greater ( $P < 0.0001$ ) than the variability seen in repeated analysis of a reference CSF sample for both 5-HIAA (32.0% vs 7.9%) and TRP (25.4% vs 7.0%), confirming the presence of significant biological variability during the 24-hr period examined. This variability could not be explained solely by meal related effects. Cosinor analysis of the 24-hr TRP

concentrations from all subjects revealed a significant diurnal pattern in CSF TRP levels, whereas the 5-HIAA data were less consistent. These studies indicate that long-term serial CSF sampling reveals diurnal and biological variability not evident in studies based on single CSF samples.

**REF ID: 4673**

**Lambert, H. C., Abrahamowicz, M., Groher, M., Wood-Dauphinee, S., & Gisel, E. G. (2005). The McGill ingestive skills assessment predicts time to death in an elderly population with neurogenic dysphagia: Preliminary evidence. *Dysphagia*, 20(2), 123-132.**

**Journal Article; Validation Studies; IM**

The McGill Ingestive Skills Assessment (MISA) is a new assessment tool which quantifies the ingestive process by scoring a meal observation. The reliability and the construct validity of the MISA have been documented. However, establishment of the ability of the MISA to predict health outcomes related to feeding difficulties would support its applicability in research and in clinical settings. Seventy-three participants of a large-scale reliability and validity study were followed for up to 563 days following evaluation with the MISA. The date of the first pulmonary infection and the date and cause of death where applicable were obtained from medical records. Individuals with no incident of pulmonary infection and who were not deceased were "censored" at the date of followup. Survival analyses revealed that the MISA scores are predictive of death using a Cox proportional hazards model, and of time to pulmonary infection using a flexible model. Scores on the Solid Ingestion and Self-feeding scales are predictive of death using the Cox model, and the Texture Management scale is predictive of death using the flexible model. This effect remains statistically significant even when MISA scores are adjusted for the participant's age. These findings support the validity of the MISA for use with elderly individuals with neurogenic ingestive skill loss residing in long-term care facilities.

**REF ID: 4712**

**Lambert, H. C., Gisel, E. G., Groher, M. E., & Wood-Dauphinee, S. (2003). McGill ingestive skills assessment (MISA): Development and first field test of an evaluation of functional ingestive skills of elderly persons. *Dysphagia*, 18(2), 101-113.**

**Evaluation Studies; Journal Article; D; IM**

There is a lack of reliable and valid clinical assessment tools for individuals with loss of ingestive skills. The McGill Ingestive Skills Assessment (MISA) was developed to facilitate the reliable and valid bedside assessment of elderly persons with feeding difficulties. Items were generated by a literature review and selected with the collaboration of a multidisciplinary team. The first version of the MISA comprised 190 items in 7 scales, covering the domains of medical history, mealtime environment, physical characteristics of the patient, food textures consumed, solid ingestion, liquid ingestion, and behaviors related to self-feeding. The first field test for item selection included 50 individuals, aged 60 years and older, living in the community, supervised housing, and long-term care centers. After field testing, 134 items were eliminated due to poor face validity, redundancy, or poor psychometric performance. The remaining 56 items were provided with 4 response categories and were reorganized into 5 scales. The revised version was field tested to determine its preliminary psychometric properties on 33 individuals, 60 years of age and older, residing in a long-term care center. Six items were eliminated due to redundancy after the second field test. Analyses of the revised version resulted in the elimination of another 6 items that were redundant or that demonstrated poor reliability. Internal consistency of all scales is  $\geq 0.86$  and interrater agreement is  $\geq 0.92$ . These analyses suggest that the psychometric properties of the MISA are adequate for diagnosis and treatment planning. This supports its readiness for clinical use following further reliability and validity testing with a larger sample.

**REF ID: 4739**

**Langer, P., Wild, A., Celik, I., Kopp, I., Bergenfelz, A., & Bartsch, D. K. (2001). Prospective controlled trial of a standardized meal stimulation test in the detection of pancreaticoduodenal endocrine tumours in patients with multiple endocrine neoplasia type 1. *The British Journal of Surgery*, 88(10), 1403-1407.**

**Clinical Trial; Controlled Clinical Trial; Journal Article; AIM; IM**

**BACKGROUND:** Use of a standardized meal stimulation test has been recommended for the early diagnosis of pancreaticoduodenal endocrine tumours (PETs) in patients with multiple endocrine neoplasia type 1 (MEN 1). The diagnostic value of this test was re-evaluated. **METHODS:** In a prospective, controlled trial 58 standardized meal stimulation tests (563 kcal) were performed in 12 patients with MEN 1 and histologically, biochemically and/or radiologically confirmed PETs (group 1), 11 carriers of an MEN 1 mutation with no evidence of PETs (group 2) and in 27 healthy controls (group 3). Serum pancreatic polypeptide (PP) and gastrin concentrations were measured before and during the test meal. **RESULTS:** Patients in group 1 had significantly higher mean basal serum PP and gastrin concentrations than patients in group 2 and controls ( $P < 0.05$ ). In all three groups an increase in serum PP was observed after meal stimulation, but there was no significant difference between the groups. No increase in gastrin level was found in any of the groups after meal stimulation. **CONCLUSION:** The standardized meal stimulation test does not reliably indicate the presence of PETs in patients with MEN 1, whereas raised basal serum PP and gastrin levels do. The expensive and time-consuming meal test can be excluded from MEN 1 screening programmes.

LC, V., DJ, M., WH, H., & RW, J. (2001). The influence of low-, normal-, and high-carbohydrate meals on blood pressure in elderly patients with postprandial hypotension. *The journals of gerontology. series A, biological sciences and medical sciences.* (pp. M744-8)

LC, V., R, S., & RW, J. (2003). The effect of meals at different mealtimes on blood pressure and symptoms in geriatric patients with postprandial hypotension. *The journals of gerontology. series A, biological sciences and medical sciences.* (pp. 1031-1035)

**REF ID: 4672**

**LeCheminant, J. D., Jacobsen, D. J., Hall, M. A., & Donnelly, J. E. (2005). A comparison of meal replacements and medication in weight maintenance after weight loss. *Journal of the American College of Nutrition, 24(5), 347-353.***

**Journal Article; Randomized Controlled Trial; IM**

**OBJECTIVE:** To compare the use of meal replacements or medication during weight maintenance subsequent to weight loss using a very low-energy diet (VLED) in overweight or obese adults.

**DESIGN:** Participants followed a liquid VLED of 2177 kJ for 12 weeks followed by 4 weeks of re-orientation to solid foods. Participants were randomized at week 16 to receive either meal replacements or Orlistat both combined with a structured meal plan containing an energy value calculated to maintain weight loss. **SUBJECTS:** Sixty-four women (age = 49.9 +/- 10 y, weight = 101.6 +/- 17.1 kg, height = 164.9 +/- 6.0 cm, BMI = 36.7 +/- 5.4 kg/m<sup>2</sup>) and 28 men (age = 53.7 +/- 9.6 y, weight = 121.8 +/- 16.0 kg, height = 178.7 +/- 5.6 cm, BMI = 37.8 +/- 4.9 kg/m<sup>2</sup>) completed a 1 year weight management program. Behavioral weight management clinics included topics on lifestyle, physical activity (PA), and nutrition. Participants met for 90 min weekly for 26 weeks, and then biweekly for the remaining 26 weeks. **OUTCOMES:** Minutes of PA, fruits and vegetables (FV), and pedometer steps were recorded on a daily basis and reported at each group meeting. Body weight was obtained at each group meeting. **RESULTS:** During VLED, the MR group decreased body weight by 22.8 +/- 6.1 kg and the Orlistat group decreased body weight by 22.3 +/- 6.1 kg. During weight maintenance, there was no significant group by time interaction for body weight, PA, FV consumption, or pedometer steps. At week 16, the meal replacement group had a body weight of 85.4 +/- 14.3 kg that increased to 88.1 +/- 16.5 kg at 52 weeks ( $p < 0.05$ ). At week 16, the Orlistat group had a body weight of 85.7 +/- 17.9 kg that increased to 88.5 +/- 20.3 kg at 52 weeks ( $p < 0.05$ ). **CONCLUSIONS:** Subsequent to weight loss from a VLED, meal replacements and Orlistat treatments were both effective in maintaining weight significantly below baseline levels over a 52 week period of time. Meal replacements may be a viable alternative strategy to medications for weight maintenance.

**REF ID: 4726**

**Lee, A., Patrick, P., Wishart, J., Horowitz, M., & Morley, J. E. (2002). The effects of miglitol on glucagon-like peptide-1 secretion and appetite sensations in obese type 2 diabetics. *Diabetes, Obesity & Metabolism, 4(5), 329-335.***

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

**BACKGROUND:** Previous studies reported that administration of first generation alpha-glucosidase inhibitors (AGIs), such as voglibose or acarbose, produced exaggerated and sustained postprandial responses of glucagon-like peptide-1 (GLP-1), an incretin hormone from the enteroinsular axis, in healthy humans. Little is known about the postprandial release of GLP-1 after AGI therapy in diabetics. GLP-1 plays a role to mediate satiety. Any agent that substantially elevates GLP-1 levels may theoretically reduce hunger, increase satiation and limit food intake. **OBJECTIVES:** This study was performed to analyse the effect of miglitol, a more potent second generation AGI with fewer gastrointestinal side-effects, on the regulation of meal-related GLP-1 secretion and on the change of insulin-glucose dynamics as well as the release of gastric inhibitory polypeptide (GIP), another incretin hormone, after stimulation by an ordinary meal in obese type-2-diabetic subjects. Miglitol's subsequent influences on appetite sensations and food intake were also measured. **DESIGN:** In total, 8 obese type-2-diabetic women were randomized to receive treatment with 100 mg of miglitol or placebo three times a day for 2 days (six doses total) in a double-blind fashion. On day 3 of each treatment period (miglitol or placebo), measurements of GLP-1, GIP, insulin and glucose were taken periodically during 3 h after eating a 720 kcal breakfast. Appetite ratings with visual analogue scales (VASs) were used to assess ingestive behaviour hourly just before breakfast and hourly after for 6 h until immediately before lunch. The number of tuna sandwiches eaten at lunch was used to measure food consumption. **RESULTS:** The plasma GLP-1, glucose, insulin and GIP levels in response to the mixed meal were compared after the miglitol and placebo treatment. Miglitol effectively enhanced postprandial GLP-1 release and suppressed plasma GIP secretion. The ingestion of a mixed meal induced a remarkable rise in GLP-1 after miglitol as compared with placebo in overweight diabetic subjects. The meal-related rise in GLP-1 after miglitol was significantly greater at all time-points between 30 and 180 min than after the placebo. The postprandial incremental area under the curve for GLP-1 with miglitol treatment was about twofold that with the placebo. The GLP-1 level reached a maximum at 120 min after the mixed meal and steadily rose throughout the rest of the 3-h study period. In the miglitol-treated condition, the average caloric intake at lunch during a 30-min eating period was 12% lower ( $p < 0.05$ ) as compared with that after the placebo in six out of the eight subjects who exhibited a GLP-1 rise after the breakfast meal by greater than 30% from the placebo-treated condition. Correspondingly, the average rating scores were significantly lower for hunger feelings and markedly greater for sensations of satiety under the miglitol treatment; beginning 2 and 3 h, respectively, before the lunch test. **CONCLUSIONS:** Miglitol induced an enhanced and prolonged GLP-1 release at high physiological concentrations after ingesting an ordinary meal in glycaemic-controlled diabetics. The excessive postprandial GLP-1 elevation after miglitol therapy modified feeding behaviour and food intake, and thereby has potential value in regulating appetite and stabilizing body weight in obese type-2-diabetic patients.

**REF ID: 5154**

**Lengyel, C. O., Smith, J. T., Whiting, S. J., & Zello, G. A. (2004). A questionnaire to examine food service satisfaction of elderly residents in long-term care facilities. *Journal of Nutrition for the Elderly*, 24(2), 5-18.**

**Journal Article, Research, Tables/Charts**

The purpose of this study was to develop a survey tool for assessing the satisfaction of elderly long-term care (LTC) residents with the meals and food services they receive, as well as to assess quality of life issues related to eating. Food service delivery should be provided in an environment that fosters autonomy, interpersonal relations, and security. The questionnaire was administered as face-to-face interviews with 205 residents ( $\geq 65$  years of age) of 13 LTC facilities in Saskatoon, Saskatchewan, Canada (participation rate = 67%). Residents expressed some concern with food variety, quality, taste, and appearance, and with the posting of menus. Quality of life issues were mostly positive; however, residents were less satisfied with areas related to their autonomy such as food choice and snack availability.

**REF ID: 4663**

**Liddle, R. A., Toskes, P. P., Horrow, J., Ghali, J., Dachman, A., & Stong, D. (2006). Lack of trophic pancreatic effects in humans with long-term administration of ximelagatran. *Pancreas*,**

32(2), 205-210.

**Journal Article; Randomized Controlled Trial; IM**

**OBJECTIVES:** Negative feedback regulation of pancreatic proteases controls pancreatic secretion in most species and pancreatic growth in rodents. Its mechanism involves the inhibition of intraluminal proteases, resulting in sustained elevation of plasma cholecystokinin (CCK) concentrations, producing a chronic trophic stimulus to the pancreas that leads to the formation of pancreatic nodules and adenomas. Ximelagatran, whose active form, melagatran, inhibits both thrombin and the serine protease trypsin, is under clinical development as an oral anticoagulant. Recent data indicate species differences in the expression of CCK receptor subtypes in the pancreas. CCK1 receptors are abundant in rat pancreas but are either absent or present at very low levels in human pancreas. As part of the clinical studies, we examined whether long-term ximelagatran administration causes CCK release and exerts possible trophic effects on the pancreas in humans. **METHODS:** One hundred thirty patients requiring anticoagulation treatment for atrial fibrillation randomly received, in a double-blind fashion, either 36 mg oral ximelagatran twice daily or warfarin dose adjusted to an international normalized ratio of 2.0 to 3.0. Before enrollment and after 12 months of treatment, computed tomography scans of the pancreas were performed, and pancreas volumes were quantified using the summation-of-areas technique. Three months after the initiation of drug treatment, plasma CCK concentrations were measured by radioimmunoassay 120 minutes after the patients drank 240 mL of a mixed liquid meal (Ensure). **RESULTS:** After 3 months of treatment, plasma CCK concentrations did not differ between the ximelagatran and warfarin groups, 15 +/- 18 and 11 +/- 17 pmol/L (X +/- SD; P = 0.22), respectively. The initial average pancreas volumes were 82 +/- 31 and 88 +/- 28 mL in the ximelagatran and warfarin groups, respectively, and decreased to 70 +/- 25 and 75 +/- 28 mL, respectively, after 12 months of treatment. Although the decrease in pancreas volume with time was significant in each group (P = 0.0001), the magnitude of the volume reduction was similar in the 2 groups. **CONCLUSION:** In contrast to rats, in which long-term oral administration of ximelagatran stimulates pancreatic growth and adenoma formation, in humans, ximelagatran does not increase plasma CCK concentrations and has no demonstrable trophic effect on the human pancreas.

**REF ID: 4698**

**Lin, L. C., Wang, S. C., Chen, S. H., Wang, T. G., Chen, M. Y., & Wu, S. C. (2003). Efficacy of swallowing training for residents following stroke. *Journal of Advanced Nursing*, 44(5), 469-478. Clinical Trial; Controlled Clinical Trial; Journal Article; IM; N**

**BACKGROUND:** The presence of dysphagia is associated with an increased risk of mortality, malnutrition, dehydration, compromised pulmonary function, and disability. Appropriate swallowing training can establish optimal nutritional status and eliminate or reduce the risk of developing medical complications associated with swallowing impairment. **AIM(S) OF THE STUDY:** The aim of this study was to examine the functional swallowing and nutritional outcomes of swallowing training in institutionalized stroke residents with dysphagia. **DESIGN AND METHODS:** A quasi-experimental parallel cluster design was used. Seven institutions with similar bed sizes were selected. All subjects in the experimental group received a structured swallowing training programme. The subjects in the experimental group (n = 40) received 30 minutes of swallowing training each day for 6 days per week for 8 weeks. The control group (n = 21) did not receive any training. **RESULTS:** After swallowing training, mean differences in volume per second, volume per swallow, mid-arm circumference and body weight between pre- and post-training of the experimental group were significantly higher than for the control group, while mean differences in neurological examination and choking frequency during meals for the experimental group were significantly lower than in the control group. **CONCLUSION:** This study used objective timed swallowing tests, a swallowing questionnaire, and a neurological examination to evaluate the effects of swallowing training. However, videofluoroscopy is generally considered the best method for evaluating the pharyngeal and esophageal stages of swallowing, and introducing this technique is recommended for future studies. Furthermore, it is recommended that nursing professionals should conduct swallowing training protocols in stroke patients to help prevent aspiration from dysphagia.

**REF ID: 4692**

**Lundin, E. A., Zhang, J. X., Lairon, D., Tidehag, P., Aman, P., & Adlercreutz, H. et al. (2004). Effects of meal frequency and high-fibre rye-bread diet on glucose and lipid metabolism and ileal excretion of energy and sterols in ileostomy subjects. *European Journal of Clinical Nutrition*, 58(10), 1410-1419.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

**OBJECTIVE:** To investigate the effect of a rye, high-fibre diet (HFD) vs a wheat, low-fibre diet (LFD), meal frequency, nibbling (Nib, seven times a day) or ordinary (Ord, three times a day), and their combined effects on blood glucose, insulin, lipids, urinary C-peptide and ileal excretion of energy, cholesterol and bile acids in humans. **DESIGN:** LFD period with Nib or Ord meal frequency followed by an HFD diet with Nib or Ord meal frequency in randomized, crossover design. **SETTING:** Outpatients of ileostomy volunteers were called for an investigation in research ward. **SUBJECTS:** A total of 10 subjects (two female subjects, age 34 and 51 y; eight males, mean age 54.4 y, range 43-65 y) participated in the experiment. All subjects were proctocolectomized for ulcerative colitis (mean 16.0 y, range 8-29 y before the study). **INTERVENTION:** In total, 10 ileostomy subjects started with LFD for 2 weeks, the first week on either Nib (five subjects) or Ord (five subjects) and the second week on the other meal frequencies, in a crossover design, followed by a wash-out week, and continued with HFD period for 2 weeks in the same meal frequency manner. All foods consumed in both Nib or Ord regimens were identical and a high-fibre rye bread was used in the HFD period and a low-fibre wheat bread in the LFD period. **MAIN OUTCOME MEASURES:** Day-profiles of blood glucose, insulin and lipids, blood lipids before and after dietary intervention, and excretion of steroids in the effluents and C-peptide in the urine. **RESULTS:** During the Nib regimen, plasma glucose and insulin peaks were lower at the end of the day with HFD compared with LFD. Urinary C-peptide excretion was significantly higher in the day-time on LFD compared with HFD (LFD-Ord vs HFD-Ord,  $P < 0.01$ ; LFD-Nib vs HFD-Nib,  $P < 0.01$ ). Plasma free-cholesterol, total cholesterol, triglycerides and phospholipids were significantly higher ( $P < 0.05$ ) after LFD than after HFD with the Nib regimen. A higher excretion of energy ( $P < 0.05$ ) and chenodeoxycholic acid ( $P < 0.05$ ) were observed with HFD compared with LFD regardless of meal frequency. A higher daily excretion of cholic acid, total bile acids, cholesterol, net cholesterol and net sterols ( $P < 0.05$ ) was observed on HFD compared with LFD with the Nib regimen. **CONCLUSIONS:** An HFD decreased insulin secretion measured as a decreased excretion of C-peptide in urine and as decreased plasma insulin peaks at the end of the day during a Nib regimen. The smoother glycaemic responses at the end of the day during a Nib regimen may be a consequence of a second meal phenomenon, possibly related to the nature of dietary fibre complex.

**REF ID: 5178****Evidence Level III: Quasi-experimental Study**

**McDaniel, J. H., Hunt, A., Hackes, B., & Pope, J. F. (2001). Impact of dining room environment on nutritional intake of alzheimer's residents: A case study. *American Journal of Alzheimer's Disease and Other Dementias*, 16(5), 297-302.**

**Journal Article, Case Study, Research, Tables/Charts**

This case study, in a Veterans Affairs Alzheimer's unit, was conducted to evaluate noise and lighting conditions at mealtimes and to assess the food intake of ambulatory dementia residents. The case study compared the noise, lighting, and nutritional intake of 16 Alzheimer's residents eating the same cycle menu in the extended-care (EC) dining room and the Alzheimer's unit (AU) dining room five weeks later. Noise was significantly lower in the EC ( $p < \text{or} = .02$ ). Lighting was significantly higher in the EC ( $p < \text{or} = .001$ ). Intake of calories and protein was slightly higher, with some days significantly higher, in the AU. Total five-day fluid intake at breakfast was significantly higher in the AU ( $p < \text{or} = .02$ ). Although residents' total food and fluid intake was higher in the AU, the project identified a need to decrease noise and increase lighting in the AU. Lighting enhancement and noise reduction may further improve intake, which, in turn, may promote improved nutritional status.

**REF ID: 4704**

**McGruder, J., Cors, D., Tiernan, A. M., & Tomlin, G. (2003). Weighted wrist cuffs for tremor**

**reduction during eating in adults with static brain lesions. *The American Journal of Occupational Therapy : Official Publication of the American Occupational Therapy Association, 57(5), 507-516.***

**Clinical Trial; Journal Article; IM**

**OBJECTIVE:** This study examined whether weighting the forearm during feeding decreased tremors and increased functional feeding in adults with intention tremor caused by static brain lesions.

**METHOD:** Five individuals with various diagnoses, ages 30-81, were videotaped during 8 or 16 meal sessions, alternating treatment and control conditions within each meal. In this single-case design, treatment consisted of application of a weighted fabric wrist cuff and the baseline (control) condition employed an identical cuff with the weights removed. Dependent variables studied were time to acquire and deliver a bite, grams of food eaten, number of times food was spilled, number of times a compensatory technique was used, participant self-rating, and investigator rating of the severity of the tremor. **RESULTS:** All five participants demonstrated improvement during treatment in one or more of the dependent variables. t Tests of the means of baseline and treatment half-sessions incorporating conservative control of Type I error revealed the following statistically significant improvements under the weighted condition: Participants 3, 4, and 5 took less time to acquire a bite; Participants 4 and 5 made fewer spills; Participants 3 and 5 showed a diminished tremor. There were no statistically significant decreases in function on any variable for any participants during the weighted condition.

**CONCLUSION:** The application of weight to the wrist of a person with upper-extremity tremor is accompanied by some functional improvement in self-feeding for some individuals. The size of benefit seems to be sensitive to the amount of weight used.

**REF ID: 4714**

**Mohler, E. R., 3rd, Hiatt, W. R., Olin, J. W., Wade, M., Jeffs, R., & Hirsch, A. T. (2003).**

**Treatment of intermittent claudication with beraprost sodium, an orally active prostaglandin I<sub>2</sub> analogue: A double-blinded, randomized, controlled trial. *Journal of the American College of Cardiology, 41(10), 1679-1686.***

**Clinical Trial; Journal Article; Multicenter Study; Randomized Controlled Trial; AIM; IM**

**OBJECTIVES:** In the current study, we hypothesized that beraprost would: 1) improve treadmill exercise performance and quality of life; and 2) decrease rates of ischemic events in patients with intermittent claudication. **BACKGROUND:** Previous trials with beraprost sodium, an orally active prostaglandin I<sub>2</sub> analogue, in the treatment of claudication in patients with peripheral arterial disease (PAD) have been inconsistent. **METHODS:** Patients with intermittent claudication (n = 897) were randomized to receive either 40 microg three times a day of beraprost with meals (n = 385) or placebo (n = 377) in a double-blinded manner for one year. The primary efficacy parameter was treadmill-measured maximum walking distance, as assessed at three and six months after randomization. Secondary efficacy parameters included treadmill-measured pain-free walking distance and change in quality of life. **RESULTS:** There was no significant improvement in maximum walking distance in the beraprost group (16.7%) as compared with the placebo group (14.6%, p = NS). Administration of beraprost did not improve the pain-free walking distance (p = NS between treatment groups), and there was no improvement in the quality-of-life measures between the treatment groups. The incidence of critical cardiovascular events was 7.3% in the beraprost group and 11.4% in the placebo group (p = NS). There was a significant reduction in the combination of cardiovascular death and myocardial infarction in the beraprost group (p = 0.01). **CONCLUSIONS:** Despite previous investigations suggesting efficacy, these results indicate that beraprost is not an effective treatment to improve symptoms of intermittent claudication in patients with PAD. The potential benefit of beraprost on critical cardiovascular events would require confirmation in a larger prospective investigation.

**REF ID: 4685**

**Murase, Y., Yagi, K., Sugihara, M., Chujo, D., Otsuji, M., & Muramoto, H. et al. (2004). Lispro is superior to regular insulin in transient intensive insulin therapy in type 2 diabetes. *Internal Medicine (Plainsboro, N.J. : Township), 43(9), 779-786.***

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

**OBJECTIVE:** The optimal approach to relatively recent onset type 2 diabetes patients is still unknown.

We speculated that the use of short-acting insulin analogs might be of particular benefit in this context. PATIENTS AND METHODS: To explore this possibility, we compared the effect on beta- and alpha-cell function of transient intensive insulin therapy using lispro versus human regular insulin in a total of 21 type 2 diabetic patients who were randomly assigned to 14-days intensive insulin therapy consisting of bedtime NPH insulin plus three injections of mealtime lispro (n=11) or regular insulin (n=10). The dosages of both types of insulin were adjusted to attain preprandial glucose levels of <6.1 mmol/l within 1 week with similar rates of glucose decline. An oral glucose tolerance test (OGTT) was performed at day 0 (baseline), 7, and 14; plasma glucose, serum insulin, and plasma glucagon responses over 0-120 minutes were measured, and calculated as the area under the curve (AUC). RESULTS: Lispro led to a significant reduction in glucose-AUC and also an increase in insulin-AUC versus regular insulin on day 7. Glucagon secretion following OGTT was well suppressed with lispro on day 14 compared to regular insulin. CONCLUSION: Two-week intensive insulin therapy with lispro appeared to be more effective than that with regular insulin in type 2 diabetes in attaining both more rapid beta-cell rest and greater suppression of glucagon. These changes may provide significant long-term benefits.

**REF ID: 4661**

**Evidence Level II: RCT**

**Nijs, K. A., de Graaf, C., Kok, F. J., & van Staveren, W. A. (2006). Effect of family style mealtimes on quality of life, physical performance, and body weight of nursing home residents: Cluster randomised controlled trial. *BMJ (Clinical Research Ed.)*, 332(7551), 1180-1184.**

**Journal Article; Multicenter Study; Randomized Controlled Trial; AIM; IM**

OBJECTIVE: To assess the effect of family style mealtimes on quality of life, physical performance, and body weight of nursing home residents without dementia. DESIGN: Cluster randomised trial. SETTING: Five Dutch nursing homes. PARTICIPANTS: 178 residents (mean age 77 years). Two wards in each home were randomised to intervention (95 participants) or control groups (83). INTERVENTION: During six months the intervention group took their meals family style and the control group received the usual individual pre-plated service. MAIN OUTCOME MEASURES: Quality of life (perceived safety; autonomy; and sensory, physical, and psychosocial functioning), gross and fine motor function, and body weight. RESULTS: The difference in change between the groups was significant for overall quality of life (6.1 units, 95% confidence interval 2.1 to 10.3), fine motor function (1.8 units, 0.6 to 3.0), and body weight (1.5 kg, 0.6 to 2.4). CONCLUSION: Family style mealtimes maintain quality of life, physical performance, and body weight of nursing home residents without dementia. TRIAL REGISTRATION: Clinical trials NCT00114582.

**REF ID: 4690**

**Nordin, P., Hernell, H., Unosson, M., Gunnarsson, U., & Nilsson, E. (2004). Type of anaesthesia and patient acceptance in groin hernia repair: A multicentre randomised trial. *Hernia : The Journal of Hernias and Abdominal Wall Surgery*, 8(3), 220-225.**

**Clinical Trial; Journal Article; Multicenter Study; Randomized Controlled Trial; IM**

BACKGROUND: Groin hernia repair can be performed under general (GA), regional (RA), or local (LA) anaesthesia. This multicentre randomised trial evaluates patient acceptance, satisfaction, and quality of life with these three anaesthetic alternatives in hernia surgery. METHODS: One hundred and thirty-eight patients at three hospitals were randomised to one of three groups, GA, RA, or LA. Upon discharge, they were asked to complete a specially designed questionnaire with items focusing on pain, discomfort, recovery, and overall satisfaction with the anaesthetic method used. The global quality-of-life instrument EuroQol was used for estimation of health perceived. RESULTS: Significantly more patients in the LA group than in the RA group felt pain during surgery (  $P<0.001$ ). This pain was characterised as light or moderate and for the majority of LA patients was felt during infiltration of the anaesthetic agent. Postoperatively, patients in the LA group first felt pain significantly later than patients in the other two groups (  $P=0.012$ ) and significantly fewer LA patients consumed analgesics more than three times during the first postoperative day (  $P=0.002$ ). The results concerning nausea, vomiting, and time to first meal all favour LA. No difference was found among the three groups concerning overall

satisfaction and quality of life. CONCLUSION: In a general surgical setting, we found LA to be well tolerated and associated with significant advantages compared to GA and RA.

**REF ID: 4720**

**Evidence Level IV: Nonexperimental Study**

**Paquet, C., St-Arnaud-McKenzie, D., Kergoat, M. J., Ferland, G., & Dube, L. (2003). Direct and indirect effects of everyday emotions on food intake of elderly patients in institutions. *The Journals of Gerontology. Series A, Biological Sciences and Medical Sciences*, 58(2), 153-158. Comment; Journal Article; AIM; IM**

BACKGROUND: Decreased food intake is an important risk factor for malnutrition, which is highly prevalent among geriatric patients. The emotional nature of the hospitalization experience and the complex organizational setting involved in meal production and delivery services in institutions increase the risk for decreased food intake. Everyday emotions are known to have a particularly strong influence on decision-making and behavior in the elderly, and have also been shown, in younger populations, to influence food intake and its psychological antecedents, such as quality perception and satisfaction judgments. The objective of this paper is to study the direct impact of elderly patients' everyday emotions on food intake and their indirect effects mediated by quality perceptions and satisfaction judgments. METHODS: Thirty patients (20 women, 10 men, 65-92 age range) in a geriatric rehabilitation unit were observed on repeated meal episodes (average of 46 care episodes per patient) where they provided self-reports for emotions (positive emotions, anger, anxiety, and mild depressed feelings), perceived meal quality, and satisfaction. Food intake was measured in terms of energy and protein content. RESULTS: The impact on food intake was favorable, and both direct and indirect for positive emotions, direct and negative for anxiety, direct and positive for mild depressed feelings, and indirect and negative for anger. Indirect effects were mediated by quality perception judgments but not by satisfaction, which was not significantly related to food intake. CONCLUSION: Results suggest that, given their impact on food intake, measuring and monitoring patients' everyday emotions may be an important innovative strategy to improve food intake of elderly patients in institutions.

**REF ID: 5166**

**Parlesak, A., Klein, B., Schecher, K., Bode, J. C., & Bode, C. (2003). Prevalence of small bowel bacterial overgrowth and its association with nutrition intake in nonhospitalized older adults. *Journal of the American Geriatrics Society*, 51(6), 768-773.**

**Journal Article, Equations & Formulas, Research, Tables/Charts**

OBJECTIVES: To determine the prevalence of small bowel bacterial overgrowth (SBBO) in older adults and to assess whether SBBO is associated with abdominal complaints and nutrient intake. DESIGN: Cross-sectional survey. SETTING: Eight senior residence sites in Stuttgart, Germany. PARTICIPANTS: Older adults living independently in senior residence houses. MEASUREMENTS: The prevalence of SBBO was measured in 328 subjects, of whom 294 were aged 61 and older, by measuring hydrogen concentration (parts per million; ppm) in exhaled air after ingestion of 50 g glucose. Anthropometric data were obtained and nutritional status was recorded with a computer-aided diet history. RESULTS: The prevalence of a positive hydrogen breath test (>10 ppm increase) was 15.6% in older adults, compared with 5.9% in subjects aged 24 to 59. The intake of inhibitors of gastric acid production contributed significantly to the high prevalence of a positive breath test in older adults, which was associated with lower body weight, lower body mass index, lower plasma albumin concentration, and higher prevalence of diarrhea. Subjects with a positive hydrogen breath test consumed significantly less fiber, folic acid, and vitamins B2 and B6 than those without. No difference was observed in the intake of energy, protein, fat, or carbohydrates. CONCLUSION: Prevalence of SBBO is associated with reduced body weight, which is paralleled by reduced intake of several micronutrients. Malabsorption resulting from diarrhea might be an aggravating factor contributing to weight loss in these subjects.

**REF ID: 5144**

**Patch, C. S., Mason, S., CurcioBorg, F., & Tapsell, L. C. (2003). Thickened fluids: Factors affecting wastage. *Advances in Speech-Language Pathology*, 5(2), 73-77.**

### **Journal Article, Research, Tables/Charts**

There is a putative risk of dehydration in patients with dysphagia in a clinical setting. A common conception is that the thickened fluids provided to the patient are the primary cause of poor intake. Commercial supplements may be better tolerated than domestic versions, primarily due to taste and consistency. Our study compares fluid wastage of dysphagic patients consuming commercially prepared thickened fluids (RESOURCE THICKENED BEVERAGE, Novartis Consumer Health Australasia Pty Ltd) against standard domestic products, and to compare waste at snack times and mealtimes. A wastage audit was designed to investigate the effect of commercial supplements and timing of wastage in patients admitted to a rehabilitation facility, with dysphagia as assessed using a comprehensive bedside assessment (n = 63). There were no significant differences in wastage between patients supplied commercial supplements and patients supplied domestic supplements. This result was the same at both snack times and mealtimes. A significant difference was reported between the average wastage of modified commercial and domestic supplements offered at snack time (37.9 +/- 11 ml and 17.3 +/- 10 ml) compared to main mealtimes (168.7 +/- 12 ml and 167.2 +/- 11 ml) (p < 0.01). The timing of thickened supplement provision appears to be a factor on the wastage of thickened fluids, whereas the type of supplement provided is of little consequence. Further investigation is needed to determine whether the time of day in which drinks are provided is a variable of intake, or is it attributable to the patients' milieu.

#### **REF ID: 4711**

**Pearson, A., Fitzgerald, M., & Nay, R. (2003). Mealtimes in nursing homes. the role of nursing staff. *Journal of Gerontological Nursing*, 29(6), 40-47.**

#### **Journal Article; Multicenter Study; N**

The literature suggests that food service largely has become identified as a non-nursing duty and as a task that should be completed as quickly as possible. This conflicts with the evidence that social interaction at mealtimes has the potential to promote well being. Using observational and interview techniques, the social and functional context of meal service in 10 nursing homes was examined in this study. The findings from the observation of and interviews with staff are reported in this article. Three broad themes describing the cultural practices of nursing home staff during mealtimes are identified as follows: maintaining personal identity, assisting individuals to eat, and maintaining interaction. Alongside residents' general outward acquiescence to the service, nurses did not see problems and deficiencies with the service observed by the researchers or reported by the residents. Recommendations to improve mealtime service in nursing homes have been put forward in an effort to enlighten staff.

#### **REF ID: 5167**

**Pearson, A., Fitzgerald, M., & Nay, R. (2003). Mealtimes in nursing homes: The role of nursing staff. *Journal of Gerontological Nursing*, 29(6), 40-47.**

#### **Journal Article, Pictorial, Research, Tables/Charts**

The literature suggests that food service largely has become identified as a non-nursing duty and as a task that should be completed as quickly as possible. This conflicts with the evidence that social interaction at mealtimes has the potential to promote well being. Using observational and interview techniques, the social and functional context of meal service in 10 nursing homes was examined in this study. The findings from the observation of and interviews with staff are reported in this article. Three broad themes describing the cultural practices of nursing home staff during mealtimes are identified as follows: maintaining personal identity, assisting individuals to eat, and maintaining interaction. Alongside residents' general outward acquiescence to the service, nurses did not see problems and deficiencies with the service observed by the researchers or reported by the residents. Recommendations to improve mealtime service in nursing homes have been put forward in an effort to enlighten staff.

#### **REF ID: 4684**

**Raslova, K., Bogoev, M., Raz, I., Leth, G., Gall, M. A., & Hancu, N. (2004). Insulin detemir and insulin aspart: A promising basal-bolus regimen for type 2 diabetes. *Diabetes Research and Clinical Practice*, 66(2), 193-201.**

#### **Clinical Trial; Journal Article; Multicenter Study; Randomized Controlled Trial; IM**

This trial compared the efficacy and safety of basal-bolus therapy using either the soluble basal insulin analogue insulin detemir (IDet) in combination with meal-time rapid-acting analogue insulin aspart (IASp), or NPH insulin (NPH) in combination with meal-time regular human insulin (HSI). This was a 22-week, multinational, open-labelled, symmetrically randomised, parallel group trial including 395 people with type 2 diabetes (IDet + IAsp: 195, NPH + HSI: 200). At 22 weeks, HbA1c was comparable between treatments (IDet + IAsp: 7.46%, NPH + HSI: 7.52%,  $P = 0.515$ ) with decreases from baseline of 0.65% and 0.58%, respectively. Treatment with IDet + IAsp was associated with a significantly lower within-person variation in self-measured fasting plasma glucose (FPG) (SD:1.20 versus 1.54 mmol/L,  $p < 0.001$ ), as well as a lower body weight gain (0.51 versus 1.13 kg,  $p = 0.038$ ) than with NPH + HSI. The risk of nocturnal hypoglycaemia was 38% lower with IDet + IAsp than with NPH + HSI, but statistical significance was not attained ( $P = 0.14$ ). The overall safety profile was similar between the two treatments. Basal-bolus treatment with IDet + IAsp is an effective and well tolerated insulin regimen in people with type 2 diabetes, resulting in glycaemic control comparable to that of NPH + HSI, but with the advantages of less weight gain and a lower day-to-day within-person variation in FPG.

**REF ID: 5173**

**Ratner, R. E., Want, L. L., Fineman, Velte, M. J., Ruggles, J. A., & Gottlieb, A. et al. (2002). Adjunctive therapy with the amylin analogue pramlintide leads to a combined improvement in glycemic and weight control in insulin-treated subjects with type 2 diabetes. *Diabetes Technology & Therapeutics*, 4(1), 51-61.**

**Journal Article, Clinical Trial, Research, Tables/Charts**

The objective of this study was to assess the effect of mealtime amylin replacement with pramlintide on long-term glycemic and weight control in subjects with type 2 diabetes. This 52-week, randomized, placebo-controlled, multicenter, double-blind, dose-ranging study in 538 insulin-treated subjects with type 2 diabetes compared the efficacy and safety of 30-, 75-, or 150-microg doses of pramlintide, a synthetic analogue of the beta-cell hormone amylin, to placebo when injected subcutaneously three times daily (TID) with major meals. Pramlintide therapy led to a mean reduction in HbA1c of 0.9% and 1.0% from baseline to week 13 in the 75- and 150-microg dose groups, which was significant compared to placebo ( $p = 0.0004$  and  $p = 0.0002$ , respectively). In the 150-microg dose group, there was a mean reduction in HbA1c of 0.6% from baseline to week 52 ( $p = 0.0068$  compared to placebo). The greater reduction in HbA1c with pramlintide was achieved without increases in insulin use or severe hypoglycemia, and was accompanied by a significant ( $p < 0.05$ ) reduction in body weight in all dose groups compared to placebo. Three times the proportion of subjects in the 150-microg pramlintide group compared to the placebo group achieved a concomitant reduction in both HbA1c and body weight from baseline to week 52 (48% versus 16%). The most common adverse event reported with pramlintide treatment was nausea, which was mild to moderate and dissipated early in treatment. The results from this study support the safety and efficacy of pramlintide administered three times a day with major meals, in conjunction with insulin therapy, for improving long-term glycemic and weight control in subjects with type 2 diabetes.

**REF ID: 4669**

**Raynor, H. A., Niemeier, H. M., & Wing, R. R. (2006). Effect of limiting snack food variety on long-term sensory-specific satiety and monotony during obesity treatment. *Eat.Behav.*, 7(1), 1-14. Journal Article; Randomized Controlled Trial; IM**

Limiting meal variety decreases hedonic ratings of eaten foods more so than non-eaten foods, demonstrating sensory-specific satiety. Exposure to a food over time decreases the food's hedonic ratings, indicating monotony. The effect of limiting food group variety over time on long-term sensory-specific satiety and monotony is unknown. Thirty overweight adults were randomized to one of two 8-week behavioral weight loss interventions. One condition limited snack food intake to one chosen snack food (reduced variety), while the other limited snack food intake to  $<1$  serving/day (control), with no variety limit. In the reduced variety condition, hedonic ratings of the chosen snack food showed a decrease ( $p < .05$ ) over time and decreased more ( $p < .05$ ) than hedonic ratings of other snack foods. Weight loss (-7.4 +/- 5.8 lb) occurred in both conditions. Limiting food group variety over 8 weeks

produced long-term sensory-specific satiety and monotony. Future research should examine if limiting food group variety over an extended time affects intake and could be used as a technique in weight loss interventions.

**REF ID: 4716**

**Redman, B. G., Esper, P., Pan, Q., Dunn, R. L., Hussain, H. K., & Chenevert, T. et al. (2003). Phase II trial of tetrathiomolybdate in patients with advanced kidney cancer. *Clinical Cancer Research : An Official Journal of the American Association for Cancer Research*, 9(5), 1666-1672. Clinical Trial; Clinical Trial, Phase II; Journal Article; IM**

**PURPOSE:** Tetrathiomolybdate (TM), a copper-lowering agent, has been shown in preclinical murine tumor models to be antiangiogenic. We evaluated the antitumor activity of TM in patients with advanced kidney cancer in a Phase II trial. **EXPERIMENTAL DESIGN:** Fifteen patients with advanced kidney cancer were eligible to participate in this trial. TM was initiated p.o. at 40 mg three times a day with meals and 60 mg at bedtime to deplete copper. A target serum ceruloplasmin (CP) level of 5-15 mg/dl was defined as copper depletion. Doses of TM were reduced for grade 3-4 toxicity and to maintain a CP level in the target range. Once copper depletion was attained, patients underwent baseline tumor measurements and then again every 12 weeks for response assessment. Patients not exhibiting progressive disease at 12 weeks after copper depletion continued on treatment. Serum levels of Interleukin (IL)-6, IL-8, vascular endothelial growth factor (VEGF) and basic fibroblast growth factor (bFGF) were assayed pretreatment and at various time points on treatment. Dynamic contrast enhanced-magnetic resonance imaging (DCE-MRI) was performed on selected patients in an attempt to assess changes in tumor vascularity. **RESULTS:** All of the patients rapidly became copper depleted. Thirteen patients were evaluable for response. No patient had a complete response or PR. Four patients (31%) had stable disease for at least 6 months during copper depletion (median, 34.5 weeks). TM was well tolerated, with dose reductions most commonly occurring for grade 3-4 granulocytopenia of short duration not associated with febrile episodes. Serum levels of IL-6, IL-8, VEGF, and bFGF did not correlate with clinical activity. Serial DCE-MRI was performed only in four patients, and a decrease in vascularity seemed to correlate with necrosis of a tumor mass associated with tumor growth. **CONCLUSIONS:** TM is well tolerated and consistently depletes copper as measured by the serum CP level. Clinical activity was limited to stable disease for a median of 34.5 weeks in this Phase II trial in patients with advanced kidney cancer. Serum levels of proangiogenic factors IL-6, IL-8, VEGF, and bFGF may correlate with copper depletion but not with disease stability in this small cohort. TM may have a role in the treatment of kidney cancer in combination with other antiangiogenic therapies.

**REF ID: 5159**

**Richeson, N. E., & Neill, D. J. (2004). Therapeutic recreation music intervention to decrease mealtime agitation and increase food intake in older adults with dementia. *American Journal of Recreation Therapy*, 3(1), 37-41. Journal Article, Research**

This study examined the effects of a therapeutic recreation music intervention on agitation and food intake on 27 nursing home residents diagnosed with dementia (mean age 87 years). In a quasi-experimental time-series design (ABAB), agitated behaviors and percentage of food eaten were recorded during two phases: 1) a four-day baseline, and 2) a four-day intervention during which compact discs (CDs) of relaxing music were played for one hour at dinnertime. Agitation was measured using the Modified Cohen-Mansfield Agitation Inventory (Modified CMAI); percentage of food eaten was determined by reviewing participants' medical records. Agitation decreased and percentage of food eaten increased with the music intervention. The authors suggest replicating the study using more rigorous methodology and additional dependent variables.

**REF ID: 4705**

**Roach, P., Arora, V., Campaigne, B. N., Mattoo, V., Rangwala, S., & India Mix25/Mix50 Study Group. (2003). Humalog Mix50 before carbohydrate-rich meals in type 2 diabetes mellitus. *Diabetes, Obesity & Metabolism*, 5(5), 311-316. Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

**AIM:** To compare pre-meal injection of Humalog Mix50 (Mix50) and Humalog Mix25 (Humalog Mix75/25 in the US; Mix25) with respect to 2 h postprandial (2 h pp) blood glucose (BG) control after a carbohydrate-rich breakfast in patients with type 2 diabetes. **RESEARCH DESIGN AND METHODS:** One hundred and sixteen patients were enrolled in a 16-week crossover trial and received two treatment regimens in a randomized crossover fashion: (i) Mix50 before breakfast and Mix25 before the evening meal (Mix50/Mix25) and (ii) Mix25 before both breakfast and the evening meal (Mix25 twice daily). Insulin doses were adjusted according to stated glycaemic targets. After 6 and 8 weeks of treatment, the patient's usual morning insulin dose was administered, followed immediately by a test breakfast representative of the patient's usual breakfast meal. Fasting and 2 h pp BG concentrations were measured at the time of the test meal. Haemoglobin A1c (A1C) was measured, and information regarding hypoglycaemia (symptoms) was collected at the end of each treatment period. **RESULTS:** Insulin doses were similar between treatments (morning = 31-33 U, evening = 26-28 U) at endpoint. Following the test breakfast, the 2 h pp BG was lower (10.9 +/- 0.3 mmol/l vs. 12.4 +/- 0.3 mmol/l,  $p = 0.0012$ ) and the 2 h pp BG excursion was smaller (1.4 +/- 0.28 mmol/l vs. 3.5 +/- 0.28 mmol/l,  $p < 0.001$ ) during treatment with Mix50/Mix25 than during treatment with Mix25 twice daily. There was no difference between the treatments with respect to fasting BG (Mix50/Mix25, 9.5 +/- 0.3 mmol/l vs. Mix25 twice daily, 8.9 +/- 0.3 mmol/l;  $p = \text{NS}$ ), A1C (8.14% +/- 1.14% vs. 8.14% +/- 1.07%;  $p = \text{NS}$ ) or the incidence of self-reported hypoglycaemia (34% vs. 23%;  $p = \text{NS}$ ). **CONCLUSIONS:** Compared with treatment with Mix25 twice daily, treatment with Mix50 before breakfast and Mix25 before the evening meal resulted in better pp glycaemic control following a carbohydrate-rich meal, and similar fasting BG, A1C and incidence of hypoglycaemia in patients with type 2 diabetes.

**REF ID: 4738**

**Rosenblatt, M. L., Catalano, M. F., Alcocer, E., & Geenen, J. E. (2001). Comparison of sphincter of oddi manometry, fatty meal sonography, and hepatobiliary scintigraphy in the diagnosis of sphincter of oddi dysfunction. *Gastrointestinal Endoscopy*, 54(6), 697-704.**

**Clinical Trial; Journal Article; IM**

**BACKGROUND:** Sphincter of Oddi dysfunction (SOD) afflicts approximately 1% to 5% of patients after cholecystectomy. The diagnostic standard for SOD is sphincter of Oddi manometry (SOM), a technically difficult, invasive test that is frequently complicated by pancreatitis. A sensitive and accurate noninvasive imaging modality is thus needed for the diagnosis of SOD. Quantitative hepatobiliary scintigraphy (HBS) and fatty meal sonography (EMS) are frequently used for this purpose, but results vary. This study compared SOM, HBS, and EMS in the diagnosis of SOD in a large group of patients. **METHODS:** Three hundred four consecutive patients after cholecystectomy (38 men, 266 women, age 17-72 years) suspected to have SOD were evaluated by SOM, FMS, and HBS. SOM was considered abnormal if any of the following were observed: (1) increased basal pressure (greater than 40 mm Hg), (2) increased phasic activity with amplitude greater than 350 mm Hg, (3) frequency of contractions greater than 8 per minute, (4) greater than 50% of propagation sequences retrograde, and (5) paradoxical response to cholecystokinin. FMS was considered abnormal if ductal dilation was greater than 2 mm at 45 minutes after fatty meal ingestion. Quantitative HBS was performed with sequential images obtained every 5 minutes for 90 minutes to monitor excretion of the radionuclide. Time-to-peak, halftime, and downslope were calculated according to predetermined ranges. **RESULTS:** A diagnosis of SOD was made in 73 patients (24%) by using SOM as the reference standard. HBS was abnormal in 86 whereas EMS was abnormal in 22 patients. A true-positive result was obtained in 15 patients by EMS and 36 patients with HBS. EMS and HBS gave false-positive results, respectively, in 7 and 50 patients. Sensitivity of EMS was 21% and for HBS 49%, whereas specificities were 97% and 78%, respectively. EMS, HBS, or both were abnormal in 90% of patients with Geenen-Hogan Type I SOD, 50% with Type II, and 44% of Type III. Of the 73 patients who underwent sphincterotomy, 40 had a long-term response. Of those with SOD, 11 of 13 patients (85%) with an abnormal HBS and EMS had a good long-term response. **CONCLUSIONS:** In this series, the largest reported to date, correlation of FMS and HBS with SOM in the diagnosis of SOD was poor. When HBS and EMS are used together, a slight increase in sensitivity can be expected. The accuracy of EMS and HBS in the diagnosis of SOD

decreases across the spectrum from Type I to Type III SOD. EMS and HBS, nonetheless, may be of assistance in predicting long-term response to endoscopic sphincterotomy in patients with elevated sphincter of Oddi basal pressure.

**REF ID: 4689**

**Rudovich, N. N., Leyck Dieken, M. G., Rochlitz, H., & Pfeiffer, A. F. (2004). Enhancement of early- and late-phase insulin secretion and insulin sensitivity by the combination of repaglinide and metformin in type 2 diabetes mellitus. *Experimental and Clinical Endocrinology & Diabetes : Official Journal, German Society of Endocrinology [and] German Diabetes Association, 112(7), 395-400.***

**Clinical Trial; Controlled Clinical Trial; Journal Article; IM**

The effects of a combination of repaglinide and metformin on the insulin secretion pattern and insulin sensitivity were studied in a fixed-dose, open-label, placebo-controlled cross-over study. Eleven patients with T2 DM were allocated in random order to treatment with placebo or repaglinide (1 mg pre-meal 3 x/day) in combination with metformin (2550 mg/day) for one-week periods of each. At the end of each period a hyperglycaemic (HC) and a euglycaemic clamp (EC) were performed. Both early (0 - 10 min) and late (25 - 180 min) phases of insulin secretion were significantly increased during HC with repaglinide compared to placebo (263.3 +/- 133.1 vs. 443.6 +/- 138.5 pmol/l/10 min, p = 0.008 and 18 750.9 +/- 5936.4 vs. 34 508.65 +/- 9234.0 pmol/l/25 - 180 min; p = 0.008). The C-peptide concentrations under steady-state conditions were lower in EC with placebo than with repaglinide (p = 0.014). When euglycaemia was achieved in EC, the C-peptide concentrations decreased from hyperglycaemic to normoglycaemic values in the presence of repaglinide but remained higher than after placebo. The insulin sensitivity index (ISI) was increased by 35 % after 1 week of combination therapy with repaglinide plus metformin (1.11 +/- 0.03 x 10<sup>(2)</sup> vs. 0.83 +/- 0.21 x 10<sup>(2)</sup> mg x kg<sup>(-1)</sup> body weight x min<sup>(-1)</sup> x pmol<sup>(-1)</sup> x l, respectively; p = 0.033). Repaglinide increased early and late phases of insulin responses in HC, without markedly enhancing insulin secretion in euglycaemia. Repaglinide in combination with metformin produced a significant enhancement of ISI, suggesting a synergistic effect on insulin sensitivity.

**REF ID: 5179**

**Sheiham, A., & Steele, J. (2001). Does the condition of the mouth and teeth affect the ability to eat certain foods, nutrient and dietary intake and nutritional status amongst older people? *Public Health Nutrition, 4(3), 797-803.***

**Journal Article, Research, Tables/Charts**

**REF ID: 4728**

**Shepard, D. R., Mani, S., Kastrissios, H., Learned-Coughlin, S., Smith, D., & Ertel, P. et al. (2002). Estimation of the effect of food on the disposition of oral 5-fluorouracil in combination with eniluracil. *Cancer Chemotherapy and Pharmacology, 49(5), 398-402.***

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

AIMS: To determine the effect of food on the pharmacokinetics of 5-fluorouracil (5-FU) taken orally with eniluracil and to compare the performance of different pharmacokinetic analysis methods in the detection a potential food-drug interaction. METHODS: In a randomized, open-label, two-way crossover study, 12 patients received eniluracil (50 mg, orally) on days 1 and 2 and 5-FU (20 mg/m<sup>(2)</sup>, orally) on day 2 following either a 2-h fast or 20 min after a standard meal. Treatments were separated by 7 days. Timed blood samples were collected during the first two treatment periods and 5-FU concentrations determined by GC/MS. Data were analyzed and pharmacokinetic parameter estimates were obtained using a noncompartmental, two-stage and population analysis methods. RESULTS: In fasted individuals, the clearance/bioavailability of 5-FU was estimated to be 5.6 l/h. The mean absorption lag-time was 0.24 h and was followed by rapid absorption of 5-FU. Administration of 5-FU and eniluracil with food resulted in a decrease in the 5-FU absorption rate constant by 90%. As a result, the peak plasma concentration (C(max)) of 5-FU was decreased by 21% and the time to C(max) was increased 2.9-fold. Clearance of 5-FU, relative bioavailability, and area under the plasma concentration vs time curve (AUC) remained unchanged with coadministration of food. Similar results were obtained

using all three data analysis methods. CONCLUSIONS: Administration of food with oral 5-FU and eniluracil slowed absorption of 5-FU and decreased 5-FU C(max), but did not effect AUC. Further investigation of the incorporation of population pharmacokinetic approaches in food effect studies is warranted.

**REF ID: 4687**

**Shin, Y. H., Kim, T. I., Shin, M. S., & Juon, H. S. (2004). Effect of acupressure on nausea and vomiting during chemotherapy cycle for korean postoperative stomach cancer patients. *Cancer Nursing, 27(4), 267-274.***

**Clinical Trial; Controlled Clinical Trial; Journal Article; Multicenter Study; IM; N**

Despite the development of effective antiemetic drugs, nausea and vomiting remain the main side effects associated with cancer chemotherapy. The purpose of this study was to examine the effect of acupressure on emesis control in postoperative gastric cancer patients undergoing chemotherapy. Forty postoperative gastric cancer patients receiving the first cycle of chemotherapy with cisplatin and 5-Fluorouracil were divided into control and intervention groups (n = 20 each). Both groups received regular antiemesis medication; however, the intervention group received acupressure training and was instructed to perform the finger acupressure maneuver for 5 minutes on P6 (Nei-Guan) point located at 3-finger widths up from the first palmar crease, between palmaris longus and flexor carpi radialis tendons point, at least 3 times a day before chemotherapy and mealtimes or based on their needs. Both groups received equally frequent nursing visits and consultations, and reported nausea and vomiting using Rhode's Index of Nausea, Vomiting and Retching. We found significant differences between intervention and control groups in the severity of nausea and vomiting, the duration of nausea, and frequency of vomiting. This study suggests that acupressure on P6 point appears to be an effective adjunct maneuver in the course of emesis control.

**REF ID: 4674**

**Evidence Level IV: Nonexperimental Study**

**Siebolds, M., Gaedeke, O., Schwedes, U., & SMBG Study Group. (2006). Self-monitoring of blood glucose--psychological aspects relevant to changes in HbA1c in type 2 diabetic patients treated with diet or diet plus oral antidiabetic medication. *Patient Education and Counseling, 62(1), 104-110.***

**Journal Article; Multicenter Study; Randomized Controlled Trial; N**

**OBJECTIVE:** To investigate the influence of psychological aspects on glycemic control in type 2 diabetic patients treated with diet alone or diet plus oral antidiabetic medication using meal-related self-monitoring of blood glucose (SMBG). These psychological aspects refer to the process of self-management including the tendency to structure situations and activate resources (self-perception), to accept options for action (self-reflection) and to believe in self-efficacy (self-regulation). **METHODS:** In a randomized controlled 6-month group comparison study, one group (n = 113; mean age 58.7 years) used a blood glucose monitoring device, kept a blood glucose/eating diary and received standardized counseling focusing on self-perception, self-reflection and self-regulation. A control group (n = 110; mean age 60.5 years) received non-standardized counseling on diet and lifestyle. **RESULTS:** Statistically significant endpoint differences between the SMBG and the control group were seen in glycemic control (p = 0.0086) and the well-being item 'depression' (p = 0.032). All aspects of counseling were influenced by SMBG with the extent of self-perception and self-reflection gradually increasing over time. Three HbA1c response types were identified among SMBG patients: continuous-achievers, late-achievers and non-achievers. **CONCLUSION:** This study identified processes (structuring the situation and activating resources, accepting options for action and believing in self-efficacy) which lead to a change in the metabolic profile. SMBG coupled with structured counseling provided patients with a tool for taking on more self-control and resulted in an improved outlook on life. **PRACTICE IMPLICATIONS:** This short-term intervention involved a structured counseling algorithm which requires 5-10 min of physician-patient contact and a structured documentation of metabolic control by the patient and can be taught by a diabetes training team within 4 h. The identification of the different

response types might be of importance in clinical practice as it enables the physician to determine the right counseling option.

**REF ID: 5169**

**Simmons, S. F., Lam, H. Y., Rao, G., & Schnelle, J. F. (2003). Family members' preferences for nutrition interventions to improve nursing home residents' oral food and fluid intake. *Journal of the American Geriatrics Society*, 51(1), 69-74.**

**Journal Article, Research, Tables/Charts**

**OBJECTIVES:** To measure family members' preferences for nutrition interventions to improve the oral food and fluid intake of their relatives in a nursing home. **DESIGN:** Cross-sectional descriptive.

**SETTING:** Three skilled nursing facilities in Southern California. **PARTICIPANTS:** One hundred five residents from the three skilled nursing facilities and their respective family members.

**MEASUREMENTS:** A mailed questionnaire to family members that consisted of 15 forced-choice comparisons between six nutrition interventions. An assessment of oral food and fluid intake during mealtime for 3 days (nine meals) for each participant using direct observations and estimations of percentage consumed (0% to 100%) by trained research staff. **RESULTS:** In order of most to least desirable, the family members preferred the following interventions to improve their relative's oral food and fluid intake: (1) improve quality of food; (2) improve quality and quantity of feeding assistance; (3) provide multiple small meals and snacks throughout the day; (4) place resident in preferred dining location; (5) provide an oral liquid nutritional supplement between meals; and (6) provide a medication to stimulate appetite. The average +/- standard deviation total percentage intake for residents whose family members reported that they thought their relative had a problem with their intake was 50% +/- 16%. **CONCLUSIONS:** Family members prefer that other nutrition interventions be attempted before the use of oral supplements or pharmacological approaches. Family members perceive a need for interventions when residents consume, on average, only half of the food and fluid items provided during mealtime.

**REF ID: 5170**

**Evidence Level IV: Nonexperimental Study**

**Simmons, S. F., Lim, B., & Schnelle, J. F. (2002). Accuracy of minimum data set in identifying residents at risk for undernutrition: Oral intake and food complaints. *Journal of the American Medical Directors Association*, 3(3), 140-145.**

**Journal Article, Research, Tables/Charts**

**Objective:** to evaluate the accuracy of nursing home (NH) staff in documenting two Minimum Data Set (MDS) items that are used to identify residents at risk for undernutrition, low oral intake and food complaints, using standardized observation and interview assessment protocols implemented by research staff. **Design and Methods:** MDS information related to low oral intake (item K4c: <75% of most meals) and complaints about the taste of food (item K4a) was compared to independent evaluations of low oral intake and food complaints for a random sample of 75 residents in two proprietary NHs within the same month that a complete MDS assessment was due for each participant. **Direct observations** were conducted by research staff during nine mealtime periods for 3 consecutive days according to a standardized mealtime observational protocol to estimate low oral intake; and, two one-on-one interviews with residents were conducted on two consecutive days using standardized questions to assess the stability of food complaints. **Results:** Research staff documentation based on direct observation and resident interviews showed a significantly larger number of residents being identified as potentially at risk for undernutrition due to low oral intake (73%) and/or stable complaints about the taste of food (32%) as compared with NH staff documentation of MDS items K4c (44%) and K4a (0%), respectively, within the same month. A total of 47% of the participants expressed stable complaints about some aspect of the NH food service (eg, variety, appearance, temperature).

**Conclusion:** The documentation of low oral intake and food complaints on the MDS was inaccurate and resulted in a significant underestimate of residents with either of these risk factors for undernutrition.

**REF ID: 4694**

**Simmons, S. F., & Schnelle, J. F. (2004). Effects of an exercise and scheduled-toileting intervention**

**on appetite and constipation in nursing home residents. *The Journal of Nutrition, Health & Aging*, 8(2), 116-121.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

**PURPOSE:** To evaluate the effects of an exercise and scheduled-toileting intervention on appetite and constipation in nursing home (NH) residents. **METHODS:** A controlled, clinical intervention trial with 89 residents in two NHs. Research staff provided exercise and toileting assistance every two hours, four times per day, five days a week for 32 weeks. Oral food and fluid consumption during meals was measured at baseline, eight and 32 weeks. Bowel movement frequency was measured at baseline and 32 weeks. **RESULTS:** The intervention group showed significant improvements or maintenance across all measures of daily physical activity, functional performance, and strength compared to the control group. Participants in both groups consumed an average of approximately 55% of meals at all three time points (approximately 1100 calories/day) with no change over time in either group. There was also no change in the frequency of bowel movements in either group, which averaged less than one in two days for both groups; and, approximately one-half of all participants had no bowel movement in two days.

**CONCLUSIONS:** An exercise and scheduled-toileting intervention alone is not sufficient to improve oral food and fluid consumption during meals and bowel movement frequency in NH residents.

**REF ID: 4697**

**Simmons, S. F., Walker, K. A., & Osterweil, D. (2004). The effect of megestrol acetate on oral food and fluid intake in nursing home residents: A pilot study. *J.Am.Med.Dir.Assoc.*, 5(1), 24-30.**

**Clinical Trial; Controlled Clinical Trial; Journal Article; Multicenter Study; IM**

**OBJECTIVES:** The objective of this study was to evaluate the effect of megestrol acetate (Megace OS; Bristol-Myers Squibb, Princeton, NJ) on the oral food and fluid intake of nursing home (NH) residents under two conditions: usual NH care and optimal mealtime feeding assistance. **DESIGN AND**

**SETTING:** We conducted a prospective, preliminary trial in four NHs. **PARTICIPANTS:** Participants (n = 17) were recruited from a larger study designed to assess nutritional care quality. Eligibility for the Megace OS trial required participants to consistently eat less than 75% of most meals under both usual NH care and optimal feeding assistance conditions at baseline. **INTERVENTION:** Megace OS, an oral liquid suspension of megestrol acetate, was given daily in a 400-mg dose for 63 days.

**MEASUREMENTS:** Each participant's oral food and fluid intake was monitored weekly for 1 day (three meals) during which research staff conducted direct observations of usual NH care (weeks 1, 3, and 5 and day 63) or provided optimal feeding assistance (weeks 2, 4, and 6). Average total percent intake was compared from baseline across the assessment weeks of the trial under the two mealtime care conditions. **RESULTS:** Megace OS had a significant effect on oral food and fluid intake only under the optimal mealtime feeding assistance condition, in which average total percent eaten increased from 50% (+/- 15%) at baseline to 63% (+/- 14%) post-63 days of the trial. There was no change in participants' oral food and fluid intake under the usual NH care condition (average total percent intake at baseline 43% +/- 12% vs. 43% +/- 20% post-63 days). **CONCLUSION:** The results of this preliminary study suggest that Megace OS is not an effective nutritional intervention to increase oral intake under usual NH care conditions, which is often characterized by inadequate feeding assistance. However, Megace OS in combination with optimal mealtime feeding assistance does significantly increase oral intake in a frail NH sample at high risk for weight loss.

**REF ID: 5160**

**Simmons, S. F., Walker, K. A., & Osterweil, D. (2004). The effect of megestrol acetate on oral food and fluid intake in nursing home residents: A pilot study. *Journal of the American Medical Directors Association*, 5(1), 24-30.**

**Journal Article, Research, Tables/Charts**

**OBJECTIVES:** The objective of this study was to evaluate the effect of megestrol acetate (Megace OS; Bristol-Myers Squibb, Princeton, NJ) on the oral food and fluid intake of nursing home (NH) residents under two conditions: usual NH care and optimal mealtime feeding assistance. **DESIGN AND**

**SETTING:** We conducted a prospective, preliminary trial in four NHs. **PARTICIPANTS:** Participants (n = 17) were recruited from a larger study designed to assess nutritional care quality. Eligibility for the

Megace OS trial required participants to consistently eat less than 75% of most meals under both usual NH care and optimal feeding assistance conditions at baseline. INTERVENTION: Megace OS, an oral liquid suspension of megestrol acetate, was given daily in a 400-mg dose for 63 days.

MEASUREMENTS: Each participant's oral food and fluid intake was monitored weekly for 1 day (three meals) during which research staff conducted direct observations of usual NH care (weeks 1, 3, and 5 and day 63) or provided optimal feeding assistance (weeks 2, 4, and 6). Average total percent intake was compared from baseline across the assessment weeks of the trial under the two mealtime care conditions. RESULTS: Megace OS had a significant effect on oral food and fluid intake only under the optimal mealtime feeding assistance condition, in which average total percent eaten increased from 50% (+/- 15%) at baseline to 63% (+/- 14%) post-63 days of the trial. There was no change in participants' oral food and fluid intake under the usual NH care condition (average total percent intake at baseline 43% +/- 12% vs. 43% +/- 20% post-63 days). CONCLUSION: The results of this preliminary study suggest that Megace OS is not an effective nutritional intervention to increase oral intake under usual NH care conditions, which is often characterized by inadequate feeding assistance. However, Megace OS in combination with optimal mealtime feeding assistance does significantly increase oral intake in a frail NH sample at high risk for weight loss.

**REF ID: 4729**

**Siu, W. T., Leong, H. T., Law, B. K., Chau, C. H., Li, A. C., & Fung, K. H. et al. (2002).**

**Laparoscopic repair for perforated peptic ulcer: A randomized controlled trial. *Annals of Surgery*, 235(3), 313-319.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; AIM; IM**

OBJECTIVE: To compare the results of open versus laparoscopic repair for perforated peptic ulcers.

SUMMARY BACKGROUND DATA: Omental patch repair with peritoneal lavage is the mainstay of treatment for perforated peptic ulcers in many institutions. Laparoscopic repair has been used to treat perforated peptic ulcers since 1990, but few randomized studies have been carried out to compare open versus laparoscopic procedures. METHODS: From January 1994 to June 1997, 130 patients with a clinical diagnosis of perforated peptic ulcer were randomly assigned to undergo either open or laparoscopic omental patch repair. Patients were excluded for a history of upper abdominal surgery, concomitant evidence of bleeding from the ulcer, or gastric outlet obstruction. Patients with clinically sealed-off perforations without signs of peritonitis or sepsis were treated without surgery. Laparoscopic repair would be converted to an open procedure for technical difficulties, nonjuxtapyloric gastric ulcers, or perforations larger than 10 mm. A Gastrografin meal was performed 48 to 72 hours after surgery to document sealing of the perforation. The primary end-point was perioperative parenteral analgesic requirement. Secondary endpoints were operative time, postoperative pain score, length of postoperative hospital stay, complications and deaths, and the date of return to normal daily activities. RESULTS:

Nine patients with a surgical diagnosis other than perforated peptic ulcer were excluded; 121 patients entered the final analysis. There were 98 male and 23 female patients recruited, ages 16 to 89 years. The two groups were comparable in age, sex, site and size of perforations, and American Society of Anesthesiology classification. There were nine conversions in the laparoscopic group. After surgery, patients in the laparoscopic group required significantly less parenteral analgesics than those who underwent open repair, and the visual analog pain scores in days 1 and 3 after surgery were significantly lower in the laparoscopic group as well. Laparoscopic repair required significantly less time to complete than open repair. The median postoperative stay was 6 days in the laparoscopic group versus 7 days in the open group. There were fewer chest infections in the laparoscopic group. There were two intraabdominal collections in the laparoscopic group. One patient in the laparoscopic group and three patients in the open group died after surgery. CONCLUSIONS: Laparoscopic repair of perforated peptic ulcer is a safe and reliable procedure. It was associated with a shorter operating time, less postoperative pain, reduced chest complications, a shorter postoperative hospital stay, and earlier return to normal daily activities than the conventional open repair.

**REF ID: 4664**

**Son, G. R., Song, J., & Lim, Y. (2006). Translation and validation of the revised-algase wandering**

**scale (community version) among korean elders with dementia. *Aging Ment.Health., 10(2), 143-150.***

**Journal Article; IM**

The purpose of this study was to examine the psychometric properties of a Korean translated version of the Revised Algate Wandering Scale, community version (K-RAWS-CV) among persons with dementia in Korea. A cross-sectional survey design was used. After established equivalence of the instrument using back-translation and a field test, 69 community dwelling family caregivers described the wandering behavior of their family members with dementia. The overall mean of the K-RAWS-CV was 1.73 (SD=0.61, range=1-3.87). Means of each subscale ranged from 1.44 (meal-time impulsivity, MI) to 2.04 (escape behavior, EB). The reliability alpha for the overall scale was 0.96 with reliabilities for subscales ranging from 0.82 (negative outcome, NO) to 0.93 (persistent walking, PW). The correlation between the overall K-RAWS-CV and each subscale ranged from 0.52 (overall and NO) to 0.82 (overall and PW) with a mean value of 0.66. Pearson's correlations between the level of cognitive impairment and each subscale of the K-RAWS-CV demonstrated significant, moderate relationships ranging from -0.24 (MI, RW, and MMSE) to -0.39 (PW, EB and MMSE). Mean differences between wanderers and non-wanderers were statistically significant for the K-RAWS-CV overall and all subscale except for MI. Results support the validity and reliability of the K-RAWS-CV overall and the six subscales.

**REF ID: 5158**

**Stabell, A., Eide, H., Solheim, G. A., Solberg, K. N., & Rustoen, T. (2004). Nursing home residents' dependence and independence. *Journal of Clinical Nursing, 13(6), 677-686.***

**Journal Article, Research, Tables/Charts**

Background. Entering an institution constitutes one of the most difficult developmental challenges for older people, and may lead to increased dependency because of reinforcing environmental events such as the interaction pattern of the staff. Aims and objective. The aim of this paper was to describe the pattern of social interaction between nursing home residents and the nursing staff during mealtimes. Design and methods. Six residents of a nursing home in a suburb of Oslo were observed. Data were collected during 120 systematic observations. Different types of behaviour relating to the residents' level of independence when interacting with the staff were examined using a structured observational scheme developed by Baltes. Results. Data showed that the residents' maintenance of independent self-care was the most predominant behaviour. Residents were rarely socially active. The behaviour of one resident varied among meals. Observations of independent self-care maintenance during interactions between the residents and the staff were sometimes consistent and sometimes inconsistent. The response of the nursing staff to the residents' social engagement was variable. Generally, however, they did not respond at all and seldom displayed engagement-supportive behaviour. Conclusions. The results represent a challenge to the nursing staff to increase social interaction during mealtimes, and also to examine their inconsistent behaviour towards the residents. Relevance to clinical practice. Mealtime appears to be a good opportunity to foster the independence of the residents as well as to enhance social activity in the form of informal conversation. Greater consistency of staff behaviour is required, based on ethical values such as consideration of the residents' self-esteem and autonomy, thereby stimulating independent self-care at mealtimes. Inconsistent behaviour, often based on values that are not clarified, may, on the contrary, lead to increased dependence of the residents.

**REF ID: 4735**

**Stier, A. W., Stein, H. J., Allescher, H. D., Feith, M., & Schwaiger, M. (2002). A scintigraphic study of local oesophageal bolus transit: Differences between patients with barrett's oesophagus and healthy controls. *Gut, 50(2), 159-164.***

**Clinical Trial; Controlled Clinical Trial; Journal Article; AIM; IM**

BACKGROUND: In Barrett's patients, functional disorders of oesophageal motility are currently measured by oesophageal manometry. Yet abnormalities of oesophageal volume transport in the critical regions of the upper oesophageal sphincter (UOS) and lower oesophageal sphincter (LOS) cannot be determined using these methods. AIMS: To further characterise the activity of the sphincter regions, we developed a quantitative method for differentiation of oesophageal volume transport in Barrett's patients

and healthy controls. **METHODS:** We used a new technique of processing scintigraphic images, with data analysis based on a new concept of relative local transit time. Twelve patients with Barrett's oesophagus and 11 healthy volunteers were examined using alimentary scintigraphy after a semisolid test meal in a multiple swallow test. In individual scintigraphic images of five swallows we studied: (1) overall oesophageal clearance and (2) the topographic profile of the relative local transit time obtained by image conversion to a two dimensional line graph. This profile was reconstructed by assembling constituent Gauss bands, allocating their integrals to five oesophageal regions according to their band position. **RESULTS:** (1) Overall oesophageal clearance was not significantly different between the two groups. (2) In comparison with healthy volunteers, relative regional transit times of all 12 Barrett's patients were significantly increased in the hypopharyngeal region and decreased in the region of the distal oesophagus. The extent of the decrease in the region of the distal oesophagus showed a close correlation with the length of Barrett's metaplasia. **CONCLUSION:** Improvement in image processing allows alimentary scintigraphy to describe different regional patterns of oesophageal volume transport. Local oesophageal bolus transit is markedly abnormal in Barrett's patients without alteration in clearance. The presence of metaplasia itself implies a negative impact on both sphincter functions. These findings substantiate the diagnostic value of refined oesophageal scintigraphy.

**REF ID: 5153**

**Sydney, Y. M., & Fjellstrom, C. (2005). Food provision and the meal situation in elderly care -- outcomes in different social contexts. *Journal of Human Nutrition and Dietetics*, 18(1), 45-52.**

**Journal Article, Research**

**BACKGROUND:** Nutritional problems concerning older people in care can be affected both by their illness and by the standard procedures surrounding food provision, for example rigid routines of food supply and ritualized mealtime situations. **METHOD:** The aim was to study how organizational structure and staff members' routines and actions influence activities related to food and meals in different caring context in Sweden. The qualitative methodology chosen for this study was participant observation. **RESULT:** Care recipients were given different opportunities concerning what, how, when and with whom to eat, depending on where their meals were served. In restaurants, older people could choose from several foods and they could also choose the time of and company for the meal. At care units with 'part-of-day' care or 'around-the-clock' care, food choices, time and company were limited, especially at the units with 'around-the-clock' care, where the most ailing older people lived. **CONCLUSIONS:** Food provision and the mealtime situation for the elderly are shaped by the individual's living arrangements, and the social organization surrounding it, not determined by the individual's needs and wishes, including social and cultural meanings of food and meals, which could, thereby, affect nutritional intake.

**REF ID: 4657**

**Evidence Level IV: Nonexperimental Study**

**Taylor, K. A., & Barr, S. I. (2006). Provision of small, frequent meals does not improve energy intake of elderly residents with dysphagia who live in an extended-care facility. *Journal of the American Dietetic Association*, 106(7), 1115-1118.**

**Journal Article; Randomized Controlled Trial; AIM; IM**

Malnutrition and dehydration are potential consequences of dysphagia, a common swallowing disorder among elderly individuals. Providing smaller, more frequent meals has been suggested (but not demonstrated) to improve energy intake among this group. Accordingly, this study was designed to assess whether the same energy content in five vs three daily meals would improve energy intake. Thirty-seven residents of an extended-care facility, aged older than 65 years, previously evaluated for dysphagia, and receiving a texture-modified diet, agreed to participate in a crossover study with random assignment to three or five meals during an initial 4-day study period, followed by the opposite meal pattern in a second period. Six were excluded from analysis, as their medical condition deteriorated before or during the study. Food and fluids consumed by participants during each study period were weighed before and after each meal. Average energy intakes were similar between the three- and five-meal patterns (1,325+/-207 kcal/day vs 1,342+/-177 kcal/day, respectively; P=0.565); fluid intake was

higher with five meals (698±156 mL/day) vs three (612±176 mL/day; P=0.003). Because offering five daily feedings did not improve energy intakes when compared with three, dietitians caring for this vulnerable group might need to consider other nutrition intervention strategies.

**REF ID: 4730**

**Tutuian, R., Katz, P. O., Ahmed, F., Korn, S., & Castell, D. O. (2002). Over-the-counter H(2)-receptor antagonists do not compromise intragastric pH control with proton pump inhibitors. *Alimentary Pharmacology & Therapeutics*, 16(3), 473-477.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

**BACKGROUND:** Proton pump inhibitors effectively suppress intragastric acid. Nocturnal acid breakthrough occurs on any dosing regimen of oral proton pump inhibitors. Histamine(2)-receptor antagonists (H(2)RA) suppress intragastric acidity independently of meals and help to control nocturnal acid breakthrough. Because proton pump inhibitors require an acid intragastric milieu for activation, nocturnal dosing of H(2)RA might decrease the effect of proton pump inhibitors taken in the morning by decreasing their gastric-acid-driven activation. **AIM:** Assess intragastric acid control on omeprazole, 20 mg, taken every morning, after variable dosing of over-the-counter famotidine, 10 mg. **METHODS:** Twelve *Helicobacter pylori*-negative, healthy volunteers received omeprazole, 20 mg, every morning before breakfast for 15 days. Baseline studies on omeprazole, 20 mg, in the morning, were done on day 7. On nights between days 8-9, 11-12 and 14-15, famotidine, 10 mg at bedtime, and 10 mg at bedtime and/or at 05.30 h, was given in a three-way, crossover, double-blind randomized design. Intragastric pH monitoring was performed on days 9, 12 and 15, starting at 08.00 h. **RESULTS:** Percentage times intragastric pH < 4 on omeprazole, 20 mg, in the morning of the day after receiving famotidine, 10 mg, at bedtime (58.6 ± 4.8); at 05.30 h (54.1 ± 5.1); or at bedtime and at 05.30 h (54.3 ± 5.0) did not differ significantly (P=0.65) from percentage times intragastric pH on day 7 of omeprazole, 20 mg, in the morning (49.5 ± 5.1). **CONCLUSION:** Concerns over inhibition of next-day daytime proton-pump inhibitor effect should not preclude use of nocturnal H(2)RAs in patients with gastro-oesophageal reflux disease.

**REF ID: 4671**

**Valtonen, M., Niskanen, L., Kangas, A. P., & Koskinen, T. (2005). Effect of melatonin-rich night-time milk on sleep and activity in elderly institutionalized subjects. *Nord.J.Psychiatry.*, 59(3), 217-221.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

Melatonin production decreases with advancing age, leading to insomnia and changes in circadian rhythmicity. Administration of melatonin in variable doses resulting in supraphysiological or physiological night-time blood levels of melatonin has been shown to improve sleep quality in the elderly. To study the effect of low doses of melatonin, which do not affect daytime blood melatonin concentrations, night-time milk containing 10-40 ng/l melatonin was used as a drink with meals. The effect of about 0.5 l night-time milk daily on sleep quality and circadian activity was studied in elderly institutionalized subjects in two long-term double-blind, placebo-controlled, crossover studies. Night-time milk was given for 8 weeks and normal day-time milk for 8 weeks with a 1-week washout period in between. In the first study, which was performed during spring with sleep quality evaluated subjectively by specially trained nurses, 70 demented patients showed only a seasonal effect on their sleep quality. In the second study performed around the winter solstice, 81 fairly healthy subjects living in rest-homes were divided into three groups, two for the crossover study as in the first investigation with a third group consuming only normal daytime milk as a control group to evaluate the effect of season. Caregivers graded the sleep quality and activity that was monitored separately for the morning before noon and for the evening after noon. In the second study, the effect of season was recognizable in the scores for sleep quality, which increased in all groups after the winter solstice. However, there were no changes in activity in the control group or in the group that consumed night-time milk during the first period of the crossover study, whereas both morning and evening activity increased significantly in the group that consumed night-time milk during the later period. Even ultra-low doses of melatonin may benefit the elderly by increasing their daytime activity.

**REF ID: 4699**

**Vloet, L. C., Smits, R., & Jansen, R. W. (2003). The effect of meals at different mealtimes on blood pressure and symptoms in geriatric patients with postprandial hypotension. *The Journals of Gerontology. Series A, Biological Sciences and Medical Sciences*, 58(11), 1031-1035.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; AIM; IM**

**BACKGROUND:** The variability of postprandial hypotension (PPH) during the day in elderly patients is unknown. We examined the effect of meals administered at different mealtimes on postprandial blood pressure (BP) responses in geriatric patients. **METHODS:** In 14 geriatric patients (6 men and 8 women, aged 66-97) previously diagnosed with PPH, standardized liquid test meals were given in random order at breakfast, lunchtime, or dinnertime on 3 separate days. Systolic BP (SBP), diastolic BP (DBP), and heart rate (HR) were measured with an ambulatory BP device every 10 minutes from 20 minutes before until 90 minutes after each meal. Postprandial symptoms were observed continuously. **RESULTS:** Significant decreases in SBP and DBP were present after each meal ( $p < .050$ ). The maximum SBP decrease was significantly smaller at dinnertime (-18 +/- 3 mmHg) than at breakfast (-29 +/- 2 mmHg) or lunchtime (-34 +/- 4 mmHg) ( $p < .005$  between groups). Eight patients showed no PPH in the evening, whereas all patients had PPH after breakfast and lunch. The duration of PPH was significantly shorter ( $p < .001$ ), and postprandial symptoms were less frequent and less severe after dinner compared to breakfast and lunch. **CONCLUSIONS:** In geriatric patients, postprandial BP responses show a variation during the day, with significantly less PPH and fewer symptoms in the evening. Clinical implication is that, in the diagnostic process and management of PPH, the variation of the occurrence of PPH during the day should be taken into account. Through adjustment of BP decreasing activities to the time PPH is least prevalent, the risk of developing symptomatic PPH can be reduced.

**REF ID: 4675**

**Wainstein, J., Metzger, M., Boaz, M., Minuchin, O., Cohen, Y., & Yaffe, A. et al. (2005). Insulin pump therapy vs. multiple daily injections in obese type 2 diabetic patients. *Diabetic Medicine : A Journal of the British Diabetic Association*, 22(8), 1037-1046.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

**AIMS:** To compare the efficacy of insulin pump treatment with multiple daily injections in the treatment of poorly controlled obese Type 2 diabetic patients already receiving two or more daily injections of insulin plus metformin. **METHODS:** Forty obese Type 2 diabetic subjects (using insulin) were randomized to treatment with continuous subcutaneous infusion pump (CSII) (Minimed) or multiple daily insulin injections (MDI). At the end of the first 18-week treatment period, patients underwent a 12-week washout period during which they were treated with MDI plus metformin. They were then crossed-over to the other treatment for an 18-week follow-up period. Patients performed 4-point daily self blood-glucose monitoring (SBGM) on a regular basis and 7-point monitoring prior to visits 2, 8, 10 and 16. A subset of patients underwent continuous glucose monitoring using the Minimed(R) continuous glucose monitoring system (CGMS) at visits 2, 8, 10 and 16. A standard meal test was performed in which serum glucose was tested at fasting and once each hour for 6 h following a test meal. Glucose levels were plotted against time and the area under the curve (AUC) was calculated. HbA(1c), weight, daily insulin dose and hypoglycaemic episodes were recorded. **RESULTS:** In obese Type 2 diabetic patients already treated with insulin, treatment with CSII significantly reduced HbA(1c) levels compared with treatment with MDI. An additional CSII treatment benefit was demonstrated by reduced meal-test glucose AUC. Initial reduction of daily insulin requirement observed in CSII-treated subjects during the first treatment period was attributable to a period effect and did not persist over time. **CONCLUSIONS:** In the intent-to-treat analysis, CSII appeared to be superior to MDI in reducing HbA(1c) and glucose AUC values without significant change in weight or insulin dose in obese, uncontrolled, insulin-treated Type 2 diabetic subjects.

**REF ID: 4715**

**Wang, S., Boss, A. H., Kensey, K. R., & Rosenson, R. S. (2003). Variations of whole blood viscosity using rheolog-a new scanning capillary viscometer. *Clinica Chimica Acta; International Journal of Clinical Chemistry*, 332(1-2), 79-82.**

**Clinical Trial; Journal Article; IM**

**BACKGROUND:** Whole blood viscosity (WBV) values identify subjects at high risk for initial or recurrent cardiovascular events. However, these measurements have been limited to specialized centers. A new type of viscometer, Rheolog, was designed to overcome the difficulties encountered in WBV measurements using the standard rotational viscometer in a clinical environment. **METHODS:** We evaluated the 14-day variability of WBV measured by Rheolog in a single-center study of 24 healthy male subjects aged 18-75 years. WBV was measured through an 11-h period on study days 1, 8, and 14. An additional fasting WBV test was performed on study days 3, 5, and 11. **RESULTS:** Average morning measurements were higher than afternoon measurements at all shear rates. Both inter- and intraindividual variations were higher in the morning than later in the day, but the differences between pooled mean values were not significant. Interindividual variations at fasting were higher than the pre-meal or overall variations. There was a small nonsignificant increase in mean viscosity following each meal. **CONCLUSION:** WBV measurements using Rheolog have potential for clinical application because of the convenience and low variability of measurements over time.

**REF ID: 4732**

**Ward, E. C., Bishop, B., Frisby, J., & Stevens, M. (2002). Swallowing outcomes following laryngectomy and pharyngolaryngectomy. *Archives of Otolaryngology--Head & Neck Surgery, 128(2), 181-186.***

**Journal Article; AIM; IM**

**OBJECTIVES:** To determine the incidence of dysphagia (defined as the inability to manage a diet of normal consistencies) at hospital discharge and beyond 1 year postsurgery and examine the impact of persistent dysphagia on levels of disability, handicap, and well-being in patients. **DESIGN:** Retrospective review and patient contact. **SETTING:** Adult acute care tertiary hospital. **PATIENTS:** The study group, consecutively sampled from January 1993 to December 1997, comprised 55 patients who underwent total laryngectomy and 37 patients who underwent pharyngolaryngectomy with free jejunal reconstruction. Follow-up with 36 of 55 laryngectomy and 14 of 37 pharyngolaryngectomy patients was conducted 1 to 6 years postsurgery. **MAIN OUTCOME MEASURES:** Number of days until the resumption of oral intake; swallowing complications prior to and following discharge; types of diets managed at discharge and follow-up; and ratings of disability, handicap, and distress levels related to swallowing. **RESULTS:** Fifty four (98%) of the laryngectomy and 37 (100%) of the pharyngolaryngectomy patients experienced dysphagia at discharge. By approximately 3 years postsurgery, 21 (58%) of the laryngectomy and 7 (50%) of the pharyngolaryngectomy patients managed a normal diet. Pharyngolaryngectomy patients experienced increased duration of nasogastric feeding, time to resume oral intake, and incidence of early complications affecting swallowing. Patients experiencing long-term dysphagia identified significantly increased levels of disability, handicap, and distress. Patients without dysphagia also experienced slight levels of handicap and distress resulting from taste changes and increased durations required to complete meals of normal consistency. **CONCLUSIONS:** The true incidence of patients experiencing a compromise in swallowing following surgery has been underestimated. The significant impact of impaired swallowing on a patient's level of perceived disability, handicap, and distress highlights the importance of providing optimal management of this negative consequence of surgery to maximize the patient's quality of life.

**REF ID: 4662**

**Watson, R., & Green, S. M. (2006). Feeding and dementia: A systematic literature review. *Journal of Advanced Nursing, 54(1), 86-93.***

**Journal Article; Review; IM; N**

**AIM:** This paper reports a systematic review of the literature on interventions to promote oral nutritional intake of older people with dementia and feeding difficulty between 1993 and 2003. **BACKGROUND:** Older people with dementia commonly experience difficulty with feeding, especially in the later stages of the condition. This topic and related nursing care was reviewed in 1993 and the conclusion was that there was little research into interventions that nurses could use to alleviate feeding difficulty. **METHOD:** A systematic review of the literature was carried out using the CINAHL, Medline,

EMBASE and Cochrane databases and the search terms 'feeding', 'eating' and 'dementia' combined as follows: '(feeding or eating) and (dementia)'. A second search was carried out combining the search terms 'mealtimes' and 'dementia' as follows: 'mealtimes and dementia'. The literature search was carried out on 1 December 2003 and papers were included in the review if retrieved by 31 December 2003. English language papers only were retrieved. RESULTS: Sixty-seven papers were retrieved, of which 13 addressed interventions aimed at helping older people with dementia to feed. All studies reported positive outcomes but only one randomized controlled trial was reported. Music was the most common intervention but there were no standardized interventions or outcomes across the studies and none reported the use of power analysis to decide on sample size. There were problems in some studies with confounding variables. CONCLUSIONS: Further research is needed into interventions aimed at how nurses can help older people with dementia to feed. There are some promising lines of enquiry, with music being one of these, but future studies need to use adequate samples and to use power calculations and account adequately for confounding variables. There is also a need to standardize interventions and outcomes across such studies to facilitate meta-analysis.

**REF ID: 5145**

**Evidence Level I: Systematic Review**

**Watson, R., & Green, S. M. (2006). Feeding and dementia: A systematic literature review. *Journal of Advanced Nursing*, 54(1), 86-93.**

**Journal Article, Research, Systematic Review, Tables/Charts**

**Aim.** This paper reports a systematic review of the literature on interventions to promote oral nutritional intake of older people with dementia and feeding difficulty between 1993 and 2003. **Background.** Older people with dementia commonly experience difficulty with feeding, especially in the later stages of the condition. This topic and related nursing care was reviewed in 1993 and the conclusion was that there was little research into interventions that nurses could use to alleviate feeding difficulty. **Method.** A systematic review of the literature was carried out using the CINAHL, Medline, EMBASE and Cochrane databases and the search terms 'feeding', 'eating' and 'dementia' combined as follows: '(feeding or eating) and (dementia)'. A second search was carried out combining the search terms 'mealtimes' and 'dementia' as follows: 'mealtimes and dementia'. The literature search was carried out on 1 December 2003 and papers were included in the review if retrieved by 31 December 2003. English language papers only were retrieved. **Results.** Sixty-seven papers were retrieved, of which 13 addressed interventions aimed at helping older people with dementia to feed. All studies reported positive outcomes but only one randomized controlled trial was reported. Music was the most common intervention but there were no standardized interventions or outcomes across the studies and none reported the use of power analysis to decide on sample size. There were problems in some studies with confounding variables. **Conclusions.** Further research is needed into interventions aimed at how nurses can help older people with dementia to feed. There are some promising lines of enquiry, with music being one of these, but future studies need to use adequate samples and to use power calculations and account adequately for confounding variables. There is also a need to standardize interventions and outcomes across such studies to facilitate meta-analysis.

**REF ID: 4691**

**Whelan, A. P., Sutherland, W. H., McCormick, M. P., Yeoman, D. J., de Jong, S. A., & Williams, M. J. (2004). Effects of white and red wine on endothelial function in subjects with coronary artery disease. *Internal Medicine Journal*, 34(5), 224-228.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

**BACKGROUND:** Levels of anti-oxidant polyphenols are higher in red than in white wine and are thought to contribute to the reduced cardiovascular risk associated with moderate consumption of wine observed in epidemiological studies. **AIM:** To compare the acute effects of acute ingestion of white and red wine on endothelial function in subjects with coronary artery disease (CAD). **METHODS:** Fourteen subjects with proven CAD were randomised to consume white and red wine with a light meal in a single blind cross-over study. Flow-mediated dilatation (FMD) of the brachial artery was measured using high-resolution ultrasonography. Endothelial function, lipid profile, plasma alcohol and polyphenols were

measured at baseline, 60 and 360 min after wine consumption. RESULTS: At baseline, FMD was similar (white wine 1.6 +/- 1.9%, red wine 1.8 +/- 1.7%). At 360 min after ingestion of wine there was no difference in FMD, which improved nearly threefold after both wines (white wine 4.7 +/- 2.2%, red wine 3.4 +/- 2.9%; P = 0.002). There was no detectable change in plasma polyphenol levels after either wine. CONCLUSIONS: These data suggest that wine acutely improves endothelial function in patients with CAD. This improved endothelial function might contribute to a reduced risk of cardiovascular events.

**REF ID: 5175**

**Whitehouse, F., Kruger, D. F., Fineman, M., Shen, L., Ruggles, J. A., & Maggs, D. G. et al. (2002). A randomized study and open-label extension evaluating the long-term efficacy of pramlintide as an adjunct to insulin therapy in type 1 diabetes. *Diabetes Care*, 25(4), 724-730.**

**Journal Article, Clinical Trial, Research, Tables/Charts**

OBJECTIVE: To assess the effect of mealtime amylin replacement with pramlintide on long-term glycemic and weight control in patients with type 1 diabetes. RESEARCH DESIGN AND METHODS: In a 52-week, double-blind, placebo-controlled, multicenter study, 480 patients with type 1 diabetes were randomized to receive preprandial injections of placebo or 30 microg pramlintide q.i.d., in addition to existing insulin regimens. At week 20, pramlintide-treated patients were re-randomized to 30 or 60 microg pramlintide q.i.d. if decreases from baseline in HbA(1c) were <1% at week 13. Of the 342 patients who completed the 52-week study, 236 individuals (approximately 70%) elected to participate in a 1-year open-label extension in which all patients received 30 or 60 microg pramlintide q.i.d. RESULTS: Treatment with pramlintide led to a mean reduction in HbA(1c) of 0.67% from baseline to week 13 that was significantly (P < 0.0001) greater than the placebo reduction (0.16%), and a significant placebo-corrected treatment difference was sustained through week 52 (P = 0.0071). The greater HbA(1c) reduction was associated with an average weight loss, rather than weight gain, and was not accompanied by an increased overall event rate of severe hypoglycemia. In the open-label extension, mean HbA(1c) levels decreased rapidly in patients receiving pramlintide for the first time and remained at reduced levels in patients who continued pramlintide treatment. The most common adverse events reported by the pramlintide group were mild nausea and anorexia, which both occurred during the initial weeks of treatment and dissipated over time. CONCLUSIONS: Mealtime pramlintide treatment as an adjunct to insulin improved long-term glycemic control without inducing weight gain or increasing the overall risk of severe hypoglycemia in patients with type 1 diabetes.

**REF ID: 4678**

**Wisten, A., & Messner, T. (2005). Fruit and fibre (pajala porridge) in the prevention of constipation. *Scandinavian Journal of Caring Sciences*, 19(1), 71-76.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; N**

BACKGROUND AND AIMS: Constipation is a common problem in geriatric wards and in the elderly population. Although high-fibre diets can help relieve constipation non-pharmacologically in many patients, traditional laxatives still remain the standard treatment. A fibre supplement in the form of raw bran is not always well tolerated. We wanted to study the effects of a daily consumption of a fruit- and fibre-rich porridge on stool frequency, perceived well-being and the costs for laxatives, when compared with traditional treatment with laxatives, in geriatric patients. METHODS: Twenty patients in secondary geriatric wards (hospital rehabilitation wards) were randomized into an intervention group (porridge group) and a control group (standard diet without porridge) for a 1-week run-in and 2-week study, with registration of clinical data, e.g. medical treatment, laxative consumption, stool frequency and perceived well-being. RESULTS: The patients in the porridge group had a daily defaecation without laxatives on average 76% of the time (10.7/14 days) compared with 23% of the time (3.3/14 days) in the non-porridge group (p = 0.003). The discomfort was less in the porridge group (2.5 vs. 6.5 on a 10-degree visual analogue scale, p = 0.008) when compared with the control group. The cost for laxatives was 93% lower in the intervention group (2.5 vs. 37.5) for the 2-week study. CONCLUSIONS: A fibre-rich porridge was effective, well liked and tolerated and reduced the need for laxatives in geriatric patients.

We conclude that a daily fibre-rich meal ought to be included in the treatment strategies of constipation in hospital wards.

**REF ID: 4709**

**Wouters-Wesseling, W., Van Hooijdonk, C., Wagenaar, L., Bindels, J., de Groot, L., & Van Staveren, W. (2003). The effect of a liquid nutrition supplement on body composition and physical functioning in elderly people. *Clinical Nutrition (Edinburgh, Lothian)*, 22(4), 371-377.**

**Clinical Trial; Journal Article; Randomized Controlled Trial; IM**

**BACKGROUND & AIMS:** The elderly are at an increased risk of poor nutritional status which is mutually interacting with functional status. We evaluated the effects of a liquid nutrition supplement on anthropometric and functional indices in elderly people. **METHODS:** Subjects (n=68; mean age=82+/-7 years) with body mass index  $\leq 25$  kg/m<sup>2</sup> received either a supplement or a placebo for 6 months. Anthropometric (body weight, bioelectrical impedance, calf circumference), biochemical (albumin, prealbumin), functional parameters (handgrip strength, timed 'up and go' test) and dietary intake were measured. Activities of daily living and Nottingham Health Profile (NHP) were assessed. **RESULTS:** No compensation of energy intake occurred. After 6 months, the supplement group had gained more weight (+1.6 kg) than the placebo group (+0.3 kg) (P=0.03). No other significant changes in anthropometric, functional or blood parameters were seen. There was a significant improvement on the section 'sleep' of the NHP (mean change+/-SE=-0.38+/-0.19 for supplement vs 0.24+/-0.19 for placebo, P=0.03). **CONCLUSION:** Dietary supplementation led to an increase in body weight and had a positive influence on sleep in elderly persons. Supplementation did not affect energy intake from regular meals and thus resulted in additional energy intake.

**REF ID: 4665**

**Evidence Level III: Quasi-experimental Study**

**Wright, L., Hickson, M., & Frost, G. (2006). Eating together is important: Using a dining room in an acute elderly medical ward increases energy intake. *Journal of Human Nutrition and Dietetics : The Official Journal of the British Dietetic Association*, 19(1), 23-26.**

**Journal Article; Randomized Controlled Trial; IM**

**AIM:** To investigate the effect of eating in a supervised dining room, on nutritional intake and weight, for elderly patients on an acute medicine for the elderly ward. **METHOD:** Patients on the intervention ward were encouraged to attend a dining room every lunch time by a trained nursing assistant as part of the rehabilitation process. The patients on the control ward ate only by their bedside. Food intake and weight data were collected over the study period on each patient. **RESULTS:** Forty-eight patients participated in the study. At the lunch time meal studied the dining room group had higher intakes of energy compared with the controls [489 kcal (95% CI: 438-554) versus 360 kcal (95% CI: 289-448), P < 0.013]. There was no difference in protein intake between the groups [18.9 g (95% CI: 16.6-21.2) versus 17.7 g (95% CI: 13.2-22.2), P=0.63]. No significant difference in weight gain between the two groups was seen (P=0.6). However, there was a trend towards weight gain in the dining room group. **CONCLUSION:** Food intake can be improved by using a supervised dining room, and this will potentially lead to weight gain and corresponding improvements in nutritional status and rehabilitation.

**REF ID: 5146**

**Evidence Level III: Quasi-experimental Study**

**Wright, L., Hickson, M., & Frost, G. (2006). Eating together is important: Using a dining room in an acute elderly medical ward increases energy intake. *Journal of Human Nutrition and Dietetics*, 19(1), 23-26.**

**Journal Article, Research, Tables/Charts**

**AIM:** To investigate the effect of eating in a supervised dining room, on nutritional intake and weight, for elderly patients on an acute medicine for the elderly ward. **METHOD:** Patients on the intervention ward were encouraged to attend a dining room every lunch time by a trained nursing assistant as part of the rehabilitation process. The patients on the control ward ate only by their bedside. Food intake and weight data were collected over the study period on each patient. **RESULTS:** Forty-eight patients participated in the study. At the lunch time meal studied the dining room group had higher intakes of

energy compared with the controls [489 kcal (95% CI: 438-554) versus 360 kcal (95% CI: 289-448),  $P < 0.013$ ]. There was no difference in protein intake between the groups [18.9 g (95% CI: 16.6-21.2) versus 17.7 g (95% CI: 13.2-22.2),  $P=0.63$ ]. No significant difference in weight gain between the two groups was seen ( $P=0.6$ ). However, there was a trend towards weight gain in the dining room group. CONCLUSION: Food intake can be improved by using a supervised dining room, and this will potentially lead to weight gain and corresponding improvements in nutritional status and rehabilitation.

**REF ID: 5155**

**Wu, A. M. S., Tang, C. S., & Yan, E. C. (2004). Psychosocial factors associated with acceptance of old age home placement: A study of elderly Chinese in Hong Kong. *Journal of Applied Gerontology*, 23(4), 487-504.**

**Journal Article, Research, Tables/Charts**

This study examined psychosocial factors associated with the acceptance of long-term placement in old age homes (OAHs) among 185 elderly Chinese in Hong Kong. Participants were recruited from local community centers for elderly people and were individually interviewed on their willingness to enter OAHs, attitudes toward OAHs, perceived mental and physical health status, and beliefs about filial piety and independence. Results showed that only 20% of the participants indicated their willingness to enter OAHs in the coming 6 months. Among depicted services and facilities in OAHs, participants rated the quality of OAH staff as the most important, whereas the choice of food and mealtimes were viewed as the least important. Participants were more willing to enter OAHs if depicted services and facilities were provided at OAHs. Findings of the hierarchical regression analysis revealed that salient correlates of willingness to enter OAHs were positive attitudes toward OAHs, poor perceived physical health, male gender, and a low need for independence. Prior visits to OAHs and filial piety beliefs were unrelated to participants' acceptance of OAH care. Service and policy implications in promoting elderly people's sense of autonomy and acceptance of OAH care, reducing the cost of placement in OAHs, and ensuring the quality of services and care in OAHs are also discussed.

**REF ID: 5143**

**Yoshida, M., Kikutani, T., Tsuga, K., Utanohara, Y., Hayashi, R., & Akagawa, Y. (2006). Decreased tongue pressure reflects symptom of dysphagia. *Dysphagia*, 21(1), 61-65.**

**Journal Article, Pictorial, Research, Tables/Charts**

The tongue plays a key role in oropharyngeal swallowing. It has been reported that maximum isometric tongue pressure decreases with age. The risk for dysphagia resulting from low tongue strength remains unclear. This study was designed to reveal the relationship between tongue pressure and clinical signs of dysphagic tongue movement and cough and to demonstrate the clinical value of tongue pressure measurement in the evaluation of swallowing function. One hundred forty-five institutionalized elderly in five nursing homes participated. Evaluation of physical activity with self-standing up capability and mental condition with Mini Mental Status Examination (MMSE) were recorded. Maximum tongue pressure was determined using a newly developed tongue pressure measurement device. Voluntary tongue movement and signs of dysphagic cough at mealtime were inspected and evaluated by one clinically experienced dentist and speech therapist. The relationship between level of tongue pressure and incidence of cough was evaluated using logistic regression analysis with physical and mental conditions as covariates. Tongue pressure as measured by the newly developed device was significantly related to the voluntary tongue movement and incidence of cough ( $p < 0.05$ ). The results of this study suggest that tongue pressure measurement reflects clinical signs of dysphagic tongue movement and cough and that measurement of tongue pressure is useful for the bedside evaluation of swallowing.

**REF ID: 4713**

**Zahn, A., Langhans, C. D., Hoffner, S., Haberkorn, U., Rating, D., & Haass, M. et al. (2003). Measurement of gastric emptying by  $^{13}\text{C}$ -octanoic acid breath test versus scintigraphy in diabetics. *Zeitschrift Fur Gastroenterologie*, 41(5), 383-390.**

**Clinical Trial; Evaluation Studies; Journal Article; IM**

In this prospective study, we compared the assessment of gastric emptying by the  $^{13}\text{C}$ -octanoic acid breath test to gastric emptying scintigraphy in diabetics. We also examined the relationship between

gastric emptying parameters and gastric symptoms and cardiovascular autonomic function. The  $^{13}\text{C}$ -octanoic acid breath test and scintigraphy were performed simultaneously in 24 diabetics with a solid test meal (1 egg, doubly labelled with 91 mg  $^{13}\text{C}$ -octanoic acid and 50 MBq  $^{99\text{m}}\text{Tc}$ -Nanocol, 60 g white bread, 5 g margarine and 150 ml water). At fifteen-minute intervals, breath samples were taken over 4 hours and examined by mass spectrometry. In parallel, scintigraphy was performed for 2 hours at one minute intervals. Using breath test data, gastric emptying half time ( $t(1/2)$ ), lag-phase ( $t$  lag) and gastric emptying coefficient (GEC) were calculated. Subsequently, the correlation of these results with the equivalent data from scintigraphy were determined employing a regression method. To detect a cardiovascular autonomic neuropathy, a 24-h ECG recording was performed. The prevalence of gastrointestinal symptoms in our collective was assessed by a standardized questionnaire. There was a highly significant positive correlation of both  $^{13}\text{C}$ -octanoic acid breath test  $t(1/2)$  and scintigraphic  $t(1/2)$  ( $r = 0.8257$ ;  $p < 0.0001$ ) and  $^{13}\text{C}$ -octanoic acid breath test  $t$  lag and scintigraphic  $t$  lag ( $r = 0.6302$ ;  $p < 0.001$ ). The sensitivity of the  $^{13}\text{C}$ -octanoic acid breath test was 1 and the specificity was 0.73. In our study, there was no significant association of cardiovascular and gastrointestinal autonomic neuropathy. Furthermore, there was no significant relationship between the prevalence of gastrointestinal symptoms and gastric emptying disorders. We conclude that the  $^{13}\text{C}$ -octanoic acid breath test represents a suitable method to measure disordered gastric emptying in diabetics due to its highly significant positive correlation to scintigraphy and due to its validity. It is not possible to predict diabetic gastroparesis on the basis of other autonomic function disorders or because of dyspeptic symptoms.

**REF ID: 4706**

**Zhang, L., Abreu, B. C., Seale, G. S., Masel, B., Christiansen, C. H., & Ottenbacher, K. J. (2003). A virtual reality environment for evaluation of a daily living skill in brain injury rehabilitation: Reliability and validity. *Archives of Physical Medicine and Rehabilitation*, 84(8), 1118-1124.**

**Journal Article; AIM; IM**

**OBJECTIVE:** To establish the stability and validity of information collected in a virtual reality environment from persons with traumatic brain injury (TBI). **DESIGN:** Prospective correlation design to examine 3-week test-retest results for equivalence reliability between computer-simulated and natural environments. **SETTING:** A residential rehabilitation center for brain injury. **PARTICIPANTS:** Fifty-four consecutive patients with TBI who received comprehensive rehabilitation services and who were at different stages of recovery. **INTERVENTION:** An immersive virtual kitchen was developed in which a meal preparation task involving multiple steps was performed. The subjects completed meal preparation both in a virtual reality kitchen and an actual kitchen twice over a 3-week period. **MAIN OUTCOME MEASURES:** Time and errors on task completion using virtual reality assessment, actual kitchen performance (analogous to the virtual reality environment), occupational therapy (OT) evaluation, and neuropsychologic tests. **RESULTS:** The stability of performance using the simulated virtual environment was estimated with intraclass correlation coefficients (ICCs). The ICC value for total performance, based on all steps involved in the meal preparation task, was .76 ( $P < .01$ ). The construct validity of the simulated environment was examined by correlating performance in the virtual environment with that in the actual kitchen ( $r = .63$ ,  $P < .01$ ), the OT evaluation ( $r = .30$ ,  $P = .05$  for meal preparation;  $r = .40$ ,  $P = .01$  for cognitive subskills), and neuropsychologic tests ( $r = .56$ ,  $P < .01$  for the full-scale intelligence quotient [IQ];  $r = .40$ ,  $P < .01$  for the verbal IQ;  $r = .56$ ,  $P < .01$  for the performance IQ). Finally, a multiple regression analysis revealed that the virtual reality environment test was a good predictor for the actual assessment kitchen ( $\beta = .35$ ,  $P = .01$ ). **CONCLUSION:** The virtual reality system showed adequate reliability and validity as a method of assessment in persons with brain injury.